Chapter 2100 Patentability

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2103 Patent Examination Process [R-9]

I. DETERMINE WHAT APPLICANT HAS INVENTED AND IS SEEKING TO PATENT

It is essential that patent applicants obtain a prompt yet complete examination of their applications. Under the principles of compact prosecution, each claim should be reviewed for compliance with every statutory requirement for patentability in the initial review of the application, even if one or more claims are found to be deficient with respect to some statutory requirement. Thus, USPTO personnel should state all reasons and bases for rejecting claims in the first Office action. Deficiencies should be explained clearly, particularly when they serve as a basis for a rejection. Whenever practicable, USPTO personnel should indicate how rejections may be overcome and how problems may be resolved. A failure to follow this approach can lead to unnecessary delays in the prosecution of the application.

Prior to focusing on specific statutory requirements, USPTO personnel must begin examination by determining what, precisely, the applicant has invented and is seeking to patent, and how the claims relate to and define that invention. USPTO personnel will review the complete specification, including the detailed description of the invention, any specific embodiments that have been disclosed, the claims and any specific, substantial, and credible utilities that have been asserted for the invention.

After obtaining an understanding of what applicant invented, the examiner will conduct a search of the prior art and determine whether the invention as claimed complies with all statutory requirements.

A. Identify and Understand Any Utility for the Invention

The claimed invention as a whole must be useful. The purpose of this requirement is to limit patent protection to inventions that possess a certain level of "real world" value, as opposed to subject matter that represents nothing more than an idea or concept, or is simply a starting point for future investigation or research *(Brenner v. Manson*, 383 U.S. 519, 528-36, 148 USPQ 689, 693-96 (1966); *In re Fisher*, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005); *In re Ziegler*, 992 F.2d 1197, 1200-03, 26 USPQ2d 1600, 1603-06 (Fed. Cir. 1993)).

USPTO personnel should review the application to identify any asserted utility. The applicant is in the best position to explain why an invention is believed useful. Accordingly, a complete disclosure should contain some indication of the practical application for the claimed invention, i.e., why the applicant believes the claimed invention is useful. Such a statement will usually explain the purpose of the invention or how the invention may be used (e.g., a compound is believed to be useful in the treatment of a particular disorder). Regardless of the form of statement of utility, it must enable one ordinarily skilled in the art to understand why the applicant believes the claimed invention is useful. See **MPEP § 2107** for utility examination guidelines. An applicant may assert more than one utility and practical application, but only one is necessary. Alternatively, an applicant may rely on the contemporaneous art to provide that the claimed invention has a well-established utility.

B. Review the Detailed Disclosure and Specific Embodiments of the Invention To Understand What the Applicant Has Invented

The written description will provide the clearest explanation of the applicant's invention, by exemplifying the invention, explaining how it relates to the prior art and explaining the relative significance of various features of the invention. Accordingly, USPTO personnel should continue their evaluation by

(A) determining the function of the invention, that is, what the invention does when used as disclosed (e.g., the functionality of a programmed computer); and

(B) determining the features necessary to accomplish at least one asserted practical application.

Patent applicants can assist the USPTO by preparing applications that clearly set forth these aspects of an invention.

C. Review the Claims

The claims define the property rights provided by a patent, and thus require careful scrutiny. The goal of claim analysis is to identify the boundaries of the protection sought by the applicant and to understand how the claims relate to and define what the applicant has indicated is

the invention. USPTO personnel must first determine the scope of a claim by thoroughly analyzing the language of the claim before determining if the claim complies with each statutory requirement for patentability. See *In re Hiniker Co.*, 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998) ("[T]he name of the game is the claim.").

USPTO personnel should begin claim analysis by identifying and evaluating each claim limitation. For processes, the claim limitations will define steps or acts to be performed. For products, the claim limitations will define discrete physical structures or materials. Product claims are claims that are directed to either machines, manufactures or compositions of matter.

USPTO personnel are to correlate each claim limitation to all portions of the disclosure that describe the claim limitation. This is to be done in all cases, regardless of whether the claimed invention is defined using means or step plus function language. The correlation step will ensure that USPTO personnel correctly interpret each claim limitation.

The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. The following are examples of language that may raise a question as to the limiting effect of the language in a claim:

(A) statements of intended use or field of use,

(B) "adapted to" or "adapted for" clauses,

(C) "wherein" clauses, or

(D) "whereby" clauses.

This list of examples is not intended to be exhaustive. The determination of whether particular language is a limitation in a claim depends on the specific facts of the case. See, e.g., *Griffin v. Bertina*, 283 F.3d 1029, 1034, 62 USPQ2d 1431 (Fed. Cir. 2002)(finding that a "wherein" clause limited a process claim where the clause gave "meaning and purpose to the manipulative steps"). See also **MPEP §§ 2111.02** and **2111.04**.

USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. See **MPEP § 2111**. Disclosure may be express, implicit, or inherent. USPTO personnel are to give the claimed means plus function limitations their broadest reasonable interpretation consistent with all corresponding structures or materials described in the specification and their equivalents including the manner in which the claimed functions are performed. See *Kemco Sales, Inc. v. Control Papers Company, Inc.*, 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000). Further guidance in interpreting the scope of equivalents is provided in **MPEP § 2181** through **MPEP § 2186**.

While it is appropriate to use the specification to determine what applicant intends a term to mean, a positive limitation from the specification cannot be read into a claim that does not itself impose that limitation. A broad interpretation of a claim by USPTO personnel will reduce the possibility that the claim, when issued, will be interpreted more broadly than is justified or intended. An applicant can always amend a claim during prosecution to better reflect the intended scope of the claim.

Finally, when evaluating the scope of a claim, every limitation in the claim must be considered. USPTO personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, the claim as a whole must be considered. See, e.g., *Diamond v. Diehr*, 450 U.S. 175, 188-89, 209 USPQ 1, 9 (1981) ("In determining the eligibility of respondents' claimed process for patent protection under § **101**, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.").

II. CONDUCT A THOROUGH SEARCH OF THE PRIOR ART

Prior to evaluating the claimed invention under **35 U.S.C. 101**, USPTO personnel are expected to conduct a thorough search of the prior art. Generally, a thorough search involves reviewing both U.S. and foreign patents and nonpatent literature. In many cases, the result of such a search will contribute to USPTO personnel's understanding of the invention. Both claimed and unclaimed aspects of the invention described in the specification should be searched if there is a reasonable expectation that the unclaimed aspects may be later claimed. A search must take into account any structure

or material described in the specification and its equivalents which correspond to the claimed means plus function limitation, in accordance with **35 U.S.C. 112** , sixth paragraph and **MPEP § 2181** through **§ 2186** .

III. DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH 35 U.S.C. 101

A. Consider the Breadth of 35 U.S.C. 101 Under Controlling Law

Section **101** of title 35, United States Code, provides:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. 101 defines four categories of inventions that Congress deemed to be the appropriate subject matter of a patent: processes, machines, manufactures and compositions of matter. The latter three categories define "things" or "products" while the first category defines "actions" (i.e., inventions that consist of a series of steps or acts to be performed). See **35 U.S.C. 100(b)** ("The term 'process' means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.").

The subject matter which courts have found to be outside of, or exceptions to, the four statutory categories of invention is limited to abstract ideas, laws of nature and physical phenomena. *Bilski v. Kappos*, 561 U.S. ___, ___, 130 S. Ct. 3218, 3225, 95 USPQ2d 1001, ___ (2010) (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 206 USPQ 193, ___ (1980)). While this is easily stated, determining whether an applicant is seeking to patent an abstract idea, a law of nature or a physical phenomenon has proven to be challenging. These three exclusions recognize that subject matter that is not a practical application of an idea, a law of nature or a physical phenomenon is not patentable. See, e.g., *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. (20 Wall.) 498, 507 (1874) ("idea of itself is not patentable, but a new device by which it may be made practically useful is"); *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86, 94, 40 USPQ 199, 202 (1939) ("While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.").

The courts have also held that a claim may not preempt abstract ideas, laws of nature or physical phenomena; i.e., one may not patent every "substantial practical application" of an abstract idea, law of nature or physical phenomenon. This is because such a patent would "in practical effect be a patent on the [abstract idea, law of nature or physical phenomenon] itself." *Gottschalk v. Benson*, 409 U.S. 63, 71-72, 175 USPQ 673, 676 (1972). The concern over preemption was expressed as early as 1852. See *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852) ("A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.").

The Supreme Court in *Bilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3218, 95 USPQ2d 1001 (2010), underscored that the text of **35 U.S.C. 101** is expansive, specifying four independent categories of inventions eligible for protection, including processes, machines, manufactures, and compositions of matter. As stated by the Court, "[i]n choosing such expansive terms . . . modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope.") (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 USPQ 193, ___ (1980)). The Court also made clear that business methods are not "categorically outside of § **101**'s scope," stating that "a business method is simply one kind of 'method' that is, at least in some circumstances, eligible for patenting under § **101**." Examiners are reminded that **35 U.S.C. 101** is not the sole tool for determining patentability; where a claim encompasses an abstract idea, **35 U.S.C. 112** , **102** , and **103** will provide additional tools for ensuring that the claim meets the conditions for patentability. As the Court made clear in *Bilski*:

> The § **101** patent-eligibility inquiry is only a threshold test. Even if an invention qualifies as a process, machine, manufacture, or composition of matter, in order to receive the Patent Act's protection the claimed invention must also satisfy ''the conditions and requirements of this title.'' § **101**. Those requirements include that the invention be novel, see § **102**, nonobvious, see § **103**, and fully and particularly described, see § **112**.

Therefore, examiners should avoid focusing on issues of patent-eligibility under **35 U.S.C. 101** to the detriment of considering an application for compliance with the requirements of **35 U.S.C. 112**, **102**, and **103**, and should avoid treating an application solely on the basis of patent-eligibility under **35 U.S.C. 101** except in the most extreme cases.

See MPEP § 2106 for determining whether a claim is directed to patent-eligible subject matter, and MPEP § 2106.01 for further guidance regarding subject matter eligibility determinations during examination of process claims that involve laws of nature/natural correlations. Additionally, a claimed invention must be useful or have a utility that is specific, substantial and credible.

See MPEP § 2107 for a detailed discussion of the utility requirement.

IV. EVALUATE APPLICATION FOR COMPLIANCE WITH 35 U.S.C. 112

A. Determine Whether the Claimed Invention Complies with 35 U.S.C. 112, Second Paragraph Requirements

The second paragraph of 35 U.S.C. 112 contains two separate and distinct requirements: (A) that the claim(s) set forth the subject matter applicants regard as the invention, and (B) that the claim(s) particularly point out and distinctly claim the invention. An application will be deficient under the first requirement of 35 U.S.C. 112, second paragraph when evidence including admissions, other than in the application as filed, shows that an applicant has stated what he or she regards the invention to be different from what is claimed (see MPEP § 2171 - § 2172.01).

An application fails to comply with the second requirement of 35 U.S.C. 112, second paragraph when the claims do not set out and define the invention with a reasonable degree of precision and particularity. In this regard, the definiteness of the language must be analyzed, not in a vacuum, but always in light of the teachings of the disclosure as it would be interpreted by one of ordinary skill in the art. Applicant's claims, interpreted in light of the disclosure, must reasonably apprise a person of ordinary skill in the art of the invention.

The scope of a "means" limitation is defined as the corresponding structure or material set forth in the written description and equivalents thereof. See MPEP § 2181 through § 2186. See MPEP § 2173 et seq. for a discussion of a variety of issues pertaining to the 35 U.S.C. 112, second paragraph requirement that the claims particularly point out and distinctly claim the invention.

B. Determine Whether the Claimed Invention Complies with 35 U.S.C. 112, First Paragraph Requirements

The first paragraph of 35 U.S.C. 112 contains three separate and distinct requirements:

(A) adequate written description,

(B) enablement, and

(C) best mode.

1. Adequate Written Description

For the written description requirement, an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of invention. See MPEP § 2163 for further guidance with respect to the evaluation of a patent application for compliance with the written description requirement.

2. Enabling Disclosure

An applicant's specification must enable a person skilled in the art to make and use the claimed invention without undue experimentation. The fact that experimentation is complex, however, will not make it undue if a person of skill in the art typically engages in such complex experimentation.

See MPEP § 2164 et seq. for detailed guidance with regard to the enablement requirement of 35 U.S.C. 112, first paragraph.

3. Best Mode

Determining compliance with the best mode requirement requires a two-prong inquiry:

(1) at the time the application was filed, did the inventor possess a best mode for practicing the invention; and

(2) if the inventor did possess a best mode, does the written description disclose the best mode such that a person skilled in the art could practice it.

See MPEP § 2165 et seq. for additional guidance. Deficiencies related to disclosure of the best mode for carrying out the claimed invention are not usually encountered during examination of an application because evidence to support such a deficiency is seldom in the

record. Fonar, 107 F.3d at 1548-49, 41 USPQ2d at 1804-05.

VI. DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH 35 U.S.C. 102 AND 103

Reviewing a claimed invention for compliance with **35 U.S.C. 102** and **103** begins with a comparison of the claimed subject matter to what is known in the prior art. See **MPEP § 2131** - **§ 2146** for specific guidance on patentability determinations under **35 U.S.C. 102** and **103**. If no differences are found between the claimed invention and the prior art, then the claimed invention lacks novelty and is to be rejected by USPTO personnel under **35 U.S.C. 102**. Once differences are identified between the claimed invention and the prior art, those differences must be assessed and resolved in light of the knowledge possessed by a person of ordinary skill in the art. Against this backdrop, one must determine whether the invention would have been obvious at the time the invention was made. If not, the claimed invention satisfies **35 U.S.C. 103**.

VII. CLEARLY COMMUNICATE FINDINGS, CONCLUSIONS AND THEIR BASES

Once USPTO personnel have concluded the above analyses of the claimed invention under all the statutory provisions, including **35 U.S.C. 101**, **112**, **102**, and **103**, they should review all the proposed rejections and their bases to confirm that they are able to set forth a prima facie case of unpatentability. Only then should any rejection be imposed in an Office action. The Office action should clearly communicate the findings, conclusions and reasons which support them.

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2104 Patentable Subject Matter [R-9]

35 U.S.C. 101 Inventions patentable

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. 101 has been interpreted as imposing three requirements.

First, whoever invents or discovers an eligible invention may obtain only ONE patent therefor. This requirement forms the basis for statutory double patenting rejections when two applications claim the same invention, i.e. claim identical subject matter. See **MPEP § 804** for a full discussion of the prohibition against double patenting.

Second, a claimed invention must fall within one of the four eligible categories of invention, i.e., process, machine, manufacture, or composition of matter, as these categories have been interpreted by the courts. See **MPEP § 2106** for a detailed discussion of the subject matter eligibility requirements and **MPEP § 2105** for special considerations for living subject matter.

Third, a claimed invention must be useful or have a utility that is specific, substantial and credible. See **MPEP § 2107** for a detailed discussion of the utility requirement.

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2105 Patentable Subject Matter — Living Subject Matter [R-9]

The decision of the Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980), held that microorganisms produced by genetic engineering are not excluded from patent protection by **35 U.S.C. 101**. It is clear from the Supreme Court decision and opinion that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability. The test set down by the Court for patentable subject matter in this area is whether the living matter is the result of human intervention.

In view of this decision, the Office has issued these guidelines as to how **35 U.S.C. 101** will be interpreted.

The Supreme Court made the following points in the *Chakrabarty* opinion:

> 1. "Guided by these canons of construction, this Court has read the term 'manufacture' in § **101** in accordance with its dictionary definition to mean 'the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery.'"
> 2. "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."
> 3. "The Act embodied Jefferson's philosophy that 'ingenuity should receive a liberal encouragement.' 5 Writings of Thomas Jefferson, at 75-76. See

Graham v . *John Deere Co*., 383 U.S. 1, 7-10 (1966). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word 'art' with 'process,' but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 act inform us that Congress intended statutory subject matter to 'include any thing under the sun that is made by man.' S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952)."

4. "This is not to suggest that § **101** has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable."

5. "Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity."

6. "His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter — a product of human ingenuity 'having a distinctive name, character [and] use.'"

7. "Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. Here, respondent's microorganism is the result of human ingenuity and research."

8. After reference to *Funk Seed Co. & Kalo Co.*, 333 U.S. 127, 76 USPQ 280 (1948), "Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § **101**."

A review of the Court statements above as well as the whole *Chakrabarty* opinion reveals:

(A) That the Court did not limit its decision to genetically engineered living organisms;

(B) The Court enunciated a very broad interpretation of "manufacture" and "composition of matter" in **35 U.S.C. 101** (Note esp. quotes 1, 2, and 3 above);

(C) The Court set forth several tests for weighing whether patentable subject matter under **35 U.S.C. 101** is present, stating (in quote 7 above) that:

> The relevant distinction was not between living and inanimate things but between products of nature, whether living or not, and human-made inventions.

The tests set forth by the Court are (note especially the italicized portions):

(A) "The laws of nature, physical phenomena and abstract ideas" are not patentable subject matter.

(B) A "nonnaturally occurring manufacture or composition of matter — a product of human ingenuity —having a distinctive name, character, [and] use" is patentable subject matter.

(C) "[A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of... nature, free to all men and reserved exclusively to none.'"

(D) "[T]he production of articles for use from raw materials prepared by giving to these materials *new forms, qualities, properties, or combinations whether by hand labor or by machinery"* [emphasis added] is a "manufacture" under **35 U.S.C. 101**.

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Following the reasoning in *Chakrabarty*, the Board of Patent Appeals and Interferences ** determined that animals are patentable subject matter under 35 U.S.C. **101**. In *Ex parte Allen*, 2 USPQ2d 1425 (Bd. Pat. App. & Inter. 1987), the Board decided that a polyploid Pacific coast oyster could have been the proper subject of a patent under **35 U.S.C. 101** if all the criteria for patentability were satisfied. Shortly after the *Allen* decision, the Commissioner of Patents and Trademarks issued a notice (Animals - Patentability, 1077 O.G. 24, April 21, 1987) that the Patent and Trademark Office would now consider nonnaturally occurring, nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of **35 U.S.C. 101**.

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The Leahy-Smith America Invents Act (AIA), Public Law 112-29, **sec. 33(a)**, 125 Stat. 284, states:

> Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.

The legislative history of the AIA includes the following statement, which sheds light on the meaning of this provision:

> [T]he U.S. Patent Office has already issued patents on genes, stems cells, animals with human genes, and a host of non-biologic products used by humans, but it has not issued patents on claims directed to human organisms, including human embryos and fetuses. My amendment would not affect the former, but would simply affirm the latter.

157 Cong. Rec. E1177-04 (testimony of Representative Dave Weldon previously presented in connection with the Consolidated Appropriations Act, 2004, Pub. L. No. 108-199, ' 634, 118 Stat. 3, 101, and later resubmitted with regard to the AIA; see 149 Cong. Rec. E2417-01). Thus, section 33(a) of the AIA codifies existing Office policy that human organisms are not patent-eligible subject matter.

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If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human*>organism<, then a rejection under **35 U.S.C. 101**>and **AIA sec. 33(a)**<must be made indicating that the claimed invention is directed to> a human organism and is therefore <nonstatutory subject matter. >Form paragraph 7.04.01 may be used; see **MPEP § 706.03(a)**. <Furthermore, the claimed invention must be examined with regard to all issues pertinent to patentability, and any applicable rejections under **35 U.S.C. 102**, **103**, or **112** must also be made.

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With respect to plant subject matter, the Supreme Court held that patentable subject matter under **35 U.S.C. 101** includes newly developed plant breeds, even though plant protection is also available under the Plant Patent Act (**35 U.S.C. 161** - **164**) and the Plant Variety Protection Act (7 U.S.C. 2321 et. seq.). *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143-46, 122 S.Ct. 593, 605-06, 60 USPQ2d 1865, 1874 (2001) (The scope of coverage of **35 U.S.C. 101**is not limited by the Plant Patent Act or the Plant Variety Protection Act; each statute can be regarded as effective because of its different requirements and protections). In analyzing the history of the Plant Patent Act of 1930, the Court stated: "In enacting the Plant Patent Act, Congress addressed both of these concerns [the concern that plants, even those artificially bred, were products of nature for purposes of the patent law and the concern that plants were thought not amenable to the written description]. It explained at length its belief that the work of the plant breeder 'in aid of nature' was patentable invention. S. Rep. No. 315, 71st Cong., 2d Sess., 6-8 (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess., 7-9 (1930)." See also *Ex parte Hibberd*, 227 USPQ 443 (Bd. Pat. App. & Inter. 1985), wherein the Board held that plant subject matter may be the proper subject of a patent under **35 U.S.C. 101** even though such subject matter may be protected under the Plant Patent Act or the Plant Variety Protection Act.

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2106 Patent Subject Matter Eligibility [R-9]

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There are two criteria for determining subject matter eligibility and both must be satisfied. The claimed invention (1) must be directed to one of the four statutory categories, and (2) must not be wholly directed to subject matter encompassing a judicially recognized exception, as defined below. The following two step analysis is used to evaluate these criteria.

I. THE FOUR CATEGORIES OF STATUTORY SUBJECT MATTER

Step 1: Is the claim directed to one of the four patent-eligible subject matter categories: process, machine, manufacture, or composition of matter? The subject matter of the claim must be directed to one of the four subject matter categories. If it is not, the claim is not eligible for patent protection and should be rejected under **35 U.S.C. 101** , for at least this reason. A summary of the four categories of invention, as they have been defined by the courts, are:

i. Process – an act, or a series of acts or steps. See *Gottschalk v. Benson*, 409 U.S. 63, 70, 175 USPQ 673, ___ (1972) ("A process is a mode of treatment of certain materials to produce a given result. It is an *act*, or a *series of acts*, performed upon the subject-matter to be transformed and reduced to a different state or thing." (emphasis added) (quoting *Cochrane v. Deener*, 94 U.S. 780, 788, 24 L. Ed. 139, 1877 Dec. Comm'r Pat. 242 (1876)); *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1316, 75 USPQ2d 1763, ___(Fed. Cir. 2005) ("A process is a series of acts." (quoting *Minton v. Natl. Ass'n. of Securities Dealers, 336 F.3d 1373*, , 336 F.3d 1373, 1378, 67 USPQ2d 1614, ___ (Fed. Cir. 2003))). See also **35 U.S.C. 100(b)**; *Bilski v. Kappos*, 130 S. Ct. 3218, 95 USPQ2d 1001 (2010).

ii. Machine – a concrete thing, consisting of parts, or of certain devices and combination of devices. *Burr v. Duryee*, 68 U.S. (1 Wall.) 531, 570, 17 L. Ed. 650 (1863). This includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result. *Corning v. Burden*, 56 U.S. 252, 267, 14 L. Ed. 683 (1854).

iii. Manufacture – an article produced from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by handlabor or by machinery. *Diamond v. Chakrabarty*,

447 U.S. 303, 308, 206 USPQ 193, ___ (1980) (emphasis added) (quoting *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11, 51 S. Ct. 328, 75 L. Ed. 801, 1931 (Dec. Comm'r Pat. 711 (1931))).

iv. Composition of matter – all compositions of two or more substances and all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids, for example. *Chakrabarty*, 447 U.S. at 308.

Non-limiting examples of claims that are not directed to one of the statutory categories:

i. transitory forms of signal transmission (for example, a propagating electrical or electromagnetic signal *per se*), *In re Nuijten*, 500 F.3d 1346, 1357, 84 USPQ2d 1495, ___ (Fed. Cir. 2007);

ii. a naturally occurring organism, *Chakrabarty*, 447 U.S. at 308;

iii. a human *per se*, The Leahy-Smith America Invents Act (AIA), **Public Law 112-29, sec. 33**, 125 Stat. 284 (September 16, 2011);

iv. a legal contractual agreement between two parties, see *In re Ferguson*, 558 F.3d 1359, 1364, 90 USPQ2d 1035, ___ (Fed. Cir. 2009) (cert. denied);

v. a game defined as a set of rules;

vi. a computer program *per se*, *Gottschalk v. Benson*, 409 U.S. at 72;

vii. a company, *Ferguson*, 558 F.3d at 1366; and

viii. a mere arrangement of printed matter, *In re Miller*, 418 F.2d 1392, 1396, 164 USPQ 46, ___ (CCPA 1969).

A claim that covers both statutory and non-statutory embodiments (under the broadest reasonable interpretation of the claim when read in light of the specification and in view of one skilled in the art) embraces subject matter that is not eligible for patent protection and therefore is directed to non-statutory subject matter. Such claims fail the first step and should be rejected under **35 U.S.C. 101**, for at least this reason.

For example, machine readable media can encompass non-statutory transitory forms of signal transmission, such as, a propagating electrical or electromagnetic signal *per se*. See *In re Nuijten*, 500 F.3d 1346, 84 USPQ2d 1495 (Fed. Cir. 2007). When the broadest reasonable interpretation of machine readable media in light of the specification as it would be interpreted by one of ordinary skill in the art encompasses transitory forms of signal transmission, a rejection under **35 U.S.C. 101** as failing to claim statutory subject matter would be appropriate. Thus, a claim to a computer readable medium that can be a compact disc or a carrier wave covers a non-statutory embodiment and therefore should be rejected under **35 U.S.C. 101** as being directed to non-statutory subject matter.

If the claimed invention is clearly not within one of the four categories, it is not patent eligible. However, when the claim fails under Step 1 and it appears from applicant's disclosure that the claim could be amended to be directed to a statutory category, Step 2 below should still be conducted.

II. JUDICIAL EXCEPTIONS TO THE FOUR CATEGORIES

Step 2: Does the claim wholly embrace a judicially recognized exception, which includes laws of nature, physical phenomena, and abstract ideas, or is it a particular practical application of a judicial exception? See *Bilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3218, 3225, 95 USPQ2d 1001 (2010) (stating "The Court's precedents provide three specific exceptions to § **101**'s broad patent-eligibility principles: 'laws of nature, physical phenomena, and abstract ideas.'") (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 206 USPQ 193, ___ (1980)).

Determining whether the claim falls within one of the four enumerated categories of patentable subject matter recited in **35 U.S.C. 101** (i.e., process, machine, manufacture, or composition of matter) does not end the analysis because claims directed to nothing more than abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature are not eligible for patent protection. *Diamond v. Diehr*, 450 U.S. 175, 185, 209 USPQ 1, 7 (1981); accord, e.g., *Chakrabarty*, 447 U.S. at 309, 206 USPQ at 197; *Parker v. Flook*, 437 U.S. 584, 589, 198 USPQ 193, 197 (1978); *Benson*, 409 U.S. at 67-68 , 175 USPQ at 675. "A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right." *Le Roy v. Tatham,*, 55 U.S. (14 How.) 156, 175 (1852). Instead, such "manifestations of laws of nature" are "part of the storehouse of knowledge," "free to all men and reserved exclusively to none." *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130, 76 USPQ 280, 281 (1948).

Thus, "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter" under Section **101**. *Chakrabarty*, 447 U.S. at 309, 206 USPQ at 197. "Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity." *Ibid.* Nor can one patent "a novel and useful mathematical formula," *Flook*, 437 U.S. at 585, 198 USPQ at 195; electromagnetism or steam

power, *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 113-114 (1853); or "[t]he qualities of ... bacteria, ... the heat of the sun, electricity, or the qualities of metals," *Funk*, 333 U.S. at 130, 76 USPQ at 281; see *Le Roy*, 55 U.S. (14 How.) at 175.

While abstract ideas, physical phenomena, and laws of nature are not eligible for patenting, methods and products employing abstract ideas, physical phenomena, and laws of nature to perform a real-world function may well be. In evaluating whether a claim meets the requirements of **35 U.S.C. 101** , the claim must be considered as a whole to determine whether it is for a particular application of an abstract idea, physical phenomenon, or law of nature, and not for the abstract idea, physical phenomenon, or law of nature itself. *Diehr*, 450 U.S. at 188-178.

In addition to the terms laws of nature, physical phenomena, and abstract ideas, judicially recognized exceptions have been described using various other terms, including natural phenomena, scientific principles, systems that depend on human intelligence alone, disembodied concepts, mental processes and disembodied mathematical algorithms and formulas, for example. The exceptions reflect the courts' view that the basic tools of scientific and technological work are not patentable.

The claimed subject matter must not be wholly directed to a judicially recognized exception. If it is, the claim is not eligible for patent protection and should be rejected under **35 U.S.C. 101** . However, a claim that is limited to a particular practical application of a judicially recognized exception is eligible for patent protection. A "practical application" relates to how a judicially recognized exception is applied in a real world product or a process, and not merely to the result achieved by the invention. When subject matter has been reduced to a particular practical application having a real world use, the claimed practical application is evidence that the subject matter is not abstract (e.g., not purely mental) and does not encompass substantially all uses (preemption) of a law of nature or a physical phenomenon. See, e.g., *Ultramercial v. Hulu*, 657 F.3d 1323, 1329, 100 USPQ2d 1140,1145 (Fed. Cir. 2011)(stating that the patent "does not claim a mathematical algorithm, a series of purely mental steps, or any similarly abstract concept. It claims a particular method . . . a practical application of the general concept.").

A. Practical Application of Machines, Manufactures, and Compositions of Matter (Products)

If the claimed product falls within one of the three product categories of invention and does not recite judicially excepted subject matter, e.g., a law of nature, a physical phenomenon, or an abstract idea, it qualifies as eligible subject matter. If a judicial exception is recited in the claim, it must be determined if the judicially excepted subject matter has been practically applied in the product.

Eligible machines, manufactures, and compositions of matter are non-naturally occurring products typically formed of tangible elements or parts that embody a particular or specific, tangible practical application of the invention. Thus, for these product categories, a particular practical application is often self-evident based on the claim limitations that define the tangible embodiment. This is because an idea that is tangibly applied to a structure is no longer abstract, and a law of nature or physical phenomenon that is practically applied to a structure is limited to that particular application of the concept. For example, a cup is the tangible application of the abstract idea of containing a liquid and is one limited embodiment of that idea (which is no longer abstract). As another example, a magnetic door latch is the tangible application of the concept of magnetism and does not wholly embrace the concept of magnetism but, rather, is one limited application of the concept.

A claim that includes terms that imply that the invention is directed to a product, for instance by reciting "a machine comprising…", but fails to include tangible limitations in accordance with its broadest reasonable interpretation is not limited to a practical application, but rather wholly embraces or encompasses the concept upon which the invention is based. This is impermissible as such claim coverage would extend to every way of applying the abstract idea, law of nature or physical phenomenon.

A claim that includes judicially excepted subject matter and whose broadest reasonable interpretation is directed to a man-made tangible embodiment (i.e., structure) with a real world use is limited to a practical application (the subject matter has been practically applied). The reason is that the claim as a whole must be evaluated for eligibility in the same manner that a claim as a whole is evaluated for patentability under **35 U.S.C. 102**, **103** and **112**.

Once a practical application has been established, the limited occurrence of preemption must be evaluated to determine whether the claim impermissibly covers substantially all practical applications of the judicially excepted subject matter. If so, the claim is not patent-eligible. If the claim covers only a particular practical application of the judicially excepted subject matter, it is patent eligible.

The following examples show the difference between a tangible embodiment that is evidence of a particular practical application and an abstract concept that has no practical application.

(a) A claim that is directed to a machine comprising a plurality of structural elements that work together in a defined combination based on a mathematical relationship, such as a series of gears, pulleys and belts, possesses structural limitations that show that it is a tangible embodiment, providing evidence that the mathematical relationship has been applied (a practical application). Additionally, that tangible embodiment is limited by the claimed structure and would not cover all substantial practical uses of the mathematical relationship. The claim would be eligible for patent protection.

(b) On the other hand, a claim that is directed to a machine ("What is claimed is a machine that operates in accordance with F=ma.") and includes no tangible structural elements under the broadest reasonable interpretation, covers the operating principle based on a mathematical relationship with no limits on the claim scope. Thus, as no tangible embodiment is claimed, there would be no evidence of a practical application. The claim would wholly embrace the mathematical concept of F=ma and would not be eligible subject matter.

(c) As another example, a claim to a non-transitory, tangible computer readable storage medium *per se* that possesses structural limitations under the broadest reasonable interpretation standard to qualify as a manufacture would be patent-eligible subject matter. Adding additional claim limitations to the medium, such as executable instructions or stored data, to such a statutory eligible claim would not render the medium non-statutory, so long as the claim as a whole has a real world use and the medium does not cover substantially all practical uses of a judicial exception. The claim as a whole remains a tangible embodiment and qualifies as a manufacture. As explained above, the additional claim limitations would be evaluated in terms of whether they distinguish over the prior art.

B. Practical Application of Processes (Methods)

The Supreme Court in *Bilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3218, 95 USPQ2d 1001 (2010), clarified the requirements for a claim to be a statutory process. Not every claimed method qualifies as a statutory process. A process claim, to be statutory under **35 U.S.C. 101** , must be limited to a particular practical application. This ensures that the process is not simply claiming an abstract idea, or substantially all practical uses of (preempting) a law of nature, or a physical phenomenon. See **MPEP § 2106.01** for further guidance regarding subject matter eligibility determinations during examination of process claims that involve laws of nature/natural correlations.

A claim that attempts to patent an abstract idea is ineligible subject matter under **35 U.S.C. 101** . See *Bilski*, 130 S. Ct. at 3230 (''[A]ll members of the Court agree that the patent application at issue here falls outside of § 101 because it claims an abstract idea.''). The abstract idea exception has deep roots in the Supreme Court's jurisprudence. See *Bilski*, 130 S. Ct. at 3225 (citing *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 174–175 (1853)).

Bilski reaffirmed Diehr's holding that ''while an abstract idea, law of nature, or mathematical formula could not be patented, 'an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.''' See *Bilski*, 130 S. Ct. at 3230 (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)) (emphasis in original). The recitation of some structure, such as a machine, or the recitation of some transformative component will in most cases limit the claim to such an application. However, not all such recitations necessarily save the claim: ''Flook established that limiting an abstract idea to one field of use or adding token postsolution components did not make the concept patentable.'' See *Bilski*, 130 S. Ct. at 3231. Moreover, the fact that the steps of a claim might occur in the ''real world'' does not necessarily save it from a **35 U.S.C. 101** rejection. Thus, the *Bilski* claims were said to be drawn to an ''abstract idea'' despite the fact that they included steps drawn to initiating transactions. The ''abstractness'' is in the sense that there are no limitations as to the mechanism for entering into the transactions.

Consistent with the foregoing, *Bilski* holds that the following claim is abstract:

> 1. A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:
>
> (a) Initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;
>
> (b) Identifying market participants for said commodity having a counter-risk position to said consumers; and
>
> (c) Initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances

> the risk position of said series of consumer transactions.

Specifically, the Court explains:

> The concept of hedging, described in claim 1 and reduced to a mathematical formula in claim 4, is an unpatentable abstract idea, just like the algorithms at issue in *Benson* and *Flook*. Allowing petitioners to patent risk hedging would preempt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.

Bilski also held that the additional, narrowing, limitations in the dependent claims were mere field of use limitations or insignificant postsolution components, and that adding these limitations did not make the claims patent-eligible. Claims 1–9 in *Bilski* are examples of claims that run afoul of the abstract idea exception. The day after deciding *Bilski*, the Supreme Court denied certiorari in *Ferguson v. Kappos*, U.S. Supreme Court No. 09–1501, while granting, vacating, and remanding two other Federal Circuit **35 U.S.C. 101** cases. The denial of certiorari left intact the rejection of all of Ferguson's claims. Although the Federal Circuit had applied the machine-or-transformation test to reject Ferguson's process claims, the Supreme Court's disposition of Ferguson makes it likely that the Ferguson claims also run afoul of the abstract idea exception. A representative Ferguson claim is:

> 1. A method of marketing a product, comprising:
>
> Developing a shared marketing force, said shared marketing force including at least marketing channels, which enable marketing a number of related products;
>
> Using said shared marketing force to market a plurality of different products that are made by a plurality of different autonomous producing company [sic], so that different autonomous companies, having different ownerships, respectively produce said related products;
>
> Obtaining a share of total profits from each of said plurality of different autonomous producing companies in return for said using; and
>
> Obtaining an exclusive right to market each of said plurality of products in return for said using.

The following guidance presents factors that are to be considered when evaluating patent-eligibility of method claims. The factors include inquiries from the machine-or-transformation test, which remains a useful investigative tool, and inquiries gleaned from Supreme Court precedent. See *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2009) (stating that "[a] claimed process is surely patent-eligible under § **101**if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."); and *Bilski*, 130 S. Ct. at 3227 (stating, "This Court's precedents establish that the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101. The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible 'process.'").

While the Supreme Court in *Bilski* did not set forth detailed guidance, there are many factors to be considered when determining whether there is sufficient evidence to support a determination that a method claim is directed to an abstract idea. The following factors are intended to be useful examples and are not intended to be exclusive or limiting. It is recognized that new factors may be developed, particularly for emerging technologies. It is anticipated that the factors will be modified and changed to take into account developments in precedential case law and to accommodate prosecution issues that may arise in implementing this new practice.

Where the claim is written in the form of a method and is potentially a patentable process, as defined in **35 U.S.C. 100(b)**, the claim is patent-eligible so long as it is not disqualified as one of the exceptions to **35 U.S.C. 101** 's broad patent-eligibility principles; i.e., laws of nature, physical phenomena, and abstract ideas.

Taking into account the following factors, the examiner should determine whether the claimed invention, viewed as a whole, is disqualified as being a claim to an abstract idea. Relevant factors—both those in favor of patent-eligibility and those against such a finding—should be weighed in making the determination. Factors that weigh in favor of patent-eligibility satisfy the criteria of the machine-or-transformation test or provide evidence that the abstract idea has been practically applied. Factors that weigh against patent-eligibility neither satisfy the criteria of the machine-or-transformation test nor provide evidence that the abstract idea has been practically applied. Each case will present different factors, and it is likely that only some of the factors will be present in each application. It would be improper to make a conclusion based on one factor while ignoring other factors.

With respect to the factors listed below, a "field-of-use" limitation does not impose actual boundaries on the scope of the claimed invention. A field-of-use limitation merely indicates that the method is for use in a particular environment, such as "for use with a machine" or "for

transforming an article", which would not require that the machine implement the method or that the steps of the method cause the article to transform. A field-of-use limitation does not impose a meaningful limit on the claimed invention. Insignificant "extra-solution" activity means activity that is not central to the purpose of the method invented by the applicant. For example, gathering data to use in the method when all applications of the method would require some form of data gathering would not impose a meaningful limit on the claim.

1. Factors To Be Considered in an Abstract Idea Determination of a Method Claim

(a) Whether the method involves or is executed by a particular machine or apparatus

"The machine-or-transformation test is a useful and important clue, and investigative tool, for determining whether some claimed inventions are processes under § **101**." *Bilski v. Kappos*, 561 U.S. ___, ___, 130 S. Ct. 3218, 3227, 95 USPQ2d 1001, ___ (2010). If so, the claims are less likely to be drawn to an abstract idea; if not, they are more likely to be so drawn. With respect to these factors, a "machine" is a concrete thing, consisting of parts, or of certain devices and combination of devices. This includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result. This definition is interpreted broadly to include electrical, electronic, optical, acoustic, and other such devices that accomplish a function to achieve a certain result. An "apparatus" does not have a significantly different meaning from a machine and can include a machine or group of machines or a totality of means by which a designated function or specific task is executed.

Where a machine or apparatus is recited or inherent in a patent claim, the following factors are relevant:

(a) The particularity or generality of the elements of the machine or apparatus; i.e., the degree to which the machine in the claim can be specifically identified (not any and all machines). Incorporation of a particular machine or apparatus into the claimed method steps weighs toward eligibility.

For computer implemented processes, the "machine" is often disclosed as a general purpose computer. In these cases, the general purpose computer may be sufficiently "particular" when programmed to perform the process steps. Such programming creates a new machine because a general purpose computer, in effect, becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software. *In re Alappat*, 33 F.3d 1526, 1545, 31 USPQ 1545, ___ (Fed. Cir. 1994); see also *Ultramercial v. Hulu*, 657 F.3d 1323, 1329, 100 USPQ2d 1140, 1145 (Fed. Cir. 2011) (stating "a programmed computer contains circuitry unique to that computer"). However, "adding a 'computer-aided' limitation to a claim covering an abstract concept, without more, is insufficient to render [a] patent claim eligible" where the claims "are silent as to how a computer aids the method, the extent to which a computer aids the method, or the significance of a computer to the performance of the method." *DealerTrack v. Huber*, ___ F.3d ___, ___, 101 USPQ2d 1325, 1339-40 (Fed. Cir. 2012). To qualify as a particular machine under the test, the claim must clearly convey that the computer is programmed to perform the steps of the method because such programming, in effect, creates a special purpose computer limited to the use of the particularly claimed combination of elements (i.e., the programmed instructions) performing the particularly claimed combination of functions. If the claim is so abstract and sweeping that performing the process as claimed would cover substantially all practical applications of a judicial exception, such as a mathematical algorithm, the claim would not satisfy the test as the machine would not be sufficiently particular.

(b) Whether the machine or apparatus implements the steps of the method. Integral use of a machine or apparatus to achieve performance of the method weighs toward eligibility, as compared to where the machine or apparatus is merely an object on which the method operates, which weighs against eligibility. See *Cybersource v. Retail Decisions*, 654 F.3d 1366, 99 USPQ2d 1960 (Fed. Cir. 2011) ("We are not persuaded by the appellant's argument that claimed method is tied to a particular machine because it 'would not be necessary or possible without the Internet.' . . . Regardless of whether "the Internet" can be viewed as a machine, it is clear that the Internet cannot perform the fraud detection steps of the claimed method").

(c) Whether its involvement is extrasolution activity or a field-of-use, i.e., the extent to which (or how) the machine or apparatus imposes meaningful limits on the execution of the claimed method steps. Use of a machine or apparatus that contributes only nominally or insignificantly to the execution of the claimed method (e.g., in a data gathering step or in a field-of-use limitation) would weigh against eligibility. See *Bilski*, 138 S. Ct. at 3230 (citing *Parker v. Flook*, 437 U.S. 584, 590, 198 USPQ 193, ___ (1978)), and *Cybersource v. Retail Decisions*, 654 F.3d 1366, 99 USPQ2d 1690 (Fed. Cir. 2011) ("while claim 3 requires an infringer to use the Internet to obtain that data . . . [t]he Internet is merely described as the source of the data. We have held that

mere '[data-gathering] step[s] cannot make an otherwise nonstatutory claim statutory.'" *In re Grams*, 888 F.2d 835, 840, 12 USPQ2d 1824, ___ (Fed. Cir. 1989) (quoting *In re Meyer*, 688 F.2d 789, 794, 215 USPQ 193, ___ (CCPA 1982)))...

(b) Whether performance of the claimed method results in or otherwise involves a transformation of a particular article

"Transformation and reduction of an article 'to a different state or thing' is the clue to patentability of a process claim that does not include particular machines." *Bilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3218, 3227, 95 USPQ2d 1001 (2010)(quoting *Gottschalk v. Benson*, 409 U.S. 63, 70, 175 USPQ 673, ___ (1972). If such a transformation exists, the claims are less likely to be drawn to an abstract idea; if not, they are more likely to be so drawn.

An "article" includes a physical object or substance. The physical object or substance must be particular, meaning it can be specifically identified. An article can also be electronic data that represents a physical object or substance. For the test, the data should be more than an abstract value. Data can be specifically identified by indicating what the data represents, the particular type or nature of the data, and/or how or from where the data was obtained.

"Transformation" of an article means that the "article" has changed to a different state or thing. Changing to a different state or thing usually means more than simply using an article or changing the location of an article. A new or different function or use can be evidence that an article has been transformed. Manufactures and compositions of matter are the result of transforming raw materials into something new with a different function or use. Purely mental processes in which thoughts or human based actions are "changed" are not considered an eligible transformation. For data, mere "manipulation of basic mathematical constructs [i.e,] the paradigmatic 'abstract idea'," has not been deemed a transformation. *Cybersource v. Retail Decisions*, 654 F.3d 1366, 1372 n.2, 99 USPQ2d 1690, 1695 n.2 (Fed. Cir. 2011) *(quoting In re Warmerdam*, 33 F.3d 1354, 1355, 1360 (Fed. Cir. 1994). However, transformation of electronic data has been found when the nature of the data has been changed such that it has a different function or is suitable for a different use. *In re Bilski*, 545 F.3d 943, 962-63 (Fed. Cir. 2009)(*aff'd sub nom Bilski v. Kappos*, 130 S. Ct. 3218 (2010)).

Where a transformation occurs, the following factors are relevant:

(a) The particularity or generality of the transformation. The Supreme Court has stated that an invention comprising a process of "'tanning, dyeing, making waterproof cloth, vulcanizing India rubber [or] smelting ores' . . . are instances . . . where the use of chemical substances or physical acts, such as temperature control, changes articles or materials [in such a manner that is] sufficiently definite to confine the patent monopoly within rather definite bounds." *Gottschalk v. Benson*, 409 U.S. 63, 70, 175 USPQ 673, ___ (1972) (discussing *Corning v. Burden*, 15 How.(56 U.S.) 252, 267-68). A more particular transformation would weigh in favor of eligibility.

(b) The degree to which the recited article is particular; i.e., can be specifically identified (not any and all articles). A transformation applied to a generically recited article would weigh against eligibility.

(c) The nature of the transformation in terms of the type or extent of change in state or thing, for instance by having a different function or use, which would weigh toward eligibility, compared to merely having a different location, which would weigh against eligibility.

(d) The nature of the article transformed, i.e., whether it is an object or substance, weighing toward eligibility, compared to a concept such as a contractual obligation or mental judgment, which would weigh against eligibility.

(e) Whether its involvement is extrasolution activity or a field-of-use, i.e., the extent to which (or how) the transformation imposes meaningful limits on the execution of the claimed method steps. A transformation that contributes only nominally or insignificantly to the execution of the claimed method (e.g., in a data gathering step or in a field-of-use limitation) would weigh against eligibility.

(c) Whether performance of the claimed method involves an application of a law of nature, even in the absence of a particular machine, apparatus, or transformation

An application of a law of nature may represent patent-eligible subject matter even in the absence of a particular machine, apparatus, or transformation. See, e.g., *Bilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3218, 3227, 95 USPQ2d 1001 (2010)(citing *Diamond v. Diehr*, 450 U.S. 175, 187, 209 USPQ 1, ___ (1981)) (stating that

the Court had previously "explicitly declined to 'hold that no process patent could ever qualify if it did not meet [machine or transformation] requirements.") (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67, 175 USPQ 673, ___ (1972)). If such an application exists, the claims are less likely to be drawn to an abstract idea; if not, they are more likely to be so drawn. See **MPEP § 2106.01** for further guidance regarding subject matter eligibility determinations during examination of process claims that involve laws of nature/natural correlations.

Where such an application is present, the following factors are relevant:

(a) The particularity or generality of the application. Application of a law of nature having broad applicability across many fields of endeavor weighs against eligibility, such as where the claim generically recites an effect of the law of nature or claims every mode of accomplishing that effect, such that the claim would monopolize a natural force or patent a scientific fact. See *O'Reilly v. Morse*, 56 U.S. 62 (1853)(finding unpatentable a claim for "the use of electromagnetism for transmitting signals at a distance"); *The Telephone Cases*, 126 U.S. 1, 209 (1888)(discussing a method of "transmitting vocal or other sound telepgraphically ... by causing electrical undulations, similar in form to the vibrations of the air accompanying the said vocal or other sounds," stating "[Bell] had detected a secret of nature . . . .[H]e proceeded promptly to patent, not only a particular method and apparatus for availing of that law, but also the right to avail of that law by any means whatever. Thus considered he has been able to monopolize a natural force, and patent a scientific fact.").

(b) Whether the claimed method recites an application of a law of nature solely involving subjective determinations; e.g., ways to think about the law of nature. Application of a law of nature to a particular way of thinking about, or reacting to, a law of nature would weigh against eligibility. See *The Telephone Cases*, 126 U.S. at 210 (stating "[counsel for defendant] argued, that in all the cases upholding a claim for a process, the process was one capable of being sensually perceived, verified and proved by oath -- not as a matter of opinion, but as a matter of fact."), id. at 211 (discussing *Tilghman v. Proctor*, 102 U.S. 707 (1880) ("[t]here was a process, all of which lay within ordinary means of observation and verification.").

(c) Whether its involvement is extrasolution activity or a field-of-use, i.e., the extent to which (or how) the application imposes meaningful limits on the execution of the claimed method steps. An application of the law of nature that contributes only nominally or insignificantly to the execution of the claimed method (e.g., in a data gathering step or in a field-of-use limitation) would weigh against eligibility.

(d) Whether a general concept (which could also be recognized in such terms as a principle, theory, plan or scheme) is involved in executing the steps of the method

The presence of such a general concept can be a clue that the claim is drawn to an abstract idea. Where a general concept is present, the following factors are relevant:

(a) The extent to which use of the concept, as expressed in the method, would preempt its use in other fields; i.e., that the claim would effectively grant a monopoly over the concept. *Bilski v. Kappos*, 561 U.S. ___, ___, 130 S. Ct. 3218, 3231, 95 USPQ2d 1001, ___ (2010).

(b) The extent to which the claim is so abstract and sweeping as to cover both known and unknown uses of the concept, and be performed through any existing or future-devised machinery, or even without any apparatus. *Gottschalk v. Benson*, 409 U.S. 63, 68, 175 USPQ 673, ___ (1972) (stating "[h]ere the process' claim is so abstract and sweeping as to cover both known and unknown uses of the BCD to pure binary conversion. The end use may (1) vary from the operation of a train to verification of drivers' licenses to researching the law books for precedents and (2) be performed through any existing machinery or future-devised machinery or without any apparatus").

(c) The extent to which the claim would effectively cover all possible solutions to a particular problem; i.e., that the claim is a statement of the problem versus a description of a particular solution to the problem. See *The Telephone Cases*, 126 U.S. 1, 161-162 (1888) (discussing *Tilghman v. Proctor*, 102 U.S. 707 (1880)("'The claim of the patent [in Tilghman] is not for a mere principle.' . . . In that case there was a problem. Find a way, if you can, to combine each atom of water with an atom of acid. If you can do that, then you can reach this important result of resolving the neutral fats into glycerine and acids. And *Tilghman*'s solution of it was: Heat the water under such pressure that the water shall not pass into steam. This was his process; and he claimed, and the court justly allowed, great latitude in its application.")).

(d) Whether the concept is disembodied or whether it is instantiated; i.e., implemented, in some tangible way. A concept that is well-instantiated weighs in favor of eligibility.

See, e.g., *Bilski*, 138 S. Ct. at 3230 (stating that the Court in *Diehr* "concluded that because the claim was not 'an attempt to patent a mathematical formula, but rather [was] an industrial process for the molding of rubber products,' it fell within § 101's patentable subject matter." (citing *Diehr*, 450 U.S. at 192-193)). Accord *Research Corp. Technologies v. Microsoft Corp.*, 677 F.3d 859, 868-869, 97 USPQ2d 1274, ___ (Fed. Cir. 2010) (stating that the claims here "'do not seek to patent a mathematical formula'" but rather a process of halftoning in computer applications, presenting "functional and palpable applications in the field of computer technology" such that applicant's claimed invention requires instantiation (in some claims) through "a 'high contrast film,' 'a film printer,' 'a memory,' and 'printer and display devices'"); *Ultramercial v. Hulu*, 657 F.3d 1323, 1328, 100 USPQ2d 1140, 1144(Fed. Cir. 2011)(stating that the patent "does not simply claim the age-old idea that advertising can serve as currency, [but instead] a practical application of this idea.").

A concept that is not well-instantiated weighs against eligibility. See *DealerTrack v. Huber*, ___ F.3d ___, 101 USPQ2d 1325 (2012) where in the court stated:

> The claims are silent as to how a computer aids the method, the extent to which a computer aids the method, or the significance of a computer to the performance of the method. The undefined phrase "computer-aided" is no less abstract than the idea of a clearinghouse itself. Because the computer here "can be programmed to perform very different tasks in very different ways," it does not "play a significant part in permitting the claimed method to be performed." Simply adding a "computer aided" limitation to a claim covering an abstract concept, without more, is insufficient to render the claim patent eligible... "In order for the addition of a machine to impose a meaningful limit on the scope of a claim, it must play a significant part in permit-ting the claimed method to be performed, rather than function solely as an obvious mechanism for permitting a solution to be achieved more quickly, i.e., through the utilization of a computer for performing calculations."

Dealertrack, ___ F.3d at ___, 101 USPQ2d at 1339-40 (citations omitted). Furthermore, limiting an abstract idea to one field of use or adding token postsolution components does not make the concept patentable.

(e) The mechanism(s) by which the steps are implemented; e.g., whether the performance of the process is observable and verifiable rather than subjective or imperceptible. Steps that are observable and verifiable weigh in favor of eligibility. *The Telephone Cases*, 126 U.S. at 211 (discussing *Tilghman v. Proctor*, 102 U.S. 707 (1880) ("[t]here was a process, all of which lay within ordinary means of observation and verification").

(f) Examples of general concepts include, but are not limited to:

- Basic economic practices or theories (e.g., hedging, insurance, financial transactions, marketing);
- Basic legal theories (e.g., contracts, dispute resolution, rules of law);
- Mathematical concepts (e.g., algorithms, spatial relationships, geometry);
- Mental activity (e.g., forming a judgment, observation, evaluation, or opinion);
- Interpersonal interactions or relationships (e.g., conversing, dating);
- Teaching concepts (e.g., memorization, repetition);
- Human behavior (e.g., exercising, wearing clothing, following rules or instructions);
- Instructing ''how business should be conducted.''

See, e.g., *Bilski*, 138 S. Ct. at 3231 (stating "[t]he concept of hedging, described in claim 1 and reduced to a mathematical formula in claim 4, is an unpatentable abstract idea."), *In re Ferguson*, 558 F.3d 1359, 90 USPQ2d 1035 (2009) (cert. denied *Ferguson v. PTO*, June 29, 2010)(finding ineligible "methods . . . directed to organizing business or legal relationships in the structuring of a sales force (or marketing company);" *Benson*, 409 U.S. at 67 (stating "mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work."); *Bilski*, 130 S. Ct. at 3231 (quoting *Le Roy v. Tatham*, 14 How. (55 U.S.) 156, 175 ("[a] principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right")). See also *Bilski*, 130 S. Ct. at 3259 (Breyer, J. concurring).

2. Making the Determination of Eligibility

Each of the factors relevant to the particular patent application should be weighed to determine whether the method is claiming an abstract idea by covering a general concept, or combination of concepts, or whether the method is limited to a particular practical application of the concept. The presence or absence of a single factor will not be determinative as the relevant factors need to be considered and weighed to make a proper determination as to whether the claim as a whole is drawn to an abstract idea such that the claim would effectively

grant a monopoly over an abstract idea and be ineligible for patent protection.

If the factors indicate that the method claim is not merely covering an abstract idea, the claim is eligible for patent protection under **35 U.S.C. 101** and must be further evaluated for patentability under all of the statutory requirements, including utility and double patenting (**35 U.S.C. 101**); novelty (**35 U.S.C. 102**); non-obviousness (**35 U.S.C. 103**); and definiteness and adequate description, enablement, and best mode (**35 U.S.C. 112**). **35 U.S.C. 101** is merely a coarse filter and thus a determination of eligibility under **35 U.S.C. 101** is only a threshold question for patentability. **35 U.S.C. 102**, **103** , and **112** are typically the primary tools for evaluating patentability unless the claim is truly abstract, see, e.g., *Bilski v. Kappos*, 561 U.S. ___, ___, 130 S. Ct. 3218, 3229, 95 USPQ2d 1001, ___ (2010). (''[S]ome business method patents raise special problems in terms of vagueness and suspect validity.'').

If the factors indicate that the method claim is attempting to cover an abstract idea, the examiner will reject the claim under **35 U.S.C. 101** , providing clear rationale supporting the determination that an abstract idea has been claimed, such that the examiner establishes a prima facie case of patent-ineligibility. The conclusion made by the examiner must be based on the evidence as a whole. In making a rejection or if presenting reasons for allowance when appropriate, the examiner should specifically point out the factors that are relied upon in making the determination. If a claim is rejected under **35 U.S.C. 101** on the basis that it is drawn to an abstract idea, the applicant then has the opportunity to explain why the claimed method is not drawn to an abstract idea. Specifically identifying the factors used in the analysis will allow the applicant to make specific arguments in response to the rejection if the applicant believes that the conclusion that the claim is directed to an abstract idea is in error.

III. Establish on the Record a Prima Facie Case

USPTO personnel should review the totality of the evidence (e.g., the specification, claims, relevant prior art) before reaching a conclusion with regard to whether the claimed invention sets forth patent eligible subject matter. USPTO personnel must weigh the determinations made above to reach a conclusion as to whether it is more likely than not that the claimed invention as a whole either falls outside of one of the enumerated statutory classes or within one of the exceptions to statutory subject matter. "The examiner bears the initial burden … of presenting a prima facie case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). If the record as a whole suggests that it is more likely than not that the claimed invention would be considered a practical application of an abstract idea, physical phenomenon, or law of nature, then USPTO personnel should not reject the claim.

After USPTO personnel identify and explain in the record the reasons why a claim is for an abstract idea, physical phenomenon, or law of nature with no practical application, then the burden shifts to the applicant to either amend the claim or make a showing of why the claim is eligible for patent protection. See, e.g., *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995); see generally **MPEP § 2107** (Utility Guidelines).

Under the principles of compact prosecution, each claim should be reviewed for compliance with every statutory requirement for patentability in the initial review of the application, even if one or more claims are found to be deficient with respect to the patent-eligibility requirement of **35 U.S.C. 101** . Thus, Office personnel should state all non-cumulative reasons and bases for rejecting claims in the first Office action.

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2106.01 **>Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature [R-9]

I. SUMMARY

The following guidance is intended for use in subject matter eligibility determinations during examination of process claims that involve laws of nature/natural correlations, such as the claims in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. __, 132 S.Ct. 1289, 101 USPQ2d 1961 (2012) (*Mayo*). Process claims that are directed to abstract ideas, such as the claims in *Bilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3218, 95 USPQ2d 1001 (2010), should continue to be examined using the guidance set forth in **MPEP § 2106**.

The guidance set forth in this section should be followed for examination of process claims in which a law of nature, a natural phenomenon, or a naturally occurring relation or correlation (collectively referred to as a natural principle in the guidance) is a limiting element or step. In summary, process claims having a natural principle as a limiting element or step should be evaluated by determining whether the claim includes additional elements/steps or a combination of elements/steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied, and are sufficient to ensure that the claim amounts to significantly more than the natural principle itself. If the

claim as a whole satisfies this inquiry, the claim is directed to patent-eligible subject matter. If the claim as a whole does not satisfy this inquiry, it should be rejected under **35 U.S.C. 101** as being directed to non-statutory subject matter.

II. ESSENTIAL INQUIRIES FOR SUBJECT MATTER ELIGIBILITY UNDER 35 U.S.C. 101

After determining what applicant invented and establishing the broadest reasonable interpretation of the claimed invention, conduct the following three inquiries on the claim as a whole to determine whether the claim is drawn to patent-eligible subject matter. Further details regarding each inquiry are provided below.

1. **Is the claimed invention directed to a process, defined as an act, or a series of acts or steps?**If no, this analysis is not applicable. Fore product claims see **MPEP § 2106**. If yes, proceed to Inquiry 2.

2. **Does the claim focus on use of a law of nature, a natural phenomenon, or naturally occurring relation or correlation (collectively referred to as a natural principle herein)? (Is the natural principle a limiting feature of the claim?)**If no, this analysis is complete, and the claim should be analyzed to determine if an abstract idea is claimed (see **MPEP § 2106**). If yes, proceed to Inquiry 3.

3. **Does the claim include additional elements/steps or a combination of elements/steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied, and are sufficient to ensure that the claim amounts to significantly more than the natural principle itself? (Is it more than a law of nature plus the general instruction to simply "apply it"?)**If no, the claim is not patent-eligible and should be rejected. If yes, the claim is patent-eligible, and the analysis is complete.

III. DETAILED GUIDANCE FOR USING THE INQUIRIES

Determining What Applicant Invented and the Broadest Reasonable Interpretation

Review the entire specification and claims to determine what applicant believes that he or she invented. Then review the claims to determine the boundaries of patent protection sought by the applicant and to understand how the claims relate to and define what the applicant has indicated is the invention.

Claim analysis begins by identifying and evaluating each claim limitation and then considering the claim as a whole. It is improper to dissect a claimed invention into discrete elements and then evaluate the elements in isolation because it is the combination of claim limitations functioning together that establish the boundaries of the invention and limit its scope.

Establish the broadest reasonable interpretation of the claims when read in light of the specification and from the view of one of ordinary skill in the art. This same interpretation must be used to evaluate the compliance with each statutory requirement. See**MPEP § 2111** and **§ 2173** et seq. for further details of claim construction and compliance with **35 U.S.C. 112**, second paragraph, respectively.

INQUIRY 1: Process

Under this analysis, the claim must be drawn to a process. A process is defined as an act, or a series of acts or steps. Process claims are sometimes called method claims.

INQUIRY 2: Natural Principle

Does the claim focus on use of a natural principle, i.e., a law of nature, a natural phenomenon, or naturally occurring relation or correlation? (Is the natural principle a limiting feature of the claim?)

A natural principle is the handiwork of nature and occurs without the hand of man. For example, the disinfecting property of sunlight is a natural principle. The relationship between blood glucose levels and diabetes is a natural principle. A correlation that occurs naturally when a man-made product, such as a drug, interacts with a naturally occurring substance, such as blood, is also considered a natural principle because, while it takes a human action to trigger a manifestation of the correlation, the correlation exists in principle apart from any human action. These are illustrative examples and are not intended to be limiting or exclusive.

For this analysis, a claim focuses on a natural principle when the natural principle is a limiting element or step. In that case, the claim must be analyzed (in Inquiry 3) to ensure that the claim is directed to a practical application of the natural principle that amounts to substantially more than the natural principle itself. So, for instance, a claim that recites a correlation used to make a diagnosis focuses on a natural principle and would require further analysis under Inquiry 3.

If a natural principle is not a limitation of the claim, the claim does not focus on the use of a natural principle and requires no further analysis under this procedure. If the claim focuses on an abstract idea, such as steps that can

be performed entirely in one's mind, methods of controlling human activity, or mere plans for performing an action, refer to **MPEP § 2106** to evaluate eligibility.

INQUIRY 3: Practical Application and Preemption

Does the claim include additional elements/steps or a combination of elements/steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied, and are sufficient to ensure that the claim amounts to significantly more than the natural principle itself? (Is it more than a law of nature plus the general instruction to simply "apply it"?)

A claim that focuses on use of a natural principle must also include additional elements or steps to show that the inventor has practically applied, or added something significant to, the natural principle itself. See *Mayo*, 101 USPQ2d at 1966. To show integration, the additional elements or steps must relate to the natural principle in a significant way to impose a meaningful limit on the claim scope. The analysis turns on whether the claim has added enough to show a practical application. See *id.* at 1968. In other words, the claim cannot cover the natural principle itself such that it is effectively standing alone. A bare statement of a naturally occurring correlation, albeit a newly discovered natural correlation or very narrowly confined correlation, would fail this inquiry. See *id.* at 1965, 1971.

It is not necessary that every recited element or step integrate or relate to the natural principle as long as it is applied in some practical manner. However, there must be at least one additional element or step that applies, relies on or uses the natural principle so that the claim amounts to significantly more than the natural principle itself. Elements or steps that do not integrate the natural principle and are merely appended to it would not be sufficient. In other words, the additional elements or steps must not simply amount to insignificant extra-solution activity that imposes no meaningful limit on the performance of the claimed invention. See *id*. at 1966. For example, a claim to diagnosing an infection that recites the step of correlating the presence of a certain bacterium in a person's blood with a particular type of bacterial infection with the additional step of recording the diagnosis on a chart would not be eligible because the step of recording the diagnosis on the chart is extra-solution activity that is unrelated to the correlation and does not integrate the correlation into the invention.

Along with integration, the additional steps must be sufficient to ensure that the claim amounts to significantly more than the natural principle itself by including one or more elements or steps that limit the scope of the claim and do more than generally describe the natural principle with generalized instructions to "apply it." See *id.* at 1965, 1968. The additional elements or steps must narrow the scope of the claim such that others are not foreclosed from using the natural principle (a basic tool of scientific and technological work) for future innovation. Elements or steps that are well-understood, purely conventional, and routinely taken by others in order to apply the natural principle, or that only limit the use to a particular technological environment (field-of-use), would not be sufficiently specific. See id. at 1968. A claim with steps that add something of significance to the natural laws themselves would be eligible because it would confine its reach to particular patent-eligible applications of those laws, such as a typical patent on a new drug (including associated method claims) or a new way of using an existing drug. See *id.* at 1971; see also **35 U.S.C. 100(b)**. In other words, the claim must be limited so that it does not preempt the natural principle being recited by covering every substantial practical application of that principle. The process must have additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. See *id.* at 1968.

A claim that would fail this inquiry includes, for example, a claim having a limitation that describes a law of nature and additional steps that must be taken in order to apply the law of nature by establishing the conditions under which the law of nature occurs such as a step of taking a sample recited at a high level of generality to test for a naturally occurring correlation. See *id.* at 1970. Adding steps to a natural biological process that only recite well-understood, routine, conventional activity previously engaged in by researchers in the field would not be sufficient. See *id.* at 1966, 1970. A combination of steps that amounts to nothing significantly more than an instruction to doctors to "apply" applicable natural laws when treating their patients would also not be sufficient. See *id.* at 1970.

Claims that do not include a natural principle as a limitation do not raise issues of subject matter eligibility under the law of nature exception. For example, a claim directed to simply administering a man-made drug that does not recite other steps or elements directed to use of a natural principle, such as a naturally occurring correlation, would be directed to eligible subject matter. Further, a claim that recites a novel drug or a new use of an existing drug, in combination with a natural principle, would be sufficiently specific to be eligible because the claim would amount to significantly more than the natural principle itself. However, a claim does not have to be

novel or non-obvious to qualify as a subject matter eligible claim. Moreover, a claim that is deemed eligible is not necessarily patentable unless it also complies with the other statutory and non-statutory considerations for patentability under **35 U.S.C. 101** (utility and double patenting), **102**, **103**, **112**, and non-statutory double patenting.

The weighing factors used in **MPEP § 2106** are useful tools for assisting in the evaluation. For convenience, these factors and how they may assist in the analysis are summarized below.

RELEVANT FACTORS USEFUL FOR INQUIRY 3

The following factors can be used to analyze the additional features in the claim to determine whether the claim recites a patent-eligible practical application of a natural principle and assist in answering Inquiry 3 above. Many of these factors originate from past eligibility factors, including the 'Machine-or-Transformation' (M-or-T) test. However, satisfying the M-or-T factors does not ensure eligibility if the claim features that include a particular machine or transformation do not integrate the natural principle into the claimed invention to show that the natural principle is practically applied, and are not sufficient to ensure that the claim amounts to significantly more than the natural principle itself.

• Appending conventional steps, specified at a high level of generality, to a natural principle does not make the claim patent-eligible.

• Steps that amount to instructions that are well-understood, routine, conventional activity, previously engaged in by those in the field add nothing specific to the natural principle that would render it patent-eligible.

• A claim that covers known and unknown uses of a natural principle and can be performed through any existing or future-devised machinery, or even without any apparatus, would lack features that are sufficient for eligibility.

• A particular machine or transformation recited in more than general terms may be sufficient to limit the application to just one of several possible machines or just one of several possible changes in state, such that the claim does not cover every substantial practical application of a natural principle. This can be contrasted with only adding features that limit the application to a certain technological environment (e.g., for use in catalytic conversion systems), which would cover every substantial practical application in that field.

• Additional limitations that are necessary for all practical applications of the natural principle, such that everyone practicing the natural principle would be required to perform those steps or every product embodying that natural principle would be required to include those features, would not be sufficient.

• A particular machine or transformation recited in a claim can show how the natural principle is integrated into a practical application by describing the details of how that machine and its specific parts implement the natural principle (e.g., the parts of an internal combustion engine apply the concept of combustion to produce energy) or how the transformation relates to or implements the natural principle (e.g., using ionization in a manufacturing process).

• A machine or transformation that is merely nominally, insignificantly, or tangentially related to the steps or elements, e.g., data gathering or data storage, would not show integration. For example, a machine that is simply incidental to execution of the method (using a computer as a counter balance weight and not as a processing device) rather than an object that implements the method or a transformation that involves only a change of position or location of an object rather than a change in state or thing does not show that these additional features integrate the natural principle into the invention as they are incidental to the claimed invention.

• Complete absence of a machine-or-transformation in a claim signals the likelihood that the claim is directed to a natural principle and has not been instantiated (e.g., is disembodied or can be performed entirely in one's mind.)

• A mere statement of a general concept (natural principle) would effectively monopolize that concept/principle and would be insufficient. This can be contrasted with a tangible implementation with elements or steps that are recited with specificity such that all substantial applications are not covered. Such specificity may be achieved with observable and verifiable steps, for example, rather than subjective or imperceptible steps.

SAMPLE ANALYSIS

Sample Claim Drawn to a Patent-Eligible Practical Application - ***Diamond v. Diehr***

1. A method of operating a rubber-molding press for precision molded compounds with the aid of a digital computer, comprising:

providing said computer with a data base for said press including at least, natural logarithm conversion data (ln), the activation energy constant (C) unique to each batch of said compound being molded, and a constant (x) dependent upon the geometry of the particular mold of the press,

initiating an interval timer in said computer upon the closure of the press for monitoring the elapsed time of said closure,

constantly determining the temperature (Z) of the mold at a location closely adjacent to the mold cavity in the press during molding, constantly providing the computer with the temperature (Z),

repetitively calculating in the computer, at frequent intervals during each cure, the Arrhenius equation for reaction time during the cure, which is ln v = CZ + x where v is the total required cure time,

repetitively comparing in the computer at said frequent intervals during the cure each said calculation of the total required cure time calculated with the Arrhenius equation and said elapsed time,

and opening the press automatically when a said comparison indicates equivalence.

The above claim was found to be a patent-eligible practical application in *Diamond v. Diehr*, 450 U.S. 175 (1981). Recently, the Supreme Court looked back to this claim as an example of a patent-eligible practical application as explained in the following excerpt from *Mayo*:

> The Court pointed out that the basic mathematical equation, like a law of nature, was not patentable. But it found the overall process patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole. Those steps included "installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time." [ ] It nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional. And so the patentees did not "seek to pre-empt the use of [the] equation," but sought "only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process." [ ] These other steps apparently added to the formula something that in terms of patent law's objectives had significance—they transformed the process into an inventive application of the formula. See Mayo at 1969 (emphasis added).

This claim would pass Inquiries 1-3 in the above analysis as it is a process that includes the Arrhenius equation as a limitation, with additional steps that integrate the Arrhenius equation into the process and are sufficient to narrow the scope of the claim so that others are not foreclosed from using the Arrhenius equation in different applications.

Sample Claim Drawn to Ineligible Subject Matter - *Mayo v. Prometheus*

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

The above claim was found to be ineligible in *Mayo*. The Supreme Court determined that the claim focused on use of a law of nature that was given weight during prosecution of the claim – specifically the relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. See *id.* at 1967. The Court analyzed the claim as follows:

> The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws? We believe that the answer to this question is no. See *id.* at 1968.
>
> The upshot is that the three steps simply tell doctors to gather data from which they may draw an inference in light of the correlations. To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well understood, routine,

> conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities. See *id.* at 1968.

This claim would pass Inquiries 1-2 and fail Inquiry 3. It is a process claim that includes a natural principle that was construed as a limiting feature of a claim during prosecution - the natural principle being the naturally occurring relationships noted above, which are a consequence of the ways in which thiopurine compounds are metabolized by the body. The Court emphasized that while it takes a human action to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. See *id.* at 1967. The additional steps integrate the relationship into the process as the administering step involves the thiopurine drug, the determining step establishes the thiopurine drug level and the wherein clauses set forth the critical levels. The steps are not sufficient, however, to narrow the application such that others could still make use of the naturally occurring relationship in other practical applications. The claim essentially sets forth a law of nature with generalized instructions to apply it.

Making a Rejection

After performing the appropriate Inquiries, a claim that fails Inquiry 3 should be rejected under **35 U.S.C. 101** as not being drawn to patent-eligible subject matter. When making the rejection, identify the natural principle, identify that the claim is effectively directed to a natural principle itself, and explain the reason(s) that the additional claim features or combination of features, when the claim is taken as a whole, fail to integrate the natural principle into the claimed invention so that the natural principle is practically applied, and/or fail to be sufficient to ensure that the claim amounts to significantly more than the natural principle itself.

A sample rejection of the following claim could read as follows:

Claim 1. A method of determining effective dosage of insulin to a patient, comprising the steps of administering a dose of insulin to a patient, testing the patient's blood for the blood sugar level, and evaluating whether the insulin dosage is effective based on the blood sugar level.

Analysis:

> The claim passes Inquiry 1 because it is drawn to a process.
> The claim passes Inquiry 2 because a naturally occurring correlation between insulin and blood glucose levels is a limitation of the claim.
> The claim does not pass Inquiry 3 because, although the additional steps integrate or make use of the correlation in the process by administering insulin in one step and testing for the correlation in another step, the steps are not sufficient to ensure that the claim amounts to significantly more than the correlation itself since every application of the correlation would require an administration of insulin and testing of blood to observe the relationship between insulin and blood glucose levels.

The rejection:

Claim 1 is rejected under **35 U.S.C. 101** because the claimed invention is directed to non-statutory subject matter because it is not a patent-eligible practical application of a law of nature. The claim is directed to a naturally occurring correlation between insulin and blood glucose levels. The combination of steps recited in the claim taken as a whole, including the steps of administering insulin to a patient and testing blood sugar levels, are not sufficient to qualify as a patent-eligible practical application as the claim covers every substantial practical application of the correlation.

Evaluating a Response

A proper response to a rejection based on failure to claim patent-eligible subject matter would be an amendment adding additional steps/features or amending existing steps/features that integrate the natural principle into the process (by practically applying or making use of the principle) and are sufficient to limit the application of the natural principle to more than the principle itself + steps that do more than simply "apply it" at a high level of generality. Examples of both eligible and ineligible hypothetical claims follow. It would also be proper for the applicant to present persuasive arguments that the additional steps add something significantly more to the claim than merely describing the natural principle. A showing that the steps are not routine, well-known or conventional could be persuasive.

For example, a claim that uses the natural disinfecting properties of sunlight would require additional steps beyond exposing an item requiring disinfection to sunlight. The additional steps could involve constructing a sanitizing device that uses ultraviolet light for

disinfection with steps that integrate the ultraviolet light into the device and are sufficient to confine the use of the ultraviolet light to a particular application (not so broad as to cover all practical ways of applying ultraviolet light). A claim that sets forth the relationship between blood glucose levels and the incidence of diabetes would require additional steps that do significantly more to apply this principle than conventional blood sample testing or diagnostic activity based on recognizing a threshold blood glucose level. Such additional steps could involve a testing technique or treatment steps that would not be conventional or routine.

See the *2012 Interim Procedure for Laws of Nature* guidance memo issued July 3, 2012 and posted on the USPTO web site (http://www.uspto.gov/patents/law/exam/2012_interim_guidance.pdf) for additional examples. <

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2107 Guidelines for Examination of Applications for Compliance with the Utility Requirement

I. INTRODUCTION

The following Guidelines establish the policies and procedures to be followed by Office personnel in the evaluation of any patent application for compliance with the utility requirements of **35 U.S.C. 101** and **112**. These Guidelines have been promulgated to assist Office personnel in their review of applications for compliance with the utility requirement. The Guidelines do not alter the substantive requirements of **35 U.S.C. 101** and **112**, nor are they designed to obviate the examiner's review of applications for compliance with all other statutory requirements for patentability. The Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.

II. EXAMINATION GUIDELINES FOR THE UTILITY REQUIREMENT

Office personnel are to adhere to the following procedures when reviewing patent applications for compliance with the "useful invention" ("utility") requirement of **35 U.S.C. 101** and **112**, first paragraph.

(A) Read the claims and the supporting written description.(1) Determine what the applicant has claimed, noting any specific embodiments of the invention.

(2) Ensure that the claims define statutory subject matter (i.e., a process, machine, manufacture, composition of matter, or improvement thereof).

(3) If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.

(B) Review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible:(1) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.(i) A claimed invention must have a specific and substantial utility. This requirement excludes "throw-away," "insubstantial," or "nonspecific" utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. **101**.

(ii) Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.

(2) If no assertion of specific and substantial utility for the claimed invention made by the applicant is credible, and the claimed invention does not have a readily apparent well-established utility, reject the claim(s) under 35 U.S.C. **101** on the grounds that the invention as claimed lacks utility. Also reject the claims under 35 U.S.C. **112**, first paragraph, on the basis that the disclosure fails to teach how to use the invention as claimed. The 35 U.S.C. **112**, first paragraph, rejection imposed in conjunction with a 35 U.S.C. **101** rejection should incorporate by reference the grounds of the corresponding 35 U.S.C. **101** rejection.

(3) If the applicant has not asserted any specific and substantial utility for the claimed invention and it does not have a readily apparent well-established utility, impose a rejection under 35 U.S.C. **101**, emphasizing that the applicant has not disclosed a specific and substantial utility for the invention. Also impose a separate rejection under 35 U.S.C. **112**, first paragraph, on the basis that the applicant has not disclosed how to use the invention due to the lack of a specific and substantial utility. The 35 U.S.C. **101** and **112** rejections shift the burden of coming forward with evidence to the applicant to:(i) Explicitly

identify a specific and substantial utility for the claimed invention; and

(ii) Provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established at the time of filing. The examiner should review any subsequently submitted evidence of utility using the criteria outlined above. The examiner should also ensure that there is an adequate nexus between the evidence and the properties of the now claimed subject matter as disclosed in the application as filed. That is, the applicant has the burden to establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention.

(C) Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the *prima facie* showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.(1) Where the asserted utility is not specific or substantial, a *prima facie* showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The *prima facie* showing must contain the following elements:(i) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;

(ii) Support for factual findings relied upon in reaching this conclusion; and

(iii) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(2) Where the asserted specific and substantial utility is not credible, a *prima facie* showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention. The *prima facie* showing must contain the following elements:(i) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;

(ii) Support for factual findings relied upon in reaching this conclusion; and

(iii) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(3) Where no specific and substantial utility is disclosed or is well-established, a *prima facie* showing of no specific and substantial utility need only establish that applicant has not asserted a utility and that, on the record before the examiner, there is no known well-established utility.

(D) A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record.

Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.

Once a *prima facie* showing of no specific and substantial credible utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR **1.132** or a patent or a printed publication that rebuts the basis or logic of the *prima facie* showing. If the applicant responds to the *prima facie* rejection, the Office personnel should review the original disclosure, any evidence relied upon in establishing the *prima facie* showing, any claim amendments, and any new reasoning or evidence provided by the applicant in support of an asserted specific and substantial credible utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained.

If the applicant satisfactorily rebuts a *prima facie* rejection based on lack of utility under 35 U.S.C. **101**, withdraw the 35 U.S.C. **101** rejection and the corresponding rejection imposed under 35 U.S.C. **112**, first paragraph.

2107.01 General Principles Governing Utility Rejections [R-9]

35 U.S.C. 101 Inventions patentable

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof may obtain a patent

therefor, subject to the conditions and requirements of this title.

See **MPEP § 2107** for guidelines for the examination of applications for compliance with the utility requirement of **35 U.S.C. 101**.

The Office must examine each application to ensure compliance with the "useful invention" or utility requirement of **35 U.S.C. 101**. In discharging this obligation, however, Office personnel must keep in mind several general principles that control application of the utility requirement. As interpreted by the Federal courts, **35 U.S.C. 101** has*> three< purposes. First, **35 U.S.C. 101**>limits an inventor to ONE patent for a claimed invention. If more than one patent is sought, a patent applicant will receive a statutory double patenting rejection for claims included in more than one application that are directed to the same invention. See **MPEP § 804**. Second, **35 U.S.C. 101**<defines which categories of inventions are eligible for patent protection. An invention that is not a machine, an article of manufacture, a composition or a process cannot be patented. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980); *Diamond v. Diehr*, 450 U.S. 175, 209 USPQ 1 (1981)*>; *In re Nuijten*, 500 F.3d 1346, 1354, 84 USPQ2d 1495, ___ (Fed. Cir. 2007). Third <**35 U.S.C. 101** serves to ensure that patents are granted on only those inventions that are "useful." This second purpose has a Constitutional footing — Article I, Section 8 of the Constitution authorizes Congress to provide exclusive rights to inventors to promote the "useful arts." See *Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 20 USPQ2d 1094 (Fed. Cir. 1991). Thus, to satisfy the requirements of **35 U.S.C. 101**, an applicant must claim an invention that is statutory subject matter and must show that the claimed invention is "useful" for some purpose either explicitly or implicitly. Application of this latter element of **35 U.S.C. 101** is the focus of these guidelines.

Deficiencies under the "useful invention" requirement of **35 U.S.C. 101** will arise in one of two forms. The first is where it is not apparent why the invention is "useful." This can occur when an applicant fails to identify any specific and substantial utility for the invention or fails to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966); *In re Fisher*, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005); *In re Ziegler*, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993). The second type of deficiency arises in the rare instance where an assertion of specific and substantial utility for the invention made by an applicant is not credible.

I. SPECIFIC AND SUBSTANTIAL REQUIREMENTS

To satisfy **35 U.S.C. 101**, an invention must be "useful." Courts have recognized that the term "useful" used with reference to the utility requirement can be a difficult term to define. *Brenner v. Manson*, 383 U.S. 519, 529, 148 USPQ 689, 693 (1966) (simple everyday word like "useful" can be "pregnant with ambiguity when applied to the facts of life."). Where an applicant has set forth a specific and substantial utility, courts have been reluctant to uphold a rejection under **35 U.S.C. 101** solely on the basis that the applicant's opinion as to the nature of the specific and substantial utility was inaccurate. For example, in *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980), the court reversed a finding by the Office that the applicant had not set forth a "practical" utility under **35 U.S.C. 101**. In this case the applicant asserted that the composition was "useful" in a particular pharmaceutical application and provided evidence to support that assertion. Courts have used the labels "practical utility," "substantial utility," or "specific utility" to refer to this aspect of the "useful invention" requirement of **35 U.S.C. 101**. The Court of Customs and Patent Appeals has stated:

> Practical utility is a shorthand way of attributing "real-world" value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.

Nelson v. Bowler, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980).

Practical considerations require the Office to rely on the inventor's understanding of his or her invention in determining whether and in what regard an invention is believed to be "useful." Because of this, Office personnel should focus on and be receptive to assertions made by the applicant that an invention is "useful" for a particular reason.

A. Specific Utility

A "specific utility" is *specific* to the subject matter claimed and can "provide a well-defined and particular benefit to the public." *In re Fisher*, 421 F.3d 1365, 1371, 76 USPQ2d 1225, 1230 (Fed. Cir. 2005). This contrasts with a *general* utility that would be applicable to the broad class of the invention. Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that

the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. See, e.g., *In re Kirk*, 376 F.2d 936, 153 USPQ 48 (CCPA 1967); *In re Joly*, 376 F.2d 906, 153 USPQ 45 (CCPA 1967). Similarly, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. See *In re Fisher*, 421 F.3d at 1374, 76 USPQ2d at 1232 ("Any EST [expressed sequence tag] transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses…. Nothing about [applicant's] seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the [ ] application or indeed from any EST derived from any organism. Accordingly, we conclude that [applicant] has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § **101**."). A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. Assertions that fall in the former category are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear that a "useful" invention may arise from what has been disclosed by the applicant. *Knapp v. Anderson*, 477 F.2d 588, 177 USPQ 688 (CCPA 1973).

B. Substantial Utility

"[A]n application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." *Fisher*, 421 F.3d at 1371, 76 USPQ2d at 1230. The claims at issue in *Fisher* were directed to expressed sequence tags (ESTs), which are short nucleotide sequences that can be used to discover what genes and downstream proteins are expressed in a cell. The court held that "the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of [applicant's] research effort, but only tools to be used along the way in the search for a practical utility…. [Applicant] does not identify the function for the underlying protein-encoding genes. Absent such identification, we hold that the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent." *Id.* at 1376, 76 USPQ2d at 1233-34). Thus a "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

(A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;

(B) A method of treating an *unspecified* disease or condition;

(C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;

(D) A method of making a material that itself has no specific, substantial, and credible utility; and

(E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

Office personnel must be careful not to interpret the phrase "immediate benefit to the public" or similar formulations in other cases to mean that products or services based on the claimed invention must be "currently available" to the public in order to satisfy the utility requirement. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 USPQ 689, 695 (1966). Rather, any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a "substantial" utility.

C. Research Tools

Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific and substantial utility based on the setting in which the invention is to be used. One example is

inventions to be used in a research or laboratory setting. Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact "useful" in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as "research tool," "intermediate" or "for research purposes" are not helpful in determining if an applicant has identified a specific and substantial utility for the invention.

II. WHOLLY INOPERATIVE INVENTIONS; "INCREDIBLE" UTILITY

An invention that is "inoperative" (i.e., it does not operate to produce the results claimed by the patent applicant) is not a "useful" invention in the meaning of the patent law. See, e.g., *Newman v. Quigg*, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989); *In re Harwood*, 390 F.2d 985, 989, 156 USPQ 673, 676 (CCPA 1968) ("An inoperative invention, of course, does not satisfy the requirement of **35 U.S.C. 101** that an invention be useful."). However, as the Federal Circuit has stated, "[t]o violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992) (emphasis added). See also *E.I. du Pont De Nemours and Co. v. Berkley and Co.*, 620 F.2d 1247, 1260 n.17, 205 USPQ 1, 10 n.17 (8th Cir. 1980) ("A small degree of utility is sufficient . . . The claimed invention must only be capable of performing some beneficial function . . . An invention does not lack utility merely because the particular embodiment disclosed in the patent lacks perfection or performs crudely . . . A commercially successful product is not required . . . Nor is it essential that the invention accomplish all its intended functions . . . or operate under all conditions . . . partial success being sufficient to demonstrate patentable utility . . . In short, the defense of non-utility cannot be sustained without proof of total incapacity." If an invention is only partially successful in achieving a useful result, a rejection of the claimed invention as a whole based on a lack of utility is not appropriate. See *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995); *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA), *reh'g denied*, 480 F.2d 879 (CCPA 1973); *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971).

Situations where an invention is found to be "inoperative" and therefore lacking in utility are rare, and rejections maintained solely on this ground by a Federal court even rarer. In many of these cases, the utility asserted by the applicant was thought to be "incredible in the light of the knowledge of the art, or factually misleading" when initially considered by the Office. *In re Citron*, 325 F.2d 248, 253, 139 USPQ 516, 520 (CCPA 1963). Other cases suggest that on initial evaluation, the Office considered the asserted utility to be inconsistent with known scientific principles or "speculative at best" as to whether attributes of the invention necessary to impart the asserted utility were actually present in the invention. *In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977). However cast, the underlying finding by the court in these cases was that, based on the factual record of the case, it was clear that the invention could not and did not work as the inventor claimed it did. Indeed, the use of many labels to describe a single problem (e.g., a false assertion regarding utility) has led to some of the confusion that exists today with regard to a rejection based on the "utility" requirement. Examples of such cases include: an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 USPQ 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 USPQ2d 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 USPQ 687 (CCPA 1970)), a "cold fusion" process for producing energy (*In re Swartz*, 232 F.3d 862, 56 USPQ2d 1703, (Fed. Cir. 2000)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 USPQ 221 (CCPA 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 USPQ 516 (CCPA 1963)), and a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 USPQ 221 (CCPA 1970)). These examples are fact specific and should not be applied as a *per se* rule. Thus, in view of the rare nature of such cases, Office personnel should not label an asserted utility "incredible," "speculative" or otherwise unless it is clear that a rejection based on "lack of utility" is proper.

III. THERAPEUTIC OR PHARMACOLOGICAL UTILITY

Inventions asserted to have utility in the treatment of human or animal disorders are subject to the same legal requirements for utility as inventions in any other field of technology. *In re Chilowsky*, 229 F.2d 457, 461-2, 108 USPQ 321, 325 (CCPA 1956) ("There appears to be no basis in the statutes or decisions for requiring any more conclusive evidence of operativeness in one type of case than another. The character and amount of evidence

needed may vary, depending on whether the alleged operation described in the application appears to accord with or to contravene established scientific principles or to depend upon principles alleged but not generally recognized, but the degree of certainty as to the ultimate fact of operativeness or inoperativeness should be the same in all cases"); *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967) ("Thus, in the usual case where the mode of operation alleged can be readily understood and conforms to the known laws of physics and chemistry, operativeness is not questioned, and no further evidence is required."). As such, pharmacological or therapeutic inventions that provide any "immediate benefit to the public" satisfy **35 U.S.C. 101**. The utility being asserted in *Nelson* related to a compound with pharmacological utility. *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980). Office personnel should rely on *Nelson* and other cases as providing general guidance when evaluating the utility of an invention that is based on any therapeutic, prophylactic, or pharmacological activities of that invention.

Courts have repeatedly found that the mere identification of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides an "immediate benefit to the public" and thus satisfies the utility requirement. As the Court of Customs and Patent Appeals held in *Nelson v. Bowler*:

> Knowledge of the pharmacological activity of any compound is obviously beneficial to the public. It is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible, we conclude that adequate proof of any such activity constitutes a showing of practical utility.

Nelson v. Bowler, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980).

In *Nelson v. Bowler*, the court addressed the practical utility requirement in the context of an interference proceeding. Bowler challenged the patentability of the invention claimed by Nelson on the basis that Nelson had failed to sufficiently and persuasively disclose in his application a practical utility for the invention. Nelson had developed and claimed a class of synthetic prostaglandins modeled on naturally occurring prostaglandins. Naturally occurring prostaglandins are bioactive compounds that, at the time of Nelson's application, had a recognized value in pharmacology (e.g., the stimulation of uterine smooth muscle which resulted in labor induction or abortion, the ability to raise or lower blood pressure, etc.). To support the utility he identified in his disclosure, Nelson included in his application the results of tests demonstrating the bioactivity of his new substituted prostaglandins relative to the bioactivity of naturally occurring prostaglandins. The court concluded that Nelson had satisfied the practical utility requirement in identifying the synthetic prostaglandins as pharmacologically active compounds. In reaching this conclusion, the court considered and rejected arguments advanced by Bowler that attacked the evidentiary basis for Nelson's assertions that the compounds were pharmacologically active.

In *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980), an inventor claimed protection for pharmaceutical compositions for treating leukemia. The active ingredient in the compositions was a structural analog to a known anticancer agent. The applicant provided evidence showing that the claimed analogs had the same general pharmaceutical activity as the known anticancer agents. The court reversed the Board's finding that the asserted pharmaceutical utility was "incredible," pointing to the evidence that showed the relevant pharmacological activity.

In *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985), the Federal Circuit affirmed a finding by the Board of Patent Appeals and Interferences that a pharmacological utility had been disclosed in the application of one party to an interference proceeding. The invention that was the subject of the interference count was a chemical compound used for treating blood disorders. Cross had challenged the evidence in Iizuka's specification that supported the claimed utility. However, the Federal Circuit relied extensively on *Nelson v. Bowler* in finding that Iizuka's application had sufficiently disclosed a pharmacological utility for the compounds. It distinguished the case from cases where only a generalized "nebulous" expression, such as "biological properties," had been disclosed in a specification. Such statements, the court held, "convey little explicit indication regarding the utility of a compound." *Cross*, 753 F.2d at 1048, 224 USPQ at 745 (citing *In re Kirk*, 376 F.2d 936, 941, 153 USPQ 48, 52 (CCPA 1967)).

Similarly, courts have found utility for therapeutic inventions despite the fact that an applicant is at a very early stage in the development of a pharmaceutical product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition. The Federal Circuit, in *Cross v. Iizuka*, 753 F.2d 1040, 1051, 224 USPQ 739, 747-48 (Fed. Cir. 1985),

commented on the significance of data from *in vitro* testing that showed pharmacological activity:

> We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, *in vitro* testing, may establish a practical utility for the compound in question. Successful *in vitro* testing will marshal resources and direct the expenditure of effort to further *in vivo* testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an *in vivo* utility.

The Federal Circuit has reiterated that therapeutic utility sufficient under the patent laws is not to be confused with the requirements of the FDA with regard to safety and efficacy of drugs to marketed in the United States.

> FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. *Scott [v. Finney*], 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 [(Fed.Cir. 1994)]. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). Accordingly, Office personnel should not construe **35 U.S.C. 101**, under the logic of "practical" utility or otherwise, to require that an applicant demonstrate that a therapeutic agent based on a claimed invention is a safe or fully effective drug for humans. See, e.g., *In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Anthony*, 414 F.2d 1383, 162 USPQ 594 (CCPA 1969); *In re Watson*, 517 F.2d 465, 186 USPQ 11 (CCPA 1975).

These general principles are equally applicable to situations where an applicant has claimed a process for treating a human or animal disorder. In such cases, the asserted utility is usually clear — the invention is asserted to be useful in treating the particular disorder. If the asserted utility is credible, there is no basis to challenge such a claim on the basis that it lacks utility under **35 U.S.C. 101**.

See **MPEP § 2107.03** for special considerations for asserted therapeutic or pharmacological utilities.

IV. RELATIONSHIP BETWEEN 35 U.S.C. 112, FIRST PARAGRAPH, AND 35 U.S.C. 101

A deficiency under the utility prong of **35 U.S.C. 101** also creates a deficiency under **35 U.S.C. 112**, first paragraph. See *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995); *In re Jolles*, 628 F.2d 1322, 1326 n.10, 206 USPQ 885, 889 n.11 (CCPA 1980); *In re Fouche*, 439 F.2d 1237, 1243, 169 USPQ 429, 434 (CCPA 1971) ("If such compositions are in fact useless, appellant's specification cannot have taught how to use them."). Courts have also cast the **35 U.S.C. 101**/**35 U.S.C. 112** relationship such that **35 U.S.C. 112** presupposes compliance with **35 U.S.C. 101**. See *In re Ziegler*, 992 F.2d 1197, 1200-1201, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993) ("The how to use prong of section **112** incorporates as a matter of law the requirement of **35 U.S.C. 101** that the specification disclose as a matter of fact a practical utility for the invention. ... If the application fails as a matter of fact to satisfy **35 U.S.C. § 101**, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under **35 U.S.C. § 112**."); *In re Kirk*, 376 F.2d 936, 942, 153 USPQ 48, 53 (CCPA 1967) ("Necessarily, compliance with § 112 requires a description of how to use presently useful inventions, otherwise an applicant would anomalously be required to teach how to use a useless invention."). For example, the Federal Circuit noted, "[o]bviously, if a claimed invention does not have utility, the specification cannot enable one to use it." *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). As such, a rejection properly imposed under **35 U.S.C. 101** for lack of utility should be accompanied with a rejection under **35 U.S.C. 112**, first paragraph. It is equally clear that a rejection based on "lack of utility," whether grounded upon **35 U.S.C. 101** or **35 U.S.C. 112**, first paragraph, rests on the same basis (i.e., the asserted utility is not credible). To avoid confusion, any lack of utility rejection that is imposed on the basis of **35 U.S.C. 101** should be accompanied by a rejection based on **35 U.S.C. 112**, first paragraph. The **35 U.S.C. 112**, first paragraph, rejection should be set out as a separate rejection that incorporates by reference the factual basis and conclusions set forth in the **35 U.S.C. 101** rejection. The **35 U.S.C. 112**, first paragraph, rejection should indicate that because the invention as claimed does not have utility, a person skilled in the art would not be able to use the invention as claimed, and as such, the claim is

defective under 35 U.S.C. 112, first paragraph. A 35 U.S.C. 112, first paragraph, rejection based on lack of utility should not be imposed or maintained unless an appropriate basis exists for imposing a utility rejection under 35 U.S.C. 101. In other words, Office personnel should not impose a 35 U.S.C. 112, first paragraph, rejection grounded on a "lack of utility" basis unless a 35 U.S.C. 101 rejection is proper. In particular, the factual showing needed to impose a rejection under 35 U.S.C. 101 must be provided if a rejection under 35 U.S.C. 112, first paragraph, is to be imposed on "lack of utility" grounds.

It is important to recognize that 35 U.S.C. 112, first paragraph, addresses matters other than those related to the question of whether or not an invention lacks utility. These matters include whether the claims are fully supported by the disclosure (*In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991)), whether the applicant has provided an enabling disclosure of the claimed subject matter (*In re Wright*, 999 F.2d 1557, 1561-1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)), whether the applicant has provided an adequate written description of the invention and whether the applicant has disclosed the best mode of practicing the claimed invention (*Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927-928, 16 USPQ2d 1033, 1036-1037 (Fed. Cir. 1990)). See also *Transco Products Inc. v. Performance Contracting Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994); *Glaxo Inc. v. Novopharm Ltd.* 52 F.3d 1043, 34 USPQ2d 1565 (Fed. Cir. 1995). The fact that an applicant has disclosed a specific utility for an invention and provided a credible basis supporting that specific utility does not provide a basis for concluding that the claims comply with all the requirements of 35 U.S.C. 112, first paragraph. For example, if an applicant has claimed a process of treating a certain disease condition with a certain compound and provided a credible basis for asserting that the compound is useful in that regard, but to actually practice the invention as claimed a person skilled in the relevant art would have to engage in an undue amount of experimentation, the claim may be defective under 35 U.S.C. 112, but not 35 U.S.C. 101. To avoid confusion during examination, any rejection under 35 U.S.C. 112, first paragraph, based on grounds other than "lack of utility" should be imposed separately from any rejection imposed due to "lack of utility" under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph.

2107.02 Procedural Considerations Related to Rejections for Lack of Utility [R-5]

I. THE CLAIMED INVENTION IS THE FOCUS OF THE UTILITY REQUIREMENT

The claimed invention is the focus of the assessment of whether an applicant has satisfied the utility requirement. Each claim (i.e., each "invention"), therefore, must be evaluated on its own merits for compliance with all statutory requirements. Generally speaking, however, a dependent claim will define an invention that has utility if the >independent< claim **>from which the dependent claim depends is drawn to the same statutory class of invention as the dependent claim and the independent claim defines< an invention having utility. An exception to this general rule is where the utility specified for the invention defined in a dependent claim differs from that indicated for the invention defined in the independent claim from which the dependent claim depends. Where an applicant has established utility for a species that falls within an identified genus of compounds, and presents a generic claim covering the genus, as a general matter, that claim should be treated as being sufficient under 35 U.S.C. 101. Only where it can be established that other species clearly encompassed by the claim do not have utility should a rejection be imposed on the generic claim. In such cases, the applicant should be encouraged to amend the generic claim so as to exclude the species that lack utility.

It is common and sensible for an applicant to identify several specific utilities for an invention, particularly where the invention is a product (e.g., a machine, an article of manufacture or a composition of matter). However, regardless of the category of invention that is claimed (e.g., product or process), an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112; additional statements of utility, even if not "credible," do not render the claimed invention lacking in utility. See, e.g., *Raytheon v. Roper*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. 101 is clearly shown."); *In re Gottlieb*, 328 F.2d 1016, 1019, 140 USPQ 665, 668 (CCPA 1964) ("Having found that the antibiotic is useful for some purpose, it becomes unnecessary to decide whether it is in fact useful for the other purposes 'indicated' in the specification as possibly useful."); *In re Malachowski*, 530 F.2d 1402, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657

(Bd. Pat. App. & Inter. 1988). Thus, if applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established.

Statements made by the applicant in the specification or incident to prosecution of the application before the Office cannot, standing alone, be the basis for a lack of utility rejection under **35 U.S.C. 101** or **35 U.S.C. 112**. *Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. Gesellschaft m.b.h.*, 945 F.2d 1546, 1553, 20 USPQ2d 1332, 1338 (Fed. Cir. 1991) (It is not required that a particular characteristic set forth in the prosecution history be achieved in order to satisfy **35 U.S.C. 101**.). An applicant may include statements in the specification whose technical accuracy cannot be easily confirmed if those statements are not necessary to support the patentability of an invention with regard to any statutory basis. Thus, the Office should not require an applicant to strike nonessential statements relating to utility from a patent disclosure, regardless of the technical accuracy of the statement or assertion it presents. Office personnel should also be especially careful not to read into a claim unclaimed results, limitations or embodiments of an invention. See *Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 20 USPQ2d 1094 (Fed. Cir. 1991); *In re Krimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA 1961). Doing so can inappropriately change the relationship of an asserted utility to the claimed invention and raise issues not relevant to examination of that claim.

II. IS THERE AN ASSERTED OR WELL-ESTABLISHED UTILITY FOR THE CLAIMED INVENTION?

Upon initial examination, the examiner should review the specification to determine if there are any statements asserting that the claimed invention is useful for any particular purpose. A complete disclosure should include a statement which identifies a specific and substantial utility for the invention.

A. An Asserted Utility Must Be Specific and Substantial

A statement of specific and substantial utility should fully and clearly explain why the applicant believes the invention is useful. Such statements will usually explain the purpose of or how the invention may be used (e.g., a compound is believed to be useful in the treatment of a particular disorder). Regardless of the form of statement of utility, it must enable one ordinarily skilled in the art to understand why the applicant believes the claimed invention is useful.

Except where an invention has a well-established utility, the failure of an applicant to specifically identify why an invention is believed to be useful renders the claimed invention deficient under **35 U.S.C. 101** and **35 U.S.C. 112**, first paragraph. In such cases, the applicant has failed to identify a "specific and substantial utility" for the claimed invention. For example, a statement that a composition has an unspecified "biological activity" or that does not explain why a composition with that activity is believed to be useful fails to set forth a "specific and substantial utility." *Brenner v. Manson*, 383 US 519, 148 USPQ 689 (1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful insufficient under **35 U.S.C. 101**); *In re Ziegler*, 992 F.2d 1197, 1201, 26 USPQ2d 1600, 1604 (Fed. Cir. 1993) (disclosure that composition is "plastic-like" and can form "films" not sufficient to identify specific and substantial utility for invention); *In re Kirk*, 376 F.2d 936, 153 USPQ 48 (CCPA 1967) (indication that compound is "biologically active" or has "biological properties" insufficient standing alone). See also *In re Joly*, 376 F.2d 906, 153 USPQ 45 (CCPA 1967); *Kawai v. Metlesics*, 480 F.2d 880, 890, 178 USPQ 158, 165 (CCPA 1973) (contrasting description of invention as sedative which did suggest specific utility to general suggestion of "pharmacological effects on the central nervous system" which did not). In contrast, a disclosure that identifies a particular biological activity of a compound and explains how that activity can be utilized in a particular therapeutic application of the compound does contain an assertion of specific and substantial utility for the invention.

Situations where an applicant either fails to indicate why an invention is considered useful, or where the applicant inaccurately describes the utility should rarely arise. One reason for this is that applicants are required to disclose the best mode known to them of practicing the invention at the time they file their application. An applicant who omits a description of the specific and substantial utility of the invention, or who incompletely describes that utility, may encounter problems with respect to the best mode requirement of **35 U.S.C. 112**, first paragraph.

B. No Statement of Utility for the Claimed Invention in the Specification Does Not *Per Se* Negate Utility

Occasionally, an applicant will not explicitly state in the specification or otherwise assert a specific and substantial utility for the claimed invention. If no statements can be found asserting a specific and substantial utility for the claimed invention in the specification, Office personnel should determine if the claimed invention has a well-established utility. An invention has a

well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible. If an invention has a well- established utility, rejections under **35 U.S.C. 101** and **35 U.S.C. 112**, first paragraph, based on lack of utility should not be imposed. *In re Folkers*, 344 F.2d 970, 145 USPQ 390 (CCPA 1965). For example, if an application teaches the cloning and characterization of the nucleotide sequence of a well-known protein such as insulin, and those skilled in the art at the time of filing knew that insulin had a well-established use, it would be improper to reject the claimed invention as lacking utility solely because of the omitted statement of specific and substantial utility.

If a person of ordinary skill would not immediately recognize a specific and substantial utility for the claimed invention (i.e., why it would be useful) based on the characteristics of the invention or statements made by the applicant, the examiner should reject the application under **35 U.S.C. 101** and under **35 U.S.C. 112**, first paragraph, as failing to identify a specific and substantial utility for the claimed invention. The rejection should clearly indicate that the basis of the rejection is that the application fails to identify a specific and substantial utility for the invention. The rejection should also specify that the applicant must reply by indicating why the invention is believed useful and where support for any subsequently asserted utility can be found in the specification as filed. See **MPEP § 2701**.

If the applicant subsequently indicates why the invention is useful, Office personnel should review that assertion according to the standards articulated below for review of the credibility of an asserted utility.

III. EVALUATING THE CREDIBILITY OF AN ASSERTED UTILITY

A. An Asserted Utility Creates a Presumption of Utility

In most cases, an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of **35 U.S.C. 101**. See, e.g., *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Irons*, 340 F.2d 974, 144 USPQ 351 (CCPA 1965); *In re Langer*, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974); *In re Sichert*, 566 F.2d 1154, 1159, 196 USPQ 209, 212-13 (CCPA 1977). As the Court of Customs and Patent Appeals stated in *In re Langer*:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

In re Langer, 503 F.2d at 1391, 183 USPQ at 297 (emphasis in original). The "Langer" test for utility has been used by both the Federal Circuit and the Court of Customs and Patent Appeals in evaluation of rejections under **35 U.S.C. 112**, first paragraph, where the rejection is based on a deficiency under **35 U.S.C. 101**. In *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995), the Federal Circuit explicitly adopted the Court of Customs and Patent Appeals formulation of the "Langer" standard for **35 U.S.C. 112**, first paragraph rejections, as it was expressed in a slightly reworded format in *In re Marzocch*i, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971), namely:

> [A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. (emphasis added).

Thus, *Langer* and subsequent cases direct the Office to presume that a statement of utility made by an applicant is true. See *In re Langer*, 503 F.2d at 1391, 183 USPQ at 297; *In re Malachowski*, 530 F.2d 1402, 1404, 189 USPQ 432, 435 (CCPA 1976); *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). For obvious reasons of efficiency and in deference to an applicant's understanding of his or her invention, when a statement of utility is evaluated, Office personnel should not begin by questioning the truth of the statement of utility. Instead, any inquiry must start by asking if there is any reason to question the truth of the statement of utility. This can be done by simply evaluating the logic of the statements made, taking into consideration any evidence cited by the applicant. If the asserted utility is credible (i.e., believable based on the record or the nature of the invention), a rejection based on "lack of utility" is not appropriate. Clearly, Office personnel should not begin an evaluation of utility by assuming that an asserted utility is likely to

be false, based on the technical field of the invention or for other general reasons.

Compliance with **35 U.S.C. 101** is a question of fact. *Raytheon v. Roper*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983) *cert. denied*, 469 U.S. 835 (1984). Thus, to overcome the presumption of truth that an assertion of utility by the applicant enjoys, Office personnel must establish that it is more likely than not that one of ordinary skill in the art would doubt (i.e., "question") the truth of the statement of utility. The evidentiary standard to be used throughout *ex parte* examination in setting forth a rejection is a preponderance of the totality of the evidence under consideration. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) ("After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument."); *In re Corkill*, 771 F.2d 1496, 1500, 226 USPQ 1005, 1008 (Fed. Cir. 1985). A preponderance of the evidence exists when it suggests that it is more likely than not that the assertion in question is true. *Herman v. Huddleston*, 459 U.S. 375, 390 (1983). To do this, Office personnel must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. Of course, a person of ordinary skill must have the benefit of both facts and reasoning in order to assess the truth of a statement. This means that if the applicant has presented facts that support the reasoning used in asserting a utility, Office personnel must present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the applicant's assertion of utility. *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). The initial evidentiary standard used during evaluation of this question is a preponderance of the evidence (i.e., the totality of facts and reasoning suggest that it is more likely than not that the statement of the applicant is false).

B. When Is an Asserted Utility Not Credible?

Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong," even when there may be reason to believe that the assertion is not entirely accurate. Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility.

One situation where an assertion of utility would not be considered credible is where a person of ordinary skill would consider the assertion to be "incredible in view of contemporary knowledge" and where nothing offered by the applicant would counter what contemporary knowledge might otherwise suggest. Office personnel should be careful, however, not to label certain types of inventions as "incredible" or "speculative" as such labels do not provide the correct focus for the evaluation of an assertion of utility. "Incredible utility" is a conclusion, not a starting point for analysis under **35 U.S.C. 101**. A conclusion that an asserted utility is incredible can be reached only after the Office has evaluated both the assertion of the applicant regarding utility and any evidentiary basis of that assertion. The Office should be particularly careful not to start with a presumption that an asserted utility is, *per se*, "incredible" and then proceed to base a rejection under **35 U.S.C. 101** on that presumption.

Rejections under **35 U.S.C. 101**>based on a lack of credible utility< have been * sustained by federal courts **>when, for example,< the applicant failed to disclose any utility for the invention or asserted a utility that could only be true if it violated a scientific principle, such as the second law of thermodynamics, or a law of nature, or was wholly inconsistent with contemporary knowledge in the art. *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967). Special care * should be taken when assessing the credibility of an asserted therapeutic utility for a claimed invention. In such cases, a previous lack of success in treating a disease or condition, or the absence of a proven animal model for testing the effectiveness of drugs for treating a disorder in humans, should not, standing alone, serve as a basis for challenging the asserted utility under **35 U.S.C. 101**. >See MPEP § **2107.03** for additional guidance with regard to therapeutic or pharmacological utilities.<

IV. INITIAL BURDEN IS ON THE OFFICE TO ESTABLISH A PRIMA FACIE CASE AND PROVIDE EVIDENTIARY SUPPORT THEREOF

To properly reject a claimed invention under **35 U.S.C. 101**, the Office must (A) make a *prima facie* showing that the claimed invention lacks utility, and (B) provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing. *In re Gaubert*, 524 F.2d 1222, 1224, 187 USPQ 664, 666 (CCPA 1975) "Accordingly, the PTO must do more than

merely question operability - it must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." If the Office cannot develop a proper *prima facie* case and provide evidentiary support for a rejection under **35 U.S.C. 101**, a rejection on this ground should not be imposed. See, e.g., *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) ("[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.... If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent."). See also *Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 USPQ 848 (Fed. Cir. 1985) (applying *prima facie* case law to **35 U.S.C. 101**); *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984).

The *prima facie* showing must be set forth in a well-reasoned statement. Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the *prima facie* showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.

Where the asserted utility is not specific or substantial, a *prima facie* showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The *prima facie* showing must contain the following elements:

(A) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is neither both specific and substantial nor well-established;

(B) Support for factual findings relied upon in reaching this conclusion; and

(C) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

Where the asserted specific and substantial utility is not credible, a *prima facie* showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention. The *prima facie* showing must contain the following elements:

(A) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;

(B) Support for factual findings relied upon in reaching this conclusion; and

(C) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

Where no specific and substantial utility is disclosed or is well-established, a *prima facie* showing of no specific and substantial utility need only establish that applicant has not asserted a utility and that, on the record before the examiner, there is no known well-established utility.

It is imperative that Office personnel use specificity in setting forth and initial rejection under **35 U.S.C. 101** and support any factual conclusions made in the *prima facie* showing.

By using specificity, the applicant will be able to identify the assumptions made by the Office in setting forth the rejection and will be able to address those assumptions properly.

V. EVIDENTIARY REQUESTS BY AN EXAMINER TO SUPPORT AN ASSERTED UTILITY

In appropriate situations the Office may require an applicant to substantiate an asserted utility for a claimed invention. See *In re Pottier*, 376 F.2d 328, 330, 153 USPQ 407, 408 (CCPA 1967) ("When the operativeness of any process would be deemed unlikely by one of ordinary skill in the art, it is not improper for the examiner to call for evidence of operativeness."). See also *In re Jolles*, 628 F.2d 1322, 1327, 206 USPQ 885, 890 (CCPA 1980); *In re Citron*, 325 F.2d 248, 139 USPQ 516 (CCPA 1963); *In re Novak*, 306 F.2d 924, 928, 134 USPQ 335, 337 (CCPA1962). In *In re Citron*, the court held that when an "alleged utility appears to be incredible in the light of the knowledge of the art, or factually misleading, applicant must establish the asserted utility by acceptable proof." 325 F.2d at 253, 139 USPQ at 520. The court approved of the board's decision which affirmed the rejection under **35 U.S.C. 101** "in view of the art knowledge of the lack of a cure for cancer and the absence of any clinical data to substantiate the allegation." 325 F.2d at 252, 139 USPQ at 519 (emphasis in original). The court thus established a higher burden on the applicant where the statement of use is incredible or misleading. In such a case, the examiner should challenge the use and require sufficient evidence of operativeness. The purpose of this authority is to enable an applicant to cure an otherwise defective factual basis for the operability of an invention. Because this is a curative authority (e.g., evidence is requested to enable an applicant to support an assertion that is inconsistent with the facts of record

in the application), Office personnel should indicate not only why the factual record is defective in relation to the assertions of the applicant, but also, where appropriate, what type of evidentiary showing can be provided by the applicant to remedy the problem.

Requests for additional evidence should be imposed rarely, and only if necessary to support the scientific credibility of the asserted utility (e.g., if the asserted utility is not consistent with the evidence of record and current scientific knowledge). As the Federal Circuit recently noted, "[o]nly after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility." *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) (citing *In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981)). In *Brana*, the court pointed out that the purpose of treating cancer with chemical compounds does not suggest, *per se*, an incredible utility. Where the prior art disclosed "structurally similar compounds to those claimed by applicants which have been proven *in vivo* to be effective as chemotherapeutic agents against various tumor models . . ., one skilled in the art would be without basis to reasonably doubt applicants' asserted utility on its face." 51 F.3d at 1566, 34 USPQ2d at 1441. As courts have stated, "it is clearly improper for the examiner to make a demand for further test data, which as evidence would be essentially redundant and would seem to serve for nothing except perhaps to unduly burden the applicant." *In re Isaacs*, 347 F.2d 887, 890, 146 USPQ 193, 196 (CCPA 1965).

VI. CONSIDERATION OF A REPLY TO A PRIMA FACIE REJECTION FOR LACK OF UTILITY

If a rejection under **35 U.S.C. 101** has been properly imposed, along with a corresponding rejection under **35 U.S.C. 112**, first paragraph, the burden shifts to the applicant to rebut the *prima facie* showing. *In re Oetiker* , 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) ("The examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant. . . After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument."). An applicant can do this using any combination of the following: amendments to the claims, arguments or reasoning, or new evidence submitted in an affidavit or declaration under **37 CFR 1.132**, or in a printed publication. New evidence provided by an applicant must be relevant to the issues raised in the rejection. For example, declarations in which conclusions are set forth without establishing a nexus between those conclusions and the supporting evidence, or which merely express opinions, may be of limited probative value with regard to rebutting a *prima facie* case. *In re Grunwell*, 609 F.2d 486, 203 USPQ 1055 (CCPA 1979); *In re Buchner*, 929 F.2d 660, 18 USPQ2d 1331 (Fed. Cir. 1991). See **MPEP § 716.01(a)** through **§ 716.01(c)**.

If the applicant responds to the *prima facie* rejection, Office personnel should review the original disclosure, any evidence relied upon in establishing the *prima facie* showing, any claim amendments, and any new reasoning or evidence provided by the applicant in support of an asserted specific and substantial credible utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained. If the record as a whole would make it more likely than not that the asserted utility for the claimed invention would be considered credible by a person of ordinary skill in the art, the Office cannot maintain the rejection. *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

VII. EVALUATION OF EVIDENCE RELATED TO UTILITY

There is no predetermined amount or character of evidence that must be provided by an applicant to support an asserted utility, therapeutic or otherwise. Rather, the character and amount of evidence needed to support an asserted utility will vary depending on what is claimed (*Ex parte Ferguson*, 117 USPQ 229 (Bd. App. 1957)), and whether the asserted utility appears to contravene established scientific principles and beliefs. *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967); *In re Chilowsky*, 229 F.2d 457, 462, 108 USPQ 321, 325 (CCPA 1956). Furthermore, the applicant does not have to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt." *In re Irons*, 340 F.2d 974, 978, 144 USPQ 351, 354 (CCPA 1965). Nor must an applicant provide evidence such that it establishes an asserted utility as a matter of statistical certainty. *Nelson v. Bowler*, 626 F.2d 853, 856-57, 206 USPQ 881, 883-84 (CCPA 1980) (reversing the Board and rejecting Bowler's arguments that the evidence of utility was statistically insignificant. The court pointed out that a rigorous correlation is not necessary when the test is reasonably predictive of the response). See also

Rey-Bellet v. Englehardt, 493 F.2d 1380, 181 USPQ 453 (CCPA 1974) (data from animal testing is relevant to asserted human therapeutic utility if there is a "satisfactory correlation between the effect on the animal and that ultimately observed in human beings"). Instead, evidence will be sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true.

2107.03 Special Considerations for Asserted Therapeutic or Pharmacological Utilities

The Federal courts have consistently reversed rejections by the Office asserting a lack of utility for inventions claiming a pharmacological or therapeutic utility where an applicant has provided evidence that reasonably supports such a utility. In view of this, Office personnel should be particularly careful in their review of evidence provided in support of an asserted therapeutic or pharmacological utility.

I. A REASONABLE CORRELATION BETWEEN THE EVIDENCE AND THE ASSERTED UTILITY IS SUFFICIENT

As a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility. *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980). An applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in scientific journals), or any combination thereof. The applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty, nor does he or she have to provide actual evidence of success in treating humans where such a utility is asserted. Instead, as the courts have repeatedly held, all that is required is a reasonable correlation between the activity and the asserted use. *Nelson v. Bowler*, 626 F.2d 853, 857, 206 USPQ 881, 884 (CCPA 1980).

II. STRUCTURAL SIMILARITY TO COMPOUNDS WITH ESTABLISHED UTILITY

Courts have routinely found evidence of structural similarity to a compound known to have a particular therapeutic or pharmacological utility as being supportive of an assertion of therapeutic utility for a new compound. In *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980), the claimed compounds were found to have utility based on a finding of a close structural relationship to daunorubicin and doxorubicin and shared pharmacological activity with those compounds, both of which were known to be useful in cancer chemotherapy. The evidence of close structural similarity with the known compounds was presented in conjunction with evidence demonstrating substantial activity of the claimed compounds in animals customarily employed for screening anticancer agents. Such evidence should be given appropriate weight in determining whether one skilled in the art would find the asserted utility credible. Office personnel should evaluate not only the existence of the structural relationship, but also the reasoning used by the applicant or a declarant to explain why that structural similarity is believed to be relevant to the applicant's assertion of utility.

III. DATA FROM IN VITRO OR ANIMAL TESTING IS GENERALLY SUFFICIENT TO SUPPORT THERAPEUTIC UTILITY

If reasonably correlated to the particular therapeutic or pharmacological utility, data generated using *in vitro* assays, or from testing in an animal model or a combination thereof almost invariably will be sufficient to establish therapeutic or pharmacological utility for a compound, composition or process. A cursory review of cases involving therapeutic inventions where **35 U.S.C. 101** was the dispositive issue illustrates the fact that the Federal courts are not particularly receptive to rejections under **35 U.S.C. 101** based on inoperability. Most striking is the fact that in those cases where an applicant supplied a reasonable evidentiary showing supporting an asserted therapeutic utility, almost uniformly the **35 U.S.C. 101**-based rejection was reversed. See, e.g., *In re Brana*, 51 F.3d 1560, 34 USPQ 1436 (Fed. Cir. 1995); *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980); *In re Malachowski*, 530 F.2d 1402, 189 USPQ 432 (CCPA 1976); *In re Gaubert*, 530 F.2d 1402, 189 USPQ 432 (CCPA 1975); *In re Gazave*, 379 F.2d 973, 154 USPQ 92 (CCPA 1967); *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Krimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA 1961). Only in those cases where the applicant was unable to come forward with any relevant evidence to rebut a finding by the Office that the claimed invention was inoperative was a **35 U.S.C. 101** rejection affirmed by the court. *In re Citron*, 325 F.2d 248, 253, 139 USPQ 516, 520 (CCPA 1963) (therapeutic utility for an uncharacterized biological extract not supported or scientifically credible); *In re Buting*, 418 F.2d 540, 543,

163 USPQ 689, 690 (CCPA 1969) (record did not establish a credible basis for the assertion that the single class of compounds in question would be useful in treating disparate types of cancers); *In re Novak*, 306 F.2d 924, 134 USPQ 335 (CCPA 1962) (claimed compounds did not have capacity to effect physiological activity upon which utility claim based). Contrast, however, *In re Buting* to *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973), *reh'g denied*, 480 F.2d 879 (CCPA 1973), in which the court held that utility for a genus was found to be supported through a showing of utility for one species. In no case has a Federal court required an applicant to support an asserted utility with data from human clinical trials.

If an applicant provides data, whether from *in vitro* assays or animal tests or both, to support an asserted utility, and an explanation of why that data supports the asserted utility, the Office will determine if the data and the explanation would be viewed by one skilled in the art as being reasonably predictive of the asserted utility. See, e.g., *Ex parte Maas*, 9 USPQ2d 1746 (Bd. Pat. App. & Inter. 1987); *Ex parte Balzarini*, 21 USPQ2d 1892 (Bd. Pat. App. & Inter. 1991). Office personnel must be careful to evaluate all factors that might influence the conclusions of a person of ordinary skill in the art as to this question, including the test parameters, choice of animal, relationship of the activity to the particular disorder to be treated, characteristics of the compound or composition, relative significance of the data provided and, most importantly, the explanation offered by the applicant as to why the information provided is believed to support the asserted utility. If the data supplied is consistent with the asserted utility, the Office cannot maintain a rejection under **35 U.S.C. 101**.

Evidence does not have to be in the form of data from an art-recognized animal model for the particular disease or disease condition to which the asserted utility relates. Data from any test that the applicant reasonably correlates to the asserted utility should be evaluated substantively. Thus, an applicant may provide data generated using a particular animal model with an appropriate explanation as to why that data supports the asserted utility. The absence of a certification that the test in question is an industry-accepted model is not dispositive of whether data from an animal model is in fact relevant to the asserted utility. Thus, if one skilled in the art would accept the animal tests as being reasonably predictive of utility in humans, evidence from those tests should be considered sufficient to support the credibility of the asserted utility. *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Krimmel*, 292 F.2d 948, 953, 130 USPQ 215, 219 (CCPA 1961); *Ex parte Krepelka*, 231 USPQ 746 (Bd. Pat. App. & Inter. 1986). Office personnel should be careful not to find evidence unpersuasive simply because no animal model for the human disease condition had been established prior to the filing of the application. See *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956) ("The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it."); *In re Wooddy*, 331 F.2d 636, 639, 141 USPQ 518, 520 (CCPA 1964) ("It appears that no one on earth is certain as of the present whether the process claimed will operate in the manner claimed. Yet absolute certainty is not required by the law. The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it.").

IV. HUMAN CLINICAL DATA

Office personnel should not impose on applicants the unnecessary burden of providing evidence from human clinical trials. There is no decisional law that requires an applicant to provide data from human clinical trials to establish utility for an invention related to treatment of human disorders (see *In re Isaacs*, 347 F.2d 889, 146 USPQ 193 (CCPA 1963); *In re Langer*, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974)), even with respect to situations where no art-recognized animal models existed for the human disease encompassed by the claims. *Ex parte Balzarini*, 21 USPQ2d 1892 (Bd. Pat. App. & Inter. 1991) (human clinical data is not required to demonstrate the utility of the claimed invention, even though those skilled in the art might not accept other evidence to establish the efficacy of the claimed therapeutic compositions and the operativeness of the claimed methods of treating humans). Before a drug can enter human clinical trials, the sponsor, often the applicant, must provide a convincing rationale to those especially skilled in the art (e.g., the Food and Drug Administration) that the investigation may be successful. Such a rationale would provide a basis for the sponsor's expectation that the investigation may be successful. In order to determine a protocol for phase I testing, the first phase of clinical investigation, some credible rationale of how the drug might be effective or could be effective would be necessary. Thus, as a general rule, if an applicant has initiated human clinical trials for a therapeutic product or process, Office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility.

V. SAFETY AND EFFICACY CONSIDERATIONS

The Office must confine its review of patent applications to the statutory requirements of the patent law. Other

agencies of the government have been assigned the responsibility of ensuring conformance to standards established by statute for the advertisement, use, sale or distribution of drugs. The FDA pursues a two-prong test to provide approval for testing. Under that test, a sponsor must show that the investigation does not pose an unreasonable and significant risk of illness or injury and that there is an acceptable rationale for the study. As a review matter, there must be a rationale for believing that the compound could be effective. If the use reviewed by the FDA is not set forth in the specification, FDA review may not satisfy **35 U.S.C. 101**. However, if the reviewed use is one set forth in the specification, Office personnel must be extremely hesitant to challenge utility. In such a situation, experts at the FDA have assessed the rationale for the drug or research study upon which an asserted utility is based and found it satisfactory. Thus, in challenging utility, Office personnel must be able to carry their burden that there is no sound rationale for the asserted utility even though experts designated by Congress to decide the issue have come to an opposite conclusion. "FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws." *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) (citing *Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir. 1994)).

Thus, while an applicant may on occasion need to provide evidence to show that an invention will work as claimed, it is improper for Office personnel to request evidence of safety in the treatment of humans, or regarding the degree of effectiveness. See *In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Anthony*, 414 F.2d 1383, 162 USPQ 594 (CCPA 1969); *In re Watson*, 517 F.2d 465, 186 USPQ 11 (CCPA 1975); *In re Krimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA 1961); *Ex parte Jovanovics*, 211 USPQ 907 (Bd. Pat. App. & Inter. 1981).

VI. TREATMENT OF SPECIFIC DISEASE CONDITIONS

Claims directed to a method of treating or curing a disease for which there have been no previously successful treatments or cures warrant careful review for compliance with **35 U.S.C. 101**. The credibility of an asserted utility for treating a human disorder may be more difficult to establish where current scientific understanding suggests that such a task would be impossible. Such a determination has always required a good understanding of the state of the art as of the time that the invention was made. For example, prior to the 1980's, there were a number of cases where an asserted use in treating cancer in humans was viewed as "incredible." *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Buting*, 418 F.2d 540, 163 USPQ 689 (CCPA 1969); *Ex parte Stevens*, 16 USPQ2d 1379 (Bd. Pat. App. & Inter. 1990); *Ex parte Busse*, 1 USPQ2d 1908 (Bd. Pat. App. & Inter. 1986); *Ex parte Krepelka*, 231 USPQ 746 (Bd. Pat. App. & Inter. 1986); *Ex parte Jovanovics*, 211 USPQ 907 (Bd. Pat. App. & Inter. 1981). The fact that there is no known cure for a disease, however, cannot serve as the basis for a conclusion that such an invention lacks utility. Rather, Office personnel must determine if the asserted utility for the invention is credible based on the information disclosed in the application. Only those claims for which an asserted utility is not credible should be rejected. In such cases, the Office should carefully review what is being claimed by the applicant. An assertion that the claimed invention is useful in treating a symptom of an incurable disease may be considered credible by a person of ordinary skill in the art on the basis of a fairly modest amount of evidence or support. In contrast, an assertion that the claimed invention will be useful in "curing" the disease may require a significantly greater amount of evidentiary support to be considered credible by a person of ordinary skill in the art. *In re Sichert*, 566 F.2d 1154, 196 USPQ 209 (CCPA 1977); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). See also *Ex parte Ferguson*, 117 USPQ 229 (Bd. Pat. App. & Inter. 1957).

In these cases, it is important to note that the Food and Drug Administration has promulgated regulations that enable a party to conduct clinical trials for drugs used to treat life threatening and severely-debilitating illnesses, even where no alternative therapy exists. See 21 CFR 312.80-88 (1994). Implicit in these regulations is the recognition that experts qualified to evaluate the effectiveness of therapeutics can and often do find a sufficient basis to conduct clinical trials of drugs for incurable or previously untreatable illnesses. Thus, affidavit evidence from experts in the art indicating that there is a reasonable expectation of success, supported by sound reasoning, usually should be sufficient to establish that such a utility is credible.

2111 Claim Interpretation; Broadest Reasonable Interpretation [R-9]

CLAIMS MUST BE GIVEN THEIR BROADEST REASONABLE INTERPRETATION > IN LIGHT OF THE SPECIFICATION<

During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard:

> The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.* , 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." 37 CFR **1.75(d)(1)**.

415 F.3d at 1316, 75 USPQ2d at 1329. See also *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). **> Because applicant has the opportunity to amend the claims during prosecution, giving a claim its broadest reasonable interpretation will reduce the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984); *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989) ("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow."); < *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969) (Claim 9 was directed to a process of analyzing data generated by mass spectrographic analysis of a gas. The process comprised selecting the data to be analyzed by subjecting the data to a mathematical manipulation. The examiner made rejections under **35 U.S.C. 101** and **102**. In the **35 U.S.C. 102** rejection, the examiner explained that the claim was anticipated by a mental process augmented by pencil and paper markings. The court agreed that the claim was not limited to using a machine to carry out the process since the claim did not explicitly set forth the machine. The court explained that "reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from 'reading limitations of the specification into a claim,' to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim." The court found that applicant was advocating the latter, i.e., the impermissible importation of subject matter from the specification into the claim.). See also *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997) (The court held that the PTO is not required, in the course of prosecution, to interpret claims in applications in the same manner as a court would interpret claims in an infringement suit. Rather, the "PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification.").

The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999) (The Board's construction of the claim limitation "restore hair growth" as requiring the hair to be returned to its original state was held to be an incorrect interpretation of the limitation. The court held that, consistent with applicant's disclosure and the disclosure of three patents from analogous arts using the same phrase to require only some increase in hair growth, one of ordinary skill would construe "restore hair growth" to mean that the claimed method increases the amount of hair grown on the scalp, but does not necessarily produce a full head of hair.).> Thus the focus of the inquiry regarding the meaning of a claim should be what would be reasonable from the perspective of one of ordinary skill in the art. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010); *In re Buszard*, 504 F.3d 1364 (Fed. Cir. 2007). In *Buszard*, the claim was directed to a flame retardant composition comprising a flexible polyurethane foam reaction mixture. *Buszard*, 504 F.3d at 1365. The Federal Circuit found that the Board's interpretation that equated a "flexible" foam with a crushed "rigid" foam was not reasonable. *Buszard*, 504 F.3d at 1367. Persuasive argument was presented that persons experienced in the field of polyurethane foams know that a flexible mixture is different than a rigid foam mixture. *Buszard*, 504 F.3d at 1366.

See **2173.02** for further discussion of claim interpretation in the context of analyzing claims for compliance with **35 U.S.C. 112**, second paragraph. <

2111.01 Plain Meaning [R-9]

I. THE WORDS OF A CLAIM MUST BE GIVEN THEIR "PLAIN MEANING" UNLESS SUCH MEANING IS INCONSISTENT WITH THE SPECIFICATION

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Under a broadest reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification. The plain meaning of a term means the ordinary and customary meaning given to the term by those of ordinary skill in the art at the time of the invention. The ordinary and

customary meaning of a term may be evidenced by a variety of sources, including the words of the claims themselves, the specification, drawings, and prior art. However, the best source for determining the meaning of a claim term is the specification - the greatest clarity is obtained when the specification serves as a glossary for the claim terms. The presumption that a term is given its ordinary and customary meaning may be rebutted by the applicant by clearly setting forth a different definition of the term in the specification. *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997) (the USPTO looks to the ordinary use of the claim terms taking into account definitions or other "enlightenment" contained in the written description); *But c.f. In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1369 (Fed. Cir. 2004) ("We have cautioned against reading limitations into a claim from the preferred embodiment described in the specification, even if it is the only embodiment described, absent clear disclaimer in the specification."). When the specification sets a clear path to the claim language, the scope of the claims is more easily determined and the public notice function of the claims is best served.

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Although claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004) (The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation in light of the specification.). This means that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (discussed below); *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004) (Ordinary, simple English words whose meaning is clear and unquestionable, absent any indication that their use in a particular context changes their meaning, are construed to mean exactly what they say. Thus, "heating the resulting batter-coated dough to a temperature in the range of about 400^{o}F to 850^{o}F" required heating the dough, rather than the air inside an oven, to the specified temperature.).

II. IT IS IMPROPER TO IMPORT CLAIM LIMITATIONS FROM THE SPECIFICATION

"Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004). See also *Liebel-Flarsheim Co. v. Medrad Inc.*, 358 F.3d 898, 906, 69 USPQ2d 1801, 1807 (Fed. Cir. 2004)(discussing recent cases wherein the court expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment); *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) ("Interpretation of descriptive statements in a patent's written description is a difficult task, as an inherent tension exists as to whether a statement is a clear lexicographic definition or a description of a preferred embodiment. The problem is to interpret claims 'in view of the specification' without unnecessarily importing limitations from the specification into the claims."); *Altiris Inc. v. Symantec Corp.*, 318 F.3d 1363, 1371, 65 USPQ2d 1865, 1869-70 (Fed. Cir. 2003) (Although the specification discussed only a single embodiment, the court held that it was improper to read a specific order of steps into method claims where, as a matter of logic or grammar, the language of the method claims did not impose a specific order on the performance of the method steps, and the specification did not directly or implicitly require a particular order). See also paragraph IV., below. When an element is claimed using language falling under the scope of **35 U.S.C. 112**, 6th paragraph (often broadly referred to as means or step plus function language), the specification must be consulted to determine the structure, material, or acts corresponding to the function recited in the claim. *In re Donaldson*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994) (see **MPEP § 2181**- **§ 2186**).

In *In re Zletz*, *supra*, the examiner and the Board had interpreted claims reading "normally solid polypropylene" and "normally solid polypropylene having a crystalline polypropylene content" as being limited to "normally solid linear high homopolymers of propylene which have a crystalline polypropylene content." The court ruled that limitations, not present in the claims, were improperly imported from the specification. See also *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) ("Claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation'." 710 F.2d

at 802, 218 USPQ at 292 (quoting *In re Okuzawa*, 537 F.2d 545, 548, 190 USPQ 464, 466 (CCPA 1976)) (emphasis in original). The court looked to the specification to construe "essentially free of alkali metal" as including unavoidable levels of impurities but no more.). Compare *In re Weiss*, 989 F.2d 1202, 26 USPQ2d 1885 (Fed. Cir. 1993) (unpublished decision - cannot be cited as precedent) (The claim related to an athletic shoe with cleats that "break away at a preselected level of force" and thus prevent injury to the wearer. The examiner rejected the claims over prior art teaching athletic shoes with cleats not intended to break off and rationalized that the cleats would break away given a high enough force. The court reversed the rejection stating that when interpreting a claim term which is ambiguous, such as "'a preselected level of force,' we must look to the specification for the meaning ascribed to that term by the inventor." The specification had defined "preselected level of force" as that level of force at which the breaking away will prevent injury to the wearer during athletic exertion.)

III. "PLAIN MEANING" REFERS TO THE ORDINARY AND CUSTOMARY MEANING GIVEN TO THE TERM BY THOSE OF ORDINARY SKILL IN THE ART

"[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application." *Phillips v. AWH Corp.*,415 F.3d 1303, 1313, 75 USPQ2d 1321, 1326 (Fed. Cir. 2005) (*en banc*); *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003)("In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art."). It is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims. *Ferguson Beauregard/Logic Controls v. Mega Systems*, 350 F.3d 1327, 1338, 69 USPQ2d 1001, 1009 (Fed. Cir. 2003) (Dictionary definitions were used to determine the ordinary and customary meaning of the words "normal" and "predetermine" to those skilled in the art. In construing claim terms, the general meanings gleaned from reference sources, such as dictionaries, must always be compared against the use of the terms in context, and the intrinsic record must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor.); *ACTV, Inc. v. The Walt Disney Company*, 346 F.3d 1082, 1092, 68 USPQ2d 1516, 1524 (Fed. Cir. 2003) (Since there was no express definition given for the term "URL" in the specification, the term should be given its broadest reasonable interpretation consistent with the intrinsic record and take on the ordinary and customary meaning attributed to it by those of ordinary skill in the art; thus, the term "URL" was held to encompass both relative and absolute URLs.); and *E-Pass Technologies, Inc. v. 3Com Corporation*, 343 F.3d 1364, 1368, 67 USPQ2d 1947, 1949 (Fed. Cir. 2003) (Where no explicit definition for the term "electronic multi-function card" was given in the specification, this term should be given its ordinary meaning and broadest reasonable interpretation; the term should not be limited to the industry standard definition of credit card where there is no suggestion that this definition applies to the electronic multi-function card as claimed, and should not be limited to preferred embodiments in the specification.).

The ordinary and customary meaning of a term may be evidenced by a variety of sources, including "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Phillips v. AWH Corp.*, 415 F.3d at 1314, 75 USPQ2d at 1327. If extrinsic reference sources, such as dictionaries, evidence more than one definition for the term, the intrinsic record must be consulted to identify which of the different possible definitions is most consistent with applicant's use of the terms. *Brookhill-Wilk 1*, 334 F. 3d at 1300, 67 USPQ2d at 1137; see also *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998) ("Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings.") and *Vitronics Corp. v. Conceptronic Inc.*, 90 F.3d 1576, 1583, 39 USPQ2d 1573, 1577 (Fed. Cir. 1996) (construing the term "solder reflow temperature" to mean "peak reflow temperature" of solder rather than the "liquidus temperature" of solder in order to remain consistent with the specification.). If more than one extrinsic definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all consistent meanings. See e.g., *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001)(explaining the court's analytical process for determining the meaning of disputed claim terms); *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)("[W]ords in patent claims are given their ordinary meaning in the usage of the field of the invention, unless

the text of the patent makes clear that a word was used with a special meaning."). Compare *MSM Investments Co. v. Carolwood Corp.*, 259 F.3d 1335, 1339-40, 59 USPQ2d 1856, 1859-60 (Fed. Cir. 2001) (Claims directed to a method of feeding an animal a beneficial amount of methylsulfonylmethane (MSM) to enhance the animal's diet were held anticipated by prior oral administration of MSM to human patients to relieve pain. Although the ordinary meaning of "feeding" is limited to provision of food or nourishment, the broad definition of "food" in the written description warranted finding that the claimed method encompasses the use of MSM for both nutritional and pharmacological purposes.); and *Rapoport v. Dement*, 254 F.3d 1053, 1059-60, 59 USPQ2d 1215, 1219-20 (Fed. Cir. 2001) (Both intrinsic evidence and the plain meaning of the term "method for treatment of sleep apneas" supported construction of the term as being limited to treatment of the underlying sleep apnea disorder itself, and not encompassing treatment of anxiety and other secondary symptoms related to sleep apnea.).

IV. APPLICANT MAY BE OWN LEXICOGRAPHER

An applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (inventor may define specific terms used to describe invention, but must do so "with reasonable clarity, deliberateness, and precision" and, if done, must "'set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change" in meaning) (quoting *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387-88, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992)). Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999) (meaning of words used in a claim is not construed in a "lexicographic vacuum, but in the context of the specification and drawings"). Any special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998). See also *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999) and **MPEP § 2173.05(a)**. The specification should also be relied on for more than just explicit lexicography or clear disavowal of claim scope to determine the meaning of a claim term when applicant acts as his or her own lexicographer; the meaning of a particular claim term may be defined by implication, that is, according to the usage of the term in the context in the specification. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) (*en banc*); and *Vitronics Corp. v. Conceptronic Inc.*, 90 F.3d 1576, 1583, 39 USPQ2d 1573, 1577 (Fed. Cir. 1996). Compare *Merck & Co., Inc., v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1370, 73 USPQ2d 1641, 1646 (Fed. Cir. 2005), where the court held that patentee failed to redefine the ordinary meaning of "about" to mean "exactly" in clear enough terms to justify the counterintuitive definition of "about." ("When a patentee acts as his own lexicographer in redefining the meaning of particular claim terms away from their ordinary meaning, he must clearly express that intent in the written description.").

See also **MPEP § 2173.05(a)**.

2111.02 Effect of Preamble [R-3]

The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim. *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002). See *id.* at 808-10, 62 USPQ2d at 1784-86 for a discussion of guideposts that have emerged from various decisions exploring the preamble's effect on claim scope, as well as a hypothetical example illustrating these principles.

"[A] claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003)(In considering the effect of the preamble in a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the claims' recitation of a patient or a human "in need" gives life and meaning to the preamble's statement of purpose.). *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) (A preamble reciting "An abrasive article" was deemed essential to point out the invention defined by claims to an article

comprising abrasive grains and a hardened binder and the process of making it. The court stated "it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable *inter alia* of use as abrasive grains and a binder is not an 'abrasive article.'" Therefore, the preamble served to further define the structure of the article produced.).

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I. < PREAMBLE STATEMENTS LIMITING STRUCTURE

Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim."); *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention). See also *In re Stencel*, 828 F.2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987). (The claim at issue was directed to a driver for setting a joint of a threaded collar*>;< however>,< the body of the claim did not directly include the structure of the collar as part of the claimed article. The examiner did not consider the preamble, which did set forth the structure of the collar, as limiting the claim. The court found that the collar structure could not be ignored. While the claim was not directly limited to the collar, the collar structure recited in the preamble did limit the structure of the driver. "[T]he framework - the teachings of the prior art - against which patentability is measured is not all drivers broadly, but drivers suitable for use in combination with this collar, for the claims are so limited." Id. at 1073, 828 F.2d at 754.).

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II. < PREAMBLE STATEMENTS RECITING PURPOSE OR INTENDED USE

The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *Corning Glass Works*, 868 F.2d at 1257, 9 USPQ2d at 1966. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim); *STX LLC. v. Brine*, 211 F.3d 588, 591, 54 USPQ2d 1347, 1350 (Fed. Cir. 2000) (holding that the preamble phrase "which provides improved playing and handling characteristics" in a claim drawn to a head for a lacrosse stick was not a claim limitation). Compare *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333-34, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003) (In a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the preamble is not merely a statement of effect that may or may not be desired or appreciated, but rather is a statement of the intentional purpose for which the method must be performed. Thus the claim is properly interpreted to mean that the vitamin preparation must be administered to a human with a recognized need to treat or prevent pernicious anemia.); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002) (A claim at issue was directed to a method of preparing a food rich in glucosinolates wherein cruciferous sprouts are harvested prior to the 2-leaf stage. The court held that the preamble phrase "rich in glucosinolates" helps define the claimed invention, as evidenced by the specification and prosecution history, and thus is a limitation of the claim (although the claim was anticipated by prior art that produced sprouts inherently "rich in glucosinolates")).

During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of

no significance to the structure and process of making.); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim did not distinguish over the prior art apparatus). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (anticipation rejection affirmed based on Board's factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant's claim 1 (a dispensing top for dispensing popcorn in a specified manner)) and cases cited therein. See also MPEP § **2112** - § **2112.02**.

>However, a "preamble may provide context for claim construction, particularly, where … that preamble's statement of intended use forms the basis for distinguishing the prior art in the patent's prosecution history." *Metabolite Labs., Inc. v. Corp. of Am. Holdings*, 370 F.3d 1354, 1358-62, 71 USPQ2d 1081, 1084-87 (Fed. Cir. 2004). The patent claim at issue was directed to a two-step method for detecting a deficiency of vitamin B_{12} or folic acid, involving (i) assaying a body fluid for an "elevated level" of homocysteine, and (ii) "correlating" an "elevated" level with a vitamin deficiency. 370 F.3d at 1358-59, 71 USPQ2d at 1084. The court stated that the disputed claim term "correlating" can include comparing with either an unelevated level or elevated level, as opposed to only an elevated level because adding the "correlating" step in the claim during prosecution to overcome prior art tied the preamble directly to the "correlating" step. 370 F.3d at 1362, 71 USPQ2d at 1087. The recitation of the intended use of "detecting" a vitamin deficiency in the preamble rendered the claimed invention a method for "detecting," and, thus, was not limited to detecting "elevated" levels. *Id* .

See also *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d at 808-09, 62 USPQ2d at 1785 ("[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention.…Without such reliance, however, a preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention." Consequently, "preamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear reliance on those benefits or features as patentably significant."). In *Poly-America LP v. GSE Lining Tech. Inc.*, 383 F.3d 1303, 1310, 72 USPQ2d 1685, 1689 (Fed. Cir. 2004), the court stated that "a '[r]eview of the entirety of the '047 patent reveals that the preamble language relating to 'blown-film' does not state a purpose or an intended use of the invention, but rather discloses a fundamental characteristic of the claimed invention that is properly construed as a limitation of the claim….'" Compare *Intirtool, Ltd. v. Texar Corp.*, 369 F.3d 1289, 1294-96, 70 USPQ2d 1780, 1783-84 (Fed. Cir. 2004) (holding that the preamble of a patent claim directed to a "hand-held punch pliers for simultaneously punching and connecting overlapping sheet metal" was not a limitation of the claim because (i) the body of the claim described a "structurally complete invention" without the preamble, and (ii) statements in prosecution history referring to "punching and connecting" function of invention did not constitute "clear reliance" on the preamble needed to make the preamble a limitation).<

2111.03 Transitional Phrases [R-9]

The transitional phrases "comprising", "consisting essentially of" and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. > The determination of what is or is not excluded by a transitional phrase must be made on a case-by-case basis in light of the facts of each case. <

The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term 'comprising,' the terms 'containing' and 'mixture' are open-ended."). *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). In *Gillette Co. v. Energizer Holdings Inc.*, 405 F.3d 1367, 1371-73, 74 USPQ2d 1586, 1589-91 (Fed. Cir. 2005), the court held that a claim to "a safety razor blade unit comprising a guard, a cap, and a group of first, second, and third blades" encompasses razors with more than

three blades because the transitional phrase "comprising" in the preamble and the phrase "group of" are presumptively open-ended. "The word 'comprising' transitioning from the preamble to the body signals that the entire claim is presumptively open-ended." *Id.* In contrast, the court noted the phrase "group consisting of" is a closed term, which is often used in claim drafting to signal a "Markush group" that is by its nature closed. *Id.* The court also emphasized that reference to "first," "second," and "third" blades in the claim was not used to show a serial or numerical limitation but instead was used to distinguish or identify the various members of the group. *Id*.

The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("consisting of" defined as "closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith."). But see *Norian Corp. v. Stryker Corp*., 363 F.3d 1321, 1331-32, 70 USPQ2d 1508, 1516 (Fed. Cir. 2004) (holding that a bone repair kit "consisting of" claimed chemicals was infringed by a bone repair kit including a spatula in addition to the claimed chemicals because the presence of the spatula was unrelated to the claimed invention). A claim which depends from a claim which "consists of" the recited elements or steps cannot add an element or step. When the phrase "consists of" appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause; other elements are not excluded from the claim as a whole. *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 230 USPQ 45 (Fed. Cir. 1986). See also *In re Crish*, 393 F.3d 1253, 73 USPQ2d 1364 (Fed. Cir. 2004) (The claims at issue "related to purified DNA molecules having promoter activity for the human involucrin gene (hINV)." *Id.*, 73 USPQ2d at 1365. In determining the scope of applicant's claims directed to "a purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO:1 wherein said portion consists of the nucleotide sequence from … to 2473 of SEQ ID NO:1, and wherein said portion of the nucleotide sequence of SEQ ID NO:1 has promoter activity," the court stated that the use of "consists" in the body of the claims did not limit the open-ended "comprising" language in the claims (emphases added). *Id.* at 1257, 73 USPQ2d at 1367. The court held that the claimed promoter sequence designated as SEQ ID NO:1 was obtained by sequencing the same prior art plasmid and was therefore anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides . *Id.* at 1256 and 1259, 73 USPQ2d at 1366 and 1369.The court affirmed the Board's interpretation that the transition phrase "consists" did not limit the claims to only the recited numbered nucleotide sequences of SEQ ID NO:1 and that "the transition language 'comprising' allowed the claims to cover the entire involucrin gene plus other portions of the plasmid, as long as the gene contained the specific portions of SEQ ID NO:1 recited by the claim[s]" *Id.* at 1256, 73 USPQ2d at 1366.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) (Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). "A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also *Atlas Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama-Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under **35 U.S.C. 102** and **103**, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003) (Applicant's statement in the specification that "silicon contents in the coating metal should not exceed about 0.5% by weight" along with a discussion of the deleterious effects of silicon provided basis to conclude that silicon in excess of 0.5% by weight would materially alter the basic and

novel properties of the invention. Thus, "consisting essentially of" as recited in the preamble was interpreted to permit no more than 0.5% by weight of silicon in the aluminum coating.); *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although 'consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language.").

OTHER TRANSITIONAL PHRASES

Transitional phrases such as "having" must be interpreted in light of the specification to determine whether open or closed claim language is intended. See, e.g., *Lampi Corp. v. American Power Products Inc.*, 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1453 (Fed. Cir. 2000) (The term "having" was interpreted as open terminology, allowing the inclusion of other components in addition to those recited); *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l Inc.*, 246 F.3d 1336, 1348, 57 USPQ2d 1953, 1959 (Fed. Cir. 2001) (term "having" in transitional phrase "does not create a presumption that the body of the claim is open"); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997) (In the context of a cDNA having a sequence coding for human PI, the term "having" still permitted inclusion of other moieties.). The transitional phrase "composed of" has been interpreted in the same manner as either "consisting of" or "consisting essentially of," depending on the facts of the particular case. See *AFG Industries, Inc. v. Cardinal IG Company*, 239 F.3d 1239, 1245, 57 USPQ2d 1776, 1780-81 (Fed. Cir. 2001) (based on specification and other evidence, "composed of" interpreted in same manner as "consisting essentially of"); *In re Bertsch*, 132 F.2d 1014, 1019-20, 56 USPQ 379, 384 (CCPA 1942) ("Composed of" interpreted in same manner as "consisting of"; however, court further remarked that "the words 'composed of' may under certain circumstances be given, in patent law, a broader meaning than 'consisting of.'").

2111.04 "Adapted to," "Adapted for," "Wherein," and "Whereby" Clauses [R-9]

Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure. However, examples of claim language, although not exhaustive, that may raise a question as to the limiting effect of the language in a claim are:

(A) "adapted to" or "adapted for" clauses;
(B) "wherein" clauses; and
(C) "whereby" clauses.

The determination of whether each of these clauses is a limitation in a claim depends on the specific facts of the case. >See, e.g., *Griffin v. Bertina*, 283 F.3d 1029, 1034, 62 USPQ2d 1431 (Fed. Cir. 2002)(finding that a "wherein" clause limited a process claim where the clause gave "meaning and purpose to the manipulative steps").< In *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005), the court held that when a "'whereby' clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." *Id*. However, the court noted (quoting *Minton v. Nat'l Ass'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)) that a "'whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.'" *Id*.

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2111.05 Functional and Nonfunctional Descriptive Material [R-9]

USPTO personnel must consider all claim limitations when determining patentability of an invention over the prior art. *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 403-04 (Fed. Cir. 1983). Since a claim must be read as a whole, USPTO personnel may not disregard claim limitations comprised of printed matter. See *Gulack*, 703 F.2d at 1384, 217 USPQ at 403; see also *Diamond v. Diehr*, 450 U.S. 175, 191, 209 USPQ 1, 10 (1981). However, USPTO personnel need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994); *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004). The rationale behind the printed matter cases, in which, for

example, written instructions are added to a known product, has been extended to method claims in which an instructional limitation is added to a method known in the art. Similar to the inquiry for products with printed matter thereon, in such method cases the relevant inquiry is whether a new and unobvious functional relationship with the known method exists. See *In re Kao*, 639 F.3d 1057, ___, 98 USPQ2d 1799, 1811-12 (Fed. Cir. 2011); *King Pharmaceuticals Inc. v. Eon Labs Inc*., 616 F.3d 1267, ___, 95 USPQ2d 1833, 1842 (Fed. Cir. 2010).

I. Determining Whether a Functional Relationship Exists

A. Evidence For a Functional Relationship

To be given patentable weight, the printed matter and associated product must be in a functional relationship. A functional relationship can be found where the printed matter performs some function with respect to the product to which it is associated. See *Lowry*, 32 F.3d at 1584 (citing *Gulack*, 703 F.2d at 1386). For instance, indicia on a measuring cup perform the function of indicating volume within that measuring cup. See *In re Miller*, 418 F.2d 1392, 1396, 164 USPQ 46, 49 (CCPA 1969). A functional relationship can also be found where the product performs some function with respect to the printed matter to which it is associated. For instance, where a hatband places a string of numbers in a certain physical relationship to each other such that a claimed algorithm is satisfied due to the physical structure of the hatband, the hatband performs a function with respect to the string of numbers. See *Gulack*, 703 F.2d at 1386-87.

B. Evidence Against a Functional Relationship

However, where a product merely serves as a support for printed matter, no functional relationship exists. Such a situation would occur for a hatband with images displayed on the hatband but not arranged in any particular sequence. See *Gulack*, 703 F.2d at 1386. Another example in which a product merely serves as a support would occur for a deck of playing cards having images on each card. See *In re Bryan*, 2009 U.S. App. LEXIS 6667 (Fed. Cir. 2009) (unpublished). See also *Ex parte Gwinn*, 112 USPQ 439, 446-47 (Bd. App. 1955), in which the invention was directed to a set of dice by means of which a game may be played. The claims differed from the prior art solely by the printed matter in the dice. The claims were properly rejected on prior art because there was no new feature of physical structure and no new relation of printed matter to physical structure. These situations may arise where the claim as a whole is directed towards conveying a message or meaning to a human reader independent of the supporting product. For example, a claimed measuring tape having electrical wiring information thereon, or a generically claimed substrate having a picture of a golf ball thereupon, would lack a functional relationship as the claims as a whole are directed towards conveying wiring information (unrelated to the measuring tape) or an aesthetically pleasing image (unrelated to the substrate) to the reader. Additionally, where the printed matter and product do not depend upon each other, no functional relationship exists. For example, in a kit containing a set of chemicals and a printed set of instructions for using the chemicals, the instructions are not related to that particular set of chemicals. *In re Ngai*, 367 F.3d at 1339.

II. Functional Relationship Must be New and Unobvious

Once a functional relationship between the product and associated printed matter is found, the investigation shifts to the determination of whether the relationship is new and unobvious. For example, a claim to a color-coded indicia on a container in which the color indicates the expiration date of the container may give rise to a functional relationship. The claim may, however, be anticipated by prior art that reads on the claimed invention, or by a combination of prior art that teaches the claimed invention.

III. Machine-Readable Media

When determining the scope of a claim directed to a computer-readable medium containing certain programming, the examiner should first look to the relationship between the programming and the intended computer system. Where the programming performs some function with respect to the computer with which it is associated, a functional relationship will be found. For instance, a claim to computer-readable medium programmed with attribute data objects that perform the function of facilitating retrieval, addition, and removal of information in the intended computer system, establishes a functional relationship such that the claimed attribute data objects are given patentable weight. See *Lowry*, 32 F.3d at 1583-84.

However, where the claim as a whole is directed conveying a message or meaning to a human reader independent of the intended computer system, and/or the computer-readable medium merely serves as a support for information or data, no functional relationship exists. For example, a claim to a memory stick containing tables of batting averages, or tracks of recorded music, utilizes the intended computer system merely as a support for the

information. Such claims are directed toward conveying meaning to the human reader rather than towards establishing a functional relationship between recorded data and the computer.

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2112 Requirements of Rejection Based on Inherency; Burden of Proof [R-3]

The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under **35 U.S.C. 102** or **103**. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) (affirmed a **35 U.S.C. 103** rejection based in part on inherent disclosure in one of the references). See also *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

I. SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc*., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides . The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." *Id*.< See also **MPEP § 2112.01** with regard to inherency and product-by-process claims and **MPEP § 2141.02** with regard to inherency and rejections under **35 U.S.C. 103**.

II. INHERENT FEATURE NEED NOT BE RECOGNIZED AT THE TIME OF THE INVENTION

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure *at the time of invention*, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed.Cir.1999) ("If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics."); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348-49 (Fed. Cir. 1999) ("Because 'sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention.... An inherent structure, composition, or function is not necessarily known.")>; *SmithKline Beecham Corp. v. Apotex Corp*., 403 F.3d 1331, 1343-44, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound "inherently" anticipated the claimed hemihydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound "inherently results in at least trace amounts of" the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate)<.

III. A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both **35 U.S.C. 102** and **103**, expressed as a **102**/**103** rejection. "There is nothing inconsistent in concurrent rejections for obviousness under **35 U.S.C. 103** and for anticipation under **35 U.S.C. 102**." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a **35 U.S.C. 102**/**103** rejection

is appropriate for these types of claims as well as for composition claims.

IV. EXAMINER MUST PROVIDE RATIONALE OR EVIDENCE TENDING TO SHOW INHERENCY

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.). >Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category" but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species.<

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

In *In re Schreiber*, 128 F.3d 1473, 44 USPQ2d 1429 (Fed. Cir. 1997), the court affirmed a finding that a prior patent to a conical spout used primarily to dispense oil from an oil can inherently performed the functions recited in applicant's claim to a conical container top for dispensing popped popcorn. The examiner had asserted inherency based on the structural similarity between the patented spout and applicant's disclosed top, i.e., both structures had the same general shape. The court stated:

> [N]othing in Schreiber's [applicant's] claim suggests that Schreiber's container is of a 'different shape' than Harz's [patent]. In fact, [ ] an embodiment according to Harz (Fig. 5) and the embodiment depicted in Fig. 1 of Schreiber's application have the same general shape. For that reason, the examiner was justified in concluding that the opening of a conically shaped top as disclosed by Harz is inherently of a size sufficient to 'allow [ ] several kernels of popped popcorn to pass through at the same time' and that the taper of Harz's conically shaped top is inherently of such a shape 'as to by itself jam up the popped popcorn before the end of the cone and permit the dispensing of only a few kernels at a shake of a package when the top is mounted to the container.' The examiner therefore correctly found that Harz established a prima facie case of anticipation.

In re Schreiber, 128 F.3d at 1478, 44 USPQ2d at 1432.

V. ONCE A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess

the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under **35 U.S.C. 102**, on ' *prima facie* obviousness' under **35 U.S.C. 103**, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

In *In re Fitzgerald*, the claims were directed to a self-locking screw-threaded fastener comprising a metallic threaded fastener having patches of crystallizable thermoplastic bonded thereto. The claim further specified that the thermoplastic had a reduced degree of crystallization shrinkage. The specification disclosed that the locking fastener was made by heating the metal fastener to melt a thermoplastic blank which is pressed against the metal. After the thermoplastic adheres to the metal fastener, the end product is cooled by quenching in water. The examiner made a rejection based on a U.S. patent to Barnes. Barnes taught a self-locking fastener in which the patch of thermoplastic was made by depositing thermoplastic powder on a metallic fastener which was then heated. The end product was cooled in ambient air, by cooling air or by contacting the fastener with a water trough. The court first noted that the two fasteners were identical or only slightly different from each other. "Both fasteners possess the same utility, employ the same crystallizable polymer (nylon 11), and have an adherent plastic patch formed by melting and then cooling the polymer." *Id.* at 596 n.1, 619 F.2d at 70 n.l. The court then noted that the Board had found that Barnes' cooling rate could reasonably be expected to result in a polymer possessing the claimed crystallization shrinkage rate. Applicants had not rebutted this finding with evidence that the shrinkage rate was indeed different. They had only argued that the crystallization shrinkage rate was dependent on the cool down rate and that the cool down rate of Barnes was much slower than theirs. Because a difference in the cool down rate does not necessarily result in a difference in shrinkage, objective evidence was required to rebut the **35 U.S.C. 102**/**103** *prima facie* case.

In *In re Schreiber*, 128 F.3d 1473, 1478, 44 USPQ2d 1429, 1432 (Fed.Cir.1997), the court held that applicant's declaration failed to overcome a *prima facie* case of anticipation because the declaration did not specify the dimensions of either the dispensing top that was tested or the popcorn that was used. Applicant's declaration merely asserted that a conical dispensing top built according to a figure in the prior art patent was too small to jam and dispense popcorn and thus could not inherently perform the functions recited in applicant's claims. The court pointed out the disclosure of the prior art patent was not limited to use as an oil can dispenser, but rather was broader than the precise configuration shown in the patent's figure. The court also noted that the Board of Patent Appeals and Interferences found as a factual matter that a scaled-up version of the top disclosed in the patent would be capable of performing the functions recited in applicant's claim.

See **MPEP § 2113** for more information on the analogous burden of proof applied to product-by-process claims.

2112.01 Composition, Product, and Apparatus Claims [R-3]

I. PRODUCT AND APPARATUS CLAIMS — WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims were directed to a titanium alloy containing 0.2-0.4% Mo and 0.6-0.9% Ni having corrosion resistance. A Russian article disclosed a titanium alloy containing 0.25% Mo and 0.75% Ni but was silent as to corrosion resistance. The Federal Circuit held that the claim was anticipated because the percentages of Mo and Ni were squarely within the claimed ranges. The court went on to say that it was immaterial what properties the alloys had or who discovered the properties because the composition is the same and thus must necessarily exhibit the properties.).

See also *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971) (Claim 1 was directed to a parachute canopy having concentric circumferential panels radially separated from each other by radially extending tie lines. The panels were separated "such that the critical velocity of each successively larger panel will be less than the

critical velocity of the previous panel, whereby said parachute will sequentially open and thus gradually decelerate." The court found that the claim was anticipated by Menget. Menget taught a parachute having three circumferential panels separated by tie lines. The court upheld the rejection finding that applicant had failed to show that Menget did not possess the functional characteristics of the claims.); *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp . 773, 22 USPQ 313 (E.D.N.Y. 1934) (A patent to a pencil for cleaning fingernails was held invalid because a pencil of the same structure for writing was found in the prior art.).

II. COMPOSITION CLAIMS — IF THE COMPOSITION IS PHYSICALLY THE SAME, IT MUST HAVE THE SAME PROPERTIES

"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a *prima facie* case of unpatentability of Spada's polymer latexes for lack of novelty.").

III. PRODUCT CLAIMS – NONFUNCTIONAL PRINTED MATTER DOES NOT DISTINGUISH CLAIMED PRODUCT FROM OTHERWISE IDENTICAL PRIOR ART PRODUCT

Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, **>367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004)< (Claim at issue was a kit requiring instructions and a buffer agent. The Federal Circuit held that the claim was anticipated by a prior art reference that taught a kit that included instructions and a buffer agent, even though the content of the instructions differed.). See also *In re Gulack*, 703 F.2d 1381, 1385-86, 217 USPQ 401, 404 (Fed. Cir. 1983)("Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability….[T]he critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate.").

2112.02 Process Claims

PROCESS CLAIMS — PRIOR ART DEVICE ANTICIPATES A CLAIMED PROCESS IF THE DEVICE CARRIES OUT THE PROCESS DURING NORMAL OPERATION

Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986) (The claims were directed to a method of enhancing color effects produced by ambient light through a process of absorption and reflection of the light off a coated substrate. A prior art reference to *Donley* disclosed a glass substrate coated with silver and metal oxide 200-800 angstroms thick. While Donley disclosed using the coated substrate to produce architectural colors, the absorption and reflection mechanisms of the claimed process were not disclosed. However, King's specification disclosed using a coated substrate of Donley's structure for use in his process. The Federal Circuit upheld the Board's finding that "Donley inherently performs the function disclosed in the method claims on appeal when that device is used in 'normal and usual operation' " and found that a *prima facie* case of anticipation was made out. *Id.* at 138, 801 F.2d at 1326. It was up to applicant to prove that Donley's structure would not perform the claimed method when placed in ambient light.). See also *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) (Applicant claimed a process for preparing a hydrolytically-stable zeolitic aluminosilicate which included a step of "cooling the steam zeolite ... at a rate sufficiently rapid that the cooled zeolite exhibits a X-ray diffraction pattern ...." All the process limitations were expressly disclosed by a U.S. patent to Hansford except the cooling step. The court stated that any sample of Hansford's zeolite would necessarily be cooled to facilitate subsequent handling. Therefore, a *prima facie* case under **35 U.S.C. 102/103** was made. Applicant had failed to introduce any evidence comparing X-ray diffraction patterns showing a difference in cooling rate between the claimed process and that of Hansford or any data showing that the process of Hansford would result in a product with a different X-ray diffraction. Either type of evidence would have rebutted the *prima facie* case under **35 U.S.C. 102**. A further analysis would be necessary to determine if the process

was unobvious under **35 U.S.C. 103**.); *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A U.S. patent to *Dart* disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating.).

PROCESS OF USE CLAIMS — NEW AND UNOBVIOUS USES OF OLD STRUCTURES AND COMPOSITIONS MAY BE PATENTABLE

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) (Claims 1 and 6, directed to a method of effecting nonaddictive analgesia (pain reduction) in animals, were found to be anticipated by the applied prior art which disclosed the same compounds for effecting analgesia but which was silent as to addiction. The court upheld the rejection and stated that the applicants had merely found a new property of the compound and such a discovery did not constitute a new use. The court went on to reverse the rejection of claims 2-5 and 7-10 which recited a process of using a new compound. The court relied on evidence showing that the nonaddictive property of the new compound was unexpected.). See also *In re Tomlinson*, 363 F.2d 928, 150 USPQ 623 (CCPA 1966) (The claim was directed to a process of inhibiting light degradation of polypropylene by mixing it with one of a genus of compounds, including nickel dithiocarbamate. A reference taught mixing polypropylene with nickel dithiocarbamate to lower heat degradation. The court held that the claims read on the obvious process of mixing polypropylene with the nickel dithiocarbamate and that the preamble of the claim was merely directed to the result of mixing the two materials. "While the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the oldcomposition." 363 F.2d at 934, 150 USPQ at 628 (emphasis in original).).

2113 Product-by-Process Claims [R-9]

PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). >Furthermore, "[b]ecause validity is determined based on the requirements of patentability, a patent is invalid if a product made by the process recited in a product-by-process claim is anticipated by or obvious from prior art products, even if those prior art products are made by different processes." *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1370 n 14, 92 USPQ2d 1289, 1312, n 14 (Fed. Cir. 2009). However, in the context of an infringement analysis, a product-by-process claim is only infringed by a product made by the process recited in the claim. Id at 1370 ("a product in the prior art made by a different process can anticipate a product-by-process claim, but an accused product made by a different process cannot infringe a product-by-process claim."). <

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite

and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.)

ONCE A PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS FOUND AND A 35 U.S.C. 102/103 REJECTION MADE, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE

"The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983) (The claims were directed to a zeolite manufactured by mixing together various inorganic materials in solution and heating the resultant gel to form a crystalline metal silicate essentially free of alkali metal. The prior art described a process of making a zeolite which, after ion exchange to remove alkali metal, appeared to be "essentially free of alkali metal." The court upheld the rejection because the applicant had not come forward with any evidence that the prior art was not "essentially free of alkali metal" and therefore a different and unobvious product.).

Ex parte Gray, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (The prior art disclosed human nerve growth factor (b-NGF) isolated from human placental tissue. The claim was directed to b-NGF produced through genetic engineering techniques. The factor produced seemed to be substantially the same whether isolated from tissue or produced through genetic engineering. While the applicant questioned the purity of the prior art factor, no concrete evidence of an unobvious difference was presented. The Board stated that the dispositive issue is whether the claimed factor exhibits any unexpected properties compared with the factor disclosed by the prior art. The Board further stated that the applicant should have made some comparison between the two factors to establish unexpected properties since the materials appeared to be identical or only slightly different.).

THE USE OF 35 U.S.C. 102/103 REJECTIONS FOR PRODUCT-BY-PROCESS CLAIMS HAS BEEN APPROVED BY THE COURTS

"[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). >Office personnel should note that reliance on the alternative grounds of 35 U.S.C. 102 or 103 does not eliminate the need to explain both the anticipation and obviousness aspects of the rejections<.

2114 Apparatus and Article Claims — Functional Language [R-9]

For a discussion of case law which provides guidance in interpreting the functional portion of means-plus-function limitations see MPEP § 2181 - § 2186.

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I. APPARATUS CLAIMS MUST BE STRUCTURALLY DISTINGUISHABLE FROM THE PRIOR ART

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).

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II. MANNER OF OPERATING THE DEVICE DOES NOT DIFFERENTIATE APPARATUS CLAIM FROM THE PRIOR ART

A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987) (The preamble of claim 1 recited that the apparatus was "for mixing flowing developer material" and the body of the claim recited "means for mixing ..., said mixing means being stationary and completely submerged in the developer material". The claim was rejected over a reference which taught all the structural limitations of the claim for the intended use of mixing flowing developer. However, the mixer was only partially submerged in the developer material. The Board held that the amount of submersion is immaterial to the structure of the mixer and thus the claim was properly rejected.).

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III. A PRIOR ART DEVICE CAN PERFORM ALL THE FUNCTIONS OF THE APPARATUS CLAIM AND STILL NOT ANTICIPATE THE CLAIM

Even if the prior art device performs all the functions recited in the claim, the prior art cannot anticipate the claim if there is any structural difference. It should be noted, however, that means plus function limitations are met by structures which are equivalent to the corresponding structures recited in the specification. *In re Ruskin*, 347 F.2d 843, 146 USPQ 211 (CCPA 1965) as implicitly modified by *In re Donaldson*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994). See also *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.).

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IV. DETERMINING WHETHER A COMPUTER-IMPLEMENTED FUNCTIONAL CLAIM LIMITATION IS PATENTABLE OVER THE PRIOR ART UNDER 35 U.S.C. 102 AND 103

Functional claim language that is not limited to a specific structure covers all devices that are capable of performing the recited function. Therefore, if the prior art discloses a device that can inherently perform the claimed function, a rejection under **35 U.S.C. 102** or 103 may be appropriate. *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997); *In re Best*, 562 F.2d 1252, 1254 (CCPA 1977); *In re Ludtke*, 441 F.2d 660, 663-64 (CCPA 1971); *In re Swinehart*, 439 F.2d 210, 212-13 (CCPA 1971) ("[I]t is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art"). See **MPEP § 2112** for more information.

Computer-implemented functional claim limitations may also be broad because the term "computer" is commonly understood by one of ordinary skill in the art to describe a variety of devices with varying degrees of complexity and capabilities. *In re Paulsen*, 30 F.3d 1475, 1479-80 (Fed. Cir. 1994). Therefore, a claim containing the term "computer" should not be construed as limited to a computer having a specific set of characteristics and capabilities, unless the term is modified by other claim terms or clearly defined in the specification to be different from its common meaning. *Paulsen*, 30 F.3d at 1479-80. In *In re Paulsen*, the claims, directed to a portable computer, were rejected as anticipated under **35 U.S.C. 102** by a reference that disclosed a calculator, because the term "computer" was given the broadest reasonable interpretation consistent with the specification to include a calculator, and a calculator was considered to be a particular type of computer by those of ordinary skill in the art. *Paulsen*, 30 F.3d at 1479-80.

When determining whether a computer-implemented functional claim would have been obvious, examiners should note that broadly claiming an automated means to replace a manual function to accomplish the same result does not distinguish over the prior art. See *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007) ("Accommodating a prior art mechanical device that accomplishes [a desired] goal to modern electronics would have been reasonably obvious to one of ordinary skill in designing children's learning devices. Applying modern electronics to older mechanical devices has been commonplace in recent years."); *In re Venner*, 262 F.2d 91, 95 (CCPA 1958); see also **MPEP § 2144.04** . Furthermore, implementing a known function on a computer has been deemed obvious to one of ordinary skill in the art if the automation of the known function on a general purpose computer is nothing more than the

predictable use of prior art elements according to their established functions. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007); see also **MPEP § 2143** , Exemplary Rationales D and F. Likewise, it has been found to be obvious to adapt an existing process to incorporate Internet and Web browser technologies for communicating and displaying information because these technologies had become commonplace for those functions. *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1326-27 (Fed. Cir. 2008).

For more information on the obviousness determination, see **MPEP § 2141** .

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2115 Material or Article Worked Upon by Apparatus [R-2]

MATERIAL OR ARTICLE WORKED UPON DOES NOT LIMIT APPARATUS CLAIMS

"Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." *In re Young*, 75 F.2d *>996<, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

In *In re Young*, a claim to a machine for making concrete beams included a limitation to the concrete reinforced members made by the machine as well as the structural elements of the machine itself. The court held that the inclusion of the article formed within the body of the claim did not, without more, make the claim patentable.

In *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967), an apparatus claim recited "[a] taping machine comprising a supporting structure, a brush attached to said supporting structure, said brush being formed with projecting bristles which terminate in free ends to collectively define a surface to which adhesive tape will detachably adhere, and means for providing relative motion between said brush and said supporting structure while said adhesive tape is adhered to said surface." An obviousness rejection was made over a reference to Kienzle which taught a machine for perforating sheets. The court upheld the rejection stating that "the references in claim 1 to adhesive tape handling do not expressly or impliedly require any particular structure in addition to that of Kienzle." The perforating device had the structure of the taping device as claimed, the difference was in the use of the device, and "the manner or method in which such machine is to be utilized is not germane to the issue of patentability of the machine itself."

Note that this line of cases is limited to claims directed to machinery which works upon an article or material in its intended use. It does not apply to product claims or kit claims (i.e., claims directed to a plurality of articles grouped together as a kit).

2116 Material Manipulated in Process

The materials on which a process is carried out must be accorded weight in determining the patentability of a process. *Ex parte Leonard*, 187 USPQ 122 (Bd. App. 1974).

2116.01 Novel, Unobvious Starting Material or End Product [R-6]

All the limitations of a claim must be considered when weighing the differences between the claimed invention and the prior art in determining the obviousness of a process or method claim. See **MPEP § 2143.03**.

In re Ochiai, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996) addressed the issue of whether an otherwise conventional process could be patented if it were limited to making or using a nonobvious product. In both cases, the Federal Circuit held that the use of *per se* rules is improper in applying the test for obviousness under **35 U.S.C. 103**. Rather, **35 U.S.C. 103** requires a highly fact-dependent analysis involving taking the claimed subject matter as a whole and comparing it to the prior art. "A process yielding a novel and nonobvious product may nonetheless be obvious; conversely, a process yielding a well-known product may yet be nonobvious." *TorPharm, Inc. v. Ranbaxy Pharmaceuticals, Inc.*, 336 F.3d 1322, 1327, 67 USPQ2d 1511, 1514 (Fed. Cir. 2003). **

Interpreting the claimed invention as a whole requires consideration of all claim limitations. Thus, proper claim construction requires treating language in a process claim which recites the making or using of a nonobvious product as a material limitation. ** The decision in *Ochiai* specifically dispelled any distinction between processes of making a product and methods of using a product with regard to the effect of any product limitations in either type of claim.

As noted in *Brouwer*, 77 F.3d at 425, 37 USPQ2d at 1666, the inquiry as to whether a claimed invention would

have been obvious is "highly fact-specific by design". Accordingly, obviousness must be assessed on a case-by-case basis. The following decisions are illustrative of the lack of *per se* rules in applying the test for obviousness under **35 U.S.C. 103** and of the fact-intensive comparison of claimed processes with the prior art: *In re Durden*, 763 F.2d 1406, 226 USPQ 359 (Fed. Cir. 1985) (The examiner rejected a claim directed to a process in which patentable starting materials were reacted to form patentable end products. The prior art showed the same chemical reaction mechanism applied to other chemicals. The court held that the process claim was obvious over the prior art.); *In re Albertson*, 332 F.2d 379, 141 USPQ 730 (CCPA 1964) (Process of chemically reducing one novel, nonobvious material to obtain another novel, nonobvious material was claimed. The process was held obvious because the reduction reaction was old.); *In re Kanter*, 399 F.2d 249, 158 USPQ 331 (CCPA 1968) (Process of siliconizing a patentable base material to obtain a patentable product was claimed. Rejection based on prior art teaching the siliconizing process as applied to a different base material was upheld.); Cf. *In re Pleuddemann*, 910 F.2d 823, 15 USPQ2d 1738 (Fed. Cir. 1990) (Methods of bonding polymer and filler using a novel silane coupling agent held patentable even though methods of bonding using other silane coupling agents were well known because the process could not be conducted without the new agent); *In re Kuehl*, 475 F.2d 658, 177 USPQ 250 (CCPA 1973) (Process of cracking hydrocarbons using novel zeolite catalyst found to be patentable even though catalytic cracking process was old. "The test under 103 is whether in view of the prior art the invention as a whole would have been obvious at the time it was made, and the prior art here does not include the zeolite, ZK-22. The obviousness of the process of cracking hydrocarbons with ZK-22 as a catalyst must be determined without reference to knowledge of ZK-22 and its properties." 475 F.2d at 664-665, 177 USPQ at 255.); and *In re Mancy*, 499 F.2d 1289, 182 USPQ 303 (CCPA 1974) (Claim to a process for the production of a known antibiotic by cultivating a novel, unobvious microorganism was found to be patentable.).

2121 Prior Art; General Level of Operability Required to Make a Prima Facie Case [R-6]

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I. < PRIOR ART IS PRESUMED TO BE OPERABLE/ENABLING

When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also **MPEP § 716.07**.

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II. < WHAT CONSTITUTES AN "ENABLING DISCLOSURE" DOES NOT DEPEND ON THE TYPE OF PRIOR ART THE DISCLOSURE IS CONTAINED IN

The level of disclosure required within a reference to make it an "enabling disclosure" is the same no matter what type of prior art is at issue. It does not matter whether the prior art reference is a U.S. patent, foreign patent, a printed publication or other. There is no basis in the statute (**35 U.S.C. 102** or **103**) for discriminating either in favor of or against prior art references on the basis of nationality. *In re Moreton*, 288 F.2d 708, 129 USPQ 227 (CCPA 1961).

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III. EFFICACY IS NOT A REQUIREMENT FOR PRIOR ART ENABLEMENT

A prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention; "proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation." *Impax Labs. Inc. v. Aventis Pharm . Inc.*, 468 F.3d 1366, 1383, 81 USPQ2d 1001, 1013 (Fed. Cir. 2006). See also MPEP § **2122.**<

2121.01 Use of Prior Art in Rejections Where Operability Is in Question [R-3]

"In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'... ." *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v.* **>*Mayo Found. For Med. Educ. & Research*<, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003) (At issue was whether a prior art reference enabled one of ordinary skill in the art to produce Elan's claimed transgenic mouse without undue experimentation. Without a disclosure enabling one skilled in the art to produce a transgenic mouse without undue experimentation, the reference would not be applicable as prior art.). A

reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985).

I. 35 U.S.C. 102 REJECTIONS AND ADDITION OF EVIDENCE SHOWING REFERENCE IS OPERABLE

It is possible to make a **35 U.S.C. 102** rejection even if the reference does not itself teach one of ordinary skill how to practice the invention, i.e., how to make or use the article disclosed. If the reference teaches every claimed element of the article, secondary evidence, such as other patents or publications, can be cited to show public possession of the method of making and/or using. *In re Donohue*, 766 F.2d at 533, 226 USPQ at 621. See **MPEP § 2131.01** for more information on **35 U.S.C. 102** rejections using secondary references to show that the primary reference contains an "enabling disclosure."

II. 35 U.S.C. 103 REJECTIONS AND USE OF INOPERATIVE PRIOR ART

"Even if a reference discloses an inoperative device, it is prior art for all that it teaches." *Beckman Instruments v. LKB Produkter AB*, 892 F.2d 1547, 1551, 13 USPQ2d 1301, 1304 (Fed. Cir. 1989). Therefore, "a non-enabling reference may qualify as prior art for the purpose of determining obviousness under **35 U.S.C. 103**." *Symbol Techs. Inc. v. Opticon Inc.*, 935 F.2d 1569, 1578, 19 USPQ2d 1241, 1247 (Fed. Cir. 1991).

2121.02 Compounds and Compositions — What Constitutes Enabling Prior Art [R-3]

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I. < ONE OF ORDINARY SKILL IN THE ART MUST BE ABLE TO MAKE OR SYNTHESIZE

Where a process for making the compound is not developed until after the date of invention, the mere naming of a compound in a reference, without more, cannot constitute a description of the compound. *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). Note, however, that a reference is presumed operable until applicant provides facts rebutting the presumption of *>operability<. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). Therefore, applicant must provide evidence showing that a process for making was not known at the time of the invention. See the following paragraph for the evidentiary standard to be applied.

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II. < A REFERENCE DOES NOT CONTAIN AN "ENABLING DISCLOSURE" IF ATTEMPTS AT MAKING THE COMPOUND OR COMPOSITION WERE UNSUCCESSFUL BEFORE THE DATE OF INVENTION

When a prior art reference merely discloses the structure of the claimed compound, evidence showing that attempts to prepare that compound were unsuccessful before the date of invention will be adequate to show inoperability. *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1971). However, the fact that an author of a publication did not attempt to make the compound disclosed, without more, will not overcome a rejection based on that publication. *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985) (In this case, the examiner had made a rejection under **35 U.S.C. 102(b)** over a publication, which disclosed the claimed compound, in combination with two patents teaching a general process of making the particular class of compounds. The applicant submitted an affidavit stating that the authors of the publication had not actually synthesized the compound. The court held that the fact that the publication's author did not synthesize the disclosed compound was immaterial to the question of reference operability. The patents were evidence that synthesis methods were well known. The court distinguished *Wiggins*, in which a very similar rejection was reversed. In *Wiggins*, attempts to make the compounds using the prior art methods were all unsuccessful.). Compare *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968) (A claim to a compound was rejected over a patent to *De Boer* which disclosed compounds similar in structure to those claimed (obvious homologs) and a process of making these compounds. Applicant responded with an affidavit by an expert named Wiley which stated that there was no indication in the *De Boer* patent that the process disclosed in *De Boer* could be used to produce the claimed compound and that he did not believe that the process disclosed in *De Boer* could be adapted to the production of the claimed compound. The court held that the facts stated in this affidavit were legally sufficient to overcome the rejection and that applicant need not show that all known processes are

incapable of producing the claimed compound for this showing would be practically impossible.).

2121.03 Plant Genetics — What Constitutes Enabling Prior Art [R-3]

THOSE OF ORDINARY SKILL MUST BE ABLE TO GROW AND CULTIVATE THE PLANT

When the claims are drawn to plants, the reference, combined with knowledge in the prior art, must enable one of ordinary skill in the art to reproduce the plant. *In re LeGrice*, 301 F.2d 929, 133 USPQ 365 (CCPA 1962) (National Rose Society Annual of England and various other catalogues showed color pictures of the claimed roses and disclosed that applicant had raised the roses. The publications were published more than 1 year before applicant's filing date. The court held that the publications did not place the rose in the public domain. Information on the grafting process required to reproduce the rose was not included in the publications and such information was necessary for those of ordinary skill in the art (plant breeders) to reproduce the rose.). Compare *Ex parte Thomson*, 24 USPQ2d 1618 (Bd. Pat. App. & Inter. 1992) (Seeds were commercially available more than 1 year prior to applicant's filing date. One of ordinary skill in the art could grow the claimed cotton cultivar from the commercially available seeds. Thus, the publications describing the cotton cultivar had "enabled disclosures." The Board distinguished *In re LeGrice* by finding that the catalogue picture of the rose of *In re LeGrice* was the only evidence in that case. There was no evidence of commercial availability in enabling form since the asexually reproduced rose could not be reproduced from seed. Therefore, the public would not have possession of the rose by its picture alone, but the public would have possession of the cotton cultivar based on the publications and the availability of the seeds.).

>In *In re Elsner*, 381 F.3d 1125, 1126, 72 USPQ2d 1038, 1040 (Fed. Cir. 2004), prior to the critical date of a plant patent application, the plant had been sold in Germany and a foreign Plant Breeder's Rights (PBR) application for the same plant had been published in the Community Plant Variety Office *Official Gazette*. The court held that when (i) a publication identifies claimed the plant, (ii) a foreign sale occurs that puts one of ordinary skill in the art in possession of the plant itself, and (iii) such possession permits asexual reproduction of the plant without undue experimentation to one of ordinary skill in the art, then that combination of facts and events directly conveys the essential knowledge of the invention and constitutes a 35 U.S.C. **102**(b) statutory bar. 381 F.3d at 1129, 72 USPQ2d at 1041. Although the court agreed with the Board that foreign sales may enable an otherwise non-enabling printed publication, the case was remanded for additional fact-finding in order to determine if the foreign sales of the plant were known to be accessible to the skilled artisan and if the skilled artisan could have reproduced the plant asexually after obtaining it without undue experimentation. 381 F.3d at 1131, 72 USPQ2d at 1043.<

2121.04 Apparatus and Articles — What Constitutes Enabling Prior Art

PICTURES MAY CONSTITUTE AN "ENABLING DISCLOSURE"

Pictures and drawings may be sufficiently enabling to put the public in the possession of the article pictured. Therefore, such an enabling picture may be used to reject claims to the article. However, the picture must show all the claimed structural features and how they are put together. *Jockmus v. Leviton*, 28 F.2d 812 (2d Cir. 1928). See also **MPEP § 2125** for a discussion of drawings as prior art.

2122 Discussion of Utility in the Prior Art [R-6]

UTILITY NEED NOT BE DISCLOSED IN REFERENCE

In order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. *In re Schoenwald*, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992) (The application claimed compounds used in ophthalmic compositions to treat dry eye syndrome. The examiner found a printed publication which disclosed the claimed compound but did not disclose a use for the compound. The court found that the claim was anticipated since the compound and a process of making it was taught by the reference. The court explained that "no utility need be disclosed for a reference to be anticipatory of a claim to an old compound." 964 F.2d at 1124, 22 USPQ2d at 1673. It is enough that the claimed compound is taught by the reference.). >See also *Impax Labs. Inc. v. Aventis Pharm . Inc.*, 468 F.3d 1366, 1383, 8 USPQ2d 1001, 1013 (Fed. Cir. 2006) ("[P]roof of efficacy is not required

for a prior art reference to be enabling for purposes of anticipation.").<

2123 Rejection Over Prior Art's Broad Disclosure Instead of Preferred Embodiments [R-5]

I. PATENTS ARE RELEVANT AS PRIOR ART FOR ALL THEY CONTAIN

"The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)).

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). See also > *Upsher-Smith Labs. v. Pamlab, LLC*, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005)(reference disclosing optional inclusion of a particular component teaches compositions that both do and do not contain that component);< Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.").

>See also MPEP § **2131.05** and § **2145**, subsection X.D., which discuss prior art that teaches away from the claimed invention in the context of anticipation and obviousness, respectively.<

II. NONPREFERRED AND ALTERNATIVE EMBODIMENTS CONSTITUTE PRIOR ART

Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132.). Furthermore, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed…." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

2124 Exception to the Rule That the Critical Reference Date Must Precede the Filing Date

IN SOME CIRCUMSTANCES A FACTUAL REFERENCE NEED NOT ANTEDATE THE FILING DATE

In certain circumstances, references cited to show a universal fact need not be available as prior art before applicant's filing date. *In re Wilson*, 311 F.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism. Some specific examples in which later publications showing factual evidence can be cited include situations where the facts shown in the reference are evidence "that, as of an application's filing date, undue experimentation would have been required, *In re Corneil*, 347 F.2d 563, 568, 145 USPQ 702, 705 (CCPA 1965), or that a parameter absent from the claims was or was not critical, *In re Rainer*, 305 F.2d 505, 507 n.3, 134 USPQ 343, 345 n.3 (CCPA 1962), or that a statement in the specification was inaccurate, *In re Marzocchi*, 439 F.2d 220, 223 n.4, 169 USPQ 367, 370 n.4 (CCPA 1971), or that the invention was inoperative or lacked utility, *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974), or that a claim was indefinite, *In re Glass*, 492 F.2d 1228,1232 n.6, 181 USPQ 31, 34 n.6 (CCPA 1974), or that characteristics of prior art products were known, *In re Wilson*, 311 F.2d 266, 135 USPQ 442 (CCPA 1962)." *In re Koller*, 613 F.2d 819, 823 n.5, 204 USPQ 702, 706 n.5 (CCPA 1980) (quoting *In re Hogan*, 559 F.2d 595, 605 n.17, 194 USPQ 527, 537 n.17 (CCPA 1977) (emphasis in original)). However, it is impermissible to use a later factual reference to determine whether the application is enabled or described as required under **35 U.S.C. 112**, first paragraph. *In re Koller*, 613 F.2d 819, 823 n. 5, 204 USPQ 702, 706 n.5 (CCPA 1980).

References which do not qualify as prior art because they postdate the claimed invention may be relied upon to show the level of ordinary skill in the art at or around the time the invention was made. *Ex parte Erlich*, 22 USPQ 1463 (Bd. Pat. App. & Inter. 1992).

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2124.01 Tax Strategies Deemed Within the Prior Art [R-9]

I. Overview

The Leahy-Smith America Invents Act (AIA), Public Law 112-29, sec. 14, 125 Stat. 284 (September 16, 2011) provides that for purposes of evaluating an invention for novelty and nonobviousness under **35 U.S.C. 102** and **35 U.S.C. 103**, any strategy for reducing, avoiding, or deferring tax liability (hereinafter "tax strategy"), whether known or unknown at the time of the invention or application for patent, shall be deemed insufficient to differentiate a claimed invention from the prior art. As a result, applicants will no longer be able to rely on the novelty or non-obviousness of a tax strategy embodied in their claims to distinguish them from the prior art. Any tax strategy will be considered indistinguishable from all other publicly available information that is relevant to a patent's claim of originality. This provision aims to keep the ability to interpret the tax law and to implement such interpretation in the public domain, available to all taxpayers and their advisors.

The term "tax liability" is defined for purposes of this provision as referring to any liability for a tax under any Federal, State, or local law, or the law of any foreign jurisdiction, including any statute, rule, regulation, or ordinance that levies, imposes, or assesses such tax liability.

There are two exclusions to this provision. The first is that the provision does not apply to that part of an invention that is a method, apparatus, technology, computer program product, or system, that is used solely for preparing a tax or information return or other tax filing, including one that records, transmits, transfers, or organizes data related to such filing.

The second is that the provision does not apply to that part of an invention that is a method, apparatus, technology, computer program product, or system, that is used solely for financial management, to the extent that it is severable from any tax strategy or does not limit the use of any tax strategy by any taxpayer or tax advisor.

This provision took effect on September 16, 2011, and applies to any patent application that is pending on, or filed on or after, September 16, 2011, and to any patent issued on or after September 16, 2011 Accordingly, this provision will apply in a reexamination or other post-grant proceeding only to patents issued on or after September 16, 2011.

II. Examination Guidance for Claims Relating to Tax Strategies

The following procedure should be followed when examining claims relating to tax strategies.

1. Construe the claim in accordance with **MPEP § 2111** et seq.

2. Analyze the claim for compliance with **35 U.S.C. 100** and **112** in accordance with current guidance, which is unaffected by this provision.

3. Identify any limitations relating to a tax strategy, as defined above (note the listed exclusions). a. Inventions that fall within the scope of **AIA section 14** include those tax strategies especially suitable for use with tax-favored structures that must meet certain requirements, such as employee benefit plans, tax-exempt organizations, or other entities that must be structured or operated in a particular manner to obtain certain tax consequences.

b. Thus, **AIA section 14** applies if the effect of an invention is to aid in satisfying the qualification requirements for a desired tax-favored entity status, to take advantage of the specific tax benefits offered in a tax-favored structure, or to allow for tax reduction, avoidance, or deferral not otherwise automatically available in such entity or structure.

4. Evaluate the claim in view of the prior art under **35 U.S.C. 102** and **103**, treating any limitations relating to a tax strategy as being within the prior art, and not as a patentable difference between the claim and the prior art. This approach is analogous to the treatment of printed matter limitations in a claim as discussed at **MPEP § 2112.01**, subsection III. Form paragraph 7.06 may be used to indicate claim limitation(s) interpreted as a tax strategy. See **MPEP § 706.02(m)** .

III. Examples Directed to Computer-Implemented Methods

A computer-implemented method that is deemed novel and non-obvious would not be affected by this provision even if used for a tax purpose. For example, a novel and non-obvious computer-implemented method for manipulating data would not be affected by this provision even if the method organized data for a future tax filing. However, a prior art computer-implemented method would not become non-obvious by implementing a novel

and non-obvious tax strategy. That is, the presence of limitations relating to the tax strategy would not cause a claim that is otherwise within the prior art to become novel or non-obvious over the prior art.

Thus, for purposes of applying art to a software-related invention under **35 U.S.C. 102** and 103, claim limitations that are directed solely to enabling individuals to file their income tax returns or assisting them with managing their finances should be given patentable weight, except that claim limitations directed to a tax strategy should not be given patentable weight.

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2125 Drawings as Prior Art

DRAWINGS CAN BE USED AS PRIOR ART

Drawings and pictures can anticipate claims if they clearly show the structure which is claimed. *In re Mraz*, 455 F.2d 1069, 173 USPQ 25 (CCPA 1972). However, the picture must show all the claimed structural features and how they are put together. *Jockmus v. Leviton*, 28 F.2d 812 (2d Cir. 1928). The origin of the drawing is immaterial. For instance, drawings in a design patent can anticipate or make obvious the claimed invention as can drawings in utility patents. When the reference is a utility patent, it does not matter that the feature shown is unintended or unexplained in the specification. The drawings must be evaluated for what they reasonably disclose and suggest to one of ordinary skill in the art. *In re Aslanian*, 590 F.2d 911, 200 USPQ 500 (CCPA 1979). See **MPEP § 2121.04** for more information on prior art drawings as "enabled disclosures."

PROPORTIONS OF FEATURES IN A DRAWING ARE NOT EVIDENCE OF ACTUAL PROPORTIONS WHEN DRAWINGS ARE NOT TO SCALE

When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. See *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000) (The disclosure gave no indication that the drawings were drawn to scale. "[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue."). However, the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art. *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977) ("We disagree with the Solicitor's conclusion, reached by a comparison of the relative dimensions of appellant's and *Bauer's* drawing figures, that *Bauer* 'clearly points to the use of a chime length of roughly 1/2 to 1 inch for a whiskey barrel.' This ignores the fact that *Bauer* does not disclose that his drawings are to scale. ... However, we agree with the Solicitor that *Bauer's* teaching that whiskey losses are influenced by the distance the liquor needs to 'traverse the pores of the wood' (albeit in reference to the thickness of the barrelhead)" would have suggested the desirability of an increased chime length to one of ordinary skill in the art bent on further reducing whiskey losses." 569 F.2d at 1127, 193 USPQ at 335-36.)

2126 Availability of a Document as a "Patent" for Purposes of Rejection Under 35 U.S.C. 102(a), (b), and (d) [R-5]

THE NAME "PATENT" ALONE DOES NOT MAKE A DOCUMENT AVAILABLE AS A PRIOR ART PATENT UNDER 35 U.S.C. 102(a) OR (b)

What a foreign country designates to be a patent may not be a patent for purposes of rejection under **35 U.S.C. 102(a)** and (b); it is the substance of the rights conferred and the way information within the "patent" is controlled that is determinative. *In re Ekenstam*, 256 F.2d 321, 118 USPQ 349 (CCPA 1958). See the next paragraph for further explanation with respect to when a document can be applied in a rejection as a "patent." See **MPEP § 2135.01** for a further discussion of the use of "patents" in **35 U.S.C. 102(d)** rejections.

A SECRET PATENT IS NOT AVAILABLE AS A REFERENCE UNDER 35 U.S.C. 102(a) or (b) UNTIL IT IS AVAILABLE TO THE PUBLIC BUT IT MAY BE AVAILABLE UNDER 35 U.S.C. 102(d) AS OF GRANT DATE

Secret patents are defined as patents which are insufficiently accessible to the public to constitute "printed publications." Decisions on the issue of what is sufficiently accessible to be a "printed publication" are located in **MPEP § 2128** - **§ 2128.01**.

Even if a patent grants an exclusionary right (is enforceable), it is not available as prior art under **35 U.S.C. 102(a)** or (b) if it is secret or private. *In re Carlson*, 983 F.2d 1032, 1037, 25 USPQ2d 1207, 1211 (Fed. Cir. 1992). The document must be at least minimally available to the public to constitute prior art. The patent is sufficiently available to the public for the purposes of **35 U.S.C. 102(a)** or (b) if it is laid open for public

inspection or disseminated in printed form. See, e.g., *In re Carlson*,*>983< F.2d at 1037, 25 USPQ2d at 1211 ("We recognize that *Geschmacksmuster* on display for public view in remote cities in a far-away land may create a burden of discovery for one without the time, desire, or resources to journey there in person or by agent to observe that which was registered under German law. Such a burden, however, is by law imposed upon the hypothetical person of ordinary skill in the art who is charged with knowledge of all contents of the relevant prior art."). The date that the patent is made available to the public is the date it is available as a **35 U.S.C. 102(a)** or (b) reference. *In re Ekenstam*, 256 F.2d 321, 118 USPQ 349 (CCPA 1958). But a period of secrecy after granting the patent has been held to have no effect in connection with **35 U.S.C. 102**(d). These patents are usable in rejections under **35 U.S.C. 102(d)** as of the date patent rights are granted. *In re Kathawala*, 9 F.3d 942, 28 USPQ2d 1789 (Fed. Cir. 1993). See **MPEP § 2135** - **§ 2135.01** for more information on **35 U.S.C. 102(d)**.

2126.01 Date of Availability of a Patent as a Reference [R-3]

DATE FOREIGN PATENT IS EFFECTIVE AS A REFERENCE IS USUALLY THE DATE PATENT RIGHTS ARE FORMALLY AWARDED TO ITS APPLICANT

The date the patent is available as a reference is generally the date that the patent becomes enforceable. This date is the date the sovereign formally bestows patents rights to the applicant. *In re Monks*, 588 F.2d 308, 200 USPQ 129 (CCPA 1978). There is an exception to this rule when the patent is secret as of the date the rights are awarded. *In re Ekenstam*, 256 F.2d 321, 118 USPQ 349 (CCPA 1958).

Note that **MPEP § 901.05** summarizes in tabular form dates of patenting for many foreign patents. *Chisum*, Patents § 3.06[4] n.2 gives a good summary of decisions which specify reference availability dates for specific classes of foreign patents. A copy of *Chisum* is kept in the law library of the Solicitor's Office and in the Lutrelle F. Parker, Sr., Memorial Law Library located in **>the Madison West Building, Room 1C35, 600 Dulany Street, Alexandria, Virginia 22314<.

2126.02 Scope of Reference's Disclosure Which Can Be Used to Reject Claims When the Reference Is a "Patent" but Not a "Publication"

OFTEN UNCLAIMED DETAILS FOUND IN THE PATENT SPECIFICATION CAN BE RELIED ON EVEN IF PATENT IS SECRET

When the patented document is used as a patent and not as a publication, the examiner is not restricted to the information conveyed by the patent claims but may use any information provided in the specification which relates to the subject matter of the patented claims when making a rejection under **35 U.S.C. 102(a)**, (b) or (d). *Ex parte Ovist*, 152 USPQ 709, 710 (Bd. App. 1963) (The claim of an Italian patent was generic and thus embraced the species disclosed in the examples, the Board added that the entire specification was germane to the claimed invention and upheld the examiner's **35 U.S.C. 102(b)** rejection.); *In re Kathawala*, 9 F.3d 942, 28 USPQ2d 1785 (Fed. Cir. 1993) (The claims at issue where rejected under **35 U.S.C. 102(d)** by applicant's own parent applications in Greece and Spain. The applicant argued that the "invention ... patented in Spain was not the same 'invention' claimed in the U.S. application because the Spanish patent claimed processes for making [compounds for inhibition of cholesterol biosynthesis] and claims 1 and 2 were directed to the compounds themselves." 9 F.3d at 944, 28 USPQ2d at 1786. The Federal Circuit held that "when an applicant files a foreign application fully disclosing his invention and having the potential to claim his invention in a number of ways, the reference in section 102(d) to 'invention ... patented' necessarily includes all disclosed aspects of the invention." 9 F.3d at 945-46, 28 USPQ2d at 1789.)

In re Fuge, 272 F.2d 954, 957, 124 USPQ 105, 107 (CCPA 1959), does not conflict with the above decisions. This decision simply states "that, at the least, the scope of the patent embraces everything included in the [claim]." (emphasis added).

Note that the courts have interpreted the phrase "invention ... patented" in 102(a), (b), and (d) the same way and have cited decisions without regard to which of these subsections of **35 U.S.C. 102** was at issue in the particular case at hand. Therefore, it does not seem to matter to

which subsection of 102 the cases are directed; the court decisions are interchangeable as to this issue.

2127 Domestic and Foreign Patent Applications as Prior Art [R-6]

I. ABANDONED APPLICATIONS, INCLUDING PROVISIONAL APPLICATIONS

Abandoned Applications Disclosed to the Public Can Be Used as Prior Art

"An abandoned patent application may become evidence of prior art only when it has been appropriately disclosed, as, for example, when the abandoned patent [application] is reference[d] in the disclosure of another patent, in a publication, or by voluntary disclosure under [former Defensive Publication rule] **37 CFR 1.139**." *Lee Pharmaceutical v. Kreps*, 577 F.2d 610, 613, 198 USPQ 601, 605 (9th Cir. 1978). An abandoned patent application becomes available as prior art only as of the date the public gains access to it. See **37 CFR 1.14(a)(1)(ii)** and **(iv)**. However, the subject matter of an abandoned application, including both provisional and nonprovisional applications, referred to in a prior art U.S. patent >or U.S. patent application publication< may be relied on in a **35 U.S.C. 102(e)** rejection based on that patent >or patent application publication< if the disclosure of the abandoned application is actually included or incorporated by reference in the patent. Compare *In re Lund*, 376 F.2d 982, 991, 153 USPQ 625, 633 (CCPA 1967) (The court reversed a rejection over a patent which was a continuation-in-part of an abandoned application. Applicant's filing date preceded the issue date of the patent reference. The abandoned application contained subject matter which was essential to the rejection but which was not carried over into the continuation-in-part. The court held that the subject matter of the abandoned application was not available to the public as of either the parent's or the child's filing dates and thus could not be relied on in the 102(e) rejection.). See also **MPEP § 901.02**. See **MPEP § 2136.02** and **§ 2136.03** for the **35 U.S.C. 102(e)** date of a U.S. patent claiming priority under **35 U.S.C. 119** or 120.

II. APPLICATIONS WHICH HAVE ISSUED AS PATENTS

A 35 U.S.C. 102(e) Rejection Cannot Rely on Matter Which Was Canceled from the Application and Thus Did Not Get Published in the Issued Patent

Canceled matter in the application file of a U.S. patent cannot be relied upon in a rejection under **35 U.S.C. 102(e)**. *Ex Parte Stalego*, 154 USPQ 52, 53 (Bd. App. 1966). The canceled matter only becomes available as prior art as of the date the application issues into a patent since this is the date the application file history becomes available to the public. *In re Lund*, 376 F.2d 982, 153 USPQ 625 (CCPA 1967). For more information on available prior art for use in **35 U.S.C. 102(e)** rejections see **MPEP § 2136.02**.

A 102(b) Rejection Over a Published Application May Rely on Information that Was Canceled Prior to Publication

Figures that had been canceled from a Canadian patent application before issuance of the patent were available as prior art under 35 U.S.C. **102**(b) as of the date the application became publicly accessible. *Bruckelmyer v. Ground Heaters, Inc.*, 445 F.3d 1374, 78 USPQ2d 1684 (Fed. Cir. 2006).

III. FOREIGN APPLICATIONS OPEN FOR PUBLIC INSPECTION (LAID OPEN APPLICATIONS)

Laid Open Applications May Constitute "Published" Documents

When the specification is not issued in printed form but is announced in an official journal and anyone can inspect or obtain copies, it is sufficiently accessible to the public to constitute a "publication" within the meaning of **35 U.S.C. 102(a)** and (b). See *In re Wyer*, 655 F.2d 221, 210 USPQ 790 (CCPA 1981).

Older cases have held that laid open patent applications are not "published" and cannot constitute prior art. *Ex parte Haller*, 103 USPQ 332 (Bd. App. 1953). However, whether or not a document is "published" for the purposes of **35 U.S.C. 102** and **103** depends on how accessible the document is to the public. As technology has made reproduction of documents easier, the accessibility of the laid open applications has increased. Items provided in easily reproducible form have thus become "printed publications" as the phrase is used in **35 U.S.C. 102**. *In re Wyer*, 655 F.2d 221, 226, 210 USPQ 790, 794 (CCPA 1981) (Laid open Australian patent application held to be a "printed publication" even though only the abstract was published because it was laid open for public inspection, microfilmed, "diazo copies" were distributed to five suboffices having suitable reproduction equipment and the diazo copies were available for sale.). The contents of a foreign patent application should not be relied upon as prior art until the date of publication (i.e., the insertion into the laid open application) can be confirmed by an

examiner's review of a copy of the document. See MPEP § 901.05.

IV. PENDING U.S. APPLICATIONS

As specified in 37 CFR 1.14(a), all pending U.S. applications are preserved in confidence except for published applications, reissue applications, and applications in which a request to open the complete application to inspection by the public has been granted by the Office (37 CFR 1.11(b)). However, if an application that has not been published has an assignee or inventor in common with the application being examined, a rejection will be proper in some circumstances. For instance, when the claims between the two applications are not independent or distinct, a provisional double patenting rejection is made. See MPEP § 804. If the copending applications differ by at least one inventor and at least one of the applications would have been obvious in view of the other, a provisional rejection over 35 U.S.C. 102(e) or 103 is made when appropriate. See MPEP § 706.02(f)(2), § 706.02(k), § 706.02(l)(1), and § 706.02(l)(3).

See MPEP § 706.02(a), § 804 and § 2136 *et seq.* for information pertaining to rejections relying on U.S. application publications.

2128 "Printed Publications" as Prior Art [R-5]

A REFERENCE IS A "PRINTED PUBLICATION" IF IT IS ACCESSIBLE TO THE PUBLIC

A reference is proven to be a "printed publication" "upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it." *In re Wyer*, 655 F.2d 221, 210 USPQ 790 (CCPA 1981) (quoting *I.C.E. Corp. v. Armco Steel Corp.*, 250 F. Supp. 738, 743, 148 USPQ 537, 540 (SDNY 1966)) ("We agree that 'printed publication' should be approached as a unitary concept. The traditional dichotomy between 'printed' and 'publication' is no longer valid. Given the state of technology in document duplication, data storage, and data retrieval systems, the 'probability of dissemination' of an item very often has little to do with whether or not it is 'printed' in the sense of that word when it was introduced into the patent statutes in 1836. In any event, interpretation of the words 'printed' and 'publication' to mean 'probability of dissemination' and 'public accessibility' respectively, now seems to render their use in the phrase 'printed publication' somewhat redundant.") *In re Wyer*, 655 F.2d at 226, 210 USPQ at 794.

See also *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986) (Starlight Archery argued that Carella's patent claims to an archery sight were anticipated under 35 U.S.C. 102(a) by an advertisement in a Wisconsin Bow Hunter Association (WBHA) magazine and a WBHA mailer prepared prior to Carella's filing date. However, there was no evidence as to when the mailer was received by any of the addressees. Plus, the magazine had not been mailed until 10 days after Carella's filing date. The court held that since there was no proof that either the advertisement or mailer was accessible to any member of the public before the filing date there could be no rejection under 35 U.S.C. 102(a).).

ELECTRONIC PUBLICATIONS AS PRIOR ART

Status as a "Printed Publication"

An electronic publication, including an on-line database or Internet publication, is considered to be a "printed publication" within the meaning of 35 U.S.C. 102(a) and (b) provided the publication was accessible to persons concerned with the art to which the document relates. See *In re Wyer*, 655 F.2d 221, 227, 210 USPQ 790, 795 (CCPA 1981) ("Accordingly, whether information is printed, handwritten, or on microfilm or a magnetic disc or tape, etc., the one who wishes to characterize the information, in whatever form it may be, as a 'printed publication' * * * should produce sufficient proof of its dissemination or that it has otherwise been available and accessible to persons concerned with the art to which the document relates and thus most likely to avail themselves of its contents.'" (citations omitted).). See also *Amazon.com v. Barnesandnoble.com*, 73 F. Supp. 2d 1228, 53 USPQ2d 1115, 1119 (W.D. Wash. 1999) (Pages from a website were relied on by defendants as an anticipatory reference (to no avail), however status of the reference as prior art was not challenged.); *In re Epstein*, 32 F.3d 1559, 31 USPQ2d 1817 (Fed. Cir. 1994) (Database printouts of abstracts which were not themselves prior art publications were properly relied as providing evidence that the software products referenced therein were "first installed" or "released" more than one year prior to applicant's filing date.).

The Office policy requiring recordation of the field of search and search results (see MPEP § 719.05) weighs in favor of finding that Internet and on-line database references cited by the examiner are "accessible to persons concerned with the art to which the document relates and thus most likely to avail themselves of its contents."

Wyer, 655 F.2d at 221, 210 USPQ at 790. Office copies of an electronic document must be retained if the same document may not be available for retrieval in the future. This is especially important for sources such as the Internet and online databases.

Date of Availability

Prior art disclosures on the Internet or on an on-line database are considered to be publicly available as of the date the item was publicly posted. *>Absent evidence of the date that the disclosure was publicly posted, if< the publication >itself< does not include a publication date (or retrieval date), it cannot be relied upon as prior art under 35 U.S.C. **102**(a) or (b)*>. However<, it may be relied upon to provide evidence regarding the state of the art. Examiners may ask the Scientific and Technical Information Center to find the earliest date of publication >or posting<. See MPEP § **901.06(a)**, paragraph IV. G.

Extent of Teachings Relied Upon

An electronic publication, like any publication, may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art. See MPEP § **2121.0**1 and § **2123**. Note, however, that if an electronic document which is the abstract of a patent or printed publication is relied upon in a rejection under 35 U.S.C. **102** or **103**, only the text of the abstract (and not the underlying document) may be relied upon to support the rejection. In situations where the electronic version and the published paper version of the same or a corresponding patent or printed publication differ appreciably, each may need to be cited and relied upon as independent references based on what they disclose.

Internet Usage Policy

See MPEP § **904.02**(c) for the portions of the Internet Usage Policy pertaining to Internet searching and documenting search strategies. See MPEP § **707.05** for the proper citation of electronic documents.

EXAMINER NEED NOT PROVE ANYONE ACTUALLY LOOKED AT THE DOCUMENT

One need not prove someone actually looked at a publication when that publication is accessible to the public through a library or patent office. See *In re Wyer*, 655 F.2d 221, 210 USPQ 790 (CCPA 1981); *In re Hall*, 781 F.2d 897, 228 USPQ 453 (Fed. Cir. 1986).

2128.01 Level of Public Accessibility Required [R-3]

I. A THESIS PLACED IN A UNIVERSITY LIBRARY MAY BE PRIOR ART IF SUFFICIENTLY ACCESSIBLE TO THE PUBLIC

A doctoral thesis indexed and shelved in a library is sufficiently accessible to the public to constitute prior art as a "printed publication." *In re Hall*, 781 F.2d 897, 228 USPQ 453 (Fed. Cir. 1986). Even if access to the library is restricted, a reference will constitute a "printed publication" as long as a presumption is raised that the portion of the public concerned with the art would know of the invention. *In re Bayer*, 568 F.2d 1357, 196 USPQ 670 (CCPA 1978).

In *In re Hall*, general library cataloging and shelving practices showed that a doctoral thesis deposited in university library would have been indexed, cataloged and shelved and thus available to the public before the critical date. Compare *In re Cronyn*, 890 F.2d 1158, 13 USPQ2d 1070 (Fed. Cir. 1989) wherein doctoral theses were shelved and indexed by index cards filed alphabetically by student name and kept in a shoe box in the chemistry library. The index cards only listed the student name and title of the thesis. Two of three judges held that the students' theses were not accessible to the public. The court reasoned that the theses had not been either cataloged or indexed in a meaningful way since thesis could only be found if the researcher's name was known, but the name bears no relationship to the subject of the thesis. One judge, however, held that the fact that the theses were shelved in the library was enough to make them sufficiently accessible to the public. The nature of the index was not determinative. This judge relied on prior Board decisions (*Gulliksen v. Halberg*, 75 USPQ 252, 257 (Bd. App. 1937) and *Ex parte Hershberger*, 96 USPQ 54, 56 (Bd. App. 1952)), which held that shelving a single copy in a public library makes the work a "printed publication." It should be noted that these Board decisions have not been expressly overruled but have been criticized in other decisions. See *In re Tenney*, 254 F.2d 619, 117 USPQ 348 (CCPA 1958) (concurring opinion by *J.Rich*) (A document, of which there is but one copy, whether it be handwritten, typewritten or on microfilm, may be technically accessible to anyone who can find it. Such a document is not "printed" in the sense that a printing press has been used to reproduce the document. If only technical accessibility were required "logic would require the inclusion within the term [printed] of all unprinted public documents for they are all 'accessible.' While some tribunals have gone quite far in that direction, as in the

'college thesis cases' I feel they have done so unjustifiably and on the wrong theory. Knowledge is not in the possession *of the public* where there has been no dissemination, as distinguished from technical accessibility..." The real significance of the word "printed" is grounded in the " *probability* of wide circulation."). See also *Deep Welding, Inc. v. Sciaky Bros.*, 417 F.2d 1227, 163 USPQ 144 (7th Cir. 1969) (calling the holding of *Ex parte Hershberger* "extreme"). Compare *In re Bayer,* 568 F.2d 1357, 196 USPQ 670 (CCPA 1978) (A reference will constitute a "printed publication" as long as a presumption is raised that the portion of the public concerned with the art would know of the invention even if accessibility is restricted to only this part of the public. But accessibility to applicant's thesis was restricted to only three members of a graduate committee. There can be no presumption that those concerned with the art would have known of the invention in this case.).

II. ORALLY PRESENTED PAPER CAN CONSTITUTE A "PRINTED PUBLICATION" IF WRITTEN COPIES ARE AVAILABLE WITHOUT RESTRICTION

A paper which is orally presented in a forum open to all interested persons constitutes a "printed publication" if written copies are disseminated without restriction. *Massachusetts Institute of Technology v. AB Fortia,* 774 F.2d 1104, 1109, 227 USPQ 428, 432 (Fed. Cir. 1985) (Paper orally presented to between 50 and 500 persons at a scientific meeting open to all persons interested in the subject matter, with written copies distributed without restriction to all who requested, is a printed publication. Six persons requested and obtained copies.).

III. INTERNAL DOCUMENTS INTENDED TO BE CONFIDENTIAL ARE NOT "PRINTED PUBLICATIONS"

Documents and items only distributed internally within an organization which are intended to remain confidential are not "printed publications" no matter how many copies are distributed. There must be an existing policy of confidentiality or agreement to remain confidential within the organization. Mere intent to remain confidential is insufficient. *In re George*, 2 USPQ2d 1880 (Bd. Pat. App. & Inter. 1987) (Research reports disseminated in-house to only those persons who understood the policy of confidentiality regarding such reports are not printed publications even though the policy was not specifically stated in writing.); *Garret Corp. v. United States*, 422 F.2d 874, 878, 164 USPQ 521, 524 (Ct. Cl.1970) ("While distribution to government agencies and personnel alone may not constitute publication ... distribution to commercial companies without restriction on use clearly does."); *Northern Telecom Inc. v. Datapoint Corp.*, 908 F.2d 931, 15 USPQ2d 1321 (Fed. Cir. 1990) (Four reports on the AESOP-B military computer system which were not under security classification were distributed to about fifty organizations involved in the AESOP-B project. One document contained the legend "Reproduction or further dissemination is not authorized." The other documents were of the class that would contain this legend. The documents were housed in Mitre Corporation's library. Access to this library was restricted to those involved in the AESOP-B project. The court held that public access was insufficient to make the documents "printed publications.").

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IV. PUBLICLY DISPLAYED DOCUMENTS CAN CONSTITUTE A "PRINTED PUBLICATION" EVEN IF THE DURATION OF DISPLAY IS FOR ONLY A FEW DAYS AND THE DOCUMENTS ARE NOT DISSEMINATED BY COPIES OR INDEXED IN A LIBRARY OR DATABASE

A publicly displayed document where persons of ordinary skill in the art could see it and are not precluded from copying it can constitute a "printed publication," even if it is not disseminated by the distribution of reproductions or copies and/or indexed in a library or database. As stated in *In re Klopfenstein*, 380 F.3d 1345, 1348, 72 USPQ2d 1117, 1119 (Fed. Cir. 2004), "the key inquiry is whether or not a reference has been made 'publicly accessible.'" Prior to the critical date, a fourteen-slide presentation disclosing the invention was printed and pasted onto poster boards. The printed slide presentation was displayed with no confidentiality restrictions for approximately three cumulative days at two different industry events. 380 F.3d at 1347, 72 USPQ2d at 1118. The court noted that "an entirely oral presentation that includes neither slides nor copies of the presentation is without question not a 'printed publication' for the purposes of 35 U.S.C. § **102**(b). Furthermore, a presentation that includes a transient display of slides is likewise not necessarily a 'printed publication.'" 380 F.3d at 1349 n.4, 72 USPQ2d at 1122 n.4. In resolving whether or not a temporarily displayed reference that was neither distributed nor indexed was nonetheless made sufficiently publicly accessible to count as a "printed publication" under 35 U.S.C. **102**(b), the court considered the following factors: "the length of time the display was exhibited, the expertise of the target audience, the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and the simplicity or ease with which the material displayed could have been copied." 380 F.3d at 1350, 72 USPQ2d at 1120. Upon reviewing the above factors, the court concluded that the display "was sufficiently publicly accessible to count as

a 'printed publication.'" 380 F.3d at 1352, 72 USPQ2d at 1121.<

2128.02 Date Publication Is Available as a Reference

DATE OF ACCESSIBILITY CAN BE SHOWN THROUGH EVIDENCE OF ROUTINE BUSINESS PRACTICES

Evidence showing routine business practices can be used to establish the date on which a publication became accessible to the public. Specific evidence showing when the specific document actually became available is not always necessary. *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 7 USPQ2d 1057 (Fed. Cir.), *cert. denied*, 988 U.S. 892 (1988) (Court held that evidence submitted by Intel regarding undated specification sheets showing how the company usually treated such specification sheets was enough to show that the sheets were accessible by the public before the critical date.); *In re Hall*, 781 F.2d 897, 228 USPQ 453 (Fed. Cir. 1986) (Librarian's affidavit establishing normal time frame and practice for indexing, cataloging and shelving doctoral theses established that the thesis in question would have been accessible by the public before the critical date.).

A JOURNAL ARTICLE OR OTHER PUBLICATION BECOMES AVAILABLE AS PRIOR ART ON DATE OF IT IS RECEIVED BY A MEMBER OF THE PUBLIC

A publication disseminated by mail is not prior art until it is received by at least one member of the public. Thus, a magazine or technical journal is effective as of its date of publication (date when first person receives it) not the date it was mailed or sent to the publisher. *In re Schlittler*, 234 F.2d 882, 110 USPQ 304 (CCPA 1956).

2129 Admissions as Prior Art [R-6]

I. ADMISSIONS BY APPLICANT CONSTITUTE PRIOR ART

A statement by an applicant >in the specification or made< during prosecution identifying the work of another as "prior art" is an admission **>which can be relied upon for both anticipation and obviousness determinations, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. **102**. *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354, 66 USPQ2d 1331, 1337 (Fed. Cir. 2003); *Constant v. Advanced Micro-Devices Inc.*, 848 F.2d 1560, 1570, 7 USPQ2d 1057, 1063 (Fed. Cir. 1988).< However, even if labeled as "prior art," the work of the same inventive entity may not be considered prior art against the claims unless it falls under one of the statutory categories. *Id.*; see also *Reading & Bates Construction Co. v. Baker Energy Resources Corp.*, 748 F.2d 645, 650, 223 USPQ 1168, 1172 (Fed. Cir. 1984) ("[W]here the inventor continues to improve upon his own work product, his foundational work product should not, without a statutory basis, be treated as prior art solely because he admits knowledge of his own work. It is common sense that an inventor, regardless of an admission, has knowledge of his own work.").

Consequently, the examiner must determine whether the subject matter identified as "prior art" is applicant's own work, or the work of another. In the absence of another credible explanation, examiners should treat such subject matter as the work of another.

II. DISCUSSION OF PRIOR ART IN SPECIFICATION

Where the specification identifies work done by another as "prior art," the subject matter so identified is treated as admitted prior art. *In re Nomiya*, 509 F.2d 566, 571, 184 USPQ 607, 611 (CCPA 1975) (holding applicant's labeling of two figures in the application drawings as "prior art" to be an admission that what was pictured was prior art relative to applicant's improvement).

III. JEPSON CLAIMS

Drafting a claim in *Jepson* format (i.e., the format described in **37 CFR 1.75(e)**; see **MPEP § 608.01(m)**) is taken as an implied admission that the subject mater of the preamble is the prior art work of another. *In re Fout*, 675 F.2d 297, 301, 213 USPQ 532, 534 (CCPA 1982) (holding preamble of *Jepson*-type claim to be admitted prior art where applicant's specification credited another as the inventor of the subject matter of the preamble). However, this implication may be overcome where applicant gives another credible reason for drafting the claim in *Jepson* format. *In re Ehrreich*, 590 F.2d 902, 909-910, 200 USPQ 504, 510 (CCPA 1979) (holding preamble not to be admitted prior art where applicant explained that the *Jepson* format was used to avoid a double patenting rejection in a co-pending application and the examiner cited no art showing the subject matter of the preamble). Moreover, where the preamble of a *Jepson* claim describes applicant's own work, such may not be used against the claims. *Reading & Bates Construction Co. v. Baker Energy Resources Corp.*, 748

F.2d 645, 650, 223 USPQ 1168, 1172 (Fed. Cir. 1984); *Ehrreich*, 590 F.2d at 909-910, 200 USPQ at 510.

IV. INFORMATION DISCLOSURE STATEMENT (IDS)

Mere listing of a reference in an information disclosure statement is not taken as an admission that the reference is prior art against the claims. *Riverwood Int'l Corp. v. R.A. Jones & Co.* , 324 F.3d 1346, 1354-55, 66 USPQ2d 1331, 1337-38 (Fed Cir. 2003) (listing of applicant's own prior patent in an IDS does not make it available as prior art absent a statutory basis); *see also* 37 CFR **1.97(h)** ("The filing of an information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § **1.56(b)**.").

2131 Anticipation — Application of 35 U.S.C. 102(a), (b), and (e) [R-1]

35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

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(e) the invention was described in — (1) an application for patent, published under **section 122(b)**, by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in **section 351(a)** shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under **Article 21(2)** of such treaty in the English language; or

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(f) he did not himself invent the subject matter sought to be patented, or

(g)(1) during the course of an interference conducted under **section 135** or **section 291**, another inventor involved therein establishes, to the extent permitted in **section 104**, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

TO ANTICIPATE A CLAIM, THE REFERENCE MUST TEACH EVERY ELEMENT OF THE CLAIM

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). >"When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art." *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001) (claim to a system for setting a computer clock to an offset time to address the Year 2000 (Y2K) problem, applicable to records with year date data in "at least one of two-digit, three-digit, or four-digit" representations, was held anticipated by a system that offsets year dates in only two-digit formats). See also MPEP § **2131.02**.< "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Note that, in some circumstances, it is permissible to use multiple references in a **35 U.S.C. 102** rejection. See **MPEP § 2131.01**.

2131.01 Multiple Reference 35 U.S.C. 102 Rejections

Normally, only one reference should be used in making a rejection under **35 U.S.C. 102**. However, a **35 U.S.C.**

102 rejection over multiple references has been held to be proper when the extra references are cited to:

(A) Prove the primary reference contains an "enabled disclosure;"

(B) Explain the meaning of a term used in the primary reference; or

(C) Show that a characteristic not disclosed in the reference is inherent.

See paragraphs I-III below for more explanation of each circumstance.

I. TO PROVE REFERENCE CONTAINS AN "ENABLED DISCLOSURE"

Extra References and Extrinsic Evidence Can Be Used To Show the Primary Reference Contains an "Enabled Disclosure"

When the claimed composition or machine is disclosed identically by the reference, an additional reference may be relied on to show that the primary reference has an "enabled disclosure." *In re Samour*, 571 F.2d 559, 197 USPQ 1 (CCPA 1978) and *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985) (Compound claims were rejected under **35 U.S.C. 102(b)** over a publication in view of two patents. The publication disclosed the claimed compound structure while the patents taught methods of making compounds of that general class. The applicant argued that there was no motivation to combine the references because no utility was previously known for the compound and that the **35 U.S.C. 102** rejection over multiple references was improper. The court held that the publication taught all the elements of the claim and thus motivation to combine was not required. The patents were only submitted as evidence of what was in the public's possession before applicant's invention.).

II. TO EXPLAIN THE MEANING OF A TERM USED IN THE PRIMARY REFERENCE

Extra References or Other Evidence Can Be Used to Show Meaning of a Term Used in the Primary Reference

Extrinsic evidence may be used to explain but not expand the meaning of terms and phrases used in the reference relied upon as anticipatory of the claimed subject matter. *In re Baxter Travenol Labs*., 952 F.2d 388, 21 USPQ2d 1281 (Fed. Cir. 1991) (Baxter Travenol Labs. invention was directed to a blood bag system incorporating a bag containing DEHP, an additive to the plastic which improved the bag's red blood cell storage capability. The examiner rejected the claims over a technical progress report by Becker which taught the same blood bag system but did not expressly disclose the presence of DEHP. The report, however, did disclose using commercial blood bags. It also disclosed the blood bag system as "very similar to [Baxter] Travenol's commercial two bag blood container." Extrinsic evidence (depositions, declarations and Baxter Travenol's own admissions) showed that commercial blood bags, at the time Becker's report was written, contained DEHP. Therefore, one of ordinary skill in the art would have known that "commercial blood bags" meant bags containing DEHP. The claims were thus held to be anticipated.).

III. TO SHOW THAT A CHARACTERISTIC NOT DISCLOSED IN THE REFERENCE IS INHERENT

Extra Reference or Evidence Can Be Used To Show an Inherent Characteristic of the Thing Taught by the Primary Reference

"To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (The court went on to explain that "this modest flexibility in the rule that 'anticipation' requires that every element of the claims appear in a single reference accommodates situations in which the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." 948 F.2d at 1268, 20 USPQ at 1749-50.). Note that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (Two prior art references disclosed blasting compositions containing water-in-oil emulsions with identical ingredients to those claimed, in overlapping ranges with the claimed composition. The only element of the claims arguably not present in the prior art compositions was "sufficient aeration . . . entrapped to enhance sensitivity to a substantial degree." The Federal Circuit found that the emulsions described in both references would inevitably and inherently have "sufficient aeration" to sensitize the compound in the claimed ranges based on the evidence of record (including test data and expert testimony). This finding of inherency was not defeated by the fact that one of the references

taught away from air entrapment or purposeful aeration.). See also *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985). See **MPEP § 2112** - **§ 2112.02** for case law on inherency. Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See **MPEP § 2124**.

2131.02 Genus-Species Situations [R-6]

A SPECIES WILL ANTICIPATE A CLAIM TO A GENUS

"A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (Gosteli claimed a genus of 21 specific chemical species of bicyclic thia-aza compounds in Markush claims. The prior art reference applied against the claims disclosed two of the chemical species. The parties agreed that the prior art species would anticipate the claims unless applicant was entitled to his foreign priority date.).

A REFERENCE THAT CLEARLY NAMES THE CLAIMED SPECIES ANTICIPATES THE CLAIM NO MATTER HOW MANY OTHER SPECIES ARE NAMED

A genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught. The Board compared the facts to the situation in which the compound was found in the *Merck Index*, saying that "the tenth edition of the *Merck Index* lists ten thousand compounds. In our view, each and every one of those compounds is 'described' as that term is used in 35 U.S.C. § 102(a), in that publication."). *Id.* at 1718. See also *In re Sivaramakrishnan*, 673 F.2d 1383, 213 USPQ 441 (CCPA 1982) (The claims were directed to polycarbonate containing cadmium laurate as an additive. The court upheld the Board's finding that a reference specifically naming cadmium laurate as an additive amongst a list of many suitable salts in polycarbonate resin anticipated the claims. The applicant had argued that cadmium laurate was only disclosed as representative of the salts and was expected to have the same properties as the other salts listed while, as shown in the application, cadmium laurate had unexpected properties. The court held that it did not matter that the salt was not disclosed as being preferred, the reference still anticipated the claims and because the claim was anticipated, the unexpected properties were immaterial.).

A GENERIC CHEMICAL FORMULA WILL ANTICIPATE A CLAIMED SPECIES COVERED BY THE FORMULA WHEN THE SPECIES CAN BE "AT ONCE ENVISAGED" FROM THE FORMULA

When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

In *In re Petering*, the prior art disclosed a generic chemical formula "wherein X, Y, Z, P, and R' - represent either hydrogen or alkyl radicals, R a side chain containing an OH group." The court held that this formula, without more, could not anticipate a claim to 7-methyl-9-[d, l'-ribityl]-isoalloxazine because the generic formula encompassed a vast number and perhaps even an infinite number of compounds. However, the reference also disclosed preferred substituents for X, Y, Z, >P,< R, and R' as follows: where X, P, and R' are hydrogen, where Y and Z may be hydrogen or methyl, and where R is one of eight specific isoalloxazines. The court determined that this more limited generic class consisted of about 20 compounds. The limited number of compounds covered by the preferred formula in combination with the fact that the number of substituents was low at each site, the ring positions were limited, and there was a large unchanging structural nucleus, resulted in a finding that the reference sufficiently described "each of the various permutations here involved as fully as if he had drawn each structural

formula or had written each name." The claimed compound was 1 of these 20 compounds. Therefore, the reference "described" the claimed compound and the reference anticipated the claims.

In *In re Schauman*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978), claims to a specific compound were anticipated because the prior art taught a generic formula embracing a limited number of compounds closely related to each other in structure and the properties possessed by the compound class of the prior art was that disclosed for the claimed compound. The broad generic formula seemed to describe an infinite number of compounds but claim 1 was limited to a structure with only one variable substituent R. This substituent was limited to low alkyl radicals. One of ordinary skill in the art would at once envisage the subject matter within claim 1 of the reference.).

Compare *In re Meyer*, 599 F.2d 1026, 202 USPQ 175 (CCPA 1979) (A reference disclosing "alkaline chlorine or bromine solution" embraces a large number of species and cannot be said to anticipate claims to "alkali metal hypochlorite."); *Akzo N.V. v. International Trade Comm'n*, 808 F.2d 1471, 1 USPQ2d 1241 (Fed. Cir. 1986) (Claims to a process for making aramid fibers using a 98% solution of sulfuric acid were not anticipated by a reference which disclosed using sulfuric acid solution but which did not disclose using a 98% concentrated sulfuric acid solution.). See **MPEP § 2144.08** for a discussion of obviousness in genus-species situations.

2131.03 Anticipation of Ranges [R-6]

I. A SPECIFIC EXAMPLE IN THE PRIOR ART WHICH IS WITHIN A CLAIMED RANGE ANTICIPATES THE RANGE

"[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if *one* of them is in the prior art." *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (citing *In re Petering*, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)) (emphasis in original) (Claims to titanium (Ti) alloy with 0.6-0.9% nickel (Ni) and 0.2-0.4% molybdenum (Mo) were held anticipated by a graph in a Russian article on Ti-Mo-Ni alloys because the graph contained an actual data point corresponding to a Ti alloy containing 0.25% Mo and 0.75% Ni and this composition was within the claimed range of compositions.).

II. PRIOR ART WHICH TEACHES A RANGE OVERLAPPING OR TOUCHING THE CLAIMED RANGE ANTICIPATES IF THE PRIOR ART RANGE DISCLOSES THE CLAIMED RANGE WITH "SUFFICIENT SPECIFICITY"

When the prior art discloses a range which touches or overlaps the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, and the reference teaches a broad range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims. See, e.g., *Atofina v. Great Lakes Chem. Corp*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006) wherein the court held that a reference temperature range of 100-500 degrees C did not describe the claimed range of 330-450 degrees C with sufficient specificity to be anticipatory. Further, while there was a slight overlap between the reference's preferred range (150-350 degrees C) and the claimed range, that overlap was not sufficient for anticipation. "[T]he disclosure of a range is no more a disclosure of the end points of the range than it is each of the intermediate points." *Id.* at 1000, 78 USPQ2d at 1424. Any evidence of unexpected results within the narrow range may also render the claims unobvious. The question of "sufficient specificity" is similar to that of "clearly envisaging" a species from a generic teaching. See **MPEP § 2131.02**. A **35 U.S.C. 102**/**103** combination rejection is permitted if it is unclear if the reference teaches the range with "sufficient specificity." The examiner must, in this case, provide reasons for anticipation as well as a *>reasoned< statement regarding obviousness. *Ex parte Lee*, 31 USPQ2d 1105 (Bd. Pat. App. & Inter. 1993) (expanded Board). For a discussion of the obviousness of ranges see **MPEP § 2144.05**.

III. PRIOR ART WHICH TEACHES A VALUE OR RANGE THAT IS VERY CLOSE TO, BUT DOES NOT OVERLAP OR TOUCH, THE CLAIMED RANGE DOES NOT ANTICIPATE THE CLAIMED RANGE

"[A]nticipation under § 102 can be found only when the reference discloses exactly what is claimed and that where there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account." *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims to titanium (Ti) alloy with 0.8% nickel (Ni) and 0.3% molybdenum (Mo) were not anticipated by, although they were held obvious over, a graph in a Russian article

on Ti-Mo-Ni alloys in which the graph contained an actual data point corresponding to a Ti alloy containing 0.25% Mo and 0.75% Ni.).

2131.04 Secondary Considerations

Evidence of secondary considerations, such as unexpected results or commercial success, is irrelevant to **35 U.S.C. 102** rejections and thus cannot overcome a rejection so based. *In re Wiggins*, 488 F.2d 538, 543, 179 USPQ 421, 425 (CCPA 1973).

2131.05 Nonanalogous >or Disparaging Prior< Art [R-5]

"Arguments that the alleged anticipatory prior art is 'nonanalogous art' or 'teaches away from the invention' or is not recognized as solving the problem solved by the claimed invention, [are] not 'germane' to a rejection under section 102." *Twin Disc, Inc. v. United States*, 231 USPQ 417, 424 (Cl. Ct. 1986) (quoting *In re Self*, 671 F.2d 1344, 213 USPQ 1, 7 (CCPA 1982)). See also *State Contracting & Eng' g Corp. v. Condotte America, Inc.*, 346 F.3d 1057, 1068, 68 USPQ2d 1481, 1488 (Fed. Cir. 2003) (The question of whether a reference is analogous art is not relevant to whether that reference anticipates. A reference may be directed to an entirely different problem than the one addressed by the inventor, or may be from an entirely different field of endeavor than that of the claimed invention, yet the reference is still anticipatory if it explicitly or inherently discloses every limitation recited in the claims.).

A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. The question whether a reference "teaches away" from the invention is inapplicable to an anticipation analysis. *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The prior art was held to anticipate the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). >See *Upsher-Smith Labs. v. Pamlab, LLC*, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005)(claimed composition that expressly excluded an ingredient held anticipated by reference composition that optionally included that same ingredient);< see also *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (Claimed composition was anticipated by prior art reference that inherently met claim limitation of "sufficient aeration" even though reference taught away from air entrapment or purposeful aeration.).

2132 35 U.S.C. 102(a)

35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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I. "KNOWN OR USED"

"Known or Used" Means Publicly Known or Used

"The statutory language 'known or used by others in this country' (35 U.S.C. § 102(a)), means knowledge or use which is accessible to the public." *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986). The knowledge or use is accessible to the public if there has been no deliberate attempt to keep it secret. *W. L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983).

See **MPEP § 2128** - **§ 2128.02** for case law concerning public accessibility of publications.

Another's Sale of a Product Made by a Secret Process Can Be a 35 U.S.C. 102(a) Public Use if the Process Can Be Determined by Examining the Product

"The nonsecret use of a claimed process in the usual course of producing articles for commercial purposes is a public use." But a secret use of the process coupled with the sale of the product does not result in a public use of the process unless the public could learn the claimed process by examining the product. Therefore, secret use of a process by another, even if the product is commercially sold, cannot result in a rejection under **35 U.S.C. 102(a)** if an examination of the product would not reveal the process. *Id.*

II. "IN THIS COUNTRY"

Only Knowledge or Use in the U.S. Can Be Used in a 35 U.S.C. 102(a) Rejection

The knowledge or use relied on in a **35 U.S.C. 102(a)** rejection must be knowledge or use "in this country."

Prior knowledge or use which is not present in the United States, even if widespread in a foreign country, cannot be the basis of a rejection under **35 U.S.C. 102(a)**. *In re Ekenstam*, 256 F.2d 321, 118 USPQ 349 (CCPA 1958). Note that the changes made to **35 U.S.C. 104** by NAFTA (Public Law 103-182) and Uruguay Round Agreements Act (Public Law 103-465) do not modify the meaning of "in this country" as used in **35 U.S.C. 102(a)** and thus "in this country" still means in the United States for purposes of **35 U.S.C. 102(a)** rejections.

III. "BY OTHERS"

"Others" Means Any Combination of Authors or Inventors Different Than the Inventive Entity

The term "others" in **35 U.S.C. 102(a)** refers to any entity which is different from the inventive entity. The entity need only differ by one person to be "by others." This holds true for all types of references eligible as prior art under **35 U.S.C. 102(a)** including publications as well as public knowledge and use. Any other interpretation of **35 U.S.C. 102(a)** "would negate the one year [grace] period afforded under § 102(b)." *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982).

IV. "PATENTED IN THIS OR A FOREIGN COUNTRY"

See **MPEP § 2126** for information on the use of secret patents as prior art.

2132.01 Publications as 35 U.S.C. 102(a) Prior Art

35 U.S.C. 102(a) PRIMA FACIE CASE IS ESTABLISHED IF REFERENCE PUBLICATION IS "BY OTHERS"

A *prima facie* case is made out under **35 U.S.C. 102(a)** if, within 1 year of the filing date, the invention, or an obvious variant thereof, is described in a "printed publication" whose authorship differs in any way from the inventive entity unless it is stated within the publication itself that the publication is describing the applicant's work. *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). See **MPEP § 2128** for case law on what constitutes a "printed publication." Note that when the reference is a U.S. patent published within the year prior to the application filing date, a **35 U.S.C. 102(e)** rejection should be made. See **MPEP § 2136** - **§ 2136.05** for case law dealing with 102(e).

APPLICANT CAN REBUT PRIMA FACIE CASE BY SHOWING REFERENCE'S DISCLOSURE WAS DERIVED FROM APPLICANT'S OWN WORK

Applicant's disclosure of his or her own work within the year before the application filing date cannot be used against him or her under **35 U.S.C. 102(a)**. *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982) (discussed below). Therefore, where the applicant is one of the co-authors of a publication cited against his or her application, the publication may be removed as a reference by the filing of affidavits made out by the other authors establishing that the relevant portions of the publication originated with, or were obtained from, applicant. Such affidavits are called disclaiming affidavits. *Ex parte Hirschler*, 110 USPQ 384 (Bd. App. 1952). The rejection can also be overcome by submission of a specific declaration by the applicant establishing that the article is describing applicant's own work. *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). However, if there is evidence that the co-author has refused to disclaim inventorship and believes himself or herself to be an inventor, applicant's affidavit will not be enough to establish that applicant is the sole inventor and the rejection will stand. *Ex parte Kroger*, 219 USPQ 370 (Bd. Pat. App. & Int. 1982) (discussed below). It is also possible to overcome the rejection by adding the coauthors as inventors to the application if the requirements of **35 U.S.C. 116**, third paragraph are met. *In re Searles*, 422 F.2d 431, 164 USPQ 623 (CCPA 1970).

In *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982), Katz stated in a declaration that the coauthors of the publication, Chiorazzi and Eshhar, "were students working under the direction and supervision of the inventor, Dr. David H. Katz." The court held that this declaration, in combination with the fact that the publication was a research paper, was enough to establish Katz as the sole inventor and that the work described in the publication was his own. In research papers, students involved only with assay and testing are normally listed as coauthors but are not considered co-inventors.

In *Ex parte Kroger*, 219 USPQ 370 (Bd. Pat. App. & Inter. 1982), Kroger, Knaster and others were listed as authors on an article on photovoltaic power generation. The article was used to reject the claims of an application listing Kroger and Rod as inventors. Kroger and Rod submitted affidavits declaring themselves to be the inventors. The affidavits also stated that Knaster merely carried out assignments and worked under the supervision and direction of Kroger. The Board stated that if this were the only evidence in the case, it would be established, under *In re Katz*, that Kroger and Rod were the only inventors. However, in this case, there was evidence that

Knaster had refused to sign an affidavit disclaiming inventorship and Knaster had introduced evidence into the case in the form of a letter to the PTO in which he alleged that he was a co-inventor. The Board held that the evidence had not been fully developed enough to overcome the rejection. Note that the rejection had been made under **35 U.S.C. 102(f)** but the Board treated the issue the same as if it had arisen under **35 U.S.C. 102(a)**. See also case law dealing with overcoming 102(e) rejections as presented in **MPEP § 2136.05**. Many of the issues are the same.

A 37 CFR 1.131 AFFIDAVIT CAN BE USED TO OVERCOME A 35 U.S.C. 102(a) REJECTION

When the reference is not a statutory bar under **35 U.S.C. 102(b)**, (c), or (d), applicant can overcome the rejection by swearing back of the reference through the submission of an affidavit under **37 CFR 1.131**. *In re Foster,* 343 F.2d 980, 145 USPQ 166 (CCPA 1965). If the reference is disclosing applicant's own work as derived from him or her, applicant may submit either a **37 CFR 1.131** affidavit to antedate the reference or a **37 CFR 1.132** affidavit to show derivation of the reference subject matter from applicant and invention by applicant. *In re Facius,* 408 F.2d 1396, 161 USPQ 294 (CCPA 1969). See **MPEP § 715** for more information on when an affidavit under **37 CFR 1.131** can be used to overcome a reference and what evidence is required.

2133 35 U.S.C. 102(b)

35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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THE 1-YEAR GRACE PERIOD IS EXTENDED TO THE NEXT WORKING DAY IF IT WOULD OTHERWISE END ON A HOLIDAY OR WEEKEND

Publications, patents, public uses and sales must occur "more than one year prior to the date of application for patent in the United States" in order to bar a patent under **35 U.S.C. 102(b)**. However, applicant's own activity will not bar a patent if the 1-year grace period expires on a Saturday, Sunday, or Federal holiday and the application's U.S. filing date is the next succeeding business day. *Ex parte Olah* , 131 USPQ 41 (Bd. App. 1960). Despite changes to **37 CFR 1.6(a)**(2) and 1.10 which require the PTO to accord a filing date to an application as of the date of deposit as "Express Mail" with the U.S. Postal Service in accordance with **37 CFR 1.10** (e.g., a Saturday filing date), the rule changes do not affect applicant's concurrent right to defer the filing of an application until the next business day when the last day for "taking any action" falls on a Saturday, Sunday, or a Federal holiday (e.g., the last day of the 1-year grace period falls on a Saturday).

THE 1-YEAR TIME BAR IS MEASURED FROM THE U.S. FILING DATE

If one discloses his or her own work more than 1 year before the filing of the patent application, that person is barred from obtaining a patent. *In re Katz*, 687 F.2d 450, 454, 215 USPQ 14, 17 (CCPA 1982). The 1-year time bar is measured from the U.S. filing date. Thus, applicant will be barred from obtaining a patent if the public came into possession of the invention on a date before the 1-year grace period ending with the U.S. filing date. It does not matter how the public came into possession of the invention. Public possession could occur by a public use, public sale, a publication, a patent or any combination of these. In addition, the prior art need not be identical to the claimed invention but will bar patentability if it is an obvious variant thereof. *In re Foster*, 343 F.2d 980, 145 USPQ 166 (CCPA 1966). See **MPEP § 706.02** regarding the effective U.S. filing date of an application.

2133.01 Rejections of Continuation-In-Part (CIP) Applications

When applicant files a continuation-in-part whose claims are not supported by the parent application, the effective filing date is the filing date of the child CIP. Any prior art disclosing the invention or an obvious variant thereof having a critical reference date more than 1 year prior to the filing date of the child will bar the issuance of a patent under **35 U.S.C. 102(b)**. *Paperless Accounting v. Bay Area Rapid Transit System,* 804 F.2d 659, 665, 231 USPQ 649, 653 (Fed. Cir. 1986).

2133.02 Rejections Based on Publications and Patents

APPLICANT'S OWN WORK WHICH WAS AVAILABLE TO THE PUBLIC BEFORE THE GRACE PERIOD MAY BE USED IN A 35 U.S.C. 102(b) REJECTION

"Any invention described in a printed publication more than one year prior to the date of a patent application is prior art under Section 102(b), even if the

printed publication was authored by the patent applicant." *De Graffenried v. United States*, 16 USPQ2d 1321, 1330 n.7 (Cl. Ct. 1990). "Once an inventor has decided to lift the veil of secrecy from his [or her] work, he [or she] must choose between the protection of a federal patent, or the dedication of his [or her] idea to the public at large." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148, 9 USPQ2d 1847, 1851 (1989).

A 35 U.S.C. 102(b) REJECTION CREATES A STATUTORY BAR TO PATENTABILITY OF THE REJECTED CLAIMS

A rejection under **35 U.S.C. 102(b)** cannot be overcome by affidavits and declarations under **37 CFR 1.131** (Rule 131 Declarations), foreign priority dates, or evidence that applicant himself invented the subject matter. Outside the 1-year grace period, applicant is barred from obtaining a patent containing any anticipated or obvious claims. *In re Foster*, 343 F.2d 980, 984, 145 USPQ 166, 170 (CCPA 1965).

2133.03 Rejections Based on "Public Use" or "On Sale" [R-5]

35 U.S.C. 102(b) "contains several distinct bars to patentability, each of which relates to activity or disclosure more than one year prior to the date of the application. Two of these - the 'public use' and the 'on sale' objections - are sometimes considered together although it is quite clear that either may apply when the other does not." *Dart Indus. v. E.I. du Pont de Nemours & Co.*, 489 F.2d 1359, 1365, 179 USPQ 392, 396 (7th Cir. 1973). There may be a public use of an invention absent any sales activity. Likewise, there may be a nonpublic, e.g., "secret," sale or offer to sell an invention which nevertheless constitutes a statutory bar. *Hobbs v. United States*, 451 F.2d 849, 859-60, 171 USPQ 713, 720 (5th Cir. 1971).

In similar fashion, not all "public use" and "on sale" activities will necessarily occasion the identical result. Although both activities affect how an inventor may use an invention prior to the filing of a patent application, "non-commercial" **35 U.S.C. 102(b)** activity may not be viewed the same as similar "commercial" activity. See **MPEP § 2133.03(a)** and **§ 2133.03(e)(1)**. Likewise, "public use" activity by an applicant may not be considered in the same light as similar "public use" activity by one other than an applicant. See **MPEP § 2133.03(a)** and **§ 2133.03(e)(7)**. Additionally, the **>concept of< "experimental use" **>may have different< significance in "commercial" and "non-commercial" environments. See **MPEP § 2133.03(c)** and **§ 2133.03(e)** - **§ 2133.03(e)(6)**.

It should be noted that **35 U.S.C. 102(b)** may create a bar to patentability either alone, if the device in public use or placed on sale anticipates a later claimed invention, or in conjunction with **35 U.S.C. 103**, if the claimed invention would have been obvious from the device in conjunction with the prior art. *LaBounty Mfg. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1071, 22 USPQ2d 1025, 1028 (Fed. Cir. 1992).

POLICY CONSIDERATIONS

(A) "One policy underlying the [on-sale] bar is to obtain widespread disclosure of new inventions to the public via patents as soon as possible." *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1062, 12 USPQ2d 1449, 1454 (Fed. Cir. 1989).

(B) Another policy underlying the public use and on-sale bars is to prevent the inventor from commercially exploiting the exclusivity of his [or her] invention substantially beyond the statutorily authorized period. *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1062, 12 USPQ2d 1449, 1454 (Fed. Cir. 1989). See **MPEP § 2133.03(e)(1)**.

(C) Another underlying policy for the public use and on-sale bars is to discourage "the removal of inventions from the public domain which the public justifiably comes to believe are freely available." *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549, 16 USPQ2d 1587, 1591 (Fed. Cir. 1990).

2133.03(a) "Public Use" [R-5]

I. **>TEST FOR "PUBLIC USE

The public use bar under 35 U.S.C. **102**(b) arises where the invention is in public use before the critical date and is ready for patenting. *Invitrogen Corp. v. Biocrest Manufacturing L.P.*, 424 F.3d 1374, 76 USPQ2d 1741 (Fed. Cir. 2005). As explained by the court,

> The proper test for the public use prong of the § **102** (b) statutory bar is whether the purported use: (1) was accessible to the public; or (2) was commercially exploited. Commercial exploitation is a clear indication of public use, but it likely requires more than, for example, a secret offer for sale. Thus, the test for the public use prong includes the consideration of evidence relevant to experimentation, as well as, *inter alia* , the nature of the activity that occurred in public; public access to the use; confidentiality obligations imposed on members of the public who observed the use; and

> commercial exploitation…. That evidence is relevant to discern whether the use was a public use that could raise a bar to patentability, but it is distinct from evidence relevant to the ready for patenting component of *Pfaff* 's two-part test, another necessary requirement of a public use bar

Id. at 1380, 76 USPQ2d at 1744 (citations omitted). See MPEP § **2133.03(c)** for a discussion of the "ready for patenting" prong of the public use and on sale statutory bars.<

"[T]o constitute the public use of an invention it is not necessary that more than one of the patent articles should be publicly used. The use of a great number may tend to strengthen the proof, but one well defined case of such use is just as effectual to annul the patent as many." Likewise, it is not necessary that more than one person use the invention. *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881).

II. PUBLIC KNOWLEDGE IS NOT NECESSARILY PUBLIC USE UNDER 35 U.S.C. 102(b)

Mere knowledge of the invention by the public does not warrant rejection under **35 U.S.C. 102(b)**. **35 U.S.C. 102(b)** bars public use or sale, not public knowledge. *TP Labs., Inc., v. Professional Positioners, Inc.*, 724 F.2d 965, 970, 220 USPQ 577, 581 (Fed. Cir. 1984).

Note, however, that public knowledge may provide grounds for rejection under **35 U.S.C. 102(a)**. See **MPEP § 2132**.

A. Commercial Versus Noncommercial Use and the Impact of Secrecy

>There are limited circumstances in which a secret or confidential use of an invention may give rise to the public use bar. "[S]ecrecy of use alone is not sufficient to show that existing knowledge has not been withdrawn from public use; commercial exploitation is also forbidden." *Invitrogen*, 424 F.3d at 1382, 76 USPQ2d at 1745-46 (The fact that patentee secretly used the claimed invention internally before the critical date to develop future products that were never sold was by itself insufficient to create a public use bar to patentability.).<

1. "Public Use" and "Non-secret Use" Are Not Necessarily Synonymous

"Public" is not necessarily synonymous with "non-secret." The fact "that non-secret uses of the device were made [by the inventor or someone connected with the inventor] prior to the critical date is not itself dispositive of the issue of whether activity barring a patent under **35 U.S.C. 102(b)** occurred. The fact that the device was not hidden from view may make the use not secret, but nonsecret use is not *ipso facto* 'public use' activity. Nor, it must be added, is all secret use *ipso facto* not 'public use' within the meaning of the statute," if the inventor is making commercial use of the invention under circumstances which preserve its secrecy. *TP Labs., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 972, 220 USPQ 577, 583 (Fed. Cir. 1983) (citations omitted).

2. Even If the Invention Is Hidden, Inventor Who Puts Machine or Article Embodying the Invention in Public View Is Barred from Obtaining a Patent as the Invention Is in Public Use

When the inventor or someone connected to the inventor puts the invention on display or sells it, there is a "public use" within the meaning of **35 U.S.C. 102(b)** even though by its very nature an invention is completely hidden from view as part of a larger machine or article, if the invention is otherwise used in its natural and intended way and the larger machine or article is accessible to the public. *In re Blaisdell*, 242 F.2d 779, 783, 113 USPQ 289, 292 (CCPA 1957); *Hall v. Macneale*, 107 U.S. 90, 96-97 (1882); *Ex parte Kuklo*, 25 USPQ2d 1387, 1390 (Bd. Pat. App. & Inter. 1992) (Display of equipment including the structural features of the claimed invention to visitors of laboratory is public use even though public did not see inner workings of device. The person to whom the invention is publicly disclosed need not understand the significance and technical complexities of the invention.).

3. There Is No Public Use If Inventor Restricted Use to Locations Where There Was a Reasonable Expectation of Privacy and the Use Was for His or Her Own Enjoyment

An inventor's private use of the invention, for his or her own enjoyment is not a public use. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1265, 229 USPQ 805, 809 (Fed. Cir. 1986) (Inventor showed inventive puzzle to close friends while in his dorm room and later the president of the company at which he was working saw the puzzle on the inventor's desk and they discussed it. Court held that the inventor retained control and thus these actions did not result in a "public use.").

4. The Presence or Absence of a Confidentiality Agreement is Not Dispositive of the Public Use Issue

"The presence or absence of a confidentiality agreement is not dispositive of the public use issue, but 'is one factor to be considered in assessing all the evidence.'" *Bernhardt, L.L.C. v. Collezione Europa USA, Inc.*, 386 F.3d 1371, 1380-81, 72 USPQ2d, 1901, 1909 (Fed. Cir. 2004) (quoting *Moleculon Research Corp. v. CBS Inc.*, 793 F.2d 1261, 1266, 229 USPQ 805, 808 (Fed. Cir. 1986)). The court stressed that it is necessary to analyze the **>evidence of public use in the context of< policies that underlie the public use and on sale bar that include "'discouraging removal of inventions from the public domain that the public justifiably believes are freely available, prohibiting an extension of the period for exploiting an invention, and favoring prompt and widespread disclosure of inventions.'" *Bernhardt*, 386 F.3d at 1381, 72 USPQ2d at 1909. See also > *Invitrogen*, 424 F.3d at 1379, 76 USPQ2d at 1744;< MPEP § **2133.03**, Policy Considerations. **>Evidence< that the court emphasized included the "'nature of the activity that occurred in public; the public access to and knowledge of the public use; [and] whether there were any confidentiality obligations imposed on persons who observed the use.'" *Bernhardt*, 386 F.3d at 1381, 72 USPQ2d at 1909. For example, the court in Bernhardt noted that an exhibition display at issue in the case "was not open to the public, that the identification of attendees was checked against a list of authorized names by building security and later at a reception desk near the showroom, that attendees were escorted through the showroom, and that the attendees were not permitted to make written notes or take photographs inside the showroom." *Id*. The court remanded the issue of whether the exhibition display was a public use for further proceedings since the district court "focused on the absence of any confidentiality agreements and did not discuss or analyze how the totality of the circumstances surrounding" the exhibition "comports with the policies underlying the public use bar." *Id*.

B. Use by Third Parties Deriving the Invention from Applicant

An Invention Is in Public Use If the Inventor Allows Another To Use the Invention Without Restriction or Obligation of Secrecy

"Public use" of a claimed invention under **35 U.S.C. 102(b)** occurs when the inventor allows another person to use the invention without limitation, restriction or obligation of secrecy to the inventor." *In re Smith*, 714 F.2d 1127, 1134, 218 USPQ 976, 983 (Fed. Cir. 1983). The presence or absence of a confidentiality agreement is not itself determinative of the public use issue, but is one factor to be considered along with the time, place, and circumstances of the use which show the amount of control the inventor retained over the invention. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1265, 229 USPQ 805, 809 (Fed. Cir. 1986). See *Ex parte C*, 27 USPQ2d 1492, 1499 (Bd. Pat. App. & Inter. 1992) (Inventor sold inventive soybean seeds to growers who contracted and were paid to plant the seeds to increase stock for later sale. The commercial nature of the use of the seed coupled with the "on-sale" aspects of the contract and apparent lack of confidentiality requirements rose to the level of a "public use" bar.); *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881) (Public use found where inventor allowed another to use inventive corset insert, though hidden from view during use, because he did not impose an obligation of secrecy or restrictions on its use.).

C. Use by Independent Third Parties

Use by an Independent Third Party Is Public Use If It Sufficiently "Informs" the Public of the Invention or a Competitor Could Reasonably Ascertain the Invention

Any "nonsecret" use of an invention by someone unconnected to the inventor, such as someone who has independently made the invention, in the ordinary course of a business for trade or profit may be a "public use," *Bird Provision Co. v. Owens Country Sausage, Inc.*, 568 F.2d 369, 374-76, 197 USPQ 134, 138-40 (5th Cir. 1978). Additionally, even a "secret" use by another inventor of a machine or process to make a product is "public" if the details of the machine or process are ascertainable by inspection or analysis of the product that is sold or publicly displayed. *Gillman v. Stern*, 114 F.2d 28, 46 USPQ 430 (2d Cir. 1940); *Dunlop Holdings, Ltd. v. Ram Golf Corp.*, 524 F.2d 33, 36-7, 188 USPQ 481, 483-484 (7th Cir. 1975). If the details of an inventive process are not ascertainable from the product sold or displayed and the third party has kept the invention as a trade secret then that use is not a public use and will not bar a patent issuing to someone unconnected to the user. *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1550, 220 USPQ 303, 310 (Fed. Cir. 1983). However, a device qualifies as prior art if it places the claimed features in the public's possession before the critical date even if other unclaimed aspects of the device were not publicly available. *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1964-65 (Fed. Cir. 1997) (Computer reservation system was prior art even though "essential algorithms of the SABRE software were proprietary and confidential and...those aspects of the system that were readily apparent to the public would not have been sufficient to enable one skilled in the art to duplicate the [unclaimed

aspects of the] system."). The extent that the public becomes "informed" of an invention involved in public use activity by one other than an applicant depends upon the factual circumstances surrounding the activity and how these comport with the policies underlying the on sale and public use bars. *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549, 16 USPQ2d 1587, 1591 (Fed. Cir. 1990) (quoting *King Instrument Corp. v. Otari Corp.*, 767 F.2d 833, 860, 226 USPQ 402, 406 (Fed. Cir. 1985)). By way of example, in an allegedly "secret" use by a third party other than an applicant, if a large number of employees of such a party, who are not under a promise of secrecy, are permitted unimpeded access to an invention, with affirmative steps by the party to educate other employees as to the nature of the invention, the public is "informed." *Chemithon Corp. v. Proctor & Gamble Co.*, 287 F. Supp. 291, 308, 159 USPQ 139, 154 (D.Md. 1968), *aff'd.*, 427 F.2d 893, 165 USPQ 678 (4th Cir. 1970).

Even if public use activity by one other than an applicant is not sufficiently "informing," there may be adequate grounds upon which to base a rejection under **35 U.S.C. 102(f)** and **35 U.S.C. 102(g)**. See *Dunlop Holdings Ltd. v. Ram Golf Corp.*, 524 F.2d 33, 188 USPQ 481 (7th Cir. 1975). See **MPEP § 2137** and **§ 2138**.

2133.03(b) "On Sale" [R-5]

An impermissible sale has occurred if there was a definite sale, or offer to sell, more than 1 year before the effective filing date of the U.S. application and the subject matter of the sale, or offer to sell, fully anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art. *Ferag AG v. Quipp, Inc.*, 45 F.3d 1562, 1565, 33 USPQ2d 1512, 1514 (Fed. Cir. 1995). The on-sale bar of **35 U.S.C. 102(b)** is triggered if the invention is both (1) the subject of a commercial offer for sale not primarily for experimental purposes and (2) ready for patenting. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67, 48 USPQ2d 1641, 1646-47 (1998). Traditional contract law principles are applied when determining whether a commercial offer for sale has occurred. See *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1048, 61 USPQ2d 1225, 1229 (Fed. Cir. 2001), *petition for cert. filed*, 71 USLW 3093 (Jul. 03, 2002) (No. 02-39); *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041,1047, 59 USPQ2d 1121, 1126 (Fed. Cir. 2001) ("As a general proposition, we will look to the Uniform Commercial Code ('UCC') to define whether … a communication or series of communications rises to the level of a commercial offer for sale.").

I. THE MEANING OF "SALE"

A sale is a contract between parties wherein the seller agrees "to give and to pass rights of property" in return for the buyer's payment or promise "to pay the seller for the things bought or sold." *In re Caveney*, 761 F.2d 671, 676, 226 USPQ 1, 4 (Fed. Cir. 1985). A contract for the sale of goods requires a concrete offer and acceptance of that offer. See, e.g., *Linear Tech.*, 275 F.3d at 1052-54, 61 USPQ2d at 1233-34 (Court held there was no sale within the meaning of **35 U.S.C. 102(b)** where prospective purchaser submitted an order for goods at issue, but received an order acknowledgement reading "will advise-not booked." Prospective purchaser would understand that order was not accepted.).

A. Conditional Sale May Bar a Patent

An invention may be deemed to be "on sale" even though the sale was conditional. The fact that the sale is conditioned on buyer satisfaction does not, without more, prove that the sale was for an experimental purpose. *Strong v. General Elec. Co.*, 434 F.2d 1042, 1046, 168 USPQ 8, 12 (5th Cir. 1970).

B. Nonprofit Sale May Bar a Patent

A "sale" need not be for profit to bar a patent. If the sale was for the commercial exploitation of the invention, it is "on sale" within the meaning of **35 U.S.C. 102(b)**. *In re Dybel*, 524 F.2d 1393, 1401, 187 USPQ 593, 599 (CCPA 1975) ("Although selling the devices for a profit would have demonstrated the purpose of commercial exploitation, the fact that appellant realized no profit from the sales does not demonstrate the contrary.").

C. A Single Sale or Offer To Sell May Bar a Patent

Even a single sale or offer to sell the invention may bar patentability under **35 U.S.C. 102(b)**. *Consolidated Fruit-Jar Co. v. Wright*, 94 U.S. 92, 94 (1876); *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 836-37, 23 USPQ2d 1481, 1483 (Fed. Cir. 1992).

D. A Sale of Rights Is Not a Sale of the Invention and Will Not in Itself Bar a Patent

"[A]n assignment or sale of the rights in the invention and potential patent rights is not a sale of 'the invention' within the meaning of section **102**(b)." *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1267, 229 USPQ 805, 809 (Fed. Cir. 1986); see also *Elan Corp., PLC v. Andrx Pharms. Inc.*, 366 F.3d 1336, 1341, 70

USPQ2d 1722, 1728 (Fed. Cir. 2004); *In re Kollar*, 286 F.3d 1326, 1330 n.3, 1330-1331, 62 USPQ2d 1425, 1428 n.3, 1428-1429 (Fed. Cir. 2002) (distinguishing licenses which trigger the on-sale bar (e.g., a standard computer software license wherein the product is just as immediately transferred to the licensee as if it were sold), from licenses that merely grant rights to an invention which do not *per se* trigger the on-sale bar (e.g., exclusive rights to market the invention or potential patent rights)); *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1049 n. 2, 59 USPQ2d 1121, 1129 n. 2 (Fed. Cir. 2001).

E. Buyer Must Be Uncontrolled by the Seller or Offerer

A sale or offer for sale must take place between separate entities. *In re Caveney*, 761 F.2d 671, 676, 226 USPQ 1, 4 (Fed. Cir. 1985). "Where the parties to the alleged sale are related, whether there is a statutory bar depends on whether the seller so controls the purchaser that the invention remains out of the public's hands. *Ferag AG v. Quipp, Inc.*, 45 F.3d 1562, 1566, 33 USPQ2d 1512, 1515 (Fed. Cir. 1995) (Where the seller is a parent company of the buyer company, but the President of the buyer company had "essentially unfettered" management authority over the operations of the buyer company, the sale was a statutory bar.).

II. OFFERS FOR SALE

"Only an offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance (assuming consideration), constitutes an offer for sale under §102(b)." *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041,1048, 59 USPQ2d 1121, 1126 (Fed. Cir. 2001).

A. Rejected or Unreceived Offer for Sale Is Enough To Bar a Patent

Since the statute creates a bar when an invention is placed "on sale," a mere offer to sell is sufficient commercial activity to bar a patent. *In re Theis*, 610 F.2d 786, 791, 204 USPQ 188, 192 (CCPA 1979). Even a rejected offer may create an on sale bar. *UMC Elecs. v. United States*, 816 F.2d 647, 653, 2 USPQ2d 1465, 1469 (Fed. Cir. 1987). In fact, the offer need not even be actually received by a prospective purchaser. *Wende v. Horine*, 225 F. 501 (7th Cir. 1915).

B. Delivery of the Offered Item Is Not Required

"It is not necessary that a sale be consummated for the bar to operate." *Buildex v. Kason Indus., Inc.*, 849 F.2d 1461, 1463-64, 7 USPQ2d 1325, 1327-28 (Fed. Cir. 1988) (citations omitted). See also *Weatherchem Corp. v. J.L. Clark Inc.*, 163 F.3d 1326, 1333, 49 USPQ2d 1001, 1006-07 (Fed. Cir. 1998) (A signed purchase agreement prior to the critical date constituted a commercial offer; it was immaterial that there was no delivery of later patented caps and no exchange of money until after critical date.).

C. Seller Need Not Have the Goods "On Hand" when the Offer for Sale Is Made

Goods need not be "on hand" and transferred at the time of the sale or offer. The date of the offer for sale is the effective date of the "on sale" activity. *J. A. La Porte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577, 1582, 229 USPQ 435, 438 (Fed. Cir. 1986). However, the invention must be complete and "ready for patenting" (see MPEP § 2133.03(c)) before the critical date. *Pfaff v. Wells Elecs., Inc.* , 525 U.S. 55, 67, 119 S.Ct. 304, 311-12, 48 USPQ2d 1641, 1647 (1998). See also *Micro Chemical, Inc. v. Great Plains Chemical Co.*, 103 F.3d 1538, 1545, 41 USPQ2d 1238, 1243 (Fed. Cir. 1997) (The on-sale bar was not triggered by an offer to sell because the inventor "was not close to completion of the invention at the time of the alleged offer and had not demonstrated a high likelihood that the invention would work for its intended purpose upon completion."); *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 225 USPQ 634 (Fed. Cir. 1985) (Where there was no evidence that the samples shown to the potential customers were made by the new process and apparatus, the offer to sell did not rise to the level of an on sale bar.). Compare *Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.*, 731 F.2d 831, 221 USPQ 561 (Fed. Cir. 1984) (Where a "make shift" model of the inventive product was shown to the potential purchasers in conjunction with the offer to sell, the offer was enough to bar a patent under **35 U.S.C. 102(b)**.).

D. Material Terms of an Offer for Sale Must be Present

"[A] communication that fails to constitute a definite offer to sell the product and to include material terms is not an 'offer' in the contract sense." *Elan Corp., PLC v. Andrx Pharms. Inc.*, 366 F.3d 1336, 1341, 70 USPQ2d 1722, 1728 (Fed. Cir. 2004). The court stated that an "offer to enter into a license under a patent for future sale of the invention covered by the patent when and if it has been developed... is not an offer to sell the patented invention that constitutes an on-sale bar." *Id.*, 70 USPQ2d at 1726. Accordingly, the court concluded that Elan's letter was not an offer to sell a product. In addition, the court stated that the letter lacked material terms of a commercial offer

such as pricing for the product, quantities, time and place of delivery, and product specifications and that the dollar amount in the letter was not a price term for the sale of the product but rather the amount requested was to form and continue a partnership, explicitly referred to as a "licensing fee." *Id.*

III. SALE BY INVENTOR, ASSIGNEE OR OTHERS ASSOCIATED WITH THE INVENTOR IN THE COURSE OF BUSINESS

A. Sale Activity Need Not Be Public

Unlike questions of public use, there is no requirement that "on sale" activity be "public." "Public" as used in **35 U.S.C. 102(b)** modifies "use" only. "Public" does not modify "sale." *Hobbs v. United States*, 451 F.2d 849, 171 USPQ 713, 720 (5th Cir. 1971).

B. Inventor's Consent to the Sale Is Not a Prerequisite To Finding an On Sale Bar

If the invention was placed on sale by a third party who obtained the invention from the inventor, a patent is barred even if the inventor did not consent to the sale or have knowledge that the invention was embodied in the sold article. *Electric Storage Battery Co. v. Shimadzu*, 307 U.S. 5, 41 USPQ 155 (1938); *In re Blaisdell*, 242 F.2d 779, 783, 113 USPQ 289, 292 (CCPA 1957); *CTS Corp. v. Electro Materials Corp. of America*, 469 F. Supp. 801, 819, 202 USPQ 22, 38 (S.D.N.Y. 1979).

C. Objective Evidence of Sale or Offer To Sell Is Needed

In determining if a sale or offer to sell the claimed invention has occurred, a key question to ask is whether ** the inventor sold or offered for sale a product that embodies the invention claimed in the application. Objective evidence such as a description of the inventive product in the contract of sale or in another communication with the purchaser controls over an uncommunicated intent by the seller to deliver the inventive product under the contract for sale. *Ferag AG v. Quipp, Inc.*, 45 F.3d 1562, 1567, 33 USPQ2d 1512, 1516 (Fed. Cir. 1995) (On sale bar found where initial negotiations and agreement containing contract for sale neither clearly specified nor precluded use of the inventive design, but an order confirmation prior to the critical date did specify use of inventive design.). The purchaser need not have actual knowledge of the invention for it to be on sale. The determination of whether "the offered product is in fact the claimed invention may be established by any relevant evidence, such as memoranda, drawings, correspondence, and testimony of witnesses." *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1060, 12 USPQ2d 1449, 1452 (Fed. Cir. 1989). However, "what the purchaser reasonably believes the inventor to be offering is relevant to whether, on balance, the offer objectively may be said to be of the patented invention." *Envirotech Corp. v. Westech Eng'g, Inc.*, 904 F.2d 1571, 1576, 15 USPQ2d 1230, 1234 (Fed. Cir. 1990) (Where a proposal to supply a general contractor with a product did not mention a new design but, rather, referenced a prior art design, the uncommunicated intent of the supplier to supply the new design if awarded the contract did not constitute an "on sale" bar to a patent on the new design, even though the supplier's bid reflected the lower cost of the new design.).

IV. SALES BY INDEPENDENT THIRD PARTIES

A. Sales or Offers for Sale by Independent Third Parties Will Bar a Patent

Sale or offer for sale of the invention by an independent third party more than 1 year before the filing date of applicant's patent will bar applicant from obtaining a patent. "An exception to this rule exists where a patented method is kept secret and remains secret after a sale of the unpatented product of the method. Such a sale prior to the critical date is a bar if engaged in by the patentee or patent applicant, but not if engaged in by another." *In re Caveney*, 761 F.2d 671, 675-76, 226 USPQ 1, 3-4 (Fed. Cir. 1985).

B. Nonprior Art Publications Can Be Used as Evidence of Sale Before the Critical Date

Abstracts identifying a product's vendor containing information useful to potential buyers such as whom to contact, price terms, documentation, warranties, training and maintenance along with the date of product release or installation before the inventor's critical date may provide sufficient evidence of prior sale by a third party to support a rejection based on **35 U.S.C. 102(b)** or **103**. *In re Epstein*, 32 F.3d 1559, 31 USPQ2d 1817 (Fed. Cir. 1994) (Examiner's rejection was based on nonprior art published abstracts which disclosed software products meeting the claims. The abstracts specified software release dates and dates of first installation which were more than 1 year before applicant's filing date.).

2133.03(c) The "Invention" [R-5]

35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless -

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(b) the invention was…in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States

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(Emphasis added).

I. **The Invention Must Be "Ready for Patenting" **

In *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 66-68, 119 S.Ct. 304, 311-12, 48 USPQ2d 1641, 1647 (1998), the Supreme Court enunciated a two-prong test for determining whether an invention was "on sale" within the meaning of 35 U.S.C. 102(b) even if it has not yet been reduced to practice. "[T]he on-sale bar applies when two conditions are satisfied before the critical date [more than one year before the effective filing date of the U.S. application]. First, the product must be the subject of a commercial offer for sale…. Second, the invention must be ready for patenting." *Id.* at 67, 119 S.Ct. at 311-12, 48 USPQ2d at 1646-47.

>The Federal Circuit explained that the Supreme Court's "ready for patenting" prong applies in the context of both the on sale and public use bars. *Invitrogen Corp. v. Biocrest Manuf.*, 424 F.3d 1374, 1379, 76 USPQ2d 1741, 1744 (Fed. Cir. 2005)("A bar under section **102**(b) arises where, before the critical date, the invention is in public use and ready for patenting.").< "Ready for patenting," the second prong of the *Pfaff* test, "may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." *Id.* at 67, 199 S.Ct. at 311-12, 48 USPQ2d at 1647 (The patent was held invalid because the invention for a computer chip socket was "ready for patenting" when it was offered for sale more than one year prior to the application filing date. Even though the invention had not yet been reduced to practice, the manufacturer was able to produce the claimed computer chip sockets using the inventor's detailed drawings and specifications, and those sockets contained all elements of invention claimed in the patent.). See also *Weatherchem Corp. v. J.L. Clark Inc.*, 163 F.3d 1326, 1333, 49 USPQ2d 1001, 1006-07 (Fed. Cir. 1998) (The invention was held "ready for patenting" since the detailed drawings of plastic dispensing caps offered for sale "contained each limitation of the claims and were sufficiently specific to enable person skilled in art to practice the invention".).

If the invention was actually reduced to practice before being sold or offered for sale more than 1 year before filing of the application, a patent will be barred. *Vanmoor v. Wal-Mart Stores, Inc.*, 201 F.3d 1363, 1366-67, 53 USPQ2d 1377, 1379 (Fed. Cir. 2000) ("Here the pre-critical date sales were of completed cartridges made to specifications that remained unchanged to the present day, showing that any invention embodied in the accused cartridges was reduced to practice before the critical date. The *Pfaff* ready for patenting condition is also satisfied because the specification drawings, available prior to the critical date, were actually used to produce the accused cartridges."); *In re Hamilton*, 882 F.2d 1576, 1580, 11 USPQ2d 1890, 1893 (Fed. Cir. 1989). "If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics." *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed. Cir. 1999) (Claim for a particular anhydrous crystalline form of a pharmaceutical compound was held invalid under the on-sale bar of **35 U.S.C. 102(b)**, even though the parties to the U.S. sales of the foreign manufactured compound did not know the identity of the particular crystalline form.); *STX LLC. v. Brine Inc.*, 211 F.3d 588, 591, 54 USPQ2d 1347, 1350 (Fed. Cir. 2000) (Claim for a lacrosse stick was held invalid under the on-sale bar despite the argument that it was not known at the time of sale whether the sticks possessed the recited "improved playing and handling characteristics." "Subjective qualities inherent in a product, such as 'improved playing and handling', cannot serve as an escape hatch to circumvent an on-sale bar."). Actual reduction to practice in the context of an on-sale bar issue usually requires testing under actual working conditions in such a way as to demonstrate the practical utility of an invention for its intended purpose beyond the probability of failure, unless by virtue of the very simplicity of an invention its practical operativeness is clear. *Field v. Knowles*, 183 F.2d 593, 601, 86 USPQ 373, 379 (CCPA 1950); *Steinberg v. Seitz*, 517 F.2d 1359, 1363, 186 USPQ 209, 212 (CCPA 1975).

The invention need not be ready for satisfactory commercial marketing for sale to bar a patent. *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 836-37, 23 USPQ2d 1481, 1483 (Fed. Cir. 1992).

II. INVENTOR HAS SUBMITTED A 37 CFR 1.131 AFFIDAVIT OR DECLARATION

Affidavits or declarations submitted under **37 CFR 1.131** to swear behind a reference may constitute, among other things, an admission that an invention was "complete" more than 1 year before the filing of an application. See

In re Foster, 343 F.2d 980, 987-88, 145 USPQ 166, 173 (CCPA 1965); *Dart Indus. v. E.I. duPont de Nemours & Co.*, 489 F.2d 1359, 1365, 179 USPQ 392, 396 (7th Cir. 1973). Also see **MPEP § 715.10**.

III. SALE OF A PROCESS

A claimed process, which is a series of acts or steps, is not sold in the same sense as is a claimed product, device, or apparatus, which is a tangible item. "'Know-how' describing what the process consists of and how the process should be carried out may be sold in the sense that the buyer acquires knowledge of the process and obtains the freedom to carry it out pursuant to the terms of the transaction. However, such a transaction is not a 'sale' of the invention within the meaning of §**102**(b) because the process has not been carried out or performed as a result of the transaction." *In re Kollar*, 286 F.3d 1326, 1332, 62 USPQ2d 1425, 1429 (Fed. Cir. 2002). However, sale of a product made by the claimed process by the patentee or a licensee would constitute a sale of the process within the meaning of 35 U.S.C. **102**(b). See *id.* at 1333, 62 USPQ2d at 1429; *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147-48, 219 USPQ 13, 15-16 (Fed. Cir. 1983) (Even though the sale of a product made by a claimed method before the critical date did not reveal anything about the method to the public, the sale resulted in a "forfeiture" of any right to a patent to that method); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550, 220 USPQ 303, 310 (Fed. Cir. 1983). The application of 35 U.S.C. **102**(b) would also be triggered by actually performing the claimed process itself for consideration. See *Scaltech, Inc. v. Retec/Tetra, L.L.C.*, 269 F.3d 1321, 1328, 60 USPQ2d 1687, 1691(Fed. Cir. 2001) (Patent was held invalid under 35 U.S.C. **102**(b) based on patentee's offer to perform the claimed process for treating oil refinery waste more than one year before filing the patent application). Moreover, the sale of a device embodying a claimed process may trigger the on-sale bar. *Minton v. National Ass'n. of Securities Dealers, Inc.*, 336 F.3d 1373, 1378, 67 USPQ2d 1614, 1618 (Fed. Cir. 2003) (finding a fully operational computer program implementing and thus embodying the claimed method to trigger the on-sale bar). However, the sale of a prior art device different from that disclosed in a patent that is asserted after the critical date to be capable of performing the claimed method is not an on-sale bar of the process. *Poly-America LP v. GSE Lining Tech. Inc.*, 383 F.3d 1303, 1308-09, 72 USPQ2d 1685, 1688-89 (Fed. Cir. 2004) (stating that the transaction involving the sale of the prior art device did not involve a transaction of the claimed method but instead only a device different from that described in the patent for carrying out the claimed method, where the device was not used to practice the claimed method until well after the critical date, and where there was evidence that it was not even known whether the device could perform the claimed process).

2133.03(d) "In This Country"

For purposes of judging the applicability of the **35 U.S.C. 102(b)** bars, public use or on sale activity must take place in the United States. The "on sale" bar does not generally apply where both manufacture and delivery occur in a foreign country. *Gandy v. Main Belting Co.*, 143 U.S. 587, 593 (1892). However, "on sale" status can be found if substantial activity prefatory to a "sale" occurs in the United States. *Robbins Co. v. Lawrence Mfg. Co.*, 482 F.2d 426, 433, 178 USPQ 577, 583 (9th Cir. 1973). An offer for sale, made or originating in this country, may be sufficient prefatory activity to bring the offer within the terms of the statute, even though sale and delivery take place in a foreign country. The same rationale applies to an offer by a foreign manufacturer which is communicated to a prospective purchaser in the United States prior to the critical date. *CTS Corp. v. Piher Int'l Corp.*, 593 F.2d 777, 201 USPQ 649 (7th Cir. 1979).

2133.03(e) Permitted Activity; Experimental Use [R-3]

The question posed by the experimental use doctrine is "whether the primary purpose of the inventor at the time of the sale, as determined from an objective evaluation of the facts surrounding the transaction, was to conduct experimentation." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1354, 63 USPQ2d 1769, 1780 (Fed. Cir. 2002), *quoting EZ Dock v. Schafer Sys., Inc.*, 276 F.3d 1347, 1356-57, 61 USPQ2d 1289, 1295-96 (Fed. Cir. 2002) (Linn, J., concurring). Experimentation must be the primary purpose and any commercial exploitation must be incidental. **

If the use or sale was experimental, there is no bar under **35 U.S.C. 102(b)**. "A use or sale is experimental for purposes of **section 102**(b) if it represents a *bona fide* effort to perfect the invention or to ascertain whether it will answer its intended purpose.…If any commercial exploitation does occur, it must be merely incidental to the primary purpose of the experimentation to perfect the invention." *LaBounty Mfg. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1071, 22 USPQ2d 1025, 1028 (Fed. Cir. 1992) (quoting *Pennwalt Corp. v. Akzona Inc.*, 740 F.2d 1573, 1581, 222 USPQ 833, 838 (Fed. Cir. 1984)). "The experimental use exception…does not include market testing where the inventor is attempting to gauge consumer demand for his claimed invention. The purpose of such activities is commercial exploitation

and not experimentation." *In re Smith*, 714 F.2d 1127, 1134, 218 USPQ 976, 983 (Fed. Cir. 1983).

2133.03(e)(1) Commercial Exploitation [R-1]

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>One< policy of the on sale and public use bars is the prevention of inventors from exploiting their inventions commercially more than 1 year prior to the filing of a patent application. Therefore, if applicant's precritical date activity is**>a sale or offer for sale that is< an attempt at market penetration, a patent is barred. Thus, even if there is *bona fide* experimental activity, an inventor may not commercially exploit an invention more than 1 year prior to the filing date of an application. *In re Theis*, 610 F.2d 786, 793, 204 USPQ 188, 194 (CCPA 1979).

THE COMMERCIAL ACTIVITY MUST LEGITIMATELY ADVANCE DEVELOPMENT OF THE INVENTION TOWARDS COMPLETION

As the degree of commercial exploitation surrounding **35 U.S.C. 102(b)** activity increases, the burden on an applicant to establish clear and convincing evidence of experimental activity with respect to a public use becomes more difficult. Where the examiner has found a *prima facie* case of a sale or an offer to sell, this burden will rarely be met unless clear and convincing necessity for the experimentation is established by the applicant. This does not mean, of course, that there are no circumstances which would permit alleged experimental activity in an atmosphere of commercial exploitation. In certain circumstances, even a sale may be necessary to legitimately advance the experimental development of an invention if the primary purpose of the sale is experimental. *In re Theis*, 610 F.2d 786, 793, 204 USPQ 188, 194 (CCPA 1979); *Robbins Co. v. Lawrence Mfg. Co*., 482 F.2d 426, 433, 178 USPQ 577, 582 (9th Cir. 1973). However, careful scrutiny by the examiner of the objective factual circumstances surrounding such a sale is essential. See *Ushakoff v. United States*, 327 F.2d 669, 140 USPQ 341 (Ct.Cl. 1964); *Cloud v. Standard Packaging Corp.*, 376 F.2d 384, 153 USPQ 317 (7th Cir. 1967).

SIGNIFICANT FACTORS INDICATIVE OF "COMMERCIAL EXPLOITATION"

As discussed in **MPEP § 2133.03**, a policy consideration in questions of **35 U.S.C. 102(b)** activity is premature "commercial exploitation" of a "completed" or "ready for patenting" invention (see **MPEP § 2133.03(c)**). The extent of commercial activity which constitutes **35 U.S.C. 102(b)** "on sale" status depends upon the circumstances of the activity, the basic indicator being the subjective intent of the inventor as manifested through objective evidence. The following activities should be used by the examiner as indicia of this subjective intent:

(A) Preparation of various contemporaneous "commercial" documents, e.g., orders, invoices, receipts, delivery schedules, etc.;

(B) Preparation of price lists (*Akron Brass Co. v. Elkhart Brass Mfg. Co.*, 353 F.2d 704, 709, 147 USPQ 301, 305 (7th Cir. 1965) and distribution of price quotations (*Amphenol Corp. v. General. Time Corp.*, 158 USPQ 113, 117 (7th Cir. 1968));

(C) Display of samples to prospective customers (*Cataphote Corp. v. DeSoto Chemical Coatings, Inc.*, 356 F.2d 24, 27, 148 USPQ 527, 529 (9th Cir. 1966) *mod. on other grounds*, 358 F.2d 732, 149 USPQ 159 (9th Cir.), *cert. denied*, 385 U.S. 832 (1966); *Chicopee Mfg. Corp. v. Columbus Fiber Mills Co.*, 165 F.Supp. 307, 323-325, 118 USPQ 53, 65-67 (M.D.Ga. 1958));

(D) Demonstration of models or prototypes (*General Elec. Co. v. United States*, 206 USPQ 260, 266-67 (Ct. Cl. 1979); *Red Cross Mfg. v. Toro Sales Co.*, 525 F.2d 1135, 1140, 188 USPQ 241, 244-45 (7th Cir. 1975); *Philco Corp. v. Admiral Corp*., 199 F. Supp. 797, 815-16, 131 USPQ 413, 429-30 (D.Del. 1961)), especially at trade conventions (*InterRoyal Corp. v. Simmons Co.*, 204 USPQ 562, 563-65 (S.D. N.Y. 1979)), and even though no orders are actually obtained (*Monogram Mfg. v. F. & H. Mfg*.,144 F.2d 412, 62 USPQ 409, 412 (9th Cir. 1944));

(E) Use of an invention where an admission fee is charged (*In re Josserand*, 188 F.2d 486, 491, 89 USPQ 371, 376 (CCPA 1951); *Greenewalt v. Stanley*, 54 F.2d 195, 12 USPQ 122 (3d Cir. 1931)); and

(F) Advertising in publicity releases, brochures, and various periodicals (*In re Theis*, 610 F.2d 786, 792 n.6, 204 USPQ 188, 193 n. 6 (CCPA 1979); *InterRoyal Corp. v. Simmons Co*., 204 USPQ 562, 564-66 (S.D.N.Y.1979); *Akron Brass, Inc. v. Elkhart Brass Mfg., Inc.*, 353 F.2d 704, 709, 147 USPQ 301, 305 (7th Cir.1965); *Tucker Aluminum Prods. v. Grossman*, 312 F.2d 393, 394, 136 USPQ 244, 245 (9th Cir. 1963)).

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>See MPEP § **2133.03(e)(4)** for factors indicative of an experimental purpose.<

2133.03(e)(2) Intent

"When sales are made in an ordinary commercial environment and the goods are placed outside the inventor's control, an inventor's secretly held subjective intent to 'experiment,' even if true, is unavailing without objective evidence to support the contention. Under such circumstances, the customer at a minimum must be made

aware of the experimentation." *LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1072, 22 USPQ2d 1025, 1029 (Fed. Cir. 1992) (quoting *Harrington Mfg. Co. v. Powell Mfg. Co.*, 815 F.2d 1478, 1480 n.3, 2 USPQ2d 1364, 1366 n.3 (Fed. Cir. 1986); *Paragon Podiatry Laboratory, Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 25 USPQ2d 1561 (Fed. Cir. 1993) (Paragon sold the inventive units to the trade as completed devices without any disclosure to either doctors or patients of their involvement in alleged testing. Evidence of the inventor's secretly held belief that the units were not durable and may not be satisfactory for consumers was not sufficient, alone, to avoid a statutory bar.).

2133.03(e)(3) "Completeness" of the Invention [R-3]

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I. < EXPERIMENTAL USE ENDS WHEN THE INVENTION IS ACTUALLY REDUCED TO PRACTICE

Experimental use "means perfecting or completing an invention to the point of determining that it will work for its intended purpose." Therefore, experimental use "ends with an actual reduction to practice." *RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1061, 12 USPQ2d 1449, 1453 (Fed. Cir. 1989). If the examiner concludes from the evidence of record that an applicant was satisfied that an invention was in fact "complete," awaiting approval by the applicant from an organization such as Underwriters' Laboratories will not normally overcome this conclusion. *InterRoyal Corp. v. Simmons Co.*, 204 USPQ 562, 566 (S.D.N.Y. 1979); *Skil Corp. v. Rockwell Manufacturing Co.*, 358 F. Supp. 1257, 1261, 178 USPQ 562, 565 (N.D.Ill. 1973), *aff'd. in part, rev'd in part sub nom. Skil Corp. v. Lucerne Products Inc.*, 503 F.2d 745, 183 USPQ 396, 399 (7th Cir. 1974), *cert. denied*, 420 U.S. 974, 185 USPQ 65 (1975). ** See **MPEP § 2133.03(c)** for more information of what constitutes a "complete" invention.

The fact that alleged experimental activity does not lead to specific modifications or refinements of an invention is evidence, although not conclusive evidence, that such activity is not within the realm permitted by the statute. This is especially the case where the evidence of record clearly demonstrates to the examiner that an invention was considered "complete" by an inventor at the time of the activity. Nevertheless, any modifications or refinements which did result from such experimental activity must at least be a feature of the claimed invention to be of any probative value. *In re Theis*, 610 F.2d 786, 793, 204 USPQ 188, 194 (CCPA 1979).

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II. < DISPOSAL OF PROTOTYPES

Where a prototype of an invention has been disposed of by an inventor before the critical date, inquiry by the examiner should focus upon the intent of the inventor and the reasonableness of the disposal under all circumstances. The fact that an otherwise reasonable disposal of a prototype involves incidental income is not necessarily fatal. *In re Dybel*, 524 F.2d 1393, 1399, n.5, 187 USPQ 593, 597 n.5 (CCPA 1975). However, if a prototype is considered "complete" by an inventor and all experimentation on the underlying invention has ceased, unrestricted disposal of the prototype constitutes a bar under **35 U.S.C. 102(b)**. *In re Blaisdell*, 242 F.2d 779, 113 USPQ 289 (CCPA 1957); *contra*, *Watson v. Allen*, 254 F.2d 342, 117 USPQ 68 (D.C. Cir. 1958).

2133.03(e)(4) Factors Indicative of an Experimental Purpose [R-5]

The courts have considered a number of factors in determining whether a claimed invention was the subject of a commercial offer for sale primarily for purposes of experimentation. "These factors include: (1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, ... (9) the degree of commercial exploitation during testing[,] ... (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1353, 63 USPQ2d 1769, 1780 (Fed. Cir. 2002) *quoting EZ Dock v. Schafer Sys., Inc.*, 276 F.3d 1347, 1357, 61 USPQ2d 1289, 1296 (Fed. Cir. 2002) (Linn, J., concurring). >Another critical attribute of experimentation is the "customer's awareness of the purported testing in the context of a sale." *Electromotive Div. of Gen. Motors Corp. v. Transportation Sys. Div. of Gen. Elec. Co.*, 417 F.3d 1203, 1241, 75 USPQ2d 1650, 1658 (Fed. Cir. 2005).<

Once alleged experimental activity is advanced by an applicant to explain a *prima facie* case under **35 U.S.C. 102(b)**, the examiner must determine whether the scope and length of the activity were reasonable in terms of the experimental purpose intended by the applicant and the nature of the subject matter involved. No one of, or particular combination of, factors is necessarily determinative of this purpose.

See MPEP § 2133.03(e)(1) for factors indicative of commercial exploitation.

2133.03(e)(5) Experimentation and Degree of Supervision and Control [R-5]

THE INVENTOR MUST MAINTAIN SUFFICIENT CONTROL OVER THE INVENTION DURING TESTING BY THIRD PARTIES

**>The<significant determinative *>factors< in questions of experimental purpose *>are< the extent of supervision and control maintained by an inventor over an invention during an alleged period of experimentation >, and the customer's awareness of the experimentation. *Electromotive Div. of Gen. Motors Corp. v. Transportation Sys. Div. of Gen. Elec. Co.*, 417 F.3d 1203, 1214,75 USPQ2d 1650, 1658 (Fed. Ir. 2005)("control and customer awareness ordinarily must be proven if experimentation is to be found")<. Once a period of experimental activity has ended and supervision and control has been relinquished by an inventor without any restraints on subsequent use of an invention, an unrestricted subsequent use of the invention is a 35 U.S.C. 102(b) bar. *In re Blaisdell*, 242 F.2d 779, 784, 113 USPQ 289, 293 (CCPA 1957).

2133.03(e)(6) Permitted Experimental Activity and Testing [R-3]

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I. < DEVELOPMENTAL TESTING IS PERMITTED

Testing of an invention in the normal context of its technological development is generally within the realm of permitted experimental activity. Likewise, experimentation to determine utility, as that term is applied in 35 U.S.C. 101, may also constitute permissible activity. See *General Motors Corp. v. Bendix Aviation Corp.*, 123 F. Supp. 506, 521, 102 USPQ 58, 69 (N.D.Ind. 1954). For example, where an invention relates to a chemical composition with no known utility, i.e., a patent application for the composition could not be filed (35 U.S.C. 101; 35 U.S.C. 112, first paragraph), continued testing to find utility would likely be permissible under 35 U.S.C. 102(b), absent a sale of the composition or other evidence of commercial exploitation. **

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II. < MARKET TESTING IS NOT PERMITTED

Experimentation to determine product acceptance, i.e., market testing, is typical of a trader's and not an inventor's experiment and is thus not within the area of permitted experimental activity. *Smith & Davis Mfg. Co. v. Mellon*, 58 F. 705, 707 (8th Cir. 1893) Likewise, testing of an invention for the benefit of appeasing a customer, or to conduct "minor 'tune up' procedures not requiring an inventor's skills, but rather the skills of a competent technician," are also not within the exception. *In re Theis*, 610 F.2d 786, 793, 204 USPQ 188, 193-94 (CCPA 1979).

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III. < EXPERIMENTAL ACTIVITY IN THE CONTEXT OF DESIGN APPLICATIONS

The public use of an ornamental design which is directed toward generating consumer interest in the aesthetics of the design is not an experimental use. *In re Mann*, 861 F.2d 1581, 8 USPQ2d 2030 (Fed. Cir. 1988) (display of a wrought iron table at a trade show held to be public use). However, "experimentation directed to functional features of a product also containing an ornamental design may negate what otherwise would be considered a public use within the meaning of section 102(b)." *Tone Brothers, Inc. v. Sysco Corp.*, 28 F.3d 1192, 1196, 31 USPQ2d 1321, 1326 (Fed. Cir. 1994) (A study wherein students evaluated the effect of the functional features of a spice container design may be considered an experimental use.).

2133.03(e)(7) Activity of an Independent Third Party Inventor

EXPERIMENTAL USE EXCEPTION IS PERSONAL TO AN APPLICANT

The statutory bars of 35 U.S.C. 102(b) are applicable even though public use or on sale activity is by a party other than an applicant. Where an applicant presents evidence of experimental activity by such other party, the evidence will not overcome the *prima facie* case under 35 U.S.C. 102(b) based upon the activity of such party unless the activity was under the supervision and control of the applicant. *Magnetics v. Arnold Eng'g Co.*, 438 F.2d 72, 74, 168 USPQ 392, 394 (7th Cir. 1971), *Bourne v. Jones*, 114 F.Supp. 413, 419, 98 USPQ 206, 210 (S.D. Fla. 1951), *aff'd*., 207 F.2d 173, 98 USPQ 205 (5th Cir. 1953), *cert. denied*, 346 U.S. 897, 99 USPQ 490 (1953); contra, *Watson v. Allen*, 254 F.2d 342, 117 USPQ 68 (D.C.Cir. 1957). In other words, the experimental use activity exception is personal to an applicant.

2134 35 U.S.C. 102(c) [R-1]

35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless -

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(c) he has abandoned the invention.

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UNDER 35 U.S.C. 102(c), AN ABANDONMENT MUST BE INTENTIONAL

"Actual abandonment under 35 U.S.C. 102(c) requires that the inventor intend to abandon the invention, and intent can be implied from the inventor's conduct with respect to the invention. *In re Gibbs*, 437 F.2d 486, 168 USPQ 578 (CCPA 1971). Such intent to abandon the invention will not be imputed, and every reasonable doubt should be resolved in favor of the inventor." *Ex parte Dunne*, 20 USPQ2d 1479 (Bd. Pat. App. & Inter. 1991).

DELAY IN MAKING FIRST APPLICATION

Abandonment under 35 U.S.C. 102(c) requires a deliberate, though not necessarily express, surrender of any rights to a patent. To abandon the invention the inventor must intend a dedication to the public. Such dedication may be either express or implied, by actions or inactions of the inventor. Delay alone is not sufficient to infer the requisite intent to abandon. *Moore v. United States*, 194 USPQ 423, 428 (Ct. Cl. 1977) (The drafting and retention in his own files of two patent applications by inventor indicates an intent to retain his invention; delay in filing the applications was not sufficient to establish abandonment); but see *Davis Harvester Co., Inc. v. Long Mfg. Co.*, 252 F. Supp. 989, 1009-10, 149 USPQ 420, 435-436 (E.D. N.C. 1966) (Where the inventor does nothing over a period of time to develop or patent his invention, ridicules the attempts of another to develop that invention and begins to show active interest in promoting and developing his invention only after successful marketing by another of a device embodying that invention, the inventor has abandoned his invention under 35 U.S.C. 102(c).).

DELAY IN REAPPLYING FOR PATENT AFTER ABANDONMENT OF PREVIOUS PATENT APPLICATION

Where there is no evidence of expressed intent or conduct by inventor to abandon his invention, delay in reapplying for patent after abandonment of a previous application does not constitute abandonment under 35 U.S.C. 102(c). *Petersen v. Fee Int'l, Ltd.*, 381 F. Supp. 1071, 182 USPQ 264 (W.D. Okla. 1974).

DISCLOSURE WITHOUT CLAIMING IN A PRIOR ISSUED PATENT

Any inference of abandonment (i.e., intent to dedicate to the public) of subject matter disclosed but not claimed in a previously issued patent is rebuttable by an application filed at any time before a statutory bar arises. Accordingly, a rejection of a claim of a patent application under 35 U.S.C. 102(c) predicated solely on the issuance of a patent which discloses the subject matter of the claim in the application without claiming it would be improper, regardless of whether there is copendency between the application at issue and the application which issued as the patent. *In re Gibbs*, 437 F.2d 486, 168 USPQ 578 (CCPA 1971).

ONLY WHEN THERE IS A PRIORITY CONTEST CAN A LAPSE OF TIME BAR A PATENT

The mere lapse of time will not bar a patent. The only exception is when there is a priority contest under 35 U.S.C. 102(g) and applicant abandons, suppresses or conceals the invention. *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1101, 227 USPQ 337, 350 (Fed. Cir. 1985). Abandonment, suppression and concealment are treated by the courts under 35 ≥ U.S.C. ≤ 102(g). See MPEP § 2138.03 for more information on this issue.

2135 35 U.S.C. 102(d)

35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless -

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(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States.

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GENERAL REQUIREMENTS OF 35 U.S.C. 102(d)

35 U.S.C. 102(d) establishes four conditions which, if all are present, establish a bar against the granting of a patent in this country:

(A) The foreign application must be filed more than 12 months before the effective U.S. filing date (See MPEP § 706.02 regarding effective U.S. filing date of an application);

(B) The foreign application must have been filed by the same applicant as in the United States or by his or her legal representatives or assigns.

(C) The foreign patent or inventor's certificate must be actually granted (e.g., by sealing of the papers in Great Britain) before the U.S. filing date. It need not be published.

(D) The same invention must be involved.

If such a foreign patent or inventor's certificate is discovered by the examiner, the rejection is made under 35 U.S.C. 102(d) on the ground of statutory bar. See MPEP § 2135.01 for further clarification of each of the four requirements of 35 U.S.C. 102(d).

2135.01 The Four Requirements of 35 U.S.C. 102(d)

I. FOREIGN APPLICATION MUST BE FILED MORE THAN 12 MONTHS BEFORE THE EFFECTIVE U.S. FILING DATE

A. An Anniversary Date Ending on a Weekend or Holiday Results in an Extension to the Next Business Day

The U.S. application is filed in time to prevent a 35 U.S.C. 102(d) bar from arising if it is filed on the 1 year anniversary date of the filing date of the foreign application. If this day is a Saturday, Sunday or Federal holiday, the year would be extended to the following business day. See *Ex parte Olah* , 131 USPQ 41 (Bd. App. 1960.) Despite changes to 37 CFR 1.6(a)(2) and 1.10, which require the PTO to accord a filing date to an application as of the date of deposit as "Express Mail" with the U.S. Postal Service in accordance with 37 CFR 1.10 (e.g., a Saturday filing date), the rule changes do not affect applicant's concurrent right to defer the filing of an application until the next business day when the last day for "taking any action" falls on a Saturday, Sunday, or a Federal holiday (e.g., the last day of the 1-year grace period falls on a Saturday).

B. A Continuation-in-Part Breaks the Chain of Priority as to Foreign as Well as U.S. Parents

In the case where applicant files a foreign application, later files a U.S. application claiming priority based on the foreign application, and then files a continuation-in-part (CIP) application whose claims are not entitled to the filing date of the U.S. parent, the effective filing date is the filing date of the CIP and applicant cannot obtain the benefit of either the U.S. parent or foreign application filing dates. *In re Van Langenhoven*, 458 F.2d 132, 137, 173 USPQ 426, 429 (CCPA 1972). If the foreign application issues into a patent before the filing date of the CIP, it may be used in a 35 U.S.C. 102(d)/103 rejection if the subject matter added to the CIP does not render the claims nonobvious over the foreign patent. *Ex parte Appeal No. 242-47*, 196 USPQ 828 (Bd. App. 1976) (Foreign patent can be combined with other prior art to bar a U.S. patent in an obviousness rejection based on 35 U.S.C. 102(d)/103).

II. FOREIGN APPLICATION MUST HAVE BEEN FILED BY SAME APPLICANT, HIS OR HER LEGAL REPRESENTATIVE OR ASSIGNS

Note that where the U.S. application was made by two or more inventors, it is permissible for these inventors to claim priority from separate applications, each to one of the inventors or a subcombination of inventors. For instance, a U.S. application naming inventors A and B may be entitled to priority from one application to A and one to B filed in a foreign country.

III. THE FOREIGN PATENT OR INVENTOR'S CERTIFICATE WAS ACTUALLY GRANTED BEFORE THE U.S. FILING DATE

A. To Be "Patented" an Exclusionary Right Must Be Awarded to the Applicant

"Patented" means "a formal bestowal of patent rights from the sovereign to the applicant." *In re Monks*, 588 F.2d 308, 310, 200 USPQ 129, 131 (CCPA 1978); *American Infra-Red Radiant Co. v. Lambert Indus.*, 360 F.2d 977, 149 USPQ 722 (8th Cir.), *cert. denied*, 385 U.S. 920 (1966) (German Gebrauchsmuster petty patent was held to be a patent usable in a 35 U.S.C. 102(d) rejection. Gebrauchmustern are not examined and only grant a 6-year patent term. However, except as to duration, the exclusionary patent right granted is as extensive as in the U.S.).

B. A Published Application Is Not a "Patent"

An application must issue into a patent before it can be applied in a 35 U.S.C. 102(d) rejection. *Ex parte Fujishiro*, 199 USPQ 36 (Bd. App. 1977) ("Patenting," within the meaning of 35 U.S.C. 102(d), does not occur upon laying open of a Japanese utility model application (kokai or kohyo)); *Ex parte Links*, 184 USPQ 429 (Bd. App. 1974) (German applications, which have not yet been published for opposition, are published in the form of printed documents called Offenlegungsschriften 18

months after filing. These applications are unexamined or in the process of being examined at the time of publication. The Board held that an Offenlegungsschrift is not a patent under **35 U.S.C. 102(d)** even though some provisional rights are granted. The Board explained that the provisional rights are minimal and do not come into force if the application is withdrawn or refused.).

C. An Allowed Application Can Be a "Patent" for Purposes of 35 U.S.C. 102(d) as of the Date Published for Opposition Even Though It Has Not Yet Been Granted as a Patent

An examined application which has been allowed by the examiner and published to allow the public to oppose the grant of a patent has been held to be a "patent" for purposes of rejection under **35 U.S.C. 102(d)** as of the date of publication for opposition if substantial provisional enforcement rights arise. *Ex parte Beik*, 161 USPQ 795 (Bd. App. 1968) (This case dealt with examined German applications. After a determination that an application is allowable, the application is published in the form of a printed document called an Auslegeschrift. The publication begins a period of opposition were the public can present evidence showing unpatentability. Provisional patent rights are granted which are substantially the same as those available once the opposition period is over and the patent is granted. The Board found that an Auslegeschrift provides the legal effect of a patent for purposes of rejection under **35 U.S.C. 102(d)**.).

D. Grant Occurs When Patent Becomes Enforceable

The critical date of a foreign patent as a reference under **35 U.S.C. 102(d)** is the date the patent becomes enforceable (issued, sealed or granted). *In re Monks*, 588 F.2d 308, 310, 200 USPQ 129, 131 (CCPA 1978) (British reference became available as prior art on date the patent was "sealed" because as of this date applicant had the right to exclude others from making, using or selling the claimed invention.).

E. 35 U.S.C. 102(d) Applies as of Grant Date Even If There Is a Period of Secrecy After Patent Grant

A period of secrecy after granting the patent, as in Belgium and Spain, has been held to have no effect in connection with **35 U.S.C. 102(d)**. These patents are usable in rejections under **35 U.S.C. 102(d)** as of the date patent rights are granted. *In re Kathawala*, 9 F.3d 942, 28 USPQ2d 1789 (Fed. Cir. 1993) (An invention is "patented" for purposes of **35 U.S.C. 102(d)** when the patentee's rights under the patent become fixed. The fact that applicant's Spanish application was not published until after the U.S. filing date is immaterial since the Spanish patent was granted before U.S. filing.); *Gramme Elec. Co. v. Arnoux and Hochhausen Elec. Co.*, 17 F. 838, 1883 C.D. 418 (S.D.N.Y. 1883) (Rejection made under a predecessor of **35 U.S.C. 102(d)** based on an Austrian patent granted an exclusionary right for 1 year but was kept secret, at the option of the patentee, for that period. The court held that the Austrian patent grant date was the relevant date under the statute for purposes of **35 U.S.C. 102(d)** but that the patent could not have been used to in a rejection under **35 U.S.C. 102(a)** or (b).); *In re Talbott*, 443 F.2d 1397, 170 USPQ 281 (CCPA 1971) (Applicant cannot avoid a **35 U.S.C. 102(d)** rejection by exercising an option to keep the subject matter of a German Gebrauchsmuster (petty patent) in secrecy until time of U.S. filing.).

IV. THE SAME INVENTION MUST BE INVOLVED

"Same Invention" Means That the Application Claims Could Have Been Presented in the Foreign Patent

Under **35 U.S.C. 102(d)**, the "invention... patented" in the foreign country must be the same as the invention sought to be patented in the U.S. When the foreign patent contains the same claims as the U.S. application, there is no question that "the invention was first patented... in a foreign country." *In re Kathawala*, 9 F.3d 942, 945, 28 USPQ2d 1785, 1787 (Fed. Cir. 1993). However, the claims need not be identical or even within the same statutory class. If applicant is granted a foreign patent which fully discloses the invention and which gives applicant a number of different claiming options in the U.S., the reference in **35 U.S.C. 102(d)** to "'invention... patented' necessarily includes all the disclosed aspects of the invention. Thus, the section 102(d) bar applies regardless whether the foreign patent contains claims to less than all aspects of the invention." 9 F.3d at 946, 28 USPQ2d at 1788. In essence, a **35 U.S.C. 102(d)** rejection applies if applicant's foreign application supports the subject matter of the U.S. claims. *In re Kathawala*, 9 F.3d 942, 28 USPQ2d 1785 (Fed. Cir. 1993) (Applicant was granted a Spanish patent claiming a method of making a composition. The patent disclosed compounds, methods of use and processes of making the compounds. After the Spanish patent was granted, the applicant filed a U.S. application with claims directed to the compound but not the process of making it. The Federal Circuit held that it did not matter that the claims in the U.S. application were directed to the composition instead of the process because the foreign specification would have supported claims to the composition. It was immaterial that the

formulations were unpatentable pharmaceutical compositions in Spain.).

2136 35 U.S.C. 102(e) [R-3]

Revised 35 U.S.C. 102(e), as amended by the American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501 (1999)), and as further amended by the Intellectual Property and High Technology Technical Amendments Act of 2002 (Pub. L. 107-273, 116 Stat. 1758 (2002)), applies in the examination of all applications, whenever filed, and the reexamination of, or other proceedings to contest, all patents. Thus, the filing date of the application being examined is no longer relevant in determining what version of 35 U.S.C. 102(e) to apply in determining the patentability of that application, or the patent resulting from that application. The revised statutory provisions *>supersede< all previous versions of 35 U.S.C. 102(e) and 374, with only one exception, which is when the potential reference is based on an international application filed prior to November 29, 2000 (discussed further below). The provisions amending 35 U.S.C. 102(e) and 374 in Pub. L. 107-273 are completely retroactive to the effective date of the relevant provisions in the AIPA (November 29, 2000). Revised 35 U.S.C. 102(e) allows the use of certain international application publications and U.S. patent application publications, and certain U.S. patents as prior art under 35 U.S.C. 102(e) as of their respective U.S. filing dates, including certain international filing dates. The prior art date of a reference under 35 U.S.C. 102(e) may be the international filing date if the international filing date was on or after November 29, 2000, the international application designated the United States, and the international application was published by the World Intellectual Property Organization (WIPO) under the Patent Cooperation Treaty (PCT) Article 21(2) in the English language. See MPEP § 706.02(f)(1) for examination guidelines on the application of 35 U.S.C. 102(e).

35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless-

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(e) the invention was described in — (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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As mentioned above, references based on international applications that were filed prior to November 29, 2000 are subject to the former (pre-AIPA) version of 35 U.S.C. 102(e) as set forth below.

Former 35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless-

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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I. < STATUTORY INVENTION REGISTRATIONS (SIRs) ARE ELIGIBLE AS PRIOR ART UNDER 35 U.S.C. 102(e)

In accordance with 35 U.S.C. 157(c), a published SIR will be treated the same as a U.S. patent for all defensive purposes, usable as a reference as of its filing date in the same manner as a U.S. patent. A SIR is prior art under all applicable sections of 35 U.S.C. 102 including 35 U.S.C. 102(e). See MPEP § 1111.

>

II. < DEFENSIVE PUBLICATIONS ARE NOT PRIOR ART AS OF THEIR FILING DATE

The Defensive Publication Program, available between April 1968 and May 1985, provided for the voluntary publication of the abstract of the technical disclosure of a pending application under certain conditions. A defensive publication is not a patent or an application publication under 35 U.S.C. 122(b); it is a publication. Therefore, it is prior art only as of its publication date. *Ex parte Osmond*, 191 USPQ 334 (Bd. App. 1973). See MPEP § 711.06(a) for more information on Defensive Publications.

2136.01 Status of U.S. Application as a Reference [R-3]

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I. < WHEN THERE IS NO COMMON ASSIGNEE OR INVENTOR, A U.S. APPLICATION MUST ISSUE AS A PATENT OR BE PUBLISHED AS A SIR OR AS AN APPLICATION PUBLICATION BEFORE IT IS AVAILABLE AS PRIOR ART UNDER 35 U.S.C. 102(e)

In addition to U.S. patents and SIRs, certain U.S. application publications and certain international application publications are also available as prior art under 35 U.S.C. **102(e)** as of their effective U.S. filing dates (which will include certain international filing dates). See MPEP § **706.02(a)**.

>

II. < WHEN THERE IS A COMMON ASSIGNEE OR INVENTOR, A PROVISIONAL 35 U.S.C. 102(e) REJECTION OVER AN EARLIER FILED UNPUBLISHED APPLICATION CAN BE MADE

Based on the assumption that an application will ripen into a U.S. patent (or into an application publication), it is permissible to provisionally reject a later application over an earlier filed, and unpublished, application under 35 U.S.C. **102**(e) when there is a common assignee or inventor. *In re Irish* , 433 F.2d 1342, 167 USPQ 764 (CCPA 1970). In addition, a provisional 35 U.S.C. **102**(e) rejection may be made if the earlier filed copending U.S. application has been published as redacted (37 CFR **1.217**) and the subject matter relied upon in the rejection is not supported in the redacted publication of the patent application. Such a provisional rejection "serves to put applicant on notice at the earliest possible time of the possible prior art relationship between copending applications" and gives applicant the fullest opportunity to overcome the rejection by amendment or submission of evidence. In addition, since both applications are pending and usually have the same assignee, more options are available to applicant for overcoming the provisional rejection than if the other application were already issued. *Ex parte Bartfeld*, 16 USPQ2d 1714 (Bd. Pat. App. & Int. 1990) *aff'd on other grounds*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991). Note that provisional rejections over **35 U.S.C. 102(e)** are only authorized when there is a common inventor or assignee, otherwise the copending application prior to publication must remain confidential. MPEP § **706.02(f)(2)** and **§ 706.02(k)** discuss the procedures to be used in provisional rejections over **35 U.S.C. 102(e)** and 102(e)/**103**.

For applications filed on or after November 29, 1999>or pending on or after December 10, 2004<, a provisional rejection under 35 U.S.C. *__103__>(a) using prior art under 35 U.S.C. **102**(e)< is not proper if the application contains evidence that the application and the prior art reference were owned by the same person, or subject to an obligation of assignment to the same person, at the time the invention was made. The changes to 35 U.S.C. **102**(e) in the Intellectual Property and High Technology Technical Amendments Act of 2002 (Pub. L. 107-273, 116 Stat. 1758 (2002)) did not affect 35 U.S.C. **103**(c) as amended on November 29, 1999. See MPEP § **706.02(l)(1)** through § **706.02(l)(3)** for information relating to rejections under 35 U.S.C. *__103__ and evidence of common ownership.

>In addition, certain non-commonly owned references may be disqualified from being applied in a rejection under 35 U.S.C. **103**(a) due to the Cooperative Research and Technology Enhancement Act of 2004 (CREATE Act) (Public Law 108-453; 118 Stat. 3596 (2004)), which was enacted on December 10, 2004 and was effective for all patents granted on or after December 10, 2004. The CREATE Act amended 35 U.S.C. **103**(c) to provide that subject matter developed by another person shall be treated as owned by the same person or subject to an obligation of assignment to the same person for purposes of determining obviousness if certain conditions are met. 35 U.S.C. **103**(c), as amended by the CREATE Act, continues to apply only to subject matter which qualifies as prior art under 35 U.S.C. **102**(e), (f) or (g), and which is being relied upon in a rejection under 35 U.S.C. **103**. It does not apply to or affect subject matter which is applied in a rejection under 35 U.S.C. **102** or a double patenting rejection (see 37 CFR **1.78**(c) and MPEP § **804**). In addition, if the subject matter qualifies as prior art under any other subsection of 35 U.S.C. **102** (e.g., 35 U.S.C. **102**(a) or (b)) it will not be disqualified as prior art under 35 U.S.C. **103**(c). See also MPEP § **706.02(l)(1)** through § **706.02(l)(3)** for information relating to rejections under 35 U.S.C. **103** and evidence of joint research agreements.<

2136.02 Content of the Prior Art Available Against the Claims [R-3]

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I. < A 35 U.S.C. 102(e) REJECTION MAY RELY ON ANY PART OF THE PATENT OR APPLICATION PUBLICATION DISCLOSURE

Under **35 U.S.C. 102(e)**, the entire disclosure of a U.S. patent, a U.S. patent application publication, or an international application publication having an earlier effective U.S. filing date (which will include certain international filing dates) can be relied on to reject the claims. *Sun Studs, Inc. v. ATA Equip. Leasing, Inc.*, 872 F.2d 978, 983, 10 USPQ2d 1338, 1342 (Fed. Cir. 1989). See MPEP § **706.02(a).**

>

II. < REFERENCE MUST ITSELF CONTAIN THE SUBJECT MATTER RELIED ON IN THE REJECTION

When a U.S. patent, a U.S. patent application publication, or an international application publication is used to reject claims under **35 U.S.C. 102(e)**, the disclosure relied on in the rejection must be present in the issued patent or application publication. It is the earliest effective U.S. filing date (which will include certain international filing dates) of the U.S. patent or application publication being relied on as the critical reference date and subject matter not included in the patent or application publication itself can only be used when that subject matter becomes public. Portions of the patent application which were canceled are not part of the patent or application publication and thus cannot be relied on in a **35 U.S.C. 102(e)** rejection over the issued patent or application publication. *Ex parte Stalego*, 154 USPQ 52 (Bd. App. 1966). Likewise, subject matter which is disclosed in a parent application, but not included in the child continuation-in-part (CIP) cannot be relied on in a **35 U.S.C. 102(e)** rejection over the issued or published CIP. *In re Lund*, 376 F.2d 982, 153 USPQ 625 (CCPA 1967) (The examiner made a **35 U.S.C. 102(e)** rejection over an issued U.S. patent which was a continuation-in-part (CIP). The parent application of the U.S. patent reference contained an example II which was not carried over to the CIP. The court held that the subject matter embodied in the canceled example II could not be relied on as of either parent or child filing date. Thus, the use of example II subject matter to reject the claims under **35 U.S.C. 102(e)** was improper.).

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III. < THE SUPREME COURT HAS AUTHORIZED 35 U.S.C. 103 REJECTIONS BASED ON 35 U.S.C. 102(e)

U.S. patents may be used as of their filing dates to show that the claimed subject matter is anticipated or obvious. Obviousness can be shown by combining other prior art with the U.S. patent reference in a **35 U.S.C. 103** rejection. *Hazeltine Research v. Brenner*, 382 U.S. 252, 147 USPQ 429 (1965). Similarly, certain U.S. application publications and certain international application publications may also be used as of their earliest effective U.S. filing dates (which will include certain international filing dates) to show that the claimed subject matter would have been anticipated or obvious.

See MPEP § **706.02(l)(1) - § **706.02(l)(3)** for additional information on rejections under 35 U.S.C. *__103__ and evidence of common ownership >or a joint research agreement<.

2136.03 Critical Reference Date [R-6]

I. FOREIGN PRIORITY DATE

Reference's Foreign Priority Date Under 35 U.S.C. 119(a)-(d) and (f) Cannot Be Used as the 35 U.S.C. 102(e) Reference Date

35 U.S.C. 102(e) is explicitly limited to certain references "filed in the United States before the invention thereof by the applicant" (emphasis added). Foreign applications' filing dates that are claimed (via 35 U.S.C. **119**(a) – (d), (f) or **365**(a)) in applications, which have been published as U.S. or WIPO application publications or patented in the U.S., may not be used as 35 U.S.C. **102**(e) dates for prior art purposes. This includes international filing dates claimed as foreign priority dates under 35 U.S.C. **365**(a).Therefore, the foreign priority date of the reference under **35 U.S.C. 119(a)**-(d) (f), and **365(a)** cannot be used to antedate the application filing date. In contrast, applicant may be able to overcome the **35 U.S.C. 102(e)** rejection by proving he or she is entitled to his or her own **35 U.S.C. 119** priority date which is earlier than the reference's U.S. filing date. *In re Hilmer*, 359 F.2d 859, 149 USPQ 480 (CCPA 1966) (*Hilmer I*) (Applicant filed an application with a right of priority to a German application. The examiner rejected the claims over a U.S. patent to Habicht based on its Swiss priority date. The U.S. filing date of Habicht was later than the application's German priority date. The court held that the reference's Swiss priority date could not be relied on in a **35 U.S.C. 102(e)** rejection. Because the U.S. filing date of Habicht was later than the earliest effective filing date (German priority date) of the application, the rejection was reversed.). See **MPEP § 201.15** for information on procedures to be followed in considering applicant's right of priority.

Note that certain international application (PCT) filings are considered to be "filings in the United States" for purposes of applying an application publication as prior art. See **MPEP § 706.02(a)**.

II. INTERNATIONAL (PCT) APPLICATIONS; INTERNATIONAL APPLICATION PUBLICATIONS

If the potential reference resulted from, or claimed the benefit of, an international application, the following must be determined:

(A) If the international application meets the following three conditions:(1) an international filing date on or after November 29, 2000;

(2) designated the United States; and

(3) published under PCT Article 21(2) in English,

the international filing date is a U.S. filing date for prior art purposes under 35 U.S.C. 102(e). If such an international application properly claims benefit to an earlier-filed U.S. or international application, or priority to an earlier-filed U.S. provisional application, apply the reference under 35 U.S.C. 102(e) as of the earlier filing date, assuming all the conditions of 35 U.S.C. 102(e) and 35 U.S.C. 119(e), 120, or 365(c) are met. In addition, the subject matter relied upon in the rejection must be disclosed in the earlier-filed application in compliance with 35 U.S.C. 112, first paragraph, in order to give that subject matter the benefit of the earlier filing date under 35 U.S.C. 102(e). Note, where the earlier application is an international application, the earlier international application must satisfy the same three conditions (i.e., filed on or after November 29, 2000, designated the U.S., and had been published in English under PCT Article 21(2)) for the earlier international filing date to be a U.S. filing date for prior art purposes under 35 U.S.C.102(e).

(B) If the international application was filed on or after November 29, 2000, but did **not** designate the United States or was **not** published in English under PCT Article 21(2), do **not** treat the international filing date as a U.S. filing date. In this situation, do **not** apply the reference as of its international filing date, its date of completion of the 35 U.S.C. 371(c)(1), (2) and (4) requirements, or any earlier filing date to which such an international application claims benefit or priority. The reference may be applied under 35 U.S.C. 102(a) or (b) as of its publication date, or 35 U.S.C. 102(e) as of any later U.S. filing date of an application that properly claimed the benefit of the international application (if applicable).

(C) If the international application has an international filing date prior to November 29, 2000, apply the reference under the provisions of 35 U.S.C. 102 and 374, prior to the AIPA amendments:(1) For U.S. patents, apply the reference under 35 U.S.C. 102(e) as of the earlier of the date of completion of the requirements of 35 U.S.C. 371(c)(1), (2) and (4) or the filing date of the later-filed U.S. application that claimed the benefit of the international application;

(2) For U.S. application publications and WIPO publications directly resulting from international applications under PCT Article 21(2), never apply these references under 35 U.S.C. 102(e). These references may be applied as of their publication dates under 35 U.S.C. 102(a) or (b);

(3) For U.S. application publications of applications that claim the benefit under 35 U.S.C. 120 or 365(c) of an international application filed prior to November 29, 2000, apply the reference under 35 U.S.C. 102(e) as of the actual filing date of the later-filed U.S. application that claimed the benefit of the international application.

Examiners should be aware that although a publication of, or a U.S. patent issued from, an international application may not have a 35 U.S.C. 102(e) date at all, or may have a 35 U.S.C. 102(e) date that is after the effective filing date of the application being examined (so it is not "prior art"), the corresponding WIPO publication of an international application may have an earlier 35 U.S.C. 102(a) or (b) date.

III. PRIORITY FROM PROVISIONAL APPLICATION UNDER 35 U.S.C. 119(e)

The 35 U.S.C. 102(e) critical reference date of a U.S. patent or U.S. application publications and certain international application publications entitled to the benefit of the filing date of a provisional application under 35 U.S.C. 119(e) is the filing date of the provisional application with certain exceptions **if** the provisional application(s) properly supports the subject matter relied upon to make the rejection in compliance with 35 U.S.C. 112, first paragraph. See MPEP § 706.02(f)(1), examples 5 to 9. Note that international applications which (1) were filed prior to November 29, 2000, or (2) did not designate the U.S., or (3) were not published in English under PCT Article 21(2) by WIPO, may not be used to reach back (bridge) to an earlier filing date through a priority or benefit claim for prior art purposes under 35 U.S.C. 102(e).

IV. PARENT'S FILING DATE WHEN REFERENCE IS A CONTINUATION-IN-PART OF THE PARENT

Filing Date of U.S. Parent Application Can Only Be Used as the 35 U.S.C. 102(e) Date If It Supports the **>Subject Matter Relied Upon in the< Child

**>For prior art purposes, a U.S. patent or patent application publication that claims the benefit of an earlier filing date under 35 U.S.C. 120 of a prior nonprovisional application would be accorded the earlier filing date as its prior art date under 35 U.S.C. 102 (e), provided the earlier-filed application properly supports the subject matter relied upon in any rejection in compliance with 35 U.S.C. 112, first paragraph. In other words, the subject matter used in the rejection must be disclosed in the earlier-filed application in compliance with 35 U.S.C. 112, first paragraph, in order for that subject matter to be entitled to the earlier filing date under 35 U.S.C. 102(e).<

See also MPEP § 706.02(f)(1), examples 2 and 5 to 9.

V. DATE OF CONCEPTION OR REDUCTION TO PRACTICE

35 U.S.C. 102(e) Reference Date Is the Filing Date Not Date of Inventor's Conception or Reduction to Practice

If a reference available under **35 U.S.C. 102(e)** discloses, but does not claim the subject matter of the claims being examined or an obvious variant, the reference is not prior art under **35 U.S.C. 102(g)**. Furthermore, the reference does not qualify as "prior art" under 35 U.S.C. **102** as of a date earlier than its filing date based upon any prior inventive activity that is disclosed in the U.S. patent or U.S. patent application publication in the absence of evidence that the subject matter was actually reduced to practice in this country on an earlier date. See MPEP § **2138**. When the cases are not in interference, the effective date of the reference as prior art is its filing date in the United States (which will include certain international filing dates), as stated in **35 U.S.C. 102(e)**. See MPEP § **706.02(a)**. The date that the prior art subject matter was conceived or reduced to practice is of no importance when **35 U.S.C. 102(g)** is not at issue. *Sun Studs, Inc. v. ATA Equip. Leasing, Inc.*, 872 F.2d 978, 983, 10 USPQ2d 1338, 1342 (Fed. Cir. 1989) (The defendant sought to invalidate patents issued to Mason and Sohn assigned to Sun Studs. The earliest of these patents issued in June 1973. A U.S. patent to Mouat was found which issued in March 1976 and which disclosed the invention of Mason and Sohn. While the patent to Mouat issued after the Mason and Sohn patents, it was filed 7 months earlier than the earliest of the Mason and Sohn patents. Sun Studs submitted affidavits showing conception in 1969 and diligence to the constructive reduction to practice and therefore antedated the patent to Mouat. The defendant sought to show that Mouat conceived the invention in 1966. The court held that conception of the subject matter of the reference only becomes an issue when the claims of the conflicting patents cover inventions which are the same or obvious over one another. When **35 U.S.C. 102(e)** applies but not **35 U.S.C. 102(g)**, the filing date of the prior art patent is the earliest date that can be used to reject or invalidate claims.).

2136.04 Different Inventive Entity; Meaning of "By Another" [R-1]

IF THERE IS ANY DIFFERENCE IN THE INVENTIVE ENTITY, THE REFERENCE IS "BY ANOTHER"

"Another" means other than applicants, *In re Land*, 368 F.2d 866, 151 USPQ 621 (CCPA 1966), in other words, a different inventive entity. The inventive entity is different if not all inventors are the same. The fact that the application and reference have one or more inventors in common is immaterial. *Ex parte DesOrmeaux*, 25 USPQ2d 2040 (Bd. Pat. App. & Inter. 1992) (The examiner made a **35 U.S.C. 102(e)** rejection based on an issued U.S. patent to three inventors. The rejected application was a continuation-in-part of the issued parent with an extra inventor. The Board found that the patent was "by another" and thus could be used in a **35 U.S.C. 102(e)**/103 rejection of the application.).

A DIFFERENT INVENTIVE ENTITY IS PRIMA FACIE EVIDENCE THAT THE REFERENCE IS "BY ANOTHER"

As stated by the House and Senate reports on the bills enacting section **35 U.S.C. 102(e)** as part of the 1952 Patent Act, this subsection of 102 codifies the Milburn rule of *Milburn v. Davis-Bournonville*, 270 U.S. 390 (1926). The Milburn rule authorized the use of a U.S. patent containing a disclosure of the invention as a reference against a later filed application as of the U.S. patent filing date. The existence of an earlier filed U.S. application containing the subject matter claimed in the application being examined indicates that applicant was not the first inventor. Therefore, a U.S. patent, ** a U.S. patent application publication or international application publication, by a different inventive entity, whether or not the application shares some inventors in common with the patent, is *prima facie* evidence that the invention was made "by another" as set forth in *>**35 U.S.C. 102(e)**<. *In re Mathews*, 408 F.2d 1393, 161 USPQ 276 (CCPA 1969); *In re Facius*, 408 F.2d 1396, 161 USPQ 294 (CCPA 1969); *Ex parte DesOrmeaux*, 25 USPQ2d 2040 (Bd. Pat. App. & Inter. 1992). See MPEP >§ **706.02(b)** and< § **2136.05** for discussion of methods of overcoming >**35 U.S.C. 102(e)**< rejections.

2136.05 Overcoming a Rejection Under 35 U.S.C. 102(e) [R-1]

A 35 U.S.C. 102(e) REJECTION CAN BE OVERCOME BY ANTEDATING THE FILING DATE OR SHOWING THAT DISCLOSURE RELIED ON IS APPLICANT'S OWN WORK

When a prior U.S. patent, ** U.S. patent application publication>,< or international application publication* is not a statutory bar, a **35 U.S.C. 102(e)** rejection can be overcome by antedating the filing date (see **MPEP §**

2136.03 regarding critical reference date of 35 U.S.C. 102(e) prior art) of the reference by submitting an affidavit or declaration under 37 CFR 1.131 or by submitting an affidavit or declaration under 37 CFR 1.132 establishing that the relevant disclosure is applicant's own work. *In re Mathews*, 408 F.2d 1393, 161 USPQ 276 (CCPA 1969). The filing date can also be antedated by applicant's earlier foreign priority application or provisional application if 35 U.S.C. 119 is met and the foreign application or provisional application "supports" (conforms to 35 U.S.C. 112, first paragraph, requirements) all the claims of the U.S. application. *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). But a prior application which was not copending with the application at issue cannot be used to antedate a reference. *In re Costello*, 717 F.2d 1346, 219 USPQ 389 (Fed. Cir. 1983). A terminal disclaimer also does not overcome a 35 U.S.C. 102(e) rejection. See, e.g., *In re Bartfeld*, 925 F.2d 1415, 17 USPQ2d 1885 (Fed. Cir. 1991).

See MPEP § 706.02(b) for a list of methods which can be used to overcome rejections based on 35 U.S.C. 102(e) rejections. For information on the required contents of a 37 CFR 1.131 affidavit or declaration and the situations in which such affidavits and declarations are permitted see MPEP § 715. An affidavit or declaration is not appropriate if the reference describes applicant's own work. In this case, applicant must submit an affidavit or declaration under 37 CFR 1.132. See the next paragraph for more information concerning the requirements of 37 CFR 1.132 affidavits and declarations.

A 35 U.S.C. 102(e) REJECTION CAN BE OVERCOME BY SHOWING THE REFERENCE IS DESCRIBING APPLICANT'S OWN WORK

"The fact that an application has named a different inventive entity than a patent does not necessarily make that patent prior art." *Applied Materials Inc. v. Gemini Research Corp.*, 835 F.2d 279, 15 USPQ2d 1816 (Fed. Cir. 1988). The issue turns on what the evidence of record shows as to who invented the subject matter. *In re Whittle*, 454 F.2d 1193, 1195, 172 USPQ 535, 537 (CCPA 1972). In fact, even if applicant's work was publicly disclosed prior to his or her application, applicant's own work may not be used against him or her unless there is a time bar under 35 U.S.C. 102(b). *In re DeBaun*, 687 F.2d 459, 214 USPQ 933 (CCPA 1982) (citing *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982)). Therefore, when the unclaimed subject matter of a reference is applicant's own invention, applicant may overcome a *prima facie* case based on the patent, ** U.S. patent application publication>,< or international application publication, by showing that the disclosure is a description of applicant's own previous work. Such a showing can be made by proving that the patentee, or ** the inventor(s) of the U.S. patent application publication or the international application publication, was associated with applicant (e.g. worked for the same company) and learned of applicant's invention from applicant. *In re Mathews*, 408 F.2d 1393, 161 USPQ 276 (CCPA 1969). In the situation where one application is first filed by inventor X and then a later application is filed by X & Y, it must be proven that the joint invention was made first, was thereafter described in the sole applicant's patent, or ** was thereafter described in the sole applicant's U.S. patent application publication or international application publication, and then the joint application was filed. *In re Land*, 368 F.2d 866, 151 USPQ 621 (CCPA 1966).

In *In re Land*, separate U.S. patents to Rogers and to Land were used to reject a joint application to Rogers and Land under 35 U.S.C. 102(e)/103. The inventors worked for the same company (Polaroid) and in the same laboratory. All the patents flowed from the same research. In addition, the patent applications were prepared by the same attorneys, were interrelated and contained cross-references to each other. The court affirmed the rejection because (1) the inventive entities of the patents (one to Rogers and one to Land) were different from the inventive entity of the joint application (Rogers and Land) and (2) Land and Rogers brought their knowledge of their individual work with them when they made the joint invention. There was no indication that the portions of the references relied on disclosed anything they did jointly. Neither was there any showing that what they did jointly was done before the filing of the reference patent applications.

See also *In re Carreira* , 532 F.2d 1356, 189 USPQ 461 (CCPA 1976) (The examiner rejected claims to a joint application to Carreira, Kyrakakis, Solodar, and Labana under 35 U.S.C. 102(e) and 103 in view of a U.S. patent issued to Tulagin and Carreira or a patent issued to Clark. The applicants submitted declarations under 37 CFR 1.132 by Tulagin and Clark in which each declarant stated he was "not the inventor of the use of compounds having a hydroxyl group in a position ortho to an azo linkage." The court held that these statements were vague and inconclusive because the declarants did not disclose the use of this generic compound but rather species of this generic compound in their patents and it was the species which met the claims. The declaration that each did not invent the use of the generic compound does not establish that Tulagin and Clark did not invent the use of the species.)

MPEP § 715.01(a), § 715.01(c), and § 716.10 set forth more information pertaining to the contents and uses of affidavits and declarations under 37 CFR 1.132 for

antedating references. See MPEP § 706.02(l)(1) for information pertaining to rejections under 35 U.S.C. 102(e)/103 and the applicability of 35 U.S.C. 103(c).

APPLICANT NEED NOT SHOW DILIGENCE OR REDUCTION TO PRACTICE WHEN THE SUBJECT MATTER DISCLOSED IN THE REFERENCE IS APPLICANT'S OWN WORK

When the reference reflects applicant's own work, applicant need not prove diligence or reduction to practice to establish that he or she invented the subject matter disclosed in the reference. A showing that the reference disclosure arose from applicant's work coupled with a showing of conception by the applicant before the filing date of the reference will overcome the 35 U.S.C. 102(e) rejection. The showing can be made by submission of an affidavit by the inventor under 37 CFR 1.132. The other patentees need not submit an affidavit disclaiming inventorship, but, if submitted, a disclaimer by all other patentees should be considered by the examiner. *In re DeBaun* , 687 F.2d 459, 214 USPQ 933 (CCPA 1982) (Declaration submitted by DeBaun stated that he was the inventor of subject matter disclosed in the U.S. patent reference of DeBaun and Noll. Exhibits were attached to the declaration showing conception and included drawings DeBaun had prepared and given to counsel for purposes of preparing the application which issued as the reference patent. The court held that, even though the evidence was not sufficient to antedate the prior art patent under 37 CFR 1.131, diligence and/or reduction to practice was not required to show DeBaun invented the subject matter. Declarant's statement that he conceived the invention first was enough to overcome the 35 U.S.C. 102(e) rejection.).

CLAIMING OF INDIVIDUAL ELEMENTS OR SUBCOMBINATIONS IN A COMBINATION CLAIM OF THE REFERENCE DOES NOT ITSELF ESTABLISH THAT THE PATENTEE INVENTED THOSE ELEMENTS

The existence of combination claims in a reference is not evidence that the patentee invented the individual elements or subcombinations included if the elements and subcombinations are not separately claimed apart from the combination. *In re DeBaun*, 687 F.2d 459, 214 USPQ 933 (CCPA 1982) (citing *In re Facius*, 408 F.2d 1396, 1406, 161 USPQ 294, 301 (CCPA 1969)).

See also *In re Mathews* , 408 F.2d 1393, 161 USPQ 276 (CCPA 1969) (On September 15, 1961, Dewey filed an application disclosing and claiming a time delay protective device for an electric circuit. In disclosing the invention, Dewey completely described, but did not claim, a "gating means 19" invented by Mathews which was usable in the protective device. Dewey and Mathews were coworkers at General Electric Company, the assignee. Mathews filed his application on March 7, 1963, before the Dewey patent issued but almost 18 months after its filing. The Mathews application disclosed that "one illustration of a circuit embodying the present invention is shown in copending patent application S.N. 138,476-Dewey." The examiner used Dewey to reject all the Mathews claims under 35 U.S.C. 102(e). In response, Mathews submitted an affidavit by Dewey under 37 CFR 1.132. In the affidavit, Dewey stated that he did not invent the gating means 19 but had learned of the gating means through Mathews and that GE attorneys had advised that the gating means be disclosed in Dewey's application to comply with 35 U.S.C. 112, first paragraph. The examiner argued that the only way to overcome a 35 U.S.C. 102(e) rejection was by submitting an affidavit or declaration under 37 CFR 1.131 to antedate the filing date of the reference. The court reversed the rejection, holding that the totality of the evidence on record showed that Dewey derived his knowledge from Mathews who is "the original, first and sole inventor.").

2137 35 U.S.C. 102(f)

35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless -

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(f) he did not himself invent the subject matter sought to be patented.

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Where it can be shown that an applicant "derived" an invention from another, a rejection under 35 U.S.C. 102(f) is proper. *Ex parte Kusko*, 215 USPQ 972, 974 (Bd. App. 1981) ("most, if not all, determinations under section 102(f) involve the question of whether one party derived an invention from another").

While derivation will bar the issuance of a patent to the deriver, a disclosure by the deriver, absent a bar under 35 U.S.C. 102(b), will not bar the issuance of a patent to the party from which the subject matter was derived. *In re Costello* , 717 F.2d 1346, 1349, 219 USPQ 389, 390-91 (Fed. Cir. 1983) ("[a] prior art reference that is not a statutory bar may be overcome by two generally recognized methods": an affidavit under 37 CFR 1.131, or an affidavit under 37 CFR 1.132 "showing that the relevant disclosure is a description of the applicant's own work"); *In re Facius*, 408 F.2d 1396, 1407, 161 USPQ 294, 302 (CCPA 1969) (subject matter incorporated into

a patent that was brought to the attention of the patentee by applicant, and hence derived by the patentee from the applicant, is available for use against applicant unless applicant had actually invented the subject matter placed in the patent).

Where there is a published article identifying the authorship (**MPEP § 715.01(c)**) or a patent identifying the inventorship (**MPEP § 715.01(a)**) that discloses subject matter being claimed in an application undergoing examination, the designation of authorship or inventorship does not raise a presumption of inventorship with respect to the subject matter disclosed in the article or with respect to the subject matter disclosed but not claimed in the patent so as to justify a rejection under **35 U.S.C. 102(f)**. However, it is incumbent upon the inventors named in the application, in reply to an inquiry regarding the appropriate inventorship under subsection (f), or to rebut a rejection under **35 U.S.C. 102(a)** or (e), to provide a satisfactory showing by way of affidavit under **37 CFR 1.132** that the inventorship of the application is correct in that the reference discloses subject matter invented by the applicant rather than derived from the author or patentee notwithstanding the authorship of the article or the inventorship of the patent. *In re Katz*, 687 F.2d 450, 455, 215 USPQ 14, 18 (CCPA 1982) (inquiry is appropriate to clarify any ambiguity created by an article regarding inventorship, and it is then incumbent upon the applicant to provide "a satisfactory showing that would lead to a reasonable conclusion that [applicant] is the…inventor" of the subject matter disclosed in the article and claimed in the application).

DERIVATION REQUIRES COMPLETE CONCEPTION BY ANOTHER AND COMMUNICATION TO THE ALLEGED DERIVER

"The mere fact that a claim recites the use of various components, each of which can be argumentatively assumed to be old, does not provide a proper basis for a rejection under **35 U.S.C. 102(f)**." *Ex parte Billottet*, 192 USPQ 413, 415 (Bd. App. 1976). Derivation requires complete conception by another and communication of that conception by any means to the party charged with derivation prior to any date on which it can be shown that the one charged with derivation possessed knowledge of the invention. *Kilbey v. Thiele*, 199 USPQ 290, 294 (Bd. Pat. Inter. 1978).

See also *Price v. Symsek*, 988 F.2d 1187, 1190, 26 USPQ2d 1031, 1033 (Fed. Cir. 1993); *Hedgewick v. Akers*, 497 F.2d 905, 908, 182 USPQ 167, 169 (CCPA 1974). "Communication of a complete conception must be sufficient to enable one of ordinary skill in the art to construct and successfully operate the invention." *Hedgewick*, 497 F.2d at 908, 182 USPQ at 169. See also *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1577, 42 USPQ2d 1378, 1383 (Fed. Cir. 1997) (Issue in proving derivation is "whether the communication enabled one of ordinary skill in the art to make the patented invention.").

PARTY ALLEGING DERIVATION DOES NOT HAVE TO PROVE AN ACTUAL REDUCTION TO PRACTICE, DERIVATION OF PUBLIC KNOWLEDGE, OR DERIVATION IN THIS COUNTRY

The party alleging derivation "need not prove an actual reduction to practice in order to show derivation." *Scott v. Brandenburger*, 216 USPQ 326, 327 (Bd. App. 1982). Furthermore, the application of subsection (f) is not limited to public knowledge derived from another, and "the site of derivation need not be in this country to bar a deriver from patenting the subject matter." *Ex parte Andresen*, 212 USPQ 100, 102 (Bd. App. 1981).

DERIVATION DISTINGUISHED FROM PRIORITY OF INVENTION

Although derivation and priority of invention both focus on inventorship, derivation addresses originality (i.e., who invented the subject matter), whereas priority focuses on which party first invented the subject matter. *Price v. Symsek*, 988 F.2d 1187, 1190, 26 USPQ2d 1031, 1033 (Fed. Cir. 1993).

35 U.S.C. 102(f) MAY APPLY WHERE 35 U.S.C. 102(a) AND 35 U.S.C. 102(e) ARE NOT AVAILABLE STATUTORY GROUNDS FOR REJECTION

35 U.S.C. 102(f) does not require an inquiry into the relative dates of a reference and the application, and therefore may be applicable where subsections (a) and (e) are not available for references having an effective date subsequent to the effective date of the application being examined. However for a reference having a date later than the date of the application some evidence may exist that the subject matter of the reference was derived from the applicant in view of the relative dates. *Ex parte Kusko*, 215 USPQ 972, 974 (Bd. App. 1981) (The relative dates of the events are important in determining derivation; a publication dated more than a year after applicant's filing date that merely lists as literary coauthors individuals other than applicant is not the strong

evidence needed to rebut a declaration by the applicant that he is the sole inventor.).

2137.01 Inventorship [R-3]

The requirement that the applicant for a patent be the inventor is a characteristic of U.S. patent law not generally shared by other countries. Consequently, foreign applicants may misunderstand U.S. law regarding naming of the actual inventors causing an error in the inventorship of a U.S. application that may claim priority to a previous foreign application under **35 U.S.C. 119**. A request under **37 CFR 1.48(a)** is required to correct any error in naming the inventors in the U.S. application as filed. **MPEP § 201.03**. Foreign applicants may need to be reminded of the requirement for identity of inventorship between a U.S. application and a **35 U.S.C. 119** priority application. **MPEP § 201.13**.

If a determination is made that the inventive entity named in a U.S. application is not correct, such as when a request under **37 CFR 1.48(a)** is not granted or is not entered for technical reasons, but the admission therein regarding the error in inventorship is uncontroverted, a rejection under **35 U.S.C. 102(f)** should be made.

I. EXECUTORS OF OATH OR DECLARATION UNDER 37 CFR 1.63 ARE PRESUMED TO BE THE INVENTORS

The party or parties executing an oath or declaration under **37 CFR 1.63** are presumed to be the inventors. *Driscoll v. Cebalo*, 5 USPQ2d 1477, 1481 (Bd. Pat. Inter. 1982); *In re DeBaun*, 687 F.2d 459, 463, 214 USPQ 933, 936 (CCPA 1982) (The inventor of an element, *per se*, and the inventor of that element as used in a combination may differ. "The existence of combination claims does not evidence inventorship by the patentee of the individual elements or subcombinations thereof if the latter are not separately claimed apart from the combination." (quoting *In re Facius*, 408 F.2d 1396, 1406, 161 USPQ 294, 301 (CCPA 1969) (emphasis in original)); *Brader v. Schaeffer*, 193 USPQ 627, 631 (Bd. Pat. Inter. 1976) (in regard to an inventorship correction: "[a]s between inventors their word is normally taken as to who are the actual inventors" when there is no disagreement).

II. AN INVENTOR MUST CONTRIBUTE TO THE CONCEPTION OF THE INVENTION

The definition for inventorship can be simply stated: "The threshold question in determining inventorship is who conceived the invention. Unless a person contributes to the conception of the invention, he is not an inventor. … Insofar as defining an inventor is concerned, reduction to practice, *per se*, is irrelevant [except for simultaneous conception and reduction to practice, *Fiers v. Revel*, 984 F.2d 1164, 1168, 25 USPQ2d 1601, 1604-05 (Fed. Cir. 1993)]. One must contribute to the conception to be an inventor." *In re Hardee*, 223 USPQ 1122, 1123 (Comm'r Pat. 1984). See also *Board of Education ex rel. Board of Trustees of Florida State Univ. v. American Bioscience Inc.*, 333 F.3d 1330, 1340, 67 USPQ2d 1252, 1259 (Fed. Cir. 2003) ("Invention requires conception." With regard to the inventorship of chemical compounds, an inventor must have a conception of the specific compounds being claimed. "[G]eneral knowledge regarding the anticipated biological properties of groups of complex chemical compounds is insufficient to confer inventorship status with respect to specifically claimed compounds."); *Ex parte Smernoff*, 215 USPQ 545, 547 (Bd. App. 1982) ("one who suggests an idea of a result to be accomplished, rather than the means of accomplishing it, is not an coinventor"). See **MPEP § 2138.04** - **§ 2138.05** for a discussion of what evidence is required to establish conception or reduction to practice.

III. AS LONG AS THE INVENTOR MAINTAINS INTELLECTUAL DOMINATION OVER MAKING THE INVENTION, IDEAS, SUGGESTIONS, AND MATERIALS MAY BE ADOPTED FROM OTHERS

"In arriving at … conception [the inventor] may consider and adopt ideas and materials derived from many sources … [such as] a suggestion from an employee, or hired consultant … so long as he maintains intellectual domination of the work of making the invention down to the successful testing, selecting or rejecting as he goes…even if such suggestion [or material] proves to be the key that unlocks his problem." *Morse v. Porter*, 155 USPQ 280, 283 (Bd. Pat. Inter. 1965). See also *New England Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 883, 23 USPQ2d 1622, 1626 (Fed. Cir. 1992) (Adoption of the ideas and materials from another can become a derivation.).

IV. THE INVENTOR IS NOT REQUIRED TO REDUCE THE INVENTION TO PRACTICE

Difficulties arise in separating members of a team effort, where each member of the team has contributed something, into those members that actually contributed to the conception of the invention, such as the physical structure or operative steps, from those members that merely acted under the direction and supervision of the conceivers. *Fritsch v. Lin*, 21 USPQ2d 1737, 1739 (Bd. Pat. App. & Inter. 1991) (The inventor "took no part in developing the procedures…for expressing the EPO gene in mammalian host cells and isolating the resulting EPO

product." However, "it is not essential for the inventor to be personally involved in carrying out process steps…where implementation of those steps does not require the exercise of inventive skill."); *In re DeBaun*, 687 F.2d 459, 463, 214 USPQ 933, 936 (CCPA 1982) ("there is no requirement that the inventor be the one to reduce the invention to practice so long as the reduction to practice was done on his behalf").

See also *Mattor v. Coolegem*, 530 F.2d 1391, 1395, 189 USPQ 201, 204 (CCPA 1976) (one following oral instructions is viewed as merely a technician); *Tucker v. Naito*, 188 USPQ 260, 263 (Bd. Pat. Inter. 1975) (inventors need not "personally construct and test their invention"); *Davis v. Carrier*, 81 F.2d 250, 252, 28 USPQ 227, 229 (CCPA 1936) (noninventor's work was merely that of a skilled mechanic carrying out the details of a plan devised by another).

V. REQUIREMENTS FOR JOINT INVENTORSHIP

The inventive entity for a particular application is based on some contribution to at least one of the claims made by each of the named inventors. "Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent." **35 U.S.C. 116**. "[T]he statute neither states nor implies that two inventors can be 'joint inventors' if they have had no contact whatsoever and are completely unaware of each other's work." What is required is some "quantum of collaboration or connection." In other words, "[f]or persons to be joint inventors under Section **116**, there must be some element of joint behavior, such as collaboration or working under common direction, one inventor seeing a relevant report and building upon it or hearing another's suggestion at a meeting." *Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co.*, 973 F.2d 911, 916-17, 23 USPQ2d 1921, 1925-26 (Fed. Cir. 1992); *Moler v. Purdy*, 131 USPQ 276, 279 (Bd. Pat. Inter. 1960) ("it is not necessary that the inventive concept come to both [joint inventors] at the same time").

Each joint inventor must generally contribute to the conception of the invention. A coinventor need not make a contribution to every claim of a patent. A contribution to one claim is enough. "The contributor of any disclosed means of a means-plus-function claim element is a joint inventor as to that claim, unless one asserting sole inventorship can show that the contribution of that means was simply a reduction to practice of the sole inventor's broader concept." *Ethicon Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1460-63, 45 USPQ2d 1545, 1548-1551 (Fed. Cir. 1998) (The electronics technician who contributed to one of the two alternative structures in the specification to define "the means for detaining" in a claim limitation was held to be a joint inventor.).

VI. INVENTORSHIP IS GENERALLY "TO ANOTHER" WHERE THERE ARE DIFFERENT INVENTIVE ENTITIES WITH AT LEAST ONE INVENTOR IN COMMON

"[A] joint application or patent and a sole application or patent by one of the joint inventors are [by] different legal entities and accordingly, the issuance of the earlier filed application as a patent becomes a reference for everything it discloses" (*Ex parte Utschig*, 156 USPQ 156, 157 (Bd. App. 1966)) except where:

(A) the claimed invention in a later filed application is entitled to the benefit of an earlier filed application under **35 U.S.C. 120** (an overlap of inventors rather than an identical inventive entity is permissible). In this situation, a rejection under **35 U.S.C. 102(e)** is precluded. See *Applied Materials Inc. v. Gemini Research Corp.*, 835 F.2d 279, 281, 15 USPQ2d 1816, 1818 (Fed. Cir. 1988) ("The fact that an application has named a different inventive entity than a patent does not necessarily make that patent prior art."); and

(B) the subject matter developed by another person and the claimed subject matter were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person >or involved in a joint research agreement which meets the requirements of 35 U.S.C. **103**(c)(2) and (c)(3)<. In this situation, a rejection under **35 U.S.C. 102(f)**/103 or 102(g)/103, or **102(e)**/**103** for applications filed on or after November 29, 1999 >or pending on or after December 10, 2004<, is precluded by 35 U.S.C. **103**(c) >once the required evidence has been made of record in the application<. See MPEP § **706.02(l)** and § **706.02(l)(1)**.

For case law relating to inventorship by "another" involving different inventive entities with at least one inventor in common see *Ex parte DesOrmeaux*, 25 USPQ2d 2040 (Bd. Pat. App. & Inter. 1992) (the presence of a common inventor in a reference patent and a pending application does not preclude the determination that the reference inventive entity is to "another" within the meaning of **35 U.S.C. 102(e)**) and the discussion of prior art available under **35 U.S.C. 102(e)** in **MPEP § 2136.04**.

2137.02 Applicability of 35 U.S.C. 103(c) [R-3]

35 U.S.C. 103(c) states that subsection (f) of **35 U.S.C. 102** will not preclude patentability where subject matter

developed by another person, that would otherwise qualify under 35 U.S.C. 102(f), and the claimed invention of an application under examination were owned by the same person*>,< subject to an obligation of assignment to the same person>, or involved in a joint research agreement, which meets the requirements of 35 U.S.C. 103(c)(2) and (c)(3),< at the time the invention was made. See MPEP § 706.02(l) and § 2146.

2138 35 U.S.C. 102(g) [R-3]

35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless -

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(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. 102(g) issues such as conception, reduction to practice and diligence, while more commonly applied to interference matters, also arise in other contexts.

35 U.S.C. 102(g) may form the basis for an *ex parte* rejection if: (1) the subject matter at issue has been actually reduced to practice by another before the applicant's invention; and (2) there has been no abandonment, suppression or concealment. See, e.g., *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1205, 18 USPQ2d 1016, 1020 (Fed. Cir. 1991); *New Idea Farm Equipment Corp. v. Sperry Corp.*, 916 F.2d 1561, 1566, 16 USPQ2d 1424, 1428 (Fed. Cir. 1990); *E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1434, 7 USPQ2d 1129, 1132 (Fed. Cir. 1988); *Kimberly-Clark v. Johnson & Johnson*, 745 F.2d 1437, 1444-46, 223 USPQ 603, 606-08 (Fed. Cir. 1984). To qualify as prior art under 35 U.S.C. 102(g), however, there must be evidence that the subject matter was actually reduced to practice, in that conception alone is not sufficient. See *Kimberly-Clark*, 745 F.2d at 1445, 223 USPQ at 607. While the filing of an application for patent is a constructive reduction to practice, the filing of an application does not in itself provide the evidence necessary to show an actual reduction to practice of any of the subject matter disclosed in the application as is necessary to provide the basis for an *ex parte* rejection under 35 U.S.C. 102(g). Thus, absent evidence showing an actual reduction to practice (which is generally not available during *ex parte* examination), the disclosure of a United States patent application publication or patent falls under 35 U.S.C. 102(e) and not under 35 U.S.C. 102(g). *Cf. In re Zletz*, 893 F.2d 319, 323, 13 USPQ2d 1320, 1323 (Fed. Cir. 1990) (the disclosure in a reference United States patent does not fall under 35 U.S.C. 102(g) but under 35 U.S.C. 102(e)).

In addition, subject matter qualifying as prior art only under 35 U.S.C. 102(g) may also be the basis for an *ex parte* rejection under 35 U.S.C. 103. See *In re Bass* , 474 F.2d 1276, 1283, 177 USPQ 178, 183 (CCPA 1973) (in an unsuccessful attempt to utilize a 37 CFR 1.131 affidavit relating to a combination application, applicants admitted that the subcombination screen of a copending application which issued as a patent was earlier conceived than the combination). 35 U.S.C. 103(c), however, states that subsection (g) of 35 U.S.C. 102 will not preclude patentability where subject matter developed by another person, that would otherwise qualify under 35 U.S.C. 102(g), and the claimed invention of an application under examination were owned by the same person*>,< subject to an obligation of assignment to the same person>, or involved in a joint research agreement, which meets the requirements of 35 U.S.C. 103(c)(2) and (c)(3),< at the time the invention was made. See MPEP § 706.02(l) and § 2146.

For additional examples of 35 U.S.C. 102(g) issues such as conception, reduction to practice and diligence outside the context of interference matters, see *In re Costello*, 717 F.2d 1346, 219 USPQ 389 (Fed. Cir. 1983) (discussing the concepts of conception and constructive reduction to practice in the context of a declaration under 37 CFR 1.131), and *Kawai v. Metlesics*, 480 F.2d 880, 178 USPQ 158 (CCPA 1973) (holding constructive reduction to practice for priority under 35 U.S.C. 119 requires meeting the requirements of 35 U.S.C. 101 and 35 U.S.C. 112).

2138.01 Interference Practice [R-3]

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I. < 35 U.S.C. 102(g) IS THE BASIS OF INTERFERENCE PRACTICE

Subsection (g) of 35 U.S.C. 102 is the basis of interference practice for determining priority of invention

between two parties. See *Bigham v. Godtfredsen*, 857 F.2d 1415, 1416, 8 USPQ2d 1266, 1267 (Fed. Cir. 1988), **35 U.S.C. 135**, 37 CFR *>Part 41, Subparts D and E< and MPEP **Chapter 2300**. An interference is an *inter partes* proceeding directed at determining the first to invent as among the parties to the proceeding, involving two or more pending applications naming different inventors or one or more pending applications and one or more unexpired patents naming different inventors**. The United States is unusual in having a first to invent rather than a first to file system. *Paulik v. Rizkalla*, 760 F.2d 1270, 1272, 226 USPQ 224, 225 (Fed. Cir. 1985) (reviews the legislative history of the subsection in a concurring opinion by Judge Rich). The first of many to reduce an invention to practice around the same time will be the sole party to obtain a patent, *Radio Corp. of America v. Radio Eng'g Labs., Inc.*, 293 U.S. 1, 2, 21 USPQ 353, 353-4 (1934), unless another was the first to conceive and couple a later-in-time reduction to practice with diligence from a time just prior to when the second conceiver entered the field to the first conceiver's reduction to practice. *Hull v. Davenport*, 90 F.2d 103, 105, 33 USPQ 506, 508 (CCPA 1937). See the priority time charts below illustrating this point. Upon conclusion of an interference, subject matter claimed by the losing party that was the basis of the interference is rejected under **35 U.S.C. 102(g)**, unless the acts showing prior invention were not in this country.

It is noted that **35 U.S.C. 101** requires that whoever invents or discovers is the party who may obtain a patent for the particular invention or discovery. **35 U.S.C. 111** (applicant) or **35 U.S.C. 116** (applicants) set forth the requirement that the actual inventor(s) be the party who applies for a patent or that a patent be applied for on behalf of the inventor. Where it can be shown that an applicant has "derived" an invention from another, a rejection under **35 U.S.C. 102(f)** is proper. *Ex parte Kusko*, 215 USPQ 972, 974 (Bd. App. 1981) ("most, if not all, determinations under Section **102(f)** involve the question of whether one party derived an invention from another"); *Price v. Symsek*, 988 F.2d 1187, 1190, 26 USPQ2d 1031, 1033 (Fed. Cir. 1993) (Although derivation and priority of invention both focus on inventorship, derivation addresses originality, i.e., who invented the subject matter, whereas priority focuses on which party invented the subject matter first.).

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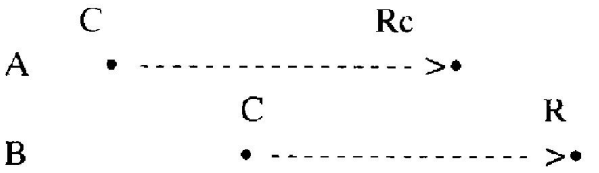
II. < PRIORITY TIME CHARTS

The following priority time charts illustrate the award of invention priority in several situations. The time charts apply to interference proceedings and are also applicable to declarations or affidavits filed under **37 CFR 1.131** to antedate references which are available as prior art under **35 U.S.C. 102(a)** or **102(e)**. Note, however, in the context of **37 CFR 1.131**, an applicant does not have to show that the invention was not abandoned, suppressed, or concealed from the time of an actual reduction to practice to a constructive reduction to practice because the length of time taken to file a patent application after an actual reduction to practice is generally of no consequence except in an interference proceeding. *Paulik v. Rizkalla*, 760 F.2d 1270, 226 USPQ 224 (Fed. Cir. 1985). See the discussion of abandonment, suppression, and concealment in **MPEP § 2138.03**.

For purposes of analysis under **37 CFR 1.131**, the conception and reduction to practice of the reference to be antedated are both considered to be on the effective filing date of domestic patent or foreign patent or the date of printed publication.

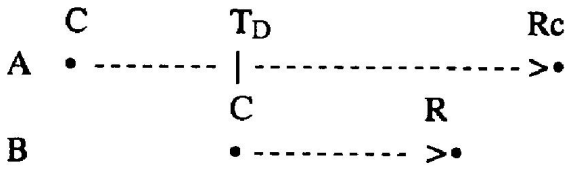
In the charts, C = conception, R = reduction to practice (either actual or constructive), Ra = actual reduction to practice, Rc = constructive reduction to practice, and T_D = commencement of diligence.

Example 1



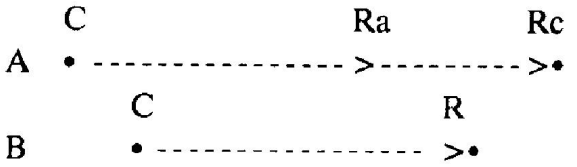
A is awarded priority in an interference, or antedates B as a reference in the context of a declaration or affidavit filed under **37 CFR 1.131**, because A conceived the invention before B and constructively reduced the invention to practice before B reduced the invention to practice. The same result would be reached if the conception date was the same for both inventors A and B.

Example 2



A is awarded priority in an interference, or antedates B as a reference in the context of a declaration or affidavit filed under 37 CFR 1.131, if A can show reasonable diligence from T_D (a point just prior to B's conception) until Rc because A conceived the invention before B, and diligently constructively reduced the invention to practice even though this was after B reduced the invention to practice.

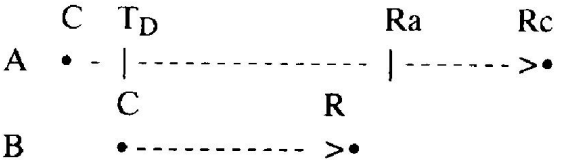
Example 3



A is awarded priority in an interference in the absence of abandonment, suppression, or concealment from Ra to Rc, because A conceived the invention before B, actually reduced the invention to practice before B reduced the invention to practice, and did not abandon, suppress, or conceal the invention after actually reducing the invention to practice and before constructively reducing the invention to practice.

A antedates B as a reference in the context of a declaration or affidavit filed under 37 CFR 1.131 because A conceived the invention before B and actually reduced the invention to practice before B reduced the invention to practice.

Example 4



A is awarded priority in an interference if A can show reasonable diligence from T_D (a point just prior to B's conception) until Ra in the absence of abandonment, suppression, or concealment from Ra to Rc, because A conceived the invention before B, diligently actually reduced the invention to practice (after B reduced the invention to practice), and did not abandon, suppress, or conceal the invention after actually reducing the invention to practice and before constructively reducing the invention to practice.

A antedates B as a reference in the context of a declaration or affidavit filed under 37 CFR 1.131 because A conceived the invention before B, and diligently actually reduced the invention to practice, even though this was after B reduced the invention to practice.

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III. < 37 CFR 1.131 DOES NOT APPLY IN INTERFERENCE PROCEEDINGS

Interference practice operates to the exclusion of *ex parte* practice under 37 CFR 1.131 which permits an applicant to show an actual date of invention prior to the effective date of a patent or literature reference applied under 35 U.S.C. 102(a) or (e), as long as the patent is not a domestic patent claiming the same patentable invention. *Ex parte Standish* , 10 USPQ2d 1454, 1457 (Bd. Pat. App. & Inter. 1988) (An application claim to the "same patentable invention" claimed in a domestic patent requires interference rather than an affidavit under 37 CFR 1.131 to antedate the patent. The term "same patentable invention" encompasses a claim that is either anticipated by or obvious in view of the subject matter recited in the patent claim.). Subject matter which is available as prior art only under 35 U.S.C. 102(g) is by definition made before the applicant made his invention and is therefore not open to further inquiry under 37 CFR 1.131.

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IV. < LOST COUNTS IN AN INTERFERENCE ARE NOT, PER SE, STATUTORY PRIOR ART

Loss of an interference count alone does not make its subject matter statutory prior art to losing party; however, lost count subject matter that is available as prior art under **35 U.S.C. 102** may be used alone or in combination with other references under **35 U.S.C. 103**. But see *In re Deckler*, 977 F.2d 1449, 24 USPQ2d 1448 (Fed. Cir. 1992) (Under the principles of *res judicata* and *collateral estoppel*, Deckler was not entitled to claims that were patentably indistinguishable from the claim lost in interference even though the subject matter of the lost count was not available for use in an obviousness rejection under **35 U.S.C. 103**.).

2138.02 "The Invention Was Made in This Country"

An invention is made when there is a conception and a reduction to practice. *Dunn v. Ragin*, 50 USPQ 472, 474 (Bd. Pat. Inter. 1941). Prior art under **35 U.S.C. 102(g)** is limited to an invention that is made. *In re Katz*, 687 F.2d 450, 454, 215 USPQ 14, 17 (CCPA 1982) (the publication of an article, alone, is not deemed a constructive reduction to practice, and therefore its disclosure does not prove that any invention within the meaning of **35 U.S.C. 102(g)** has ever been made).

Subject matter under **35 U.S.C. 102(g)** is available only if made in this country. **35 U.S.C. 104**. *Kondo v. Martel*, 220 USPQ 47 (Bd. Pat. Inter. 1983) (acts of conception, reduction to practice and diligence must be demonstrated in this country). Compare *Colbert v. Lofdahl*, 21 USPQ2d 1068, 1071 (Bd. Pat. App. & Inter. 1991) ("[i]f the invention is reduced to practice in a foreign country and knowledge of the invention was brought into this country and disclosed to others, the inventor can derive no benefit from the work done abroad and such knowledge is merely evidence of conception of the invention").

In accordance with 35 U.S.C. **102**(g)(1), a party involved in an interference proceeding under 35 U.S.C. **135** or **291** may establish a date of invention under 35 U.S.C. **104**. **35 U.S.C. 104**, as amended by GATT (Public Law 103-465, 108 Stat. 4809 (1994)) and NAFTA (Public Law 103-182, 107 Stat. 2057 (1993)), provides that an applicant can establish a date of invention in a NAFTA member country on or after December 8, 1993 or in WTO member country other than a NAFTA member country on or after January 1, 1996. Accordingly, an interference count may be won or lost on the basis of establishment of invention by one of the parties in a NAFTA or WTO member country, thereby rendering the subject matter of that count unpatentable to the other party under the principles of *res judicata* and *collateral estoppel*, even though such subject matter is not available as statutory prior art under **35 U.S.C. 102(g)**. See **MPEP § 2138.01** regarding lost interference counts which are not statutory prior art.

2138.03 "By Another Who Has Not Abandoned, Suppressed, or Concealed It"

35 U.S.C. 102(g) generally makes available as prior art within the meaning of **35 U.S.C. 103**, the prior invention of another who has not abandoned, suppressed or concealed it. *In re Bass*, 474 F.2d 1276, 177 USPQ 178 (CCPA 1973); *In re Suska*, 589 F.2d 527, 200 USPQ 497 (CCPA 1979) (The result of applying the suppression and concealment doctrine is that the inventor who did not conceal (but was the *de facto* last inventor) is treated legally as the first to invent, while the *de facto* first inventor who suppressed or concealed is treated as a later inventor. The *de facto* first inventor, by his suppression and concealment, lost the right to rely on his actual date of invention not only for priority purposes, but also for purposes of avoiding the invention of the counts as prior art.).

"The courts have consistently held that an invention, though completed, is deemed abandoned, suppressed, or concealed if, within a reasonable time after completion, no steps are taken to make the invention publicly known. Thus failure to file a patent application; to describe the invention in a publicly disseminated document; or to use the invention publicly, have been held to constitute abandonment, suppression, or concealment." *Correge v. Murphy*, 705 F.2d 1326, 1330, 217 USPQ 753, 756 (Fed. Cir. 1983) (quoting *International Glass Co. v. United States*, 408 F.2d 395, 403, 159 USPQ 434, 441 (Ct. Cl. 1968)). In *Correge*, an invention was actually reduced to practice, 7 months later there was a public disclosure of the invention, and 8 months thereafter a patent application was filed. The court held filing a patent application within 1 year of a public disclosure is not an unreasonable delay, therefore reasonable diligence must only be shown between the date of the actual reduction to practice and the public disclosure to avoid the inference of abandonment.

DURING AN INTERFERENCE PROCEEDING, AN INFERENCE OF SUPPRESSION OR CONCEALMENT MAY ARISE FROM DELAY IN FILING PATENT APPLICATION

Once an invention is actually reduced to practice an inventor need not rush to file a patent application. *Shindelar v. Holdeman*, 628 F.2d 1337, 1341, 207 USPQ

112, 116 (CCPA 1980). The length of time taken to file a patent application after an actual reduction to practice is generally of no consequence except in an interference proceeding. *Paulik v. Rizkalla*, 760 F.2d 1270, 1271, 226 USPQ 225, 226 (Fed. Cir. 1985) (suppression or concealment may be deliberate or may arise due to an inference from a "too long" delay in filing a patent application). *Peeler v. Miller*, 535 F.2d 647, 656, 190 USPQ 117,124 (CCPA 1976) ("mere delay, without more, is not sufficient to establish suppression or concealment." "What we are deciding here is that Monsanto's delay is not 'merely delay' and that Monsanto's justification for the delay is inadequate to overcome the inference of suppression created by the excessive delay." The word "mere" does not imply a total absence of a limit on the duration of delay. Whether any delay is "mere" is decided only on a case-by-case basis.).

Where a junior party in an interference relies upon an actual reduction to practice to demonstrate first inventorship, and where the hiatus in time between the date for the junior party's asserted reduction to practice and the filing of its application is unreasonably long, the hiatus may give rise to an inference that the junior party in fact suppressed or concealed the invention and the junior party will not be allowed to rely upon the earlier actual reduction to practice. *Young v. Dworkin*, 489 F.2d 1277, 1280 n.3, 180 USPQ 388, 391 n.3 (CCPA 1974) (suppression and concealment issues are to be addressed on a case-by-case basis).

SUPPRESSION OR CONCEALMENT NEED NOT BE ATTRIBUTED TO INVENTOR

Suppression or concealment need not be attributed to the inventor. *Peeler v. Miller*, 535 F.2d 647, 653-54, 190 USPQ 117, 122 (CCPA 1976) ("four year delay from the time an inventor … completes his work … and the time his assignee-employer files a patent application is, *prima facie*, unreasonably long in an interference with a party who filed first"); *Shindelar v. Holdeman*, 628 F.2d 1337, 1341-42, 207 USPQ 112, 116-17 (CCPA 1980) (A patent attorney's workload will not preclude a holding of an unreasonable delay—a total of 3 months was identified as possible of excuse in regard to the filing of an application.).

INFERENCE OF SUPPRESSION OR CONCEALMENT IS REBUTTABLE

Notwithstanding a finding of suppression or concealment, a constructive reduction to practice such as renewed activity just prior to other party's entry into field coupled with the diligent filing of an application would still cause the junior party to prevail. *Lutzker v. Plet*, 843 F.2d 1364, 1367-69, 6 USPQ2d 1370, 1371-72 (Fed. Cir. 1988) (activities directed towards commercialization not sufficient to rebut inference); *Holmwood v. Cherpeck*, 2 USPQ2d 1942, 1945 (Bd. Pat. App. & Inter. 1986) (the inference of suppression or concealment may be rebutted by showing activity directed to perfecting the invention, preparing the application, or preparing other compounds within the scope of the generic invention); *Engelhardt v. Judd*, 369 F.2d 408, 411, 151 USPQ 732, 735 (CCPA 1966) ("We recognize that an inventor of a new series of compounds should not be forced to file applications piecemeal on each new member as it is synthesized, identified and tested for utility. A reasonable amount of time should be allowed for completion of the research project on the whole series of new compounds, and a further reasonable time period should then be allowed for drafting and filing the patent application(s) thereon."); *Bogoslowsky v. Huse*, 142 F.2d 75, 77, 61 USPQ 349, 351 (CCPA 1944) (The doctrine of suppression and concealment is not applicable to conception without an actual reduction to practice.).

ABANDONMENT

A finding of suppression or concealment may not amount to a finding of abandonment wherein a right to a patent is lost. *Steierman v. Connelly*, 197 USPQ 288, 289 (Comm'r Pat. 1976); *Correge v. Murphy*, 705 F.2d 1326, 1329, 217 USPQ 753, 755 (Fed. Cir. 1983) (an invention cannot be abandoned until it is first reduced to practice).

2138.04 "Conception" [R-5]

Conception has been defined as "the complete performance of the mental part of the inventive act" and it is "the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice…." *Townsend v. Smith*, 36 F.2d 292, 295, 4 USPQ 269, 271 (CCPA 1930). "[C]onception is established when the invention is made sufficiently clear to enable one skilled in the art to reduce it to practice without the exercise of extensive experimentation or the exercise of inventive skill." *Hiatt v. Ziegler*, 179 USPQ 757, 763 (Bd. Pat. Inter. 1973). Conception has also been defined as a disclosure of an invention which enables one skilled in the art to reduce the invention to a practical form without "exercise of the inventive faculty." *Gunter v. Stream*, 573 F.2d 77, 197 USPQ 482 (CCPA 1978). See also *Coleman v. Dines*, 754 F.2d 353, 224 USPQ 857 (Fed. Cir. 1985) (It is settled that in establishing conception a party must show possession of every feature recited in the count, and that every limitation of the count must have been known to the inventor at the time of the alleged

conception. Conception must be proved by corroborating evidence.); *Hybritech Inc. v. Monoclonal Antibodies Inc.*, 802 F. 2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986) (Conception is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.") *; Hitzeman v. Rutter*, 243 F.3d 1345, 58 USPQ2d 1161 (Fed. Cir. 2001) (Inventor's "hope" that a genetically altered yeast would produce antigen particles having the particle size and sedimentation rates recited in the claims did not establish conception, since the inventor did not show that he had a "definite and permanent understanding" as to whether or how, or a reasonable expectation that, the yeast would produce the recited antigen particles.).

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I. < CONCEPTION MUST BE DONE IN THE MIND OF THE INVENTOR

The inventor must form a definite and permanent idea of the complete and operable invention to establish conception. *Bosies v. Benedict*, 27 F.3d 539, 543, 30 USPQ2d 1862, 1865 (Fed. Cir. 1994) (Testimony by a noninventor as to the meaning of a variable of a generic compound described in an inventor's notebook was insufficient as a matter of law to establish the meaning of the variable because the testimony was not probative of what the inventors conceived.).

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II. < AS LONG AS THE INVENTOR MAINTAINS INTELLECTUAL DOMINATION OVER MAKING THE INVENTION, IDEAS, SUGGESTIONS, AND MATERIALS MAY BE ADOPTED FROM OTHERS

An inventor may consider and adopt ideas, suggestions and materials derived from many sources: a suggestion from an employee, a hired consultant or a friend even if the adopted material proves to be the key that unlocks the problem so long as the inventor "maintains intellectual domination of the work of making the invention down to the successful testing, selecting or rejecting…." *Morse v. Porter*, 155 USPQ 280, 283 (Bd. Pat. Inter. 1965); *Staehelin v. Secher*, 24 USPQ2d 1513, 1522 (Bd. Pat. App. & Inter. 1992) ("evidence of conception naming only one of the actual inventive entity inures to the benefit of and serves as evidence of conception by the complete inventive entity").

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III. < CONCEPTION REQUIRES CONTEMPORANEOUS RECOGNITION AND APPRECIATION OF THE INVENTION

There must be a contemporaneous recognition and appreciation of the invention for there to be conception. *Silvestri v. Grant*, 496 F.2d 593, 596, 181 USPQ 706, 708 (CCPA 1974) ("an accidental and unappreciated duplication of an invention does not defeat the patent right of one who, though later in time was the first to recognize that which constitutes the inventive subject matter"); > *Invitrogen, Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052, 1064, 77 USPQ2d 1161, 1169 (Fed. Cir. 2005)(In situations where there is unrecognized accidental duplication, establishing conception requires evidence that the inventor actually made the invention and understood the invention to have the features that comprise the inventive subject matter at issue).< *Langer v. Kaufman*, 465 F.2d 915, 918, 175 USPQ 172, 174 (CCPA 1972) (new form of catalyst was not recognized when it was first produced; conception cannot be established *nunc pro tunc*). However, an inventor does not need to know that the invention will work for there to be complete conception. *Burroughs Wellcome Co. v. Barr Labs., Inc*., 40 F.3d 1223, 1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994) (Draft patent application disclosing treatment of AIDS with AZT reciting dosages, forms, and routes of administration was sufficient to collaborate conception whether or not the inventors believed the inventions would work based on initial screening tests.) Furthermore, the inventor does not need to appreciate the patentability of the invention. *Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1341, 60 USPQ2d 1519, 1523 (Fed. Cir. 2001).

The first to conceive of a species is not necessarily the first to conceive of the generic invention. *In re Jolley*, 308 F.3d 1317, 1323 n.2, 64 USPQ2d 1901, 1905 n.2 (Fed. Cir. 2002). Further, while conception of a species within a genus may constitute conception of the genus, conception of one species and the genus may not constitute conception of another species in the genus. *Oka v. Youssefyeh*, 849 F.2d 581, 7 USPQ2d 1169 (Fed. Cir. 1988) (conception of a chemical requires both the idea of the structure of the chemical and possession of an operative method of making it). See also *Amgen v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (in the isolation of a gene, defining a gene by its principal biological property is not sufficient for conception absent an ability to envision the detailed constitution as well as a method for obtaining it); *Fiers v. Revel*, 984 F.2d 1164, 1170, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993) ("[b]efore reduction to practice, conception only of a process for making a substance, without conception of a structural or equivalent

definition of that substance, can at most constitute a conception of the substance claimed as a process" but cannot constitute conception of the substance; as "conception is not enablement," conception of a purified DNA sequence coding for a specific protein by function and a method for its isolation that could be carried out by one of ordinary skill in the art is not conception of that material).

On rare occasions conception and reduction to practice occur simultaneously. *Alpert v. Slatin*, 305 F.2d 891, 894, 134 USPQ 296, 299 (CCPA 1962). "[I]n some unpredictable areas of chemistry and biology, there is no conception until the invention has been reduced to practice." *MacMillan v. Moffett*, 432 F.2d 1237, 1234-40, 167 USPQ 550, 552-553 (CCPA 1970). See also *Hitzeman v. Rutter*, 243 F.3d 1345, 58 USPQ2d 1161 (Fed. Cir. 2001) (conception simultaneous with reduction to practice where appellant lacked reasonable certainty that yeast's performance of certain intracellular processes would result in the claimed antigen particles); *Dunn v. Ragin*, 50 USPQ 472, 475 (Bd. Pat. Inter. 1941) (a new variety of asexually reproduced plant is conceived and reduced to practice when it is grown and recognized as a new variety). Under these circumstances, conception is not complete if subsequent experimentation reveals factual uncertainty which "so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice." *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1229, 32 USPQ2d 1915, 1920 (Fed. Cir. 1994).

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IV. < A PREVIOUSLY ABANDONED APPLICATION WHICH WAS NOT COPENDING WITH A SUBSEQUENT APPLICATION IS EVIDENCE ONLY OF CONCEPTION

An abandoned application with which no subsequent application was copending serves to abandon benefit of the application's filing as a constructive reduction to practice and the abandoned application is evidence only of conception. *In re Costello*, 717 F.2d 1346, 1350, 219 USPQ 389, 392 (Fed. Cir. 1983).

2138.05 "Reduction to Practice" [R-5]

Reduction to practice may be an actual reduction or a constructive reduction to practice which occurs when a patent application on the claimed invention is filed. The filing of a patent application serves as conception and constructive reduction to practice of the subject matter described in the application. Thus the inventor need not provide evidence of either conception or actual reduction to practice when relying on the content of the patent application. *Hyatt v. Boone*, 146 F.3d 1348, 1352, 47 USPQ2d 1128, 1130 (Fed. Cir. 1998). A reduction to practice can be done by another on behalf of the inventor. *De Solms v. Schoenwald*, 15 USPQ2d 1507, 1510 (Bd. Pat. App. & Inter. 1990). "While the filing of the original application theoretically constituted a constructive reduction to practice at the time, the subsequent abandonment of that application also resulted in an abandonment of the benefit of that filing as a constructive reduction to practice. The filing of the original application is, however, evidence of conception of the invention." *In re Costello*, 717 F.2d 1346, 1350, 219 USPQ 389, 392 (Fed. Cir. 1983)(The second application was not co-pending with the original application and it did not reference the original application. Because of the requirements of 35 U.S.C. **120** had not been satisfied, the filing of the original application was not recognized as constructive reduction to practice of the invention.).

I. CONSTRUCTIVE REDUCTION TO PRACTICE REQUIRES COMPLIANCE WITH 35 U.S.C. 112, FIRST PARAGRAPH

When a party to an interference seeks the benefit of an earlier-filed U.S. patent application, the earlier application must meet the requirements of 35 U.S.C. **120** and 35 U.S.C. **112**, first paragraph for the subject matter of the count. The earlier application must meet the enablement requirement and must contain a written description of the subject matter of the interference count. *Hyatt v. Boone*, 146 F.3d 1348, 1352, 47 USPQ2d 1128, 1130 (Fed. Cir. 1998). Proof of a constructive reduction to practice requires sufficient disclosure under the "how to use" and "how to make" requirements of **35 U.S.C. 112**, first paragraph. *Kawai v. Metlesics*, 480 F.2d 880, 886, 178 USPQ 158, 163 (CCPA 1973) (A constructive reduction to practice is not proven unless the specification discloses a practical utility where one would not be obvious. Prior art which disclosed an anticonvulsant compound which differed from the claimed compound only in the absence of a $-CH_2-$ group connecting two functional groups was not sufficient to establish utility of the claimed compound because the compounds were not so closely related that they could be presumed to have the same utility.). The purpose of the written description requirement is "to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him." *In re Edwards*, 568 F.2d 1349, 1351-52, 196 USPQ 465, 467 (CCPA 1978). The written description must include all of the limitations of the interference count, or the applicant must show that any absent text is necessarily comprehended in the description provided and would have been so understood

at the time the patent application was filed. Furthermore, the written description must be sufficient, when the entire specification is considered, such that the "necessary and only reasonable construction" that would be given it by a person skilled in the art is one that clearly supports each positive limitation in the count. *Hyatt v. Boone*, 146 F.3d at 1354-55, 47 USPQ2d at 1130-1132 (Fed. Cir. 1998) (The claim could be read as describing subject matter other than that of the count and thus did not establish that the applicant was in possession of the invention of the count.). See also *Bigham v. Godtfredsen*, 857 F.2d 1415, 1417, 8 USPQ2d 1266, 1268 (Fed. Cir. 1988) ("[t]he generic term halogen comprehends a limited number of species, and ordinarily constitutes a sufficient written description of the common halogen species," except where the halogen species are patentably distinct).

II. REQUIREMENTS TO ESTABLISH ACTUAL REDUCTION TO PRACTICE

"In an interference proceeding, a party seeking to establish an actual reduction to practice must satisfy a two-prong test: (1) the party constructed an embodiment or performed a process that met every element of the interference count, and (2) the embodiment or process operated for its intended purpose." *Eaton v. Evans*, 204 F.3d 1094, 1097, 53 USPQ2d 1696, 1698 (Fed. Cir. 2000).

The same evidence sufficient for a constructive reduction to practice may be insufficient to establish an actual reduction to practice, which requires a showing of the invention in a physical or tangible form that shows every element of the count. *Wetmore v. Quick*, 536 F.2d 937, 942, 190 USPQ 223, 227 (CCPA 1976). For an actual reduction to practice, the invention must have been sufficiently tested to demonstrate that it will work for its intended purpose, but it need not be in a commercially satisfactory stage of development. >See, e.g., *Scott v. Finney*, 34 F.3d 1058, 1062, 32 USPQ2d 1115, 1118-19 (Fed. Cir. 1994)(citing numerous cases wherein the character of the testing necessary to support an actual reduction to practice varied with the complexity of the invention and the problem it solved).< If a device is so simple, and its purpose and efficacy so obvious, construction alone is sufficient to demonstrate workability. *King Instrument Corp. v. Otari Corp*., 767 F.2d 853, 860, 226 USPQ 402, 407 (Fed. Cir. 1985).

For additional cases pertaining to the requirements necessary to establish actual reduction to practice see *DSL Dynamic Sciences, Ltd. v. Union Switch & Signal, Inc.*, 928 F.2d 1122, 1126, 18 USPQ2d 1152, 1155 (Fed. Cir. 1991) ("events occurring after an alleged actual reduction to practice can call into question whether reduction to practice has in fact occurred"); ** *Fitzgerald v. Arbib*, 268 F.2d 763, 765-66, 122 USPQ 530, 531-32 (CCPA 1959) ("the reduction to practice of a three-dimensional design invention requires the production of an article embodying that design" in "other than a mere drawing")>; *Birmingham v. Randall*, 171 F.2d 957, 80 USPQ 371, 372 (CCPA 1948) (To establish an actual reduction to practice of an invention directed to a method of making a product, it is not enough to show that the method was performed. "[S]uch an invention is not reduced to practice until it is established that the product made by the process is satisfactory, and [ ] this may require successful testing of the product.")<.

III. TESTING REQUIRED TO ESTABLISH AN ACTUAL REDUCTION TO PRACTICE

"The nature of testing which is required to establish a reduction to practice depends on the particular facts of each case, especially the nature of the invention." *Gellert v. Wanberg*, 495 F.2d 779, 783, 181 USPQ 648, 652 (CCPA 1974) ("an invention may be tested sufficiently … where less than all of the conditions of actual use are duplicated by the tests"); *Wells v. Fremont*, 177 USPQ 22, 24-5 (Bd. Pat. Inter. 1972) ("even where tests are conducted under 'bench' or laboratory conditions, those conditions must 'fully duplicate each and every condition of actual use' or if they do not, then the evidence must establish a relationship between the subject matter, the test condition and the intended functional setting of the invention," but it is not required that all the conditions of all actual uses be duplicated, such as rain, snow, mud, dust and submersion in water).

IV. REDUCTION TO PRACTICE REQUIRES RECOGNITION AND APPRECIATION OF THE INVENTION

The invention must be recognized and appreciated for a reduction to practice to occur. "The rule that conception and reduction to practice cannot be established nunc pro tunc simply requires that in order for an experiment to constitute an actual reduction to practice, there must have been contemporaneous appreciation of the invention at issue by the inventor…. Subsequent testing or later recognition may not be used to show that a party had contemporaneous appreciation of the invention. However, evidence of subsequent testing may be admitted for the purpose of showing that an embodiment was produced and that it met the limitations of the count." *Cooper v. Goldfarb*, 154 F.3d 1321, 1331, 47 USPQ2d 1896, 1904 (Fed. Cir. 1998) (citations omitted). *Meitzner v. Corte*, 537 F.2d 524, 528, 190 USPQ 407, 410 (CCPA 1976) (there can be no conception or reduction to practice of a new form or of a process using such a new form of an otherwise old composition where there has been no

recognition or appreciation of the existence of the new form); *Estee Lauder, Inc. v. L'Oreal S.A.*, 129 F.3d 588, 593, 44 USPQ2d 1610, 1615 (Fed. Cir. 1997) ("[W]hen testing is necessary to establish utility, there must be recognition and appreciation that the tests were successful for reduction to practice to occur." A showing that testing was completed before the critical date, and that testing ultimately proved successful, was held insufficient to establish a reduction to practice before the critical date, since the success of the testing was not appreciated or recognized until after the critical date.); *Parker v. Frilette*, 462 F.2d 544, 547, 174 USPQ 321, 324 (CCPA 1972) ("[an] inventor need not understand precisely why his invention works in order to achieve an actual reduction to practice").

V. RECOGNITION OF THE INVENTION BY ANOTHER MAY INURE TO THE BENEFIT OF THE INVENTOR

"Inurement involves a claim by an inventor that, as a matter of law, the acts of another person should accrue to the benefit of the inventor." *Cooper v. Goldfarb*, 154 F.3d 1321, 1331, 47 USPQ2d 1896, 1904 (Fed. Cir. 1998). Before a non-inventor's recognition of the utility of the invention can inure to the benefit of the inventor, the following three-prong test must be met: (1) the inventor must have conceived of the invention, (2) the inventor must have had an expectation that the embodiment tested would work for the intended purpose of the invention, and (3) the inventor must have submitted the embodiment for testing for the intended purpose of the invention. *Genentech Inc. v. Chiron Corp.*, 220 F.3d 1345, 1354, 55 USPQ2d 1636, 1643 (Fed. Cir. 2000). In *Genentech*, a non-inventor hired by the inventors to test yeast samples for the presence of the fusion protein encoded by the DNA construct of the invention recognized the growth-enhancing property of the fusion protein, but did not communicate this recognition to the inventors. The court found that because the inventors did not submit the samples for testing growth-promoting activity, the intended purpose of the invention, the third prong was not satisfied and the uncommunicated recognition of the activity of the fusion protein by the non-inventor did not inure to their benefit. See also *Cooper v. Goldfarb*, 240 F.3d 1378, 1385, 57 USPQ2d 1990, 1995 (Fed. Cir. 2001) (Cooper sent to Goldfarb samples of a material for use in vascular grafts. At the time the samples were sent, Cooper was unaware of the importance of the fibril length of the material. Cooper did not at any time later convey to, or request from, Goldfarb any information regarding fibril length. Therefore, Goldfarb's determination of the fibril lengths of the material could not inure to Cooper's benefit.).

VI. IN AN INTERFERENCE PROCEEDING, ALL LIMITATIONS OF A COUNT MUST BE REDUCED TO PRACTICE

The device reduced to practice must include every limitation of the count. *Fredkin v. Irasek*, 397 F.2d 342, 158 USPQ 280, 285 (CCPA 1968); every limitation in a count is material and must be proved to establish an actual reduction to practice. *Meitzner v. Corte*, 537 F.2d 524, 528, 190 USPQ 407, 410. See also *Hull v. Bonis*, 214 USPQ 731, 734 (Bd. Pat. Inter. 1982) (no doctrine of equivalents—remedy is a preliminary motion to amend the count to conform to the proofs).

VII. CLAIMED INVENTION IS NOT ACTUALLY REDUCED TO PRACTICE UNLESS THERE IS A KNOWN UTILITY

Utility for the invention must be known at the time of the reduction to practice. *Wiesner v. Weigert*, 666 F.2d 582, 588, 212 USPQ 721, 726 (CCPA 1981) (except for plant and design inventions); *Azar v. Burns*, 188 USPQ 601, 604 (Bd. Pat. Inter. 1975) (a composition and a method cannot be actually reduced to practice unless the composition and the product produced by the method have a practical utility); *Ciric v. Flanigen*, 511 F.2d 1182, 1185, 185 USPQ 103, 105-6 (CCPA 1975) ("when a count does not recite any particular utility, evidence establishing a substantial utility for any purpose is sufficient to prove a reduction to practice"; "the demonstrated similarity of ion exchange and adsorptive properties between the newly discovered zeolites and known crystalline zeolites … have established utility for the zeolites of the count"); *Engelhardt v. Judd*, 369 F.2d 408, 411, 151 USPQ 732, 735 (CCPA 1966) (When considering an actual reduction to practice as a bar to patentability for claims to compounds, it is sufficient to successfully demonstrate utility of the compounds in animals for somewhat different pharmaceutical purposes than those asserted in the specification for humans.); *Rey-Bellet v. Engelhardt*, 993 F.2d 1380, 1384, 181 USPQ 453, 455 (CCPA 1974) (Two categories of tests on laboratory animals have been considered adequate to show utility and reduction to practice: first, tests carried out to prove utility in humans where there is a satisfactory correlation between humans and animals, and second, tests carried out to prove utility for treating animals.).

VIII. A PROBABLE UTILITY MAY NOT BE SUFFICIENT TO ESTABLISH UTILITY

A probable utility does not establish a practical utility, which is established by actual testing or where the utility can be "foretold with certainty." *Bindra v. Kelly*, 206

USPQ 570, 575 (Bd. Pat. Inter. 1979) (Reduction to practice was not established for an intermediate useful in the preparation of a second intermediate with a known utility in the preparation of a pharmaceutical. The record established there was a high degree of probability of a successful preparation because one skilled in the art may have been motivated, in the sense of **35 U.S.C. 103**, to prepare the second intermediate from the first intermediate. However, a strong probability of utility is not sufficient to establish practical utility.); *Wu v. Jucker*, 167 USPQ 467, 472 (Bd. Pat. Inter. 1968) (screening test where there was an indication of possible utility is insufficient to establish practical utility). But see *Nelson v. Bowler*, 628 F.2d 853, 858, 206 USPQ 881, 885 (CCPA 1980) (Relevant evidence is judged as a whole for its persuasiveness in linking observed properties to suggested uses. Reasonable correlation between the two is sufficient for an actual reduction to practice.).

2138.06 "Reasonable Diligence" [R-1]

The diligence of **35 U.S.C. 102(g)** relates to reasonable "attorney-diligence" and "engineering-diligence" (*Keizer v. Bradley*, 270 F.2d 396, 397, 123 USPQ 215, 216 (CCPA 1959)), which does not require that "an inventor or his attorney … drop all other work and concentrate on the particular invention involved…." *Emery v. Ronden*, 188 USPQ 264, 268 (Bd. Pat. Inter. 1974).

CRITICAL PERIOD FOR ESTABLISHING DILIGENCE BETWEEN ONE WHO WAS FIRST TO CONCEIVE BUT LATER TO REDUCE TO PRACTICE THE INVENTION

The critical period for diligence for a first conceiver but second reducer begins not at the time of conception of the first conceiver but just prior to the entry in the field of the party who was first to reduce to practice and continues until the first conceiver reduces to practice. *Hull v. Davenport*, 90 F.2d 103, 105, 33 USPQ 506, 508 (CCPA 1937) ("lack of diligence from the time of conception to the time immediately preceding the conception date of the second conceiver is not regarded as of importance except as it may have a bearing upon his subsequent acts"). What serves as the entry date into the field of a first reducer is dependent upon what is being relied on by the first reducer, e.g., conception plus reasonable diligence to reduction to practice (*Fritsch v. Lin*, 21 USPQ2d 1731, 1734 (Bd. Pat. App. & Inter. 1991), *Emery v. Ronden*, 188 USPQ 264, 268 (Bd. Pat. Inter. 1974)); an actual reduction to practice or a constructive reduction to practice by the filing of either a U.S. application (*Rebstock v. Flouret*, 191 USPQ 342, 345 (Bd. Pat. Inter. 1975)) or reliance upon priority under **35 U.S.C. 119** of a foreign application (*Justus v. Appenzeller*, 177 USPQ 332, 339 (Bd. Pat. Inter. 1971) (chain of priorities under **35 U.S.C. 119** and **120**, priority under **35 U.S.C. 119** denied for failure to supply certified copy of the foreign application during pendency of the application filed within the twelfth month)).

THE ENTIRE PERIOD DURING WHICH DILIGENCE IS REQUIRED MUST BE ACCOUNTED FOR BY EITHER AFFIRMATIVE ACTS OR ACCEPTABLE EXCUSES

An applicant must account for the entire period during which diligence is required. *Gould v. Schawlow* , 363 F.2d 908, 919, 150 USPQ 634, 643 (CCPA 1966) (Merely stating that there were no weeks or months that the invention was not worked on is not enough.); *In re Harry* , 333 F.2d 920, 923, 142 USPQ 164, 166 (CCPA 1964) (statement that the subject matter "was diligently reduced to practice" is not a showing but a mere pleading). A 2-day period lacking activity has been held to be fatal. *In re Mulder* , 716 F.2d 1542, 1545, 219 USPQ 189, 193 (Fed. Cir. 1983) (**37 CFR 1.131** issue); *Fitzgerald v. Arbib*, 268 F.2d 763, 766, 122 USPQ 530, 532 (CCPA 1959) (Less than 1 month of inactivity during critical period. Efforts to exploit an invention commercially do not constitute diligence in reducing it to practice. An actual reduction to practice in the case of a design for a three-dimensional article requires that it should be embodied in some structure other than a mere drawing.); *Kendall v. Searles*, 173 F.2d 986, 993, 81 USPQ 363, 369 (CCPA 1949) (Diligence requires that applicants must be specific as to dates and facts.).

The period during which diligence is required must be accounted for by either affirmative acts or acceptable excuses. *Rebstock v. Flouret*, 191 USPQ 342, 345 (Bd. Pat. Inter. 1975); *Rieser v. Williams*, 225 F.2d 419, 423, 118 USPQ 96, 100 (CCPA 1958) (Being last to reduce to practice, party cannot prevail unless he has shown that he was first to conceive and that he exercised reasonable diligence during the critical period from just prior to opponent's entry into the field); *Griffith v. Kanamaru*, 816 F.2d 624, 2 USPQ2d 1361 (Fed. Cir. 1987) (Court generally reviewed cases on excuses for inactivity including vacation extended by ill health and daily job demands, and held lack of university funding and personnel are not acceptable excuses.); *Litchfield v. Eigen*, 535 F.2d 72, 190 USPQ 113 (CCPA 1976) (budgetary limits and availability of animals for testing not sufficiently described); *Morway v. Bondi*, 203 F.2d 741, 749, 97 USPQ 318, 323 (CCPA 1953) (voluntarily laying aside inventive concept in pursuit of other projects is generally not an acceptable excuse although there may be circumstances creating exceptions); *Anderson v. Crowther*, 152 USPQ 504, 512 (Bd. Pat. Inter. 1965)

(preparation of routine periodic reports covering all accomplishments of the laboratory insufficient to show diligence); *Wu v. Jucker*, 167 USPQ 467, 472-73 (Bd. Pat. Inter. 1968) (applicant improperly allowed test data sheets to accumulate to a sufficient amount to justify interfering with equipment then in use on another project); *Tucker v. Natta*, 171 USPQ 494,498 (Bd. Pat. Inter. 1971) ("[a]ctivity directed toward the reduction to practice of a genus does not establish, *prima facie*, diligence toward the reduction to practice of a species embraced by said genus"); *Justus v. Appenzeller*, 177 USPQ 332, 340-1 (Bd. Pat. Inter. 1971) (Although it is possible that patentee could have reduced the invention to practice in a shorter time by relying on stock items rather than by designing a particular piece of hardware, patentee exercised reasonable diligence to secure the required hardware to actually reduce the invention to practice. "[I]n deciding the question of diligence it is immaterial that the inventor may not have taken the expeditious course….").

WORK RELIED UPON TO SHOW REASONABLE DILIGENCE MUST BE DIRECTLY RELATED TO THE REDUCTION TO PRACTICE

The work relied upon to show reasonable diligence must be directly related to the reduction to practice of the invention in issue. *Naber v. Cricchi*, 567 F.2d 382, 384, 196 USPQ 294, 296 (CCPA 1977), *cert. denied*, 439 U.S. 826 (1978). >See also *Scott v. Koyama*, 281 F.3d 1243, 1248-49, 61 USPQ2d 1856, 1859 (Fed. Cir. 2002) (Activities directed at building a plant to practice the claimed process of producing tetrafluoroethane on a large scale constituted efforts toward actual reduction to practice, and thus were evidence of diligence. The court distinguished cases where diligence was not found because inventors either discontinued development or failed to complete the invention while pursuing financing or other commercial activity.); *In re Jolley*, 308 F.3d 1317, 1326-27, 64 USPQ2d 1901, 1908-09 (Fed. Cir. 2002) (diligence found based on research and procurement activities related to the subject matter of the interference count).< "[U]nder some circumstances an inventor should also be able to rely on work on closely related inventions as support for diligence toward the reduction to practice on an invention in issue." *Ginos v. Nedelec*, 220 USPQ 831, 836 (Bd. Pat. Inter. 1983) (work on other closely related compounds that were considered to be part of the same invention and which were included as part of a grandparent application). "The work relied upon must be directed to attaining a reduction to practice of the subject matter of the counts. It is not sufficient that the activity relied on concerns related subject matter." *Gunn v. Bosch*, 181 USPQ 758, 761 (Bd. Pat. Inter. 1973) (An actual reduction to practice of the invention at issue which occurred when the inventor was working on a different invention "was fortuitous, and not the result of a continuous intent or effort to reduce to practice the invention here in issue. Such fortuitousness is inconsistent with the exercise of diligence toward reduction to practice of that invention." 181 USPQ at 761. Furthermore, evidence drawn towards work on improvement of samples or specimens generally already in use at the time of conception that are but one element of the oscillator circuit of the count does not show diligence towards the construction and testing of the overall combination.); *Broos v. Barton*, 142 F.2d 690, 691, 61 USPQ 447, 448 (CCPA 1944) (preparation of application in U.S. for foreign filing constitutes diligence); *De Solms v. Schoenwald*, 15 USPQ2d 1507 (Bd. Pat. App. & Inter. 1990) (principles of diligence must be given to inventor's circumstances including skill and time; requirement of corroboration applies only to testimony of inventor); *Huelster v. Reiter*, 168 F.2d 542, 78 USPQ 82 (CCPA 1948) (if inventor was not able to make an actual reduction to practice of the invention, he must also show why he was not able to constructively reduce the invention to practice by the filing of an application).

DILIGENCE REQUIRED IN PREPARING AND FILING PATENT APPLICATION

The diligence of attorney in preparing and filing patent application inures to the benefit of the inventor. Conception was established at least as early as the date a draft of a patent application was finished by a patent attorney on behalf of the inventor. Conception is less a matter of signature than it is one of disclosure. Attorney does not prepare a patent application on behalf of particular named persons, but on behalf of the true inventive entity. Six days to execute and file application is acceptable. *Haskell v. Coleburne*, 671 F.2d 1362, 213 USPQ 192, 195 (CCPA 1982). See also *Bey v. Kollonitsch*, 866 F.2d 1024, 231 USPQ 967 (Fed. Cir. 1986) (Reasonable diligence is all that is required of the attorney. Reasonable diligence is established if attorney worked reasonably hard on the application during the continuous critical period. If the attorney has a reasonable backlog of unrelated cases which he takes up in chronological order and carries out expeditiously, that is sufficient. Work on a related case(s) that contributed substantially to the ultimate preparation of an application can be credited as diligence.).

END OF DILIGENCE PERIOD IS MARKED BY EITHER ACTUAL OR CONSTRUCTIVE REDUCTION TO PRACTICE

"[I]t is of no moment that the end of that period [for diligence] is fixed by a constructive, rather than an actual,

reduction to practice." *Justus v. Appenzeller*, 177 USPQ 332, 340-41 (Bd. Pat. Inter. 1971).

2141 Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 [R-9]

35 U.S.C. 103 Conditions for patentability; non-obvious subject matter.

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in **section 102** of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(b) (1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under **section 102** and nonobvious under subsection (a) of this section shall be considered nonobvious if-(A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and

(B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.

(2) A patent issued on a process under paragraph (1)-(A) shall also contain the claims to the composition of matter used in or made by that process, or

(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding **section 154**.

(3) For purposes of paragraph (1), the term "biotechnological process" means-(A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to-(i) express an exogenous nucleotide sequence,

(ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or

(iii) express a specific physiological characteristic not naturally associated with said organism;

(B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and

(C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

(c) (1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of **section 102** of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

(2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if — (A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

(B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(3) For purposes of paragraph (2), the term "joint research agreement" means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.

EXAMINATION GUIDELINES FOR DETERMINING OBVIOUSNESS UNDER 35 U.S.C. 103

These guidelines are intended to assist Office personnel to make a proper determination of obviousness under 35 U.S.C. **103**, and to provide an appropriate supporting rationale in view of the recent decision by the Supreme Court in *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. 398, 82 USPQ2d 1385 (2007). The guidelines are based on the Office's current understanding of the law, and are believed to be fully consistent with the binding precedent of the Supreme Court. **> The *KSR* decision reinforced earlier decisions that validated a more flexible approach to providing reasons for obviousness. However, the Supreme Court's pronouncement in *KSR* has clearly undermined the continued viability of cases such as *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002), insofar as *Lee* appears to require a strict basis in record evidence as a reason to modify the prior art. As the Federal Circuit has explained:

> At the time [of the decision in *In re Lee*], we required the PTO to identify record evidence of a teaching, suggestion, or motivation to combine references because "[o]mission of a relevant factor required by precedent is both legal error and arbitrary agency action." However, this did not preclude examiners from employing common sense. More recently [in *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1366

> (Fed.Cir.2006)], we explained that that use of common sense does not require a "specific hint or suggestion in a particular reference," only a reasoned explanation that avoids conclusory generalizations.

Perfect Web Technologies, Inc. v. InfoUSA, Inc., 587 F.3d 1324, 1329 (Fed. Cir. 2009) (citations omitted).

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These guidelines do not constitute substantive rule making and hence do not have the force and effect of law. They have been developed as a matter of internal Office management and are not intended to create any right or benefit, substantive or procedural, enforceable by any party against the Office. Rejections will continue to be based upon the substantive law, and it is these rejections that are appealable. Consequently, any failure by Office personnel to follow the guidelines is neither appealable nor petitionable.

I. The *KSR* Decision and Principles of the Law of Obviousness

The Supreme Court in *KSR* reaffirmed the familiar framework for determining obviousness as set forth in *Graham v. John Deere Co*. (383 U.S. 1, 148 USPQ 459 (1966)), but stated that the Federal Circuit had erred by applying the teaching-suggestion-motivation (TSM) test in an overly rigid and formalistic way. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1391. Specifically, the Supreme Court stated that the Federal Circuit had erred in four ways: (1) "by holding that courts and patent examiners should look only to the problem the patentee was trying to solve " (*Id*. at ___, 82 USPQ2d at 1397); (2) by assuming "that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem" (*Id*.); (3) by concluding "that a patent claim cannot be proved obvious merely by showing that the combination of elements was 'obvious to try'" (*Id*.); and (4) by overemphasizing "the risk of courts and patent examiners falling prey to hindsight bias" and as a result applying "[r]igid preventative rules that deny factfinders recourse to common sense" (*Id.*).

In *KSR*, the Supreme Court particularly emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art," *Id.* at ___, 82 USPQ2d at 1395, and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at ___, 82 USPQ2d at 1395. The Supreme Court stated that there are "[t]hree cases decided after *Graham* [that] illustrate this doctrine." Id. at ___, 82 USPQ2d at 1395. (1) "In *United States v. Adams*, . . . [t]he Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." Id. at ___, 82 USPQ2d at 1395. (2) "In *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, . . . [t]he two [pre-existing elements] in combination did no more than they would in separate, sequential operation." *Id.* at ___, 82 USPQ2d at 1395. (3) "[I]n *Sakraida v. AG Pro, Inc.*, the Court derived . . . the conclusion that when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." Id. at ___, 82 USPQ2d at 1395-96 (Internal quotations omitted.). The principles underlining these cases are instructive when the question is whether a patent application claiming the combination of elements of prior art would have been obvious. The Supreme Court further stated that:

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *Id.* at ___, 82 USPQ2d at 1396.

When considering obviousness of a combination of known elements, the operative question is thus "whether the improvement is more than the predictable use of prior art elements according to their established functions." *Id* . at ___, 82 USPQ2d at 1396.

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The Supreme Court's flexible approach to the obviousness inquiry is reflected in numerous pre- *KSR* decisions; see **MPEP § 2144**. That section provides many lines of reasoning to support a determination of obviousness based upon earlier legal precedent that had condoned the use of particular examples of what may be considered common sense or ordinary routine practice (e.g., making integral, changes in shape, making adjustable). Thus, the type of reasoning sanctioned by the opinion in KSR has long been a part of the patent examination process.

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II. The Basic Factual Inquiries of *Graham v. John Deere Co.*

An invention that would have been obvious to a person of ordinary skill at the time of the invention is not patentable. See 35 U.S.C. **103(a)**. As reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. **103** is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

(A) **>Determining the scope and content of< the prior art; and

(B) Ascertaining the differences between the claimed invention and the prior art; and

(C) Resolving the level of ordinary skill in the pertinent art.

Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel. *Id*. at 17-18, 148 USPQ at 467. Such evidence, sometimes referred to as "secondary considerations," may include evidence of commercial success, long-felt but unsolved needs, failure of others, and unexpected results. The evidence may be included in the specification as filed, accompany the application on filing, or be provided in a timely manner at some other point during the prosecution. The weight to be given any objective evidence is made on a case-by-case basis. The mere fact that an applicant has presented evidence does not mean that the evidence is dispositive of the issue of obviousness.

The question of obviousness must be resolved on the basis of these factual determinations. While each case is different and must be decided on its own facts, the *Graham* factors, including secondary considerations when present, are the controlling inquiries in any obviousness analysis. The *Graham* factors were reaffirmed and relied upon by the Supreme Court in its consideration and determination of obviousness in the fact situation presented in *KSR*, 550 U.S. at ___, 82 USPQ2d at 1391 (2007). The Supreme Court has utilized the *Graham* factors in each of its obviousness decisions since *Graham*. See *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 189 USPQ 449, *reh'g denied*, 426 U.S. 955 (1976); *Dann v. Johnston*, 425 U.S. 219, 189 USPQ 257 (1976); and *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969). As stated by the Supreme Court in *KSR*, "While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls." *KSR*, 550 U.S. at ___, 82 USPQ2d at 1391.

Office Personnel As Factfinders

Office personnel fulfill the critical role of factfinder when resolving the *Graham* inquiries. It must be remembered that while the ultimate determination of obviousness is a legal conclusion, the underlying *Graham* inquiries are factual. When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.

Once the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. **103**. 35 U.S.C. **132** requires that the applicant be notified of the reasons for the rejection of the claim so that he or she can decide how best to proceed. Clearly setting forth findings of fact and the rationale(s) to support a rejection in an Office action leads to the prompt resolution of issues pertinent to patentability.

In short, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge. This is so regardless of whether the source of that knowledge and ability was documentary prior art, general knowledge in the art, or common sense. What follows is a discussion of the *Graham* factual inquiries.

A. Determining the Scope and Content of the Prior Art

In determining the scope and content of the prior art, Office personnel must first obtain a thorough understanding of the invention disclosed and claimed in the application under examination by reading the specification, including the claims, to understand what the applicant has invented. See MPEP § **904**. The scope of the claimed invention must be clearly determined by giving the claims the "broadest reasonable interpretation consistent with the specification." See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316, 75 USPQ2d 1321, 1329 (Fed. Cir. 2005) and MPEP § **2111**. Once the scope of the claimed invention is determined, Office personnel must then determine what to search for and where to search.

1. What To Search For:

The search should cover the claimed subject matter and should also cover the disclosed features which might reasonably be expected to be claimed. See MPEP § **904.02**. Although a rejection need not be based on a teaching or suggestion to combine, a preferred search will be directed to finding references that provide such a teaching or suggestion if they exist.

2. Where To Search:

Office personnel should continue to follow the general search guidelines set forth in MPEP § **904** to § **904.03** regarding search of the prior art. Office personnel are reminded that, for purposes of 35 U.S.C. **103**, prior art can be either in the field of applicant's endeavor or be reasonably pertinent to the particular problem with which the applicant was concerned. Furthermore, prior art that is in a field of endeavor other than that of the applicant (as noted by the Court in *KSR*, "[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one," 550 U.S. at ___, 82 USPQ2d at 1396 (emphasis added)), or solves a problem which is different from that which the applicant was trying to solve, may also be considered for the purposes of 35 U.S.C. **103**. (The Court in *KSR* stated that "[t]he first error…in this case was…holding that courts and patent examiners should look only to the problem the patentee was trying to solve. The Court of Appeals failed to recognize that the problem motivating the patentee may be only one of many addressed by the patent's subject matter…The second error [was]…that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem." 550 U.S. at ___, 82 USPQ2d at 1397. Federal Circuit case law prior to the Supreme Court's decision in *KSR* is generally in accord with these statements by the *KSR* Court. See e.g., *In re Dillon*, 919 F.2d 688, 693, 16 USPQ2d 1897, 1902 (Fed. Cir. 1990) (*en banc*) ("[I]t is not necessary in order to establish a *prima facie* case of obviousness that both a structural similarity between a claimed and prior art compound (or a key component of a composition) be shown and that there be a suggestion in or expectation from **the prior art** that the claimed compound or composition will have the same or a similar utility **as one newly discovered by applicant**"); *In re Lintner*, 458 F.2d 1013, 1018, 173 USPQ 560, 562 (CCPA 1972) ("The fact that [applicant] uses sugar for a different purpose does not alter the conclusion that its use in a prior art composition would be *prima facie* obvious from the purpose disclosed in the references.").).

For a discussion of what constitutes prior art, see MPEP § **901** to § **901.06(d)** and § **2121** to § **2129**.

B. Ascertaining the Differences Between the Claimed Invention and the Prior Art

Ascertaining the differences between the claimed invention and the prior art requires interpreting the claim language, see MPEP § **2111**, and considering both the invention and the prior art as a whole. See MPEP § **2141.02**.

C. Resolving the Level of Ordinary Skill in the Art

Any obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill. A finding as to the level of ordinary skill may be used as a partial basis for a resolution of the issue of obviousness.

The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. Factors that may be considered in determining the level of ordinary skill in the art may include: (1) "type of problems encountered in the art;" (2) "prior art solutions to those problems;" (3) "rapidity with which innovations are made;" (4) "sophistication of the technology; and" (5) "educational level of active workers in the field.>" *In re GPAC*, 57 F.3d 1573, 1579, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995). "<In a given case, every factor may not be present, and one or more factors may predominate."**> *Id.*. See also< *Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986); *Environmental Designs, Ltd. V. Union Oil Co.*, 713 F.2d 693, 696, 218 USPQ 865, 868 (Fed. Cir. 1983).

"A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. at ___, 82 USPQ2d at 1397. "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* Office personnel may also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at ___, 82 USPQ2d at 1396.

In addition to the factors above, Office personnel may rely on their own technical expertise to describe the knowledge and skills of a person of ordinary skill in the art. The Federal Circuit has stated that examiners and administrative patent judges on the Board are "persons of scientific competence in the fields in which they work" and that their findings are "informed by their scientific knowledge, as to the meaning of prior art references to

persons of ordinary skill in the art." *In re Berg* , 320 F.3d 1310, 1315, 65 USPQ2d 2003, 2007 (Fed. Cir. 2003).> In addition, examiners "are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art ." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299 (Fed. Cir. 2008) (quoting *Am. Hoist & Derrick Co. v. Sowa &Sons*, 725 F.2d 1350, 1359 (Fed. Cir. 1984). See **MPEP § 2141** for a discussion of the level of ordinary skill. <

III. RATIONALES TO SUPPORT REJECTIONS UNDER 35 U.S.C. 103

Once the *Graham* factual inquiries are resolved, Office personnel must determine whether the claimed invention would have been obvious to one of ordinary skill in the art.

> The obviousness analysis cannot be confined by . . . overemphasis on the importance of published articles and the explicit content of issued patents. . . . . In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. *KSR* , 550 U.S. at ___, 82 USPQ2d at 1396.

Prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The prior art reference (or references when combined) need not teach or suggest all the claim limitations, however, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. The "mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness." *Dann v. Johnston*, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976). The gap between the prior art and the claimed invention may not be "so great as to render the [claim] nonobvious to one reasonably skilled in the art." *Id* . In determining obviousness, neither the particular motivation to make the claimed invention nor the problem the inventor is solving controls. The proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts. See 35 U.S.C. **103(a)**. Factors other than the disclosures of the cited prior art may provide a basis for concluding that it would have been obvious to one of ordinary skill in the art to bridge the gap. The rationales discussed below outline reasoning that may be applied to find obviousness in such cases.

If the search of the prior art and the resolution of the *Graham* factual inquiries reveal that an obviousness rejection may be made using the familiar teaching-suggestion-motivation (TSM) rationale, then such a rejection should be made. Although the Supreme Court in *KSR* cautioned against an overly rigid application of TSM, it also recognized that TSM was one of a number of valid rationales that could be used to determine obviousness. (According to the Supreme Court, establishment of the TSM approach to the question of obviousness "captured a helpful insight." 550 U.S. at ___, 82 USPQ2d at 1396 (citing *In re Bergel*, 292 F.2d 955, 956-57, 130 USPQ 206, 207-208 (1961)). Furthermore, the Court explained that "[t]here is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis." 550 U.S. at ___, 82 USPQ2d at 1396. The Supreme Court also commented that the Federal Circuit "no doubt has applied the test in accord with these principles [set forth in *KSR*] in many cases." 550 U.S. at ___, 82 USPQ2d at 1396). Office personnel should also consider whether one or more of the other rationales set forth below support a conclusion of obviousness. The Court in KSR identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham*. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1395-97. Note that the list of rationales provided below is not intended to be an all-inclusive list. Other rationales to support a conclusion of obviousness may be relied upon by Office personnel.

The key to supporting any rejection under 35 U.S.C. **103** is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. **103** should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include:

(A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution of one known element for another to obtain predictable results;

(C) Use of known technique to improve similar devices (methods, or products) in the same way;

(D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;

(E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. See MPEP § **2143** for a discussion of the rationales listed above along with examples illustrating how the cited rationales may be used to support a finding of obviousness. See also MPEP § **2144** - § **2144.09** for additional guidance regarding support for obviousness determinations.

IV. APPLICANT'S REPLY

Once Office personnel have established the *Graham* factual findings and concluded that the claimed invention would have been obvious, the burden then shifts to the applicant to (A) show that the Office erred in these findings or (B) provide other evidence to show that the claimed subject matter would have been nonobvious. 37 CFR **1.111(b)** requires applicant to distinctly and specifically point out the supposed errors in the Office's action and reply to every ground of objection and rejection in the Office action. The reply must present arguments pointing out the specific distinction believed to render the claims patentable over any applied references.

If an applicant disagrees with any factual findings by the Office, an effective traverse of a rejection based wholly or partially on such findings must include a reasoned statement explaining why the applicant believes the Office has erred substantively as to the factual findings. A mere statement or argument that the Office has not established a *prima facie* case of obviousness or that the Office's reliance on common knowledge is unsupported by documentary evidence will not be considered substantively adequate to rebut the rejection or an effective traverse of the rejection under 37 CFR **1.111(b)**. Office personnel addressing this situation may repeat the rejection made in the prior Office action and make the next Office action final. *See* MPEP § **706.07(a)**.

V. CONSIDERATION OF APPLICANT'S REBUTTAL EVIDENCE

Office personnel should consider all rebuttal evidence that is timely presented by the applicants when reevaluating any obviousness determination. Rebuttal evidence may include evidence of "secondary considerations," such as "commercial success, long felt but unsolved needs, [and] failure of others" *(Graham v. John Deere Co.*, 383 U.S. at 17, 148 USPQ at 467), and may also include evidence of unexpected results. As set forth above, Office personnel must articulate findings of fact that support the rationale relied upon in an obviousness rejection. As a result, applicants are likely to submit evidence to rebut the fact finding made by Office personnel. For example, in the case of a claim to a combination, applicants may submit evidence or argument to demonstrate that:

(A) one of ordinary skill in the art could not have combined the claimed elements by known methods (e.g., due to technological difficulties);

(B) the elements in combination do not merely perform the function that each element performs separately; or

(C) the results of the claimed combination were unexpected.

Once the applicant has presented rebuttal evidence, Office personnel should reconsider any initial obviousness determination in view of the entire record. See, e.g., *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984); *In re Eli Lilly & Co.*, 90 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). All the rejections of record and proposed rejections and their bases should be reviewed to confirm their continued viability. The Office action should clearly communicate the Office's findings and conclusions, articulating how the conclusions are supported by the findings. The procedures set forth in MPEP § **706.07(a)** are to be followed in determining whether an action may be made final.

See MPEP § **2145** concerning consideration of applicant's rebuttal evidence. See also MPEP § **716** to § **716.10** regarding affidavits or declarations filed under 37 CFR **1.132** for purposes of traversing grounds of rejection.

2141.01 Scope and Content of the Prior Art [R-6]

I. PRIOR ART AVAILABLE UNDER 35 U.S.C. 102 IS AVAILABLE UNDER 35 U.S.C. 103

"Before answering *Graham's* 'content' inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. § 102." *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597 (Fed. Cir.), *cert. denied*, 481 U.S. 1052 (1987). Subject matter that is prior art under **35 U.S.C. 102** can be used to support a rejection under section 103. *Ex parte Andresen*, 212 USPQ 100, 102 (Bd. Pat. App. & Inter. 1981) ("it appears to us that the commentator [of 35

U.S.C.A.] and the [congressional] committee viewed section 103 as including all of the various bars to a patent as set forth in section 102.").

>Furthermore, admitted prior art can be relied upon for both anticipation and obviousness determinations, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. **102**. *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354, 66 USPQ2d 1331, 1337 (Fed. Cir. 2003); *Constant v. Advanced Micro-Devices Inc.*, 848 F.2d 1560, 1570, 7 USPQ2d 1057, 1063 (Fed. Cir. 1988). See MPEP § **2129** for discussion of admissions as prior art.<

A **35 U.S.C. 103** rejection is based on **35 U.S.C. 102(a)**, 102(b), 102(e), etc. depending on the type of prior art reference used and its publication or issue date. For instance, an obviousness rejection over a U.S. patent which was issued more than 1 year before the filing date of the application is said to be a statutory bar just as if it anticipated the claims under 35 U.S.C. 102(b). Analogously, an obviousness rejection based on a publication which would be applied under 102(a) if it anticipated the claims can be overcome by swearing behind the publication date of the reference by filing an affidavit or declaration under **37 CFR 1.131**.

For an overview of what constitutes prior art under **35 U.S.C. 102,** see **MPEP § 901** - **§ 901.06(d)** and **§ 2121** - **§ 2129**.

II. SUBSTANTIVE CONTENT OF THE PRIOR ART

See **MPEP § 2121** - **§ 2129** for case law relating to the substantive content of the prior art (e.g., availability of inoperative devices, extent to which prior art must be enabling, broad disclosure rather than preferred embodiments, admissions, etc.).

III. CONTENT OF THE PRIOR ART IS DETERMINED AT THE TIME THE INVENTION WAS MADE TO AVOID HINDSIGHT

The requirement "at the time the invention was made" is to avoid impermissible hindsight. See **MPEP § 2145**, paragraph X.A. for a discussion of rebutting applicants' arguments that a rejection is based on hindsight.

"It is difficult but necessary that the decisionmaker forget what he or she has been taught . . . about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the **art. >...<" *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

IV. 35 U.S.C. 103(c) — EVIDENCE REQUIRED TO SHOW CONDITIONS OF 35 U.S.C. 103 (c) APPLY

An applicant who wants to avail himself or herself of the benefits of **35 U.S.C. 103(c)** has the burden of establishing that subject matter which only qualifies as prior art under subsection (e), (f) or (g) of section **102** used in a rejection under 35 U.S.C. **103**(a) and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. *Ex parte Yoshino*, 227 USPQ 52 (Bd. Pat. App. & Inter. 1985). Likewise, an applicant who wants to avail himself or herself of the benefits of the joint research provisions of 35 U.S.C. **103**(c) (for applications pending on or after December 10, 2004) has the burden of establishing that:

(A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

(B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

This prior art disqualification is only applicable for subject matter which only qualifies as prior art under subsection (e), (f) or (g) of 35 U.S.C. **102** used in a rejection under 35 U.S.C. **103**(a).

Note that for applications filed prior to November 29, 1999, **and granted as patents prior to December 10, 2004, 35 U.S.C. 103(c)** is limited on its face to subject matter developed by another person which qualifies as prior art only under subsection (f) or (g) of section 102. See **MPEP § 706.02(l)(1)**. See also *In re Bartfeld*, 925 F.2d 1450, 1453-54, 17 USPQ2d 1885, 1888 (Fed. Cir. 1991) (Applicant attempted to overcome a **35 U.S.C. 102(e)/103** rejection with a terminal disclaimer by alleging that the public policy intent of 35 U.S.C **103(c)** was to prohibit the use of "secret" prior art in obviousness determinations. The court rejected this argument, holding "We may not disregard the unambiguous exclusion of § 102(e) from the statute's purview.").

See **MPEP § 706.02(l)(2)** for the requirements which must be met to establish common ownership or a joint research agreement.

2141.01(a) Analogous and Nonanalogous Art [R-9]

I. TO RELY ON A REFERENCE UNDER 35 U.S.C. 103, IT MUST BE ANALOGOUS PRIOR ART

>In order for a reference to be proper for use in an obviousness rejection under **35 U.S.C. 103** , the reference must be analogous art to the claimed invention. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). <The examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed. " *KSR International Co. v. Teleflex Inc.*, 550 U.S. **>398, 420, 82 USPQ2d 1385, 1397 (2007). " This does not require that the reference be from the same field of endeavor as the claimed invention, in light of the Supreme Court's instruction that "[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). Rather, a reference is analogous art to the claimed invention if: (1) the reference is from the same field of endeavor as the claimed invention (even if it addresses a different problem); or (2) the reference is reasonably pertinent to the problem faced by the inventor (even if it is not in the same field of endeavor as the claimed invention). See Bigio, 381 F.3d at 1325.

In order for a reference to be "reasonably pertinent" to the problem, it must "logically [] have commended itself to an inventor's attention in considering his problem. " *In re Icon Health and Fitness, Inc.*, 496 F.3d 1374, 1379-80 (Fed. Cir. 2007)(quoting *In re Clay*, 966 F.2d 656,658 (Fed. Cir. 1992)). A recent decision from the U.S. Court of Appeals for the Federal Circuit, *In re Klein*, F.3d -9 98 USPQ2d 1991 (Fed. Cir. June 2011), is instructive as to the "reasonably pertinent" prong for determining whether a reference is analogous art. In determining whether a reference is reasonably pertinent, an examiner should consider the problem faced by the inventor, as reflected - either explicitly or implicitly - in the specification. In order to support a determination that a reference is reasonably pertinent, it may be appropriate to include a statement of the examiner's understanding of the problem. The question of whether a reference is reasonably pertinent often turns on how the problem to be solved is perceived. If the problem to be solved is viewed in a narrow or constrained way, and such a view is not consistent with the specification, the scope of available prior art may be inappropriately limited. It may be necessary for the examiner to explain why an inventor seeking to solve the identified problem would have looked to the reference in an attempt to find a solution to the problem.

Any argument by the applicant that the examiner has misconstrued the problem to be solved, and as a result has improperly relied on nonanalogous art, should be fully considered in light of the specification. In evaluating the applicant's argument, the examiner should look to the teachings of the specification and the inferences that would reasonably have been drawn from the specification by a person of ordinary skill in the art as a guide to understanding the problem to be solved. A prior art reference not in the same field of endeavor as the claimed invention must be reasonably pertinent to the problem to be solved in order to qualify as analogous art and be applied in an obviousness rejection.<

II. CONSIDER SIMILARITIES AND DIFFERENCES IN STRUCTURE AND FUNCTION

While Patent Office classification of references and the cross-references in the official search notes of the class definitions are some evidence of "nonanalogy" or "analogy" respectively, the court has found "the similarities and differences in structure and function of the inventions to carry far greater weight." *In re Ellis*, 476 F.2d 1370, 1372, 177 USPQ 526, 527 (CCPA 1973) (The structural similarities and functional overlap between the structural gratings shown by one reference and the shoe scrapers of the type shown by another reference were readily apparent, and therefore the arts to which the reference patents belonged were reasonably pertinent to the art with which appellant's invention dealt (pedestrian floor gratings).).

III. ANALOGY IN THE CHEMICAL ARTS

See, for example, *Ex parte Bland*, 3 USPQ2d 1103 (Bd. Pat App. & Inter. 1986) (Claims were drawn to a particulate composition useful as a preservative for an animal foodstuff (or a method of inhibiting fungus growth in an animal foodstuff therewith) comprising verxite having absorbed thereon propionic acid. All references were concerned with absorbing biologically active materials on carriers, and therefore the teachings in each of the various references would have been pertinent to the problems in the other references and the invention at hand.); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983) (Problem confronting

inventor was preventing electrostatic buildup in PTFE tubing caused by hydrocarbon fuel flow while precluding leakage of fuel. Two prior art references relied upon were in the rubber hose art, both referencing the problem of electrostatic buildup caused by fuel flow. The court found that because PTFE and rubber are used by the same hose manufacturers and experience the same and similar problems, a solution found for a problem experienced with either PTFE or rubber hosing would be looked to when facing a problem with the other.); *In re Mlot-Fijalkowski*, 676 F.2d 666, 213 USPQ 713 (CCPA 1982) (Problem faced by appellant was enhancement and immobilization of dye penetrant indications. References which taught the use of dyes and finely divided developer materials to produce colored images preferably in, but not limited to, the duplicating paper art were properly relied upon because the court found that appellant's problem was one of dye chemistry, and a search for its solution would include the dye arts in general.).

IV. ANALOGY IN THE MECHANICAL ARTS

See, for example, *Stevenson v. International Trade Comm.*, 612 F.2d 546, 550, 204 USPQ 276, 280 (CCPA 1979) ("In a simple mechanical invention a broad spectrum of prior art must be explored and it is reasonable to permit inquiry into other areas where one of ordinary skill in the art would be aware that similar problems exist."). See also *In re Bigio*, 381 F.3d 1320, 1325-26, 72 USPQ2d 1209, 1211-12 (Fed. Cir. 2004). The patent application claimed a "hair brush" having a specific bristle configuration. The Board affirmed the examiner's rejection of the claims as being obvious in view of prior art patents disclosing toothbrushes. 381 F.3d at 1323, 72 USPQ2d at 1210. The applicant disputed that the patent references constituted analogous art. On appeal, the court upheld the Board's interpretation of the claim term "hair brush" to encompass any brush that may be used for any bodily hair, including facial hair. 381 F.3d at 1323-24, 72 USPQ2d at 1211. With this claim interpretation, the court applied the "field of endeavor test" for analogous art and determined that the references were within the field of applicant's endeavor and hence was analogous art because toothbrushes are structurally similar to small brushes for hair, and a toothbrush could be used to brush facial hair. 381 F.3d at 1326, 72 USPQ2d at 1212.

Also see *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986) (Applicant's claims related to double-acting high pressure gas transmission line compressors in which the valves could be removed easily for replacement. The Board relied upon references which taught either a double-acting piston pump or a double-acting piston compressor. The court agreed that since the cited pumps and compressors have essentially the same function and structure, the field of endeavor includes both types of double-action piston devices for moving fluids.); *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 227 USPQ 766 (Fed. Cir. 1985) (Claims at issue were directed to an instrument marker pen body, the improvement comprising a pen arm holding means having an integrally molded hinged member for folding over against the pen body. Although the patent owners argued the hinge and fastener art was nonanalogous, the court held that the problem confronting the inventor was the need for a simple holding means to enable frequent, secure attachment and easy removal of a marker pen to and from a pen arm, and one skilled in the pen art trying to solve that problem would have looked to the fastener and hinge art.); and *Ex parte Goodyear Tire & Rubber Co.*, 230 USPQ 357 (Bd. Pat. App. & Inter. 1985) (A reference in the clutch art was held reasonably pertinent to the friction problem faced by applicant, whose claims were directed to a braking material, because brakes and clutches utilize interfacing materials to accomplish their respective purposes.).

V. ANALOGY IN THE ELECTRICAL ARTS

See, for example, *Medtronic, Inc. v. Cardiac Pacemakers*, 721 F.2d 1563, 220 USPQ 97 (Fed. Cir. 1983) (Patent claims were drawn to a cardiac pacemaker which comprised, among other components, a runaway inhibitor means for preventing a pacemaker malfunction from causing pulses to be applied at too high a frequency rate. Two references disclosed circuits used in high power, high frequency devices which inhibited the runaway of pulses from a pulse source. The court held that one of ordinary skill in the pacemaker designer art faced with a rate-limiting problem would look to the solutions of others faced with rate limiting problems, and therefore the references were in an analogous art.).

VI. EXAMPLES OF ANALOGY IN THE DESIGN ARTS

See **MPEP § 1504.03** for a discussion of the relevant case law setting forth the general requirements for analogous art in design applications.

For examples of analogy in the design arts, see *In re Rosen*, 673 F.2d 388, 213 USPQ 347 (CCPA 1982) (The design at issue was a coffee table of contemporary styling. The court held designs of contemporary furniture other than coffee tables, such as the desk and circular glass table top designs of the references relied upon, would reasonably fall within the scope of the knowledge of the designer of ordinary skill.); *Ex parte Pappas*, 23 USPQ2d 1636 (Bd. Pat. App. & Inter. 1992) (At issue was an

ornamental design for a feed bunk with an inclined corner configuration. Examiner relied upon references to a bunk lacking the inclined corners claimed by appellant and the *Architectural Precast Concrete Drafting Handbook*. The Board found the *Architectural Precast Concrete Drafting Handbook* was analogous art, noting that a bunk may be a wood or concrete trough, and that both references relied upon "disclose structures in which at least one upstanding leg is generally perpendicular to a base portion to define a corner configuration between the leg and base portion."); *In re Butera*, 1 F.3d 1252, 28 USPQ2d 1399 (Fed. Cir. 1993) (unpublished - not citable as precedent) (The claimed invention, a spherical design for a combined insect repellent and air freshener, was rejected by the Board as obvious over a single reference to a design for a metal ball anode. The court reversed, holding the reference design to be nonanalogous art. "A prior design is of the type claimed if it has the same general use as that claimed in the design patent application . . . . One designing a combined insect repellent and air freshener would therefore not have reason to know of or look to a design for a metal ball anode." 28 USPQ2d at 1400.).

2141.02 Differences Between Prior Art and Claimed Invention [R-5]

Ascertaining the differences between the prior art and the claims at issue requires interpreting the claim language, and considering both the invention and the prior art references as a whole. See **MPEP § 2111** - **§ 2116.01** for case law pertaining to claim interpretation.

I. THE CLAIMED INVENTION AS A WHOLE MUST BE CONSIDERED

In determining the differences between the prior art and the claims, the question under **35 U.S.C. 103** is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983) (Claims were directed to a vibratory testing machine (a hard-bearing wheel balancer) comprising a holding structure, a base structure, and a supporting means which form "a single integral and gaplessly continuous piece." *Nortron* argued the invention is just making integral what had been made in four bolted pieces, improperly limiting the focus to a structural difference from the prior art and failing to consider the invention as a whole. The prior art perceived a need for mechanisms to dampen resonance, whereas the inventor eliminated the need for dampening via the one-piece gapless support structure. "Because that insight was contrary to the understandings and expectations of the art, the structure effectuating it would not have been obvious to those skilled in the art." 713 F.2d at 785, 218 USPQ at 700 (citations omitted).).

See also *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) (Claims were directed to a three step process for preparing sweetened foods and drinks. The first two steps were directed to a process of producing high purity maltose (the sweetener), and the third was directed to adding the maltose to foods and drinks. The parties agreed that the first two steps were unobvious but formed a known product and the third step was obvious. The Solicitor argued the preamble was directed to a process for preparing foods and drinks sweetened mildly and thus the specific method of making the high purity maltose (the first two steps in the claimed process) should not be given weight, analogizing with product-by-process claims. The court held "due to the admitted unobviousness of the first two steps of the claimed combination of steps, the subject matter as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made." 535 F.2d at 69, 190 USPQ at 17 (emphasis in original). The preamble only recited the purpose of the process and did not limit the body of the claim. Therefore, the claimed process was a three step process, not the product formed by two steps of the process or the third step of using that product.).

II. DISTILLING THE INVENTION DOWN TO A "GIST" OR "THRUST" OF AN INVENTION DISREGARDS "AS A WHOLE" REQUIREMENT

Distilling an invention down to the "gist" or "thrust" of an invention disregards the requirement of analyzing the subject matter "as a whole." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (restricting consideration of the claims to a 10% per second rate of stretching of unsintered PTFE and disregarding other limitations resulted in treating claims as though they read differently than allowed); *Bausch & Lomb v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 447-49, 230 USPQ 416, 419-20 (Fed. Cir. 1986), *cert. denied*, 484 U.S. 823 (1987) (District court focused on the "concept of forming ridgeless depressions having smooth rounded edges using a laser beam to vaporize the material," but "disregarded express limitations that the product be an ophthalmic lens formed of a transparent cross-linked polymer and that the laser marks be surrounded by a smooth surface of unsublimated polymer."). See also *Jones v. Hardy*, 727 F.2d 1524, 1530, 220 USPQ 1021, 1026 (Fed. Cir. 1984) ("treating the advantage as the invention disregards statutory requirement that the invention be viewed 'as a whole'"); *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561,

1 USPQ2d 1593 (Fed. Cir.), *cert. denied*, 481 U.S. 1052 (1987) (district court improperly distilled claims down to a one word solution to a problem).

III. DISCOVERING SOURCE/CAUSE OF A PROBLEM IS PART OF "AS A WHOLE" INQUIRY

"[A] patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103." *In re Sponnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969). However, "discovery of the cause of a problem . . does not always result in a patentable invention. . . . [A] different situation exists where the solution is obvious from prior art which contains the same solution for a similar problem." *In re Wiseman*, 596 F.2d 1019, 1022, 201 USPQ 658, 661 (CCPA 1979) (emphasis in original).

In *In re Sponnoble*, the claim was directed to a plural compartment mixing vial wherein a center seal plug was placed between two compartments for temporarily isolating a liquid-containing compartment from a solids-containing compartment. The claim differed from the prior art in the selection of butyl rubber with a silicone coating as the plug material instead of natural rubber. The prior art recognized that leakage from the liquid to the solids compartment was a problem, and considered the problem to be a result of moisture passing around the center plug because of microscopic fissures inherently present in molded or blown glass. The court found the inventor discovered the cause of moisture transmission was through the center plug, and there was no teaching in the prior art which would suggest the necessity of selecting applicant's plug material which was more impervious to liquids than the natural rubber plug of the prior art.

In *In re Wiseman*, 596 F.2d at 1022, 201 USPQ at 661, claims directed to grooved carbon disc brakes wherein the grooves were provided to vent steam or vapor during a braking action to minimize fading of the brakes were rejected as obvious over a reference showing carbon disc brakes without grooves in combination with a reference showing grooves in noncarbon disc brakes for the purpose of cooling the faces of the braking members and eliminating dust, thereby reducing fading of the brakes. The court affirmed the rejection, holding that even if applicants discovered the cause of a problem, the solution would have been obvious from the prior art which contained the same solution (inserting grooves in disc brakes) for a similar problem.

IV. APPLICANTS ALLEGING DISCOVERY OF A SOURCE OF A PROBLEM MUST PROVIDE SUBSTANTIATING EVIDENCE

Applicants who allege they discovered the source of a problem must provide evidence substantiating the allegation, either by way of affidavits or declarations, or by way of a clear and persuasive assertion in the specification. *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979) (unsubstantiated statement of counsel was insufficient to show appellants discovered source of the problem); *In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983) (Claims were directed to a method for redeeming merchandising coupons which contain a UPC "5-by-5" bar code wherein, among other steps, the memory at each supermarket would identify coupons by manufacturer and transmit the data to a central computer to provide an audit thereby eliminating the need for clearinghouses and preventing retailer fraud. In challenging the propriety of an obviousness rejection, appellant argued he discovered the source of a problem (retailer fraud and manual clearinghouse operations) and its solution. The court found appellant's specification did not support the argument that he discovered the source of the problem with respect to retailer fraud, and that the claimed invention failed to solve the problem of manual clearinghouse operations.).

V. DISCLOSED INHERENT PROPERTIES ARE PART OF "AS A WHOLE" INQUIRY

"In determining whether the invention as a whole would have been obvious under **35 U.S.C. 103**, we must first delineate the invention as a whole. In delineating the invention as a whole, we look not only to the subject matter which is literally recited in the claim in question... but also to those properties of the subject matter which are inherent in the subject matter *and* are disclosed in the specification. . . Just as we look to a chemical and its properties when we examine the obviousness of a composition of matter claim, it is this invention *as a whole*, and not some part of it, which must be obvious under **35 U.S.C. 103**." *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1977) (emphasis in original) (citations omitted) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The court found the invention as a whole was the ratio of 0.12 and its inherent property that the claimed devices maximized treatment capacity regardless of other variables in the devices. The prior art did not recognize that treatment capacity was a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result-effective variable.). See also *In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963) ("From the standpoint

of patent law, a compound and all its properties are inseparable.").

Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). See **MPEP § 2112** for the requirements of rejections based on inherency.

VI. PRIOR ART MUST BE CONSIDERED IN ITS ENTIRETY, INCLUDING DISCLOSURES THAT TEACH AWAY FROM THE CLAIMS

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (Claims were directed to a process of producing a porous article by expanding shaped, unsintered, highly crystalline poly(tetrafluoroethylene) (PTFE) by stretching said PTFE at a 10% per second rate to more than five times the original length. The prior art teachings with regard to unsintered PTFE indicated the material does not respond to conventional plastics processing, and the material should be stretched slowly. A reference teaching rapid stretching of conventional plastic polypropylene with reduced crystallinity combined with a reference teaching stretching unsintered PTFE would not suggest rapid stretching of highly crystalline PTFE, in light of the disclosures in the art that teach away from the invention, i.e., that the conventional polypropylene should have reduced crystallinity before stretching, and that PTFE should be stretched slowly.).

However, "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed…." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). >See also **MPEP § 2123**.<

2141.03 Level of Ordinary Skill in the Art [R-6]

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I. < FACTORS TO CONSIDER IN DETERMINING LEVEL OF ORDINARY SKILL

**>The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. Factors that may be considered in determining the level of ordinary skill in the art may include: (A) "type of problems encountered in the art;" (B) "prior art solutions to those problems;" (C) "rapidity with which innovations are made;" (D) "sophistication of the technology; and" (E) "educational level of active workers in the field. In a given case, every factor may not be present, and one or more factors may predominate." *In re GPAC*, 57 F.3d 1573, 1579, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995); *Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986); *Environmental Designs, Ltd. V. Union Oil Co.*, 713 F.2d 693, 696, 218 USPQ 865, 868 (Fed. Cir. 1983).

"A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007). "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* Office personnel may also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at ___, 82 USPQ2d at 1396. <

The "hypothetical 'person having ordinary skill in the art' to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art." *Ex parte Hiyamizu*, 10 USPQ2d 1393, 1394 (Bd. Pat. App. & Inter. 1988) (The Board disagreed with the examiner's definition of one of ordinary skill in the art (a doctorate level engineer or scientist working at least 40 hours per week in semiconductor research or development), finding that the hypothetical person is not definable by way of credentials, and that the evidence in the application did not support the conclusion that such a person would require a doctorate or equivalent knowledge in science or engineering.).

References which do not qualify as prior art because they postdate the claimed invention may be relied upon to show the level of ordinary skill in the art at or around the time the invention was made. *Ex parte Erlich*, 22 USPQ 1463 (Bd. Pat. App. & Inter. 1992). Moreover, documents not available as prior art because the documents were not widely disseminated may be used to demonstrate the level of ordinary skill in the art. For example, the document may be relevant to establishing "a motivation to combine which is implicit in the knowledge of one of ordinary skill in the art." *National Steel Car Ltd. v. Canadian Pacific Railway Ltd.*, 357 F.3d 1319, 1338, 69 USPQ2d 1641, 1656 (Fed. Cir. 2004)(holding that a drawing made by an engineer that was not prior art may nonetheless "be used to demonstrate a motivation to combine implicit in the knowledge of one of ordinary skill in the art").

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II. < SPECIFYING A PARTICULAR LEVEL OF SKILL IS NOT NECESSARY WHERE THE PRIOR ART ITSELF REFLECTS AN APPROPRIATE LEVEL

If the only facts of record pertaining to the level of skill in the art are found within the prior art of record, the court has held that an invention may be held to have been obvious without a specific finding of a particular level of skill where the prior art itself reflects an appropriate level. *Chore-Time Equipment, Inc. v. Cumberland Corp.*, 713 F.2d 774, 218 USPQ 673 (Fed. Cir. 1983). See also *Okajima v. Bourdeau*, 261 F.3d 1350, 1355, 59 USPQ2d 1795, 1797 (Fed. Cir. 2001).

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III. < ASCERTAINING LEVEL OF ORDINARY SKILL IS NECESSARY TO MAINTAIN OBJECTIVITY

"The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry." *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718, 21 USPQ2d 1053, 1057 (Fed. Cir. 1991). The examiner must ascertain what would have been obvious to one of ordinary skill in the art at the time the invention was made, and not to the inventor, a judge, a layman, those skilled in remote arts, or to geniuses in the art at hand. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 218 USPQ 865 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984).

2142 Legal Concept of Prima Facie Obviousness [R-9]

The legal concept of *prima facie* obviousness is a procedural tool of examination which applies broadly to all arts. It allocates who has the burden of going forward with production of evidence in each step of the examination process. See *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); *In re Saunders*, 444 F.2d 599, 170 USPQ 213 (CCPA 1971); *In re Tiffin*, 443 F.2d 394, 170 USPQ 88 (CCPA 1971), *amended*, 448 F.2d 791, 171 USPQ 294 (CCPA 1971); *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968). The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness. If, however, the examiner does produce a *prima facie* case, the burden of coming forward with evidence or arguments shifts to the applicant who may submit additional evidence of nonobviousness, such as comparative test data showing that the claimed invention possesses improved properties not expected by the prior art. The initial evaluation of *prima facie* obviousness thus relieves both the examiner and applicant from evaluating evidence beyond the prior art and the evidence in the specification as filed until the art has been shown to render obvious the claimed invention.

To reach a proper determination under **35 U.S.C. 103**, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

ESTABLISHING A PRIMA FACIE CASE OF OBVIOUSNESS

The key to supporting any rejection under 35 U.S.C. **103** is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. **103** should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR* , 550 U.S. at ___ , 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval).

>It remains true that "[t]he determination of obviousness is dependent on the facts of each case." *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1089 (Fed. Cir. 2008) (citing *Graham*, 383 U.S. at 17-18 (1966)).< If the examiner determines there is factual support for rejecting the claimed invention under **35 U.S.C. 103**, the examiner must then consider any evidence supporting the patentability of the claimed invention, such as any evidence in the specification or any other evidence submitted by the applicant. The ultimate determination of patentability is based on the entire record, by a

preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The legal standard of "a preponderance of evidence" requires the evidence to be more convincing than the evidence which is offered in opposition to it. With regard to rejections under **35 U.S.C. 103**, the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e., the reference teachings establish a *prima facie* case of obviousness) is more probable than not.

When an applicant submits evidence, whether in the specification as originally filed or in reply to a rejection, the examiner must reconsider the patentability of the claimed invention. The decision on patentability must be made based upon consideration of all the evidence, including the evidence submitted by the examiner and the evidence submitted by the applicant. A decision to make or maintain a rejection in the face of all the evidence must show that it was based on the totality of the evidence. Facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion of obviousness was reached, not against the conclusion itself. *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990).

See *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984) for a discussion of the proper roles of the examiner's *prima facie* case and applicant's rebuttal evidence in the final determination of obviousness. See **MPEP § 706.02(j)** for a discussion of the proper contents of a rejection under **35 U.S.C. 103**.

2143 Examples of Basic Requirements of a Prima Facie Case of Obviousness [R-9]

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395-97 (2007) identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham*. The key to supporting any rejection under 35 U.S.C. **103** is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. **103** should be made explicit. >In *Ball Aerosol v. Limited Brands*, 555 F.3d 984 (Fed. Cir. 2009), the Federal Circuit offered additional instruction as to the need for an explicit analysis. The Federal Circuit explained that the Supreme Court's requirement for an explicit analysis does not require record evidence of an explicit teaching of a motivation to combine in the prior art.

> [T]he analysis that "should be made explicit" refers not to the teachings in the prior art of a motivation to combine, but to the court's analysis. . . . Under the flexible inquiry set forth by the Supreme Court, the district court therefore erred by failing to take account of "the inferences and creative steps," or even routine steps, that an inventor would employ and by failing to find a motivation to combine related pieces from the prior art.

Ball Aerosol, 555 F.3d at 993. The Federal Circuit's directive in *Ball Aerosol* was addressed to a lower court, but it applies to Office personnel as well. When setting forth a rejection, Office personnel are to continue to make appropriate findings of fact as explained in **MPEP § 2141** and **§ 2143**, and must provide a reasoned explanation as to why the invention as claimed would have been obvious to a person of ordinary skill in the art at the time of the invention. This requirement for explanation remains even in situations in which Office personnel may properly rely on intangible realities such as common sense and ordinary ingenuity.<

EXEMPLARY RATIONALES

Exemplary rationales that may support a conclusion of obviousness include:

(A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution of one known element for another to obtain predictable results;

(C) Use of known technique to improve similar devices (methods, or products) in the same way;

(D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;

(E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Note that the list of rationales provided is not intended to be an all-inclusive list. Other rationales to support a conclusion of obviousness may be relied upon by Office personnel. Any rationale employed must provide a link between the factual findings and the legal conclusion of obviousness.

It is important for Office personnel to recognize that when they do choose to formulate an obviousness rejection using one of the rationales suggested by the Supreme Court in KSR and discussed herein, they are to adhere to the guidance provided regarding the necessary factual findings. It remains Office policy that appropriate factual findings are required in order to apply the enumerated rationales properly.

The subsections below include discussions of each rationale along with examples illustrating how the cited rationales may be used to support a finding of obviousness. >Some examples use the facts of pre-KSR cases to show how the rationales suggested by the Court in KSR may be used to support a finding of obviousness.< The cases cited (from which the facts were derived) may not necessarily stand for the proposition that the particular rationale is the basis for the court's holding of obviousness>, but they do illustrate consistency of past decisions with the lines of reasoning laid out in KSR. Other examples are post-KSR decisions that show how the Federal Circuit has applied the principles of KSR. Cases are included that illustrate findings of obviousness as well as nonobviousness.< Note that, in some instances, a single case is used in different subsections to illustrate the use of more than one rationale to support a finding of obviousness. It will often be the case that, once the *Graham* inquiries have been satisfactorily resolved, a conclusion of obviousness may be supported by more than one line of reasoning.

A. Combining Prior Art Elements According to Known Methods To Yield Predictable Results

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

(1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;

(2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely performs the same function as it does separately;

(3) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and

(4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1395; *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950). "[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1:

The claimed invention in *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969) was a paving machine which combined several well-known elements onto a single chassis. Standard prior art paving machines typically combined equipment for spreading and shaping asphalt onto a single chassis. The patent claim included the well-known element of a radiant-heat burner attached to the side of the paver for the purpose of preventing cold joints during continuous strip paving. The prior art used radiant heat for softening the asphalt to make patches, but did not use radiant heat burners to achieve continuous strip paving. All of the component parts were known in the prior art. The only difference was the combination of the "old elements" into a single device by mounting them on a single chassis. The Court found that the operation of the heater was in no way dependent on the operation of the other equipment, and that a separate heater could also be used in conjunction with a standard paving machine to achieve the same results. The Court concluded that "[t]he convenience of putting the burner together with the other elements in one machine, though perhaps a matter of great convenience, did not produce a 'new' or 'different function'" and that to those skilled in the art the use of the old elements in combination would have been obvious. *Id.* at 60, 163 USPQ at 674.

Note that combining known prior art elements is not sufficient to render the claimed invention obvious if the results would not have been predictable to one of ordinary skill in the art. *United States v. Adams*, 383 U.S. 39, 51-52, 148 USPQ 479, 483-84 (1966). In *Adams*, the

claimed invention was to a battery with one magnesium electrode and one cuprous chloride electrode that could be stored dry and activated by the addition of plain water or salt water. Although magnesium and cuprous chloride were individually known battery components, the Court concluded that the claimed battery was nonobvious. The Court stated that "[d]espite the fact that each of the elements of the Adams battery was well known in the prior art, to combine them as did Adams required that a person reasonably skilled in the prior art must ignore" the teaching away of the prior art that such batteries were impractical and that water-activated batteries were successful only when combined with electrolytes detrimental to the use of magnesium electrodes. *Id*. at 42-43, 50-52, 148 USPQ at 480, 483. "When the prior art teaches away from combining certain known elements, discovery of successful means of combining them is more likely to be nonobvious." *KSR*, 550 U.S. at ___, 82 USPQ2d at 1395.

Example 2:

The claimed invention in *Ruiz v. AB Chance Co.*, 357 F.3d 1270, 69 USPQ2d 1686 (Fed. Cir. 2004) was directed to a system which employs a screw anchor for underpinning existing foundations and a metal bracket to transfer the building load onto the screw anchor. The prior art (Fuller) used screw anchors for underpinning existing structural foundations. Fuller used a concrete haunch to transfer the load of the foundation to the screw anchor. The prior art (Gregory) used a push pier for underpinning existing structural foundations. Gregory taught a method of transferring load using a bracket, specifically: a metal bracket transfers the foundation load to the push pier. The pier is driven into the ground to support the load. Neither reference showed the two elements of the claimed invention – screw anchor and metal bracket – used together. The court found that "artisans knew that a foundation underpinning system requires a means of connecting the foundation to the load-bearing member." *Id*. at 1276, 69 USPQ2d at 1691.

The nature of the problem to be solved – underpinning unstable foundations – as well as the need to connect the member to the foundation to accomplish this goal, would have led one of ordinary skill in the art to choose an appropriate load bearing member and a compatible attachment. Therefore, it would have been obvious to use a metal bracket (as shown in Gregory) in combination with the screw anchor (as shown in Fuller) to underpin unstable foundations.

>

Example 3:

The case of *In re Omeprazole Patent Litigation*, 536 F.3d 1361 (Fed. Cir. 2008), is one in which the claims in question were found to be nonobvious in the context of an argument to combine prior art elements. The invention involved applying enteric coatings to a drug in pill form for the purpose of ensuring that the drug did not disintegrate before reaching its intended site of action. The drug at issue was omeprazole, the generic name for gastric acid inhibitor marketed as Prilosec®. The claimed formulation included two layers of coatings over the active ingredient.

The district court found that Astra's patent in suit was infringed by defendants Apotex and Impax. The district court rejected Apotex's defense that the patents were invalid for obviousness. Apotex had argued that the claimed invention was obvious because coated omeprazole tablets were known from a prior art reference, and because secondary subcoatings in pharmaceutical preparations generally were also known. There was no evidence of unpredictability associated with applying two different enteric coatings to omeprazole. However, Astra's reason for applying an intervening subcoating between the prior art coating and omeprazole had been that the prior art coating was actually interacting with omeprazole, thereby contributing to undesirable degradation of the active ingredient. This degradation of omeprazole by interaction with the prior art coating had not been recognized in the prior art. Therefore, the district court reasoned that based on the evidence available, a person of ordinary skill in the art would have had no reason to include a subcoating in an omeprazole pill formulation.

The Federal Circuit affirmed the district court's decision that the claimed invention was not obvious. Even though subcoatings for enteric drug formulation were known, and there was no evidence of undue technical hurdles or lack of a reasonable expectation of success, the formulation was nevertheless not obvious because the flaws in the prior art formulation that had prompted the modification had not been recognized. Thus there would have been no reason to modify the initial formulation, even though the modification could have been done. Moreover, a person of skill in the art likely would have chosen a different modification even if he or she had recognized the problem.

Office personnel should note that in this case the modification of the prior art that had been presented as an argument for obviousness was an extra process step that added an additional component to a known, successfully marketed formulation. The proposed modification thus amounted to extra work and greater

expense for no apparent reason. This is not the same as combining known prior art elements A and B when each would have been expected to contribute its own known properties to the final product. In the *Omeprazole* case, in view of the expectations of those of ordinary skill in the art, adding the subcoating would not have been expected to confer any particular desirable property on the final product. Rather, the final product obtained according to the proposed modifications would merely have been expected to have the same functional properties as the prior art product.

The Omeprazole case can also be analyzed in view of the discovery of a previously unknown problem by the patentee. If the adverse interaction between active agent and coating had been known, it might well have been obvious to use a subcoating. However, since the problem had not been previously known, there would have been no reason to incur additional time and expense to add another layer, even though the addition would have been technologically possible. This is true because the prior art of record failed to mention any stability problem, despite the acknowledgment during testimony at trial that there was a known theoretical reason that omeprazole might be subject to degradation in the presence of the known coating material.

Example 4:

The case of *Crocs, Inc. v. U.S. International Trade Commission*, 598 F.3d 1294 (Fed. Cir. 2010), is a decision in which the claimed foam footwear was held by the Federal Circuit to be nonobvious over a combination of prior art references.

The claims involved in the obviousness issue were from Crocs' U.S. Patent No. 6,993,858, and were drawn to footwear in which a one-piece molded foam base section formed the top of the shoe (the upper) and the sole. A strap also made of foam was attached to the foot opening of the upper, such that the strap could provide support to the Achilles portion of the wearer's foot. The strap was attached via connectors that allowed it to be in contact with the base section, and to pivot relative to the base section. Because both the base portion and the strap were made of foam, friction between the strap and the base section allowed the strap to maintain its position after pivoting. In other words, the foam strap did not fall under the force of gravity to a position adjacent to the heel of the base section.

The International Trade Commission (ITC) determined that the claims were obvious over the combination of two pieces of prior art. The first was the Aqua Clog, which was a shoe that corresponded to the base section of the footwear of the '858 patent. The second was the Aguerre patent, which taught heel straps made of elastic or another flexible material. In the ITC's view, the claimed invention was obvious because the prior art Aqua Clog differed from the claimed invention only as to the presence of the strap, and a suitable strap was taught by Aguerre.

The Federal Circuit disagreed. The Federal Circuit stated that the prior art did not teach foam heel straps, or that a foam heel strap should be placed in contact with a foam base. The Federal Circuit pointed out that the prior art actually counseled against using foam as a material for the heel strap of a shoe.

> The record shows that the prior art would actually discourage and teach away from the use of foam straps. An ordinary artisan in this field would not add a foam strap to the foam Aqua Clog because foam was likely to stretch and deform, in addition to causing discomfort for a wearer. The prior art depicts foam as unsuitable for straps.

Id. at 1309.

The Federal Circuit continued, stating that even if – contrary to fact – the claimed invention had been a combination of elements that were known in the prior art, the claims still would have been nonobvious. There was testimony in the record that the loose fit of the heel strap made the shoe more comfortable for the wearer than prior art shoes in which the heel strap was constantly in contact with the wearer's foot. In the claimed footwear, the foam heel strap contacted the wearer's foot only when needed to help reposition the foot properly in the shoe, thus reducing wearer discomfort that could arise from constant contact. This desirable feature was a result of the friction between the base section and the strap that kept the strap in place behind the Achilles portion of the wearer's foot. The Federal Circuit pointed out that this combination "yielded more than predictable results." Id. at 1310. Aguerre had taught that friction between the base section and the strap was a problem rather than an advantage, and had suggested the use of nylon washers to reduce friction. Thus the Federal Circuit stated that even if all elements of the claimed invention had been taught by the prior art, the claims would not have been obvious because the combination yielded more than predictable results.

The Federal Circuit's discussion in Crocs serves as a reminder to Office personnel that merely pointing to the presence of all claim elements in the prior art is not a complete statement of a rejection for obviousness. In accordance with MPEP § 2143 A(3), a proper rejection

based on the rationale that the claimed invention is a combination of prior art elements also includes a finding that results flowing from the combination would have been predictable to a person of ordinary skill in the art. MPEP § 2143 A(3). If results would not have been predictable, Office personnel should not enter an obviousness rejection using the combination of prior art elements rationale, and should withdraw such a rejection if it has been made.

Example 5:

Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356 (Fed. Cir. 2008), involved a segmented and mechanized cover for trucks, swimming pools, or other structures. The claim was found to be obvious over the prior art applied.

A first prior art reference taught that a reason for making a segmented cover was ease of repair, in that a single damaged segment could be readily removed and replaced when necessary. A second prior art reference taught the advantages of a mechanized cover for ease of opening. The Federal Circuit noted that the segmentation aspect of the first reference and the mechanization function of the second perform in the same way after combination as they had before. The Federal Circuit further observed that a person of ordinary skill in the art would have expected that adding replaceable segments as taught by the first reference to the mechanized cover of the other would result in a cover that maintained the advantageous properties of both of the prior art covers.

Thus, the Sundance case points out that a hallmark of a proper obviousness rejection based on combining known prior art elements is that one of ordinary skill in the art would reasonably have expected the elements to maintain their respective properties or functions after they have been combined.

Example 6:

In the case of *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335 (Fed Cir. 2009), an "apparent reason to combine" in conjunction with the technical ability to optimize led to the conclusion that the claimed invention would have been obvious.

The invention in question was a method of treating meat to reduce the incidence of pathogens, by spraying the meat with an antibacterial solution under specified conditions. The parties did not dispute that a single prior art reference had taught all of the elements of the claimed invention, except for the pressure limitation of "at least 50 psi."

FMC had argued at the district court that the claimed invention would have been obvious in view of the first prior art reference mentioned above in view of a second reference that had taught the advantages of spray-treating at pressures of 20 to 150 psi when treating meat with a different antibacterial agent. The district court did not find FMC's argument to be convincing, and denied the motion for judgment as a matter of law that the claim was obvious.

Disagreeing with the district court, the Federal Circuit stated that "there was an apparent reason to combine these known elements – namely to increase contact between the [antibacterial solution] and the bacteria on the meat surface and to use the pressure to wash additional bacteria off the meat surface." Id. at 1350. The Federal Circuit explained that because the second reference had taught "using high pressure to improve the effectiveness of an antimicrobial solution when sprayed onto meat, and because an ordinarily skilled artisan would have recognized the reasons for applying [the claimed antibacterial solution] using high pressure and would have known how to do so, Ecolab's claims combining high pressure with other limitations disclosed in FMC's patent are invalid as obvious." Id.

When considering the question of obviousness, Office personnel should keep in mind the capabilities of a person of ordinary skill. In Ecolab, the Federal Circuit stated:

> Ecolab's expert admitted that one skilled in the art would know how to adjust application parameters to determine the optimum parameters for a particular solution. The question then is whether it would have been obvious to combine the high pressure parameter disclosed in the Bender patent with the PAA methods disclosed in FMC's '676 patent. The answer is yes.

Id. If optimization of the application parameters had not been within the level of ordinary skill in the art, the outcome of the Ecolab case may well have been different.

Example 7:

In the case of *Wyers v. Master Lock Co.*, 616 F.3d 1231 (Fed. Cir. 2010), the Federal Circuit held that the claimed barbell-shaped hitch pin locks used to secure trailers to vehicles were obvious.

The court discussed two different sets of claims in Wyers, both drawn to improvements over the prior art hitch pin locks. The first improvement was a removable sleeve that could be placed over the shank of the hitch pin lock so that the same lock could be used with towing apertures of varying sizes. The second improvement was an external flat flange seal adapted to protect the internal lock mechanism from contaminants. Wyers had admitted that each of several prior art references taught every element of the claimed inventions except for the removable sleeve and the external covering. Master Lock had argued that these references, in combination with additional references teaching the missing elements, would have rendered the claims obvious. The court first addressed the question of whether the additional references relied on by Master Lock were analogous prior art. As to the reference teaching the sleeve improvement, the court concluded that it dealt specifically with using a vehicle to tow a trailer, and was therefore in the same field of endeavor as Wyers' sleeve improvement. The reference teaching the sealing improvement dealt with a padlock rather than a lock for a tow hitch. The court noted that Wyers' specification had characterized the claimed invention as being in the field of locking devices, thus at least suggesting that the sealed padlock reference was in the same field of endeavor. However, the court also observed that even if sealed padlocks were not in the same field of endeavor, they were nevertheless reasonably pertinent to the problem of avoiding contamination of a locking mechanism for tow hitches. The court explained that the Supreme Court's decision in KSR "directs [it] to construe the scope of analogous art broadly." Id. at XX. For these reasons, the court found that Master Lock's asserted references were analogous prior art, and therefore relevant to the obviousness inquiry.

The court then turned to the question of whether there would have been adequate motivation to combine the prior art elements as had been urged by Master Lock. The court recalled the Graham inquiries, and also emphasized the "expansive and flexible" post-KSR approach to obviousness that must not "deny factfinders recourse to common sense." Id. at XX. (quoting KSR, 550 U.S. at 415 and 421). The court stated:

> KSR and our later cases establish that the legal determination of obviousness may include recourse to logic, judgment, and common sense, in lieu of expert testimony. . . . Thus, in appropriate cases, the ultimate inference as to the existence of a motivation to combine references may boil down to a question of "common sense," appropriate for resolution on summary judgment or JMOL.

Id. at 15 (citing *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1329 (Fed. Cir. 2009); *Ball Aerosol*, 555 F.3d at 993).

After reviewing these principles, the court proceeded to explain why adequate motivation to combine had been established in this case. With regard to the sleeve improvement, it pointed out that the need for different sizes of hitch pins was well known in the art, and that this was a known source of inconvenience and expense for users. The court also mentioned the marketplace aspect of the issue, noting that space on store shelves was at a premium, and that removable sleeves addressed this economic concern. As to the sealing improvement, the court pointed out that both internal and external seals were well-known means to protect locks from contaminants. The court concluded that the constituent elements were being employed in accordance with their recognized functions, and would have predictably retained their respective functions when combined as suggested by Master Lock. The court cited In re O'Farrell, 853 F.2d 894, 904 (Fed. Cir. 1988) for the proposition that a reasonable expectation of success is a requirement for a proper determination of obviousness.

Office personnel should note that although the Federal Circuit invoked the idea of common sense in support of a conclusion of obviousness, it did not end its explanation there. Rather, the court explained why a person of ordinary skill in the art at the time of the invention, in view of the facts relevant to the case, would have found the claimed inventions to have been obvious. The key to supporting any rejection under **35 U.S.C. 103** is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under **35 U.S.C. 103** should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." See **MPEP § 2141**, subsection III. Office personnel should continue to provide a reasoned explanation for every obviousness rejection.

Example 8:

The claim in *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009), was directed to a polyaxial pedicle screw used in spinal surgeries that included a compression member for pressing a screw head against a receiver member. A prior art reference (Puno) disclosed all of the elements of the claim except for the compression member. Instead, the screw head in Puno

was separated from the receiver member to achieve a shock absorber effect, allowing some motion between receiver member and the vertebrae. The missing compression member was readily found in another prior art reference (Anderson), which disclosed an external fracture immobilization splint for immobilizing long bones with a swivel clamp capable of polyaxial movement until rigidly secured by a compression member. It was asserted during trial that a person of ordinary skill would have recognized that the addition of Anderson's compression member to Puno's device would have achieved a rigidly locked polyaxial pedicle screw covered by the claim.

In conducting its analysis, the Federal Circuit noted that the "predictable result" discussed in *KSR* refers not only to the expectation that prior art elements are capable of being physically combined, but also that the combination would have worked for its intended purpose. In this case, it was successfully argued that Puno "teaches away" from a rigid screw because Puno warned that rigidity increases the likelihood that the screw will fail within the human body, rendering the device inoperative for its intended purpose. In fact, the reference did not merely express a general preference for pedicle screws having a "shock absorber" effect, but rather expressed concern for failure and stated that the shock absorber feature "decrease[s] the chance of failure of the screw of the bone-screw interface" because "it prevent[s] direct transfer of load from the rod to the bone-screw interface." Thus, the alleged reason to combine the prior art elements of Puno and Anderson—increasing the rigidity of the screw—ran contrary to the prior art that taught that increasing rigidity would result in a greater likelihood of failure. In view of this teaching and the backdrop of collective teachings of the prior art, the Federal Circuit determined that Puno teaches away from the proposed combination such that a person of ordinary skill would have been deterred from combining the references as proposed. Secondary considerations evaluated by the Federal Circuit relating to failure by others and copying also supported the view that the combination would not have been obvious at the time of the invention.

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B. Simple Substitution of One Known Element for Another To Obtain Predictable Results

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

(1) a finding that the prior art contained a device (method, product, etc.) which differed from the claimed device by the substitution of some components (step, element, etc.) with other components;

(2) a finding that the substituted components and their functions were known in the art;

(3) a finding that one of ordinary skill in the art could have substituted one known element for another, and the results of the substitution would have been predictable; and

(4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that the substitution of one known element for another yields predictable results to one of ordinary skill in the art. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1:

The claimed invention in *In re Fout* , 675 F.2d 297, 213 USPQ 532 (CCPA 1982) was directed to a method for decaffeinating coffee or tea. The prior art (Pagliaro) method produced a decaffeinated vegetable material and trapped the caffeine in a fatty material (such as oil). The caffeine was then removed from the fatty material by an aqueous extraction process. Applicant (Fout) substituted an evaporative distillation step for the aqueous extraction step. The prior art (Waterman) suspended coffee in oil and then directly distilled the caffeine through the oil. The court found that "[b]ecause both Pagliaro and Waterman teach a method for separating caffeine from oil, it would have been *prima facie* obvious to substitute one method for the other. Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious." *Id*. at 301, 213 USPQ at 536.

Example 2:

The invention in *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988) was directed to a method for synthesizing a protein in a transformed bacterial host species by substituting a heterologous gene for a gene native to the host species. Generally speaking, protein synthesis *in vivo* followed the path of DNA to RNA to protein. Although the prior art Polisky article (authored by two of the three inventors of the application) had explicitly suggested employing the method described for protein synthesis, the inserted heterologous gene exemplified in the article was one that normally did not proceed all the way to the protein production step, but instead terminated with the RNA. A second reference to Bahl had described a general method of inserting chemically synthesized DNA into a plasmid. Thus, it would have been obvious to one of ordinary skill in the

art to replace the prior art gene with another gene known to lead to protein production, because one of ordinary skill in the art would have been able to carry out such a substitution, and the results were reasonably predictable.

In response to applicant's argument that there had been significant unpredictability in the field of molecular biology at the time of the invention, the court stated that the level of skill was quite high and that the teachings of Polisky, even taken alone, contained detailed enabling methodology and included the suggestion that the modification would be successful for synthesis of proteins.

This is not a situation where the rejection is a statement that it would have been "obvious to try" without more. Here there was a reasonable expectation of success. "Obviousness does not require absolute predictability of success." *Id*. at 903, 7 USPQ2d at 1681.

Example 3:

The fact pattern in *Ruiz v. AB Chance Co.*, 357 F.3d 1270, 69 USPQ2d 1686 (Fed. Cir. 2004) is set forth above in Example 2 in subsection A.

The prior art showed differing load-bearing members and differing means of attaching the foundation to the member. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the metal bracket taught in Gregory for Fuller's concrete haunch for the predictable result of transferring the load.

Example 4:

The claimed invention in *Ex parte Smith* , 83 USPQ2d 1509 (Bd. Pat. App. & Int. 2007), was a pocket insert for a bound book made by gluing a base sheet and a pocket sheet of paper together to form a continuous two-ply seam defining a closed pocket. The prior art (Wyant) disclosed at least one pocket formed by folding a single sheet and securing the folder portions along the inside margins using any convenient bonding method. The prior art (Wyant) did not disclose bonding the sheets to form a continuous two-ply seam. The prior art (Dick) disclosed a pocket that is made by stitching or otherwise securing two sheets along three of its four edges to define a closed pocket with an opening along its fourth edge.

In considering the teachings of Wyant and Dick, the Board "found that (1) each of the claimed elements is found within the scope and content of the prior art; (2) one of ordinary skill in the art could have combined the elements as claimed by methods known at the time the invention was made; and (3) one of ordinary skill in the art would have recognized at the time the invention was made that the capabilities or functions of the combination were predictable." Citing *KSR*, the Board concluded that "[t]he substitution of the continuous, two-ply seam of Dick for the folded seam of Wyant thus is no more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

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Example 5:

The claimed invention in *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374 (Fed. Cir. 2007), was directed to a treadmill with a folding tread base that swivels into an upright storage position, including a gas spring connected between the tread base and the upright structure to assist in stably retaining the tread base in the storage position. On reexamination, the examiner rejected the claims as obvious based on a combination of references including an advertisement (Damark) for a folding treadmill demonstrating all of the claim elements other than the gas spring, and a patent (Teague) with a gas spring. Teague was directed to a bed that folds into a cabinet using a novel dual-action spring that reverses force as the mechanism passes a neutral position, rather than a single-action spring that would provide a force pushing the bed closed at all times. The dual-action spring reduced the force required to open the bed from the closed position, while reducing the force required to lift the bed from the open position.

The Federal Circuit addressed the propriety of making the combination since Teague comes from a different field than the application. Teague was found to be reasonably pertinent to the problem addressed in the application because the folding mechanism did not require any particular focus on treadmills, but rather generally addressed problems of supporting the weight of such a mechanism and providing a stable resting position.

Other evidence was considered concerning whether one skilled in the art would have been led to combine the teachings of Damark and Teague. Appellant argued that Teague teaches away from the invention because it directs one skilled in the art not to use single-action springs and does not satisfy the claim limitations as the dual-action springs would render the invention inoperable. The Federal Circuit considered the arguments and found that while Teague at most teaches away from using single-action springs to decrease the opening force, it actually instructed that single-action springs provide the result desired by the inventors, which was to increase the opening force provided by gravity. As to inoperability, the claims were not limited to single-action springs and

were so broad as to encompass anything that assists in stably retaining the tread base, which is the function that Teague accomplished. Additionally, the fact that the counterweight mechanism from Teague used a large spring, which appellant argued would overpower the treadmill mechanism, ignores the modifications that one skilled in the art would make to a device borrowed from the prior art. One skilled in the art would size the components from Teague appropriately for the application.

ICON is another useful example for understanding the scope of analogous art. The art applied concerned retaining mechanisms for folding beds, not treadmills. When determining whether a reference may properly be applied to an invention in a different field of endeavor, it is necessary to consider the problem to be solved. It is certainly possible that a reference may be drawn in such a way that its usefulness as a teaching is narrowly restricted. However, in *ICON*, the "treadmill" concept was too narrow a lens through which to view the art in light of the prior art teachings concerning the problem to be solved. The Teague reference was analogous art because "Teague and the current application both address the need to stably retain a folding mechanism," id. at 1378, and because "nothing about ICON's folding mechanism requires any particular focus on treadmills," id. at 1380.

ICON is also informative as to the relationship between the problem to be solved and existence of a reason to combine. "Indeed, while perhaps not dispositive of the issue, the finding that Teague, by addressing a similar problem, provides analogous art to ICON's application goes a long way towards demonstrating a reason to combine the two references. Because ICON's broad claims read on embodiments addressing that problem as described by Teague, the prior art here indicates a reason to incorporate its teachings." Id. at 1380-81.

The Federal Circuit's discussion in *ICON* also makes clear that if the reference does not teach that a combination is undesirable, then it cannot be said to teach away. An assessment of whether a combination would render the device inoperable must not "ignore the modifications that one skilled in the art would make to a device borrowed from the prior art." Id. at 1382.

Example 6:

Agrizap, Inc. v. Woodstream Corp., 520 F.3d 1337 (Fed. Cir. 2008), involved a stationary pest control device for electrocution of pests such as rats and gophers, in which the device is set in an area where the pest is likely to encounter it. The only difference between the claimed device and the prior art stationary pest control device was that the claimed device employed a resistive electrical switch, while the prior art device used a mechanical pressure switch. A resistive electrical switch was taught in two prior art patents, in the contexts of a hand-held pest control device and a cattle prod.

In determining that the claimed invention was obvious, the Federal Circuit noted that "[t]he asserted claims simply substitute a resistive electrical switch for the mechanical pressure switch" employed in the prior art device. Id. at 1344. In this case, the prior art concerning the hand-held devices revealed that the function of the substituted resistive electrical switch was well known and predictable, and that it could be used in a pest control device. According to the Federal Circuit, the references that taught the hand-held devices showed that "the use of an animal body as a resistive switch to complete a circuit for the generation of an electric charge was already well known in the prior art." Id. Finally, the Federal Circuit noted that the problem solved by using the resistive electrical switch in the prior art hand-held devices – malfunction of mechanical switches due to dirt and dampness – also pertained to the prior art stationary pest control device.

The Federal Circuit recognized *Agrizap* as "a textbook case of when the asserted claims involve a combination of familiar elements according to known methods that does no more than yield predictable results." Id. *Agrizap* exemplifies a strong case of obviousness based on simple substitution that was not overcome by the objective evidence of nonobviousness offered. It also demonstrates that analogous art is not limited to the field of applicant's endeavor, in that one of the references that used an animal body as a resistive switch to complete a circuit for the generation of an electric charge was not in the field of pest control.

Example 7:

The invention at issue in *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008), was a method for auctioning municipal bonds over the Internet. A municipality could offer a package of bond instruments of varying principal amounts and maturity dates, and an interested buyer would then submit a bid comprising a price and interest rate for each maturity date. It was also possible for the interested buyer to bid on a portion of the offering. The claimed invention considered all of the noted parameters to determine the best bid. It operated on conventional Web browsers and allowed participants to monitor the course of the auction.

The only difference between the prior art bidding system and the claimed invention was the use of a conventional Web browser. At trial, the district court had determined that Muniauction's claims were not obvious. Thomson argued that the claimed invention amounted to incorporating a Web browser into a prior art auction system, and was therefore obvious in light of *KSR*. Muniauction rebutted the argument by offering evidence of skepticism by experts, copying, praise, and commercial success. Although the district court found the evidence to be persuasive of nonobviousness, the Federal Circuit disagreed. It noted that a nexus between the claimed invention and the proffered evidence was lacking because the evidence was not coextensive with the claims at issue. For this reason, the Federal Circuit determined that Muniauction's evidence of secondary considerations was not entitled to substantial weight.

The Federal Circuit analogized this case to Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., 485 F.3d 1157 (Fed. Cir. 2007). The *Leapfrog* case involved a determination of obviousness based on application of modern electronics to a prior art mechanical children's learning device. In Leapfrog, the court had noted that market pressures would have prompted a person of ordinary skill to use modern electronics in the prior art device. Similarly in Muniauction, market pressures would have prompted a person of ordinary skill to use a conventional Web browser in a method of auctioning municipal bonds.

Example 8:

In *Aventis Pharma Deutschland v. Lupin Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007), the claims were drawn to the 5(S) stereoisomer of the blood pressure drug ramipril in stereochemically pure form, and to compositions and methods requiring 5(S) ramipril. The 5(S) stereoisomer is one in which all five stereocenters in the ramipril molecule are in the S rather than the R configuration. A mixture of various stereoisomers including 5(S) ramipril had been taught by the prior art. The question before the court was whether the purified single stereoisomer would have been obvious over the known mixture of stereoisomers.

The record showed that the presence of multiple S stereocenters in drugs similar to ramipril was known to be associated with enhanced therapeutic efficacy. For example, when all of the stereocenters were in the S form in the related drug enalapril (SSS enalapril) as compared with only two stereocenters in the S form (SSR enalapril), the therapeutic potency was 700 times as great. There was also evidence to indicate that conventional methods could be used to separate the various stereoisomers of ramipril. The district court saw the issue as a close case, because, in its view, there was no clear motivation in the prior art to isolate 5(S) ramipril. However, the Federal Circuit disagreed, and found that the claims would have been obvious. The Federal Circuit cautioned that requiring such a clearly stated motivation in the prior art to isolate 5(S) ramipril ran counter to the Supreme Court's decision in KSR. The court stated:

> Requiring an explicit teaching to purify the 5(S) stereoisomer from a mixture in which it is the active ingredient is precisely the sort of rigid application of the TSM test that was criticized in *KSR*.

Id. at 1301. The Aventis court also relied on the settled principle that in chemical cases, structural similarity can provide the necessary reason to modify prior art teachings. The Federal Circuit also addressed the kind of teaching that would be sufficient in the absence of an explicitly stated prior art-based motivation, explaining that an expectation of similar properties in light of the prior art can be sufficient, even without an explicit teaching that the compound will have a particular utility.

In the chemical arts, the cases involving so-called "lead compounds" form an important subgroup of the obviousness cases that are based on substitution. The Federal Circuit has had a number of opportunities since the KSR decision to discuss the circumstances under which it would have been obvious to modify a known compound to arrive at a claimed compound. The following cases explore the selection of a lead compound, the need to provide a reason for any proposed modification, and the predictability of the result.

Example 9:

Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd., 533 F.3d 1353 (Fed. Cir. 2008), concerns the pharmaceutical compound rabeprazole. Rabeprazole is a proton pump inhibitor for treating stomach ulcers and related disorders. The Federal Circuit affirmed the district court's summary judgment of nonobviousness, stating that no reason had been advanced to modify the prior art compound in a way that would destroy an advantageous property.

Co-defendant Teva based its obviousness argument on the structural similarity between rabeprazole and lansoprazole. The compounds were recognized as sharing a common core, and the Federal Circuit characterized lansoprazole as a "lead compound." The prior art compound lansoprazole was useful for the same indications as rabeprazole, and differed from rabeprazole only in that lansoprazole has a trifluoroethoxy substituent

at the 4-position of the pyridine ring, while rabeprazole has a methoxypropoxy substituent. The trifluoro substituent of lansoprazole was known to be a beneficial feature because it conferred lipophilicity to the compound. The ability of a person of ordinary skill to carry out the modification to introduce the methoxypropoxy substituent, and the predictability of the result were not addressed.

Despite the significant similarity between the structures, the Federal Circuit did not find any reason to modify the lead compound. According to the Federal Circuit:

> Obviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound. . . . In keeping with the flexible nature of the obviousness inquiry, *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 127 S.Ct. 1727, 1739, 167 L.Ed.2d 705 (2007), the requisite motivation can come from any number of sources and need not necessarily be explicit in the art. See *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1301 (Fed. Cir. 2007). Rather "it is sufficient to show that the claimed and prior art compounds possess a 'sufficiently close relationship . . . to create an expectation,' in light of the totality of the prior art, that the new compound will have 'similar properties' to the old." Id. (quoting *Dillon*, 919 F.2d at 692).

Eisai, 533 F.3d at 1357. The prior art taught that introducing a fluorinated substituent was known to increase lipophilicity, so a skilled artisan would have expected that replacing the trifluoroethoxy substituent with a methoxypropoxy substituent would have reduced the lipophilicity of the compound. Thus, the prior art created the expectation that rabeprazole would be less useful than lansoprazole as a drug for treating stomach ulcers and related disorders because the proposed modification would have destroyed an advantageous property of the prior art compound. The compound was not obvious as argued by Teva because, upon consideration of all of the facts of the case, a person of ordinary skill in the art at the time of the invention would not have had a reason to modify lansoprazole so as to form rabeprazole.

Office personnel are cautioned that the term "lead compound" in a particular opinion can have a contextual meaning that may vary from the way a pharmaceutical chemist might use the term. In the field of pharmaceutical chemistry, the term "lead compound" has been defined variously as "a chemical compound that has pharmacological or biological activity and whose chemical structure is used as a starting point for chemical modifications in order to improve potency, selectivity, or pharmacokinetic parameters;" "[a] compound that exhibits pharmacological properties which suggest its development;" and "a potential drug being tested for safety and efficacy." See, e.g., http://en.wikipedia.org/wiki/Lead_compound, accessed January 13, 2010; www.combichemistry.com/glossary_k.html, accessed January 13, 2010; and www.buildingbiotechnology.com/glossary4.php, accessed January 13, 2010.

The Federal Circuit in *Eisai* makes it clear that from the perspective of the law of obviousness, any known compound might possibly serve as a lead compound: "Obviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound." *Eisai*, 533 F.3d at 1357. Thus, Office personnel should recognize that a proper obviousness rejection of a claimed compound that is useful as a drug might be made beginning with an inactive compound, if, for example, the reasons for modifying a prior art compound to arrive at the claimed compound have nothing to do with pharmaceutical activity. The inactive compound would not be considered to be a lead compound by pharmaceutical chemists, but could potentially be used as such when considering obviousness. Office personnel might also base an obviousness rejection on a known compound that pharmaceutical chemists would not select as a lead compound due to expense, handling issues, or other business considerations. However, there must be some reason for starting with that lead compound other than the mere fact that the "lead compound" merely exists. See *Altana Pharma AG v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 999, 1007 (Fed. Cir. 2009) (holding that there must be some reason "to select and modify a known compound"); *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs, Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008).

Example 10:

A chemical compound was also found to be nonobvious in *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989 (Fed. Cir. 2009). The compound at issue was risedronate – the active ingredient of Procter & Gamble's osteoporosis drug Actonel®. Risedronate is an example of a bisphosphonate, which is a class of compounds known to inhibit bone resorption.

When Procter & Gamble sued Teva for infringement, Teva defended by arguing invalidity for obviousness over one of Procter & Gamble's earlier patents. The prior art patent did not teach risedronate, but instead taught thirty-six other similar compounds including 2-pyr EHDP that were potentially useful with regard to osteoporosis. Teva argued obviousness on the basis of structural similarity to 2-pyr EHDP, which is a positional isomer of risedronate.

The district court found no reason to select 2-pyr EHDP as a lead compound in light of the unpredictable nature of the art, and no reason to modify it so as to obtain risedronate. In addition, there were unexpected results as to potency and toxicity. Therefore the district court found that Teva had not made a prima facie case, and even if it had, it was rebutted by evidence of unexpected results.

The Federal Circuit affirmed the district court's decision. The Federal Circuit did not deem it necessary in this case to consider the question of whether 2-pyr EHDP had been appropriately selected as a lead compound. Rather, the Federal Circuit stated that if 2-pyr EHDP is presumed to be an appropriate lead compound, there must be both a reason to modify it so as to make risedronate, and a reasonable expectation of success. Here there was no evidence that the necessary modifications would have been routine, so there would have been no reasonable expectation of success.

Procter & Gamble is also informative in its discussion of the treatment of secondary considerations of non-obviousness. Although the court found that no prima facie case of obviousness had been presented, it proceeded to analyze Procter & Gamble's proffered evidence countering the alleged prima facie case in some detail, thus shedding light on the proper treatment of such evidence.

The Federal Circuit noted in dicta that even if a *prima facie* case of obviousness had been established, sufficient evidence of unexpected results was introduced to rebut such a showing. At trial, the witnesses consistently testified that the properties of risedronate were not expected, offering evidence that researchers did not predict either the potency or the low dose at which the compound was effective, and that the superior properties were unexpected and could not be predicted. Tests comparing risedronate to a compound in the prior art reference showed that risedronate outperformed the other compound by a substantial margin, could be administered in a greater amount without an observable toxic effect, and was not lethal at the same levels as the other compound. The weight of the evidence and the credibility of the witnesses were sufficient to show unexpected results that would have rebutted an obviousness determination. Thus, nonobviousness can be shown when a claimed invention is shown to have unexpectedly superior properties when compared to the prior art.

The court then addressed the evidence of commercial success of risedronate and the evidence that risedronate met a long felt need. The court pointed out that little weight was to be afforded to the commercial success because the competing product was also assigned to Procter & Gamble. However, the Federal Circuit affirmed the district court's conclusion that risedronate met a long-felt, unsatisfied need. The court rejected Teva's contention that because the competing drug was available before Actonel7, there was no unmet need that the invention satisfied. The court emphasized that whether there was a long-felt unsatisfied need is to be evaluated based on the circumstances as of the filing date of the challenged invention – not as of the date that the invention is brought to market.

It should be noted that the lead compound cases do not stand for the proposition that identification of a single lead compound is necessary in every obviousness rejection of a chemical compound. For example, one might envision a suggestion in the prior art to formulate a compound having certain structurally defined moieties, or moieties with certain properties. If a person of ordinary skill would have known how to synthesize such a compound, and the structural and/or functional result could reasonably have been predicted, then a prima facie case of obviousness of the claimed chemical compound might exist even without identification a particular lead compound. As a second example, it could be possible to view a claimed compound as consisting of two known compounds attached via a chemical linker. The claimed compound might properly be found to have been obvious if there would have been a reason to link the two, if one of ordinary skill would have known how to do so, and if the resulting compound would have been the predictable result of the linkage procedure. Thus, Office personnel should recognize that in certain situations, it may be proper to reject a claimed chemical compound as obvious even without identifying a single lead compound.

Example 11:

Although the decision reached by the Federal Circuit in *Altana Pharma AG v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 999 (Fed. Cir. 2009), involved a motion for preliminary injunction and did not include a final determination of obviousness, the case is nevertheless instructive as to the issue of selecting a lead compound.

The technology involved in *Altana* was the compound pantoprazole, which is the active ingredient in Altana's antiulcer drug Protonix®. Pantoprazole belongs to a class of compounds known as proton pump inhibitors that are used to treat gastric acid disorders in the stomach.

Altana accused Teva of infringement. The district court denied Altana's motion for preliminary injunction for failure to establish a likelihood of success on the merits, determining that Teva had demonstrated a substantial question of invalidity for obviousness in light of one of Altana's prior patents. Altana's patent discussed a compound referred to as compound 12, which was one of eighteen compounds disclosed. The claimed compound pantoprazole was structurally similar to compound 12. The district court found that one of ordinary skill in the art would have selected compound 12 as a lead compound for modification, and the Federal Circuit affirmed.

Obviousness of a chemical compound in view of its structural similarity to a prior art compound may be shown by identifying some line of reasoning that would have led one of ordinary skill in the art to select and modify the prior art compound in a particular way to produce the claimed compound. The necessary line of reasoning can be drawn from any number of sources and need not necessarily be explicitly found in the prior art of record. The Federal Circuit determined that ample evidence supported the district court's finding that compound 12 was a natural choice for further development. For example, Altana's prior art patent claimed that its compounds, including compound 12, were improvements over the prior art; compound 12 was disclosed as one of the more potent of the eighteen compounds disclosed; the patent examiner had considered the compounds of Altana's prior art patent to be relevant during the prosecution of the patent in suit; and experts had opined that one of ordinary skill in the art would have selected the eighteen compounds to pursue further investigation into their potential as proton pump inhibitors.

In response to Altana's argument that the prior art must point to only a single lead compound for further development, the Federal Circuit stated that a "restrictive view of the lead compound test would present a rigid test similar to the teaching-suggestion-motivation test that the Supreme Court explicitly rejected in KSR . . . . The district court in this case employed a flexible approach – one that was admittedly preliminary – and found that the defendants had raised a substantial question that one of skill in the art would have used the more potent compounds of [Altana's prior art] patent, including compound 12, as a starting point from which to pursue further development efforts. That finding was not clearly erroneous." Id. at 1008.

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C. Use of Known Technique To Improve Similar Devices (Methods, or Products) in the Same Way

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

(1) a finding that the prior art contained a "base" device (method, or product) upon which the claimed invention can be seen as an "improvement;"

(2) a finding that the prior art contained a "comparable" device (method, or product that is not the same as the base device) that has been improved in the same way as the claimed invention;

(3) a finding that one of ordinary skill in the art could have applied the known "improvement" technique in the same way to the "base" device (method, or product) and the results would have been predictable to one of ordinary skill in the art; and

(4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that a method of enhancing a particular class of devices (methods, or products) has been made part of the ordinary capabilities of one skilled in the art based upon the teaching of such improvement in other situations. One of ordinary skill in the art would have been capable of applying this known method of enhancement to a "base" device (method, or product) in the prior art and the results would have been predictable to one of ordinary skill in the art. The Supreme Court in *KSR* noted that if the actual application of the technique would have been beyond the skill of one of ordinary skill in the art, then using the technique would not have been obvious. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1:

The claimed invention in *In re Nilssen*, 851 F.2d 1401, 7 USPQ2d 1500 (Fed. Cir. 1988) was directed to a "means by which the self-oscillating inverter in a power-line-operated inverter-type fluorescent lamp ballast is disabled in case the output current from the inverter exceeds some pre-established threshold level for more than a very brief period." *Id*. at 1402, 7 USPQ2d at 1501 That is, the current output was monitored, and if the current output exceeded some threshold for a specified

short time, an actuation signal was sent and the inverter was disabled to protect it from damage.

The prior art (a USSR certificate) described a device for protecting an inverter circuit in an undisclosed manner via a control means. The device indicated the high-load condition by way of the control means, but did not indicate the specific manner of overload protection. The prior art (Kammiller) disclosed disabling the inverter in the event of a high-load current condition in order to protect the inverter circuit. That is, the overload protection was achieved by disabling the inverter by means of a cutoff switch.

The court found "it would have been obvious to one of ordinary skill in the art to use the threshold signal produced in the USSR device to actuate a cutoff switch to render the inverter inoperative as taught by Kammiller." *Id*. at 1403, 7 USPQ2d at 1502. That is, using the known technique of a cutoff switch for protecting a circuit to provide the protection desired in the inverter circuit of the USSR document would have been obvious to one of ordinary skill.

Example 2:

The fact pattern in *Ruiz v. AB Chance Co*. 357 F.3d 1270, 69 USPQ2d 1686 (Fed. Cir. 2004) is set forth above in Example 2 in subsection A.

The nature of the problem to be solved may lead inventors to look at references relating to possible solutions to that problem. *Id*. at 1277, 69 USPQ2d at 1691. Therefore, it would have been obvious to use a metal bracket (as shown in Gregory) with the screw anchor (as shown in Fuller) to underpin unstable foundations.

D. Applying a Known Technique to a Known Device (Method, or Product) Ready for Improvement To Yield Predictable Results

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

(1) a finding that the prior art contained a "base" device (method, or product) upon which the claimed invention can be seen as an "improvement;"

(2) a finding that the prior art contained a known technique that is applicable to the base device (method, or product);

(3) a finding that one of ordinary skill in the art would have recognized that applying the known technique would have yielded predictable results and resulted in an improved system; and

(4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to a known device (method, or product) that was ready for improvement and the results would have been predictable to one of ordinary skill in the art. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1:

The claimed invention in *Dann v. Johnston*, 425 U.S. 219, 189 USPQ 257 (1976) was directed towards a system (i.e., computer) for automatic record keeping of bank checks and deposits. In this system, a customer would put a numerical category code on each check or deposit slip. The check processing system would record these on the check in magnetic ink, just as it does for amount and account information. With this system in place, the bank can provide statements to customers that are broken down to give subtotals for each category. The claimed system also allowed the bank to print reports according to a style requested by the customer. As characterized by the Court, "[u]nder respondent's invention, then, a general purpose computer is programmed to provide bank customers with an individualized and categorized breakdown of their transactions during the period in question." *Id*. at 222, 189 USPQ at 259.

BASE SYSTEM - The nature of the use of data processing equipment and computer software in the banking industry was that banks routinely did much of the record-keeping automatically. In routine check processing, the system read any magnetic ink characters identifying the account and routing. The system also read the amount of the check and then printed that value in a designated area of the check. The check was then sent through a further data processing step which used the magnetic ink information to generate the appropriate records for transactions and for posting to the appropriate accounts. These systems included generating periodic statements for each account, such as the monthly statement sent to checking account customers.

IMPROVED SYSTEM - The claimed invention supplemented this system by recording a category code which can then be utilized to track expenditures by category. Again, the category code will be a number

recorded on the check (or deposit slip) which will be read, converted into a magnetic ink imprint, and then processed in the data system to include the category code. This enabled reporting of data by category as opposed to only allowing reporting by account number.

KNOWN TECHNIQUE - This is an application of a technique from the prior art – the use of account numbers (generally used to track an individual's total transactions) to solve the problem of how to track categories of expenditures to more finely account for a budget. That is, account numbers (identifying data capable of processing in the automatic data processing system) were used to distinguish between different customers. Furthermore, banks have long segregated debits attributable to service charges within any given separate account and have rendered their customers subtotals for those charges. Previously, one would have needed to set up separate accounts for each category and thus receive separate reports. Supplementing the account information with additional digits (the category codes) solved the problem by effectively creating a single account that can be treated as distinct accounts for tracking and reporting services. That is, the category code merely allowed what might previously have been separate accounts to be handled as a single account, but with a number of sub-accounts indicated in the report.

The basic technique of putting indicia on data which then enabled standard sorting, searching, and reporting yielded no more than the predictable outcome which one of ordinary skill would have expected to achieve with this common tool of the trade and was therefore an obvious expedient. The Court held that "[t]he gap between the prior art and respondent's system is simply not so great as to render the system nonobvious to one reasonably skilled in the art." *Id.* at 230, 189 USPQ at 261.

Example 2:

The fact pattern in *In re Nilssen* , 851 F.2d 1401, 7 USPQ2d 1500 (Fed. Cir. 1988) is set forth above in Example 1 in subsection C.

The court found "it would have been obvious to one of ordinary skill in the art to use the threshold signal produced in the USSR device to actuate a cutoff switch to render the inverter inoperative as taught by Kammiller." *Id*. at 1403, 7 USPQ2d at 1502. The known technique of using a cutoff switch would have predictably resulted in protecting the inverter circuit. Therefore, it would have been within the skill of the ordinary artisan to use a cutoff switch in response to the actuation signal to protect the inverter.

E. "Obvious To Try" – Choosing From a Finite Number of Identified, Predictable Solutions, With a Reasonable Expectation of Success

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

(1) a finding that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem;

(2) a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem;

(3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success; and

(4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR*, 550 U.S. at ___, 82 USPQ2d at 1397. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

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The question of whether a claimed invention can be shown to be obvious based on an "obvious to try" line of reasoning has been explored extensively by the Federal Circuit in several cases since the *KSR* decision. The case law in this area is developing quickly in the chemical arts, although the rationale has been applied in other art areas as well.

Some commentators on the *KSR* decision have expressed a concern that because inventive activities are always carried out in the context of what has come before and not in a vacuum, few inventions will survive scrutiny under an obvious to try standard. The cases decided since KSR have proved this fear to have been unfounded. Courts appear to be applying the KSR requirement for "a finite number of identified predictable solutions" in a manner that places particular emphasis on predictability and the reasonable expectations of those of ordinary skill in the art.

The Federal Circuit pointed out the challenging nature of the task faced by the courts – and likewise by Office personnel – when considering the viability of an obvious to try argument: "The evaluation of the choices made by a skilled scientist, when such choices lead to the desired result, is a challenge to judicial understanding of how technical advance is achieved in the particular field of science or technology." *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1352 (Fed. Cir. 2008). The Federal Circuit cautioned that an obviousness inquiry based on an obvious to try rationale must always be undertaken in the context of the subject matter in question, "including the characteristics of the science or technology, its state of advance, the nature of the known choices, the specificity or generality of the prior art, and the predictability of results in the area of interest." *Id*.

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Example 1:

The claimed invention in *Pfizer, Inc. v. Apotex, Inc .*, 480 F.3d 1348, 82 USPQ2d 1321 (Fed. Cir. 2007) was directed to the amlodipine besylate drug product, which is commercially sold in tablet form in the United States under the trademark Norvasc®. At the time of the invention, amlodipine was known as was the use of besylate anions. Amlodipine was known to have the same therapeutic properties as were being claimed for the amlodipine besylate but Pfizer discovered that the besylate form had better manufacturing properties (e.g., reduced "stickiness").

Pfizer argued that the results of forming amlodipine besylate would have been unpredictable and therefore nonobvious. The court rejected the notion that unpredictability could be equated with nonobviousness here, because there were only a finite number (53) of ***pharmaceutically acceptable*** salts to be tested for improved properties.

The court found that one of ordinary skill in the art having problems with the machinability of amlodipine would have looked to forming a salt of the compound and would have been able to narrow the group of potential salt-formers to a group of 53 anions known to form pharmaceutically acceptable salts, which would be an acceptable number to form "a reasonable expectation of success."

Example 2:

The claimed invention in *Alza Corp. v. Mylan Laboratories, Inc. ,* 464 F.3d 1286, 80 USPQ2d 1001 (Fed. Cir. 2006) was drawn to sustained-release formulations of the drug oxybutynin in which the drug is released at a specified rate over a 24-hour period. Oxybutynin was known to be highly water-soluble, and the specification had pointed out that development of sustained-release formulations of such drugs presented particular problems.

A prior art patent to Morella had taught sustained-release compositions of highly water-soluble drugs, as exemplified by a sustained-release formulation of morphine. Morella had also identified oxybutynin as belonging to the class of highly water-soluble drugs. The Baichwal prior art patent had taught a sustained-release formulation of oxybutynin that had a different release rate than the claimed invention. Finally, the Wong prior art patent had taught a generally applicable method for delivery of drugs over a 24-hour period. Although Wong mentioned applicability of the disclosed method to several categories of drugs to which oxybutynin belonged, Wong did not specifically mention its applicability to oxybutynin.

The court found that because the absorption properties of oxybutynin would have been reasonably predictable at the time of the invention, there would have been a reasonable expectation of successful development of a sustained-release formulation of oxybutynin as claimed. The prior art, as evidenced by the specification, had recognized the obstacles to be overcome in development of sustained-release formulations of highly water-soluble drugs, and had suggested a finite number of ways to overcome these obstacles. The claims were obvious because it would have been obvious to try the known methods for formulating sustained-release compositions, with a reasonable expectation of success. The court was not swayed by arguments of a lack of absolute predictability.

Example 3:

**> The Federal Circuit's decision in *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009), affirmed the Office's determination in *Ex parte Kubin*, 83 USPQ2d 1410 (Bd. Pat. App. & Int. 2007) that the claims in question, directed to an isolated nucleic acid molecule, would have been obvious over the prior art applied. < The claim stated that the nucleic acid encoded a particular polypeptide. The encoded polypeptide was identified in the claim by its partially specified sequence, and by its ability to bind to a specified protein.

A prior art patent to Valiante taught the polypeptide encoded by the claimed nucleic acid, but did not disclose either the sequence of the polypeptide, or the claimed

isolated nucleic acid molecule. However, Valiante did disclose that by employing conventional methods such as those disclosed by a prior art laboratory manual by Sambrook, the sequence of the polypeptide could be determined, and the nucleic acid molecule could be isolated. In view of Valiante's disclosure of the polypeptide, and of routine prior art methods for sequencing the polypeptide and isolating the nucleic acid molecule, the Board found that a person of ordinary skill in the art would have had a reasonable expectation that a nucleic acid molecule within the claimed scope could have been successfully obtained.

Relying on *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995), appellant argued that it was improper for the Office to use the polypeptide of the Valiante patent together with the methods described in Sambrook to reject a claim drawn to a specific nucleic acid molecule without providing a reference showing or suggesting a structurally similar nucleic acid molecule. Citing *KSR*, the Board stated that "when there is motivation to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." The Board noted that the problem facing those in the art was to isolate a specific nucleic acid, and there were a limited number of methods available to do so. The Board concluded that the skilled artisan would have had reason to try these methods with the reasonable expectation that at least one would be successful. Thus, isolating the specific nucleic acid molecule claimed was "the product not of innovation but of ordinary skill and common sense."

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The Board's reasoning was substantially adopted by the Federal Circuit. However, it is important to note that in the Kubin decision, the Federal Circuit held that "the Supreme Court in *KSR* unambiguously discredited" the Federal Circuit's decision in *Deuel*, insofar as it "implies the obviousness inquiry cannot consider that the combination of the claim's constituent elements was 'obvious to try.'" *Kubin*, 561 F.3d at 1358. Instead, *Kubin* stated that *KSR* "resurrects" the Federal Circuit's own wisdom in *O'Farrell*, in which "to differentiate between proper and improper applications of 'obvious to try,'" the Federal Circuit "outlined two classes of situations where 'obvious to try' is erroneously equated with obviousness under § 103." *Kubin*, 561 F.3d at 1359. These two classes of situations are: (1) when what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful; and (2) when what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. Id. (citing *O'Farrell*, 853 F.2d at 903).

Example 4:

Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350 (Fed. Cir. 2007), is an example of a chemical case in which the Federal Circuit found that the claim was not obvious. The claimed compound was pioglitazone, a member of a class of drugs known as thiazolidinediones (TZDs) marketed by Takeda as a treatment for Type 2 diabetes. The *Takeda* case brings together the concept of a "lead compound" and the obvious-to-try argument.

Alphapharm had filed an Abbreviated New Drug Application with the Food and Drug Administration, which was a technical act of infringement of Takeda's patent. When Takeda brought suit, Alphapharm's defense was that Takeda's patent was invalid due to obviousness. Alphapharm argued that a two-step modification – involving homologation and ring-walking – of a known compound identified as "compound b" would have produced pioglitazone, and that it was therefore obvious.

The district court found that there would have been no reason to select compound b as a lead compound. There were a large number of similar prior art TZD compounds; fifty-four were specifically identified in Takeda's prior patent, and the district court observed that "hundreds of millions" were more generally disclosed. Although the parties agreed that compound b represented the closest prior art, one reference had taught certain disadvantageous properties associated with compound b, which according to the district court would have taught the skilled artisan not to select that compound as a lead compound. The district court found no prima facie case of obviousness, and stated that even if a prima facie case had been established, it would have been overcome in this case in view of the unexpected lack of toxicity of pioglitazone.

The Federal Circuit affirmed the decision of the district court, citing the need for a reason to modify a prior art compound. The Federal Circuit quoted KSR, stating:

> The KSR Court recognized that "[w]hen there is a design need or market pressure to solve a problem

> and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." KSR, 127 S.Ct. at 1732. In such circumstances, "the fact that a combination was obvious to try might show that it was obvious under § 103." Id. That is not the case here. Rather than identify predictable solutions for antidiabetic treatment, the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation. Significantly, the closest prior art compound (compound b, the 6-methyl) exhibited negative properties that would have directed one of ordinary skill in the art away from that compound. Thus, this case fails to present the type of situation contemplated by the Court when it stated that an invention may be deemed obvious if it was "obvious to try." The evidence showed that it was not obvious to try.

Takeda, 492 F.3d at 1359.

Accordingly, Office personnel should recognize that the obvious to try rationale does not apply when the appropriate factual findings cannot be made. In Takeda, there was a recognized need for treatment of diabetes. However, there was no finite number of identified, predictable solutions to the recognized need, and no reasonable expectation of success. There were numerous known TZD compounds, and although one clearly represented the closest prior art, its known disadvantages rendered it unsuitable as a starting point for further research, and taught the skilled artisan away from its use. Furthermore, even if there had been reason to select compound b, there had been no predictability or reasonable expectation of success associated with the particular modifications necessary to transform compound b into the claimed compound pioglitazone. Thus, an obviousness rejection based on an obvious to try rationale was not appropriate in this situation.

Example 5:

The case of *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs, Inc.*, 520 F.3d 1358 (Fed. Cir. 2008), provides another example in which a chemical compound was determined not to be obvious. The claimed subject matter was topiramate, which is used as an anti-convulsant.

In the course of working toward a new anti-diabetic drug, Ortho-McNeil's scientist had unexpectedly discovered that a reaction intermediate had anti-convulsant properties. Mylan's defense of invalidity due to obviousness rested on an obvious to try argument. However, Mylan did not explain why it would have been obvious to begin with an anti-diabetic drug precursor, especially the specific one that led to topiramate, if one had been seeking an anti-convulsant drug. The district court ruled on summary judgment that Ortho-McNeil's patent was not invalid for obviousness.

The Federal Circuit affirmed. The Federal Circuit pointed out that there was no apparent reason why a person of ordinary skill would have chosen the particular starting compound or the particular synthetic pathway that led to topiramate as an intermediate. Furthermore, there would have been no reason to test that intermediate for anticonvulsant properties if treating diabetes had been the goal. The Federal Circuit recognized an element of serendipity in this case, which runs counter to the requirement for predictability. Summarizing their conclusion with regard to Mylan's obvious to try argument, the Federal Circuit stated:

> [T]his invention, contrary to Mylan's characterization, does not present a finite (and small in the context of the art) number of options easily traversed to show obviousness. . . . KSR posits a situation with a finite, and in the context of the art, small or easily traversed, number of options that would convince an ordinarily skilled artisan of obviousness. . . . [T]his clearly is not the easily traversed, small and finite number of alternatives that KSR suggested might support an inference of obviousness.

Id. at 1364. Thus, Ortho-McNeil helps to clarify the Supreme Court's requirement in KSR for "a finite number" of predictable solutions when an obvious to try rationale is applied: under the Federal Circuit's case law "finite" means "small or easily traversed" in the context of the art in question. As taught in Abbott, discussed above, it is essential that the inquiry be placed in the context of the subject matter at issue, and each case must be decided on its own facts.

Example 6:

In *Bayer Schering Pharma A.G. v. Barr Labs., Inc.*, 575 F.3d 1341 (Fed. Cir. 2009), the claimed invention was an oral contraceptive containing micronized drospirenone marketed as Yasmin®. The prior art compound drospirenone was known to be a poorly water-soluble, acid-sensitive compound with contraceptive effects. It was also known in the art that micronization improves the solubility of poorly water soluble drugs.

Based on the known acid sensitivity, Bayer had studied how effectively an enteric-coated drospirenone tablet delivered a formulation as compared to an intravenous injection of the same formulation to measure the "absolute bioavailability" of the drug. Bayer added an unprotected (normal) drospirenone tablet and compared its bioavailability to that of the enteric-coated formulation and the intravenous delivery. Bayer expected to find that the enteric-coated tablet would produce a lower bioavailability than an intravenous injection, while the normal pill would produce an even lower bioavailability than the enteric-coated tablet. However, they found that despite observations that drospirenone would quickly isomerize in a highly acidic environment (supporting the belief that an enteric coating would be necessary to preserve bioavailability), the normal pill and the enteric-coated pill resulted in the same bioavailability. Following this study, Bayer developed micronized drospirenone in a normal pill, the basis for the disputed patent.

The district court found that a person having ordinary skill in the art would have considered the prior art result that a structurally related compound, spirorenone, though acid-sensitive, would nevertheless absorb in vivo, would have suggested the same result for drospirenone. It also found that while another reference taught that drospirenone isomerizes in vitro when exposed to acid simulating the human stomach, a person of ordinary skill would have been aware of the study's shortcomings, and would have verified the findings as suggested by a treatise on the science of dosage form design, which would have then showed that no enteric coating was necessary.

The Federal Circuit held that the patent was invalid because the claimed formulation was obvious. The Federal Circuit reasoned that the prior art would have funneled the formulator toward two options. Thus, the formulator would not have been required to try all possibilities in a field unreduced by the prior art. The prior art was not vague in pointing toward a general approach or area of exploration, but rather guided the formulator precisely to the use of either a normal pill or an enteric-coated pill.

It is important for Office personnel to recognize that the mere existence of a large number of options does not in and of itself lead to a conclusion of nonobviousness. Where the prior art teachings lead one of ordinary skill in the art to a narrower set of options, then that reduced set is the appropriate one to consider when determining obviousness using an obvious to try rationale.

Example 7:

The case of *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075 (Fed. Cir. 2008), also sheds light on the obvious to try line of reasoning. The claimed compound was clopidogrel, which is the dextrorotatory isomer of methyl alpha-5(4,5,6,7-tetrahydro(3,2-c)thienopyridyl)(2-chlorophenyl)-acetate. Clopidogrel is an anti-thrombotic compound used to treat or prevent heart attack or stroke. The racemate, or mixture of dextrorotatory and levorotatory (D- and L-) isomers of the compound, was known in the prior art. The two forms had not previously been separated, and although the mixture was known to have anti-thrombotic properties, the extent to which each of the individual isomers contributed to the observed properties of the racemate was not known and was not predictable.

The district court assumed that in the absence of any additional information, the D-isomer would have been prima facie obvious over the known racemate. However, in view of the evidence of unpredicted therapeutic advantages of the D-isomer presented in the case, the district court found that any prima facie case of obviousness had been overcome. At trial, the experts for both parties testified that persons of ordinary skill in the art could not have predicted the degree to which the isomers would have exhibited different levels of therapeutic activity and toxicity. Both parties' experts also agreed that the isomer with greater therapeutic activity would most likely have had greater toxicity. Sanofi witnesses testified that Sanofi's own researchers had believed that the separation of the isomers was unlikely to have been productive, and experts for both parties agreed that it was difficult to separate isomers at the time of the invention. Nevertheless, when Sanofi ultimately undertook the task of separating the isomers, it found that they had the "rare characteristic of 'absolute stereoselectivity,'" whereby the D-isomer provided all of the favorable therapeutic activity but no significant toxicity, while the L-isomer produced no therapeutic activity but virtually all of the toxicity. Based on this record, the district court concluded that Apotex had not met its burden of proving by clear and convincing evidence that Sanofi's patent was invalid for obviousness. The Federal Circuit affirmed the district court's conclusion.

Office personnel should recognize that even when only a small number of possible choices exist, the obvious to try line of reasoning is not appropriate when, upon consideration of all of the evidence, the outcome would not have been reasonably predictable and the inventor would not have had a reasonable expectation of success. In Bayer, there were art-based reasons to expect that both the normal pill and the enteric-coated pill would be

therapeutically suitable, even though not all prior art studies were in complete agreement. Thus, the result obtained was not unexpected. In Sanofi, on the other hand, there was strong evidence that persons of ordinary skill in the art, prior to the separation of the isomers, would have had no reason to expect that the D-isomer would have such strong therapeutic advantages as compared with the L-isomer. In other words, the result in Sanofi was unexpected.

Example 8:

In *Rolls-Royce, PLC v. United Technologies Corp.*, 603 F.3d 1325 (Fed. Cir. 2010), the Federal Circuit addressed the obvious to try rationale in the context of a fan blade for jet engines. The case had arisen out of an interference proceeding. Finding that the district court had correctly determined that there was no interference-in-fact because Rolls-Royce's claims would not have been obvious in light of United's application, the Federal Circuit affirmed.

The Federal Circuit described the fan blade of the count as follows:

> Each fan blade has three regions – an inner, an intermediate, and an outer region. The area closest to the axis of rotation at the hub is the inner region. The area farthest from the center of the engine and closest to the casing surrounding the engine is the outer region. The intermediate region falls in between. The count defines a fan blade with a swept-forward inner region, a swept-rearward intermediate region, and forward-leaning outer region.

Id. at 1328.

United had argued that it would have been obvious for a person of ordinary skill in the art to try a fan blade design in which the sweep angle in the outer region was reversed as compared with prior art fan blades from rearward to forward sweep, in order to reduce endwall shock. The Federal Circuit disagreed with United's assessment that the claimed fan blade would have been obvious based on an obvious to try rationale. The Federal Circuit pointed out that in a proper obvious to try approach to obviousness, the possible options for solving a problem must have been "known and finite." Id. at 1339, citing Abbott, 544 F.3d at 1351. In this case, there had been no suggestion in the prior art that would have suggested that changing the sweep angle as Rolls-Royce had done would have addressed the issue of endwall shock. Thus, the Federal Circuit concluded that changing the sweep angle "would not have presented itself as an option at all, let alone an option that would have been obvious to try." Rolls-Royce, 603 F.3d at 1339. The decision in Rolls-Royce is a reminder to Office personnel that the obvious to try rationale can properly be used to support a conclusion of obviousness only when the claimed solution would have been selected from a finite number of potential solutions known to persons of ordinary skill in the art.

Example 9:

The case of *Perfect Web Technologies, Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1328 29 (Fed. Cir. 2009), provides an example in which the Federal Circuit held that a claimed method for managing bulk e-mail distribution was obvious on the basis of an obvious to try argument. In Perfect Web, the method required selecting the intended recipients, transmitting the e-mails, determining how many of the e-mails had been successfully received, and repeating the first three steps if a pre-determined minimum number of intended recipients had not received the e-mail.

The Federal Circuit affirmed the district court's determination on summary judgment that the claimed invention would have been obvious. Failure to meet a desired quota of e mail recipients was a recognized problem in the field of e-mail marketing. The prior art had also recognized three potential solutions: increasing the size of the initial recipient list; resending e-mails to recipients who did not receive them on the first attempt; and selecting a new recipient list and sending e-mails to them. The last option corresponded to the fourth step of the invention as claimed.

The Federal Circuit noted that based on "simple logic," selecting a new list of recipients was more likely to result in the desired outcome than resending to those who had not received the e-mail on the first attempt. There had been no evidence of any unexpected result associated with selecting a new recipient list, and no evidence that the method would not have had a reasonable likelihood of success. Thus, the Federal Circuit concluded that, as required by KSR, there were a "finite number of identified, predictable solutions," and that the obvious to try inquiry properly led to the legal conclusion of obviousness.

The Federal Circuit in *Perfect Web* also discussed the role of common sense in the determination of obviousness. The district court had cited *KSR* for the proposition that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton," and found that "the final step [of the claimed invention] is merely the logical result of common sense application of the maxim 'try, try

again.'" In affirming the district court, the Federal Circuit undertook an extended discussion of common sense as it has been applied to the obviousness inquiry, both before and since the KSR decision.

The Federal Circuit pointed out that application of common sense is not really an innovation in the law of obviousness when it stated, "Common sense has long been recognized to inform the analysis of obviousness if explained with sufficient reasoning." *Perfect Web*, 587 F.3d at 1328 (emphasis added). The Federal Circuit then provided a review of a number of precedential cases that inform the understanding of common sense, including *In re Bozek*, 416 F.2d 1385, 1390 (CCPA 1969) (explaining that a patent examiner may rely on "common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference") and *In re Zurko*, 258 F.3d 1379, 1383, 1385 (Fed. Cir. 2001) (clarifying that a factual foundation is needed in order for an examiner to invoke "good common sense" in a case in which "basic knowledge and common sense was not based on any evidence in the record"). The Federal Circuit implicitly acknowledged in *Perfect Web* that the kind of strict evidence-based teaching, suggestion, or motivation required in *In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002), is not an absolute requirement for an obviousness rejection in light of the teachings of *KSR*. The Federal Circuit explained that "[a]t the time [of the Lee decision], we required the PTO to identify record evidence of a teaching, suggestion, or motivation to combine references." However, *Perfect Web* went on to state that even under Lee, common sense could properly be applied when analyzing evidence relevant to obviousness. Citing *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006), and *In re Kahn*, 441 F.3d 977 (Fed. Cir. 2006), two cases decided shortly before the Supreme Court's decision in *KSR*, the Federal Circuit noted that although "a reasoned explanation that avoids conclusory generalizations" is required to use common sense, identification of a "specific hint or suggestion in a particular reference" is not.

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F. Known Work in One Field of Endeavor May Prompt Variations of It for Use in Either the Same Field or a Different One Based on Design Incentives or Other Market Forces if the Variations Are Predictable to One of Ordinary Skill in the Art

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

(1) a finding that the scope and content of the prior art, whether in the same field of endeavor as that of the applicant's invention or a different field of endeavor, included a similar or analogous device (method, or product);

(2) a finding that there were design incentives or market forces which would have prompted adaptation of the known device (method, or product);

(3) a finding that the differences between the claimed invention and the prior art were encompassed in known variations or in a principle known in the prior art;

(4) a finding that one of ordinary skill in the art, in view of the identified design incentives or other market forces, could have implemented the claimed variation of the prior art, and the claimed variation would have been predictable to one of ordinary skill in the art; and

(5) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claimed invention would have been obvious is that design incentives or other market forces could have prompted one of ordinary skill in the art to vary the prior art in a predictable manner to result in the claimed invention. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

Example 1:

The fact pattern in *Dann v. Johnston*, 425 U.S. 219, 189 USPQ 257 (1976) is set forth above in Example 1 in subsection D.

The Court found that the problem addressed by applicant – the need to give more detailed breakdown by a category of transactions – was closely analogous to the task of keeping track of the transaction files of individual business units. *Id*. at 229, 189 USPQ at 261. Thus, an artisan in the data processing area would have recognized the similar class of problem and the known solutions of the prior art and it would have been well within the ordinary skill level to implement the system in the different environment. The Court held that "[t]he gap between the prior art and respondent's system is simply not so great as to render the system nonobvious to one reasonably skilled in the art." *Id.* at 230, 189 USPQ at 261.

Example 2:

The claimed invention in *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 82 USPQ2d 1687 (Fed. Cir. 2007) was directed to a learning device to help young children read phonetically. The claim read as follows:

An interactive learning device, comprising:

a housing including a plurality of switches;

a sound production device in communication with the switches and including a processor and a memory;

at least one depiction of a sequence of letters, each letter being associable with a switch; and

a reader configured to communicate the identity of the depiction to the processor,

wherein selection of a depicted letter activates an associated switch to communicate with the processor, causing the sound production device to generate a signal corresponding to a sound associated with the selected letter, the sound being determined by a position of the letter in the sequence of letter.

The court concluded that the claimed invention would have been obvious in view of the combination of two pieces of prior art, (1) Bevan (which showed an electro-mechanical toy for phonetic learning), (2) the Super Speak & Read device (SSR) (an electronic reading toy), and the knowledge of one of ordinary skill in the art.

The court made clear that there was no technological advance beyond the skill shown in the SSR device. The court stated that "one of ordinary skill in the art of children's learning toys would have found it obvious to combine the Bevan device with the SSR to update it using modern electronic components in order to gain the commonly understood benefits of such adaptation, such as decreased size, increased reliability, simplified operation, and reduced cost. While the SSR only permits generation of a sound corresponding to the first letter of a word, it does so using electronic means. The combination is thus the adaptation of an old idea or invention (Bevan) using newer technology that is commonly available and understood in the art (the SSR)."

The court found that the claimed invention was but a variation on already known children's toys. This variation presented no nonobvious advance over other toys. The court made clear that there was no technological advance beyond the skill shown in the SSR device. The court found that "[a]ccomodating a prior art mechanical device that accomplishes that goal to modern electronics would have been reasonably obvious to one of ordinary skill in designing children's learning devices. Applying modern electronics to older mechanical devices has been commonplace in recent years."

Example 3:

The claimed invention in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007) was an adjustable pedal assembly with a fixed pivot point and an electronic pedal-position sensor attached to the assembly support. The fixed pivot point meant that the pivot was not changed as the pedal was adjusted. The placement of the sensor on the assembly support kept the sensor fixed while the pedal was adjusted.

Conventional gas pedals operated by a mechanical link which adjusted the throttle based on the travel of the pedal from a set position. The throttle controlled the combustion process and the available power generated by the engine. Newer cars used computer controlled throttles in which a sensor detected the motion of the pedal and sent signals to the engine to adjust the throttle accordingly. At the time of the invention, the marketplace provided a strong incentive to convert mechanical pedals to electronic pedals, and the prior art taught a number of methods for doing so. The prior art (Asano) taught an adjustable pedal with a fixed pivot point with mechanical throttle control. The prior art ('936 patent to Byler) taught an electronic pedal sensor which was placed on a pivot point in the pedal assembly and that it was preferable to detect the pedal's position in the pedal mechanism rather than in the engine. The prior art (Smith) taught that to prevent the wires connecting the sensor to the computer from chafing and wearing out, the sensor should be put on a fixed part of the pedal assembly rather than in or on the pedal's footpad. The prior art (Rixon) taught an adjustable pedal assembly (sensor in the footpad) with an electronic sensor for throttle control. There was no prior art electronic throttle control that was combined with a pedal assembly which kept the pivot point fixed when adjusting the pedal.

The Court stated that "[t]he proper question to have asked was whether a pedal designer of ordinary skill, facing the wide range of needs created by developments in the field of endeavor, would have seen a benefit to upgrading Asano with a sensor." *Id*. at ___, 82 USPQ2d at 1399. The Court found that technological developments in the automotive design would have prompted a designer to upgrade Asano with an electronic sensor. The next question was where to attach the sensor. Based on the prior art, a designer would have known to place the sensor on a nonmoving part of the pedal structure and the most obvious nonmoving point on the structure from which a sensor can easily detect the pedal's position was a pivot point. The Court concluded that it would have been obvious to upgrade Asano's fixed pivot point adjustable pedal by replacing the mechanical assembly for throttle

control with an electronic throttle control and to mount the electronic sensor on the pedal support structure.

Example 4:

The claimed invention in *Ex parte Catan* , 83 USPQ2d 1568 (bd. Pat. App. & Int. 2007), was a consumer electronics device using bioauthentication to authorize sub-users of an authorized credit account to place orders over a communication network up to a pre-set maximum sub-credit limit.

The prior art (Nakano) disclosed a consumer electronics device like the claimed invention, except that security was provided by a password authentication device rather than a bioauthentication device. The prior art (Harada) disclosed that the use of a bioauthentication device (fingerprint sensor) on a consumer electronics device (remote control) to provide bioauthentication information (fingerprint) was known in the prior art at the time of the invention. The prior art (Dethloff) also disclosed that it was known in the art at the time of the invention to substitute bioauthentication for PIN authentication to enable a user to access credit via a consumer electronics device.

The Board found that the prior art "shows that one of ordinary skill in the consumer electronic device art at the time of the invention would have been familiar with using bioauthentication information interchangeably with or in lieu of PINs to authenticate users." The Board concluded that one of ordinary skill in the art of consumer electronic devices would have found it obvious to update the prior art password device with the modern bioauthentication component and thereby gain, predictably, the commonly understood benefits of such adaptation, that is, a secure and reliable authentication procedure.

(G) Some Teaching, Suggestion, or Motivation in the Prior Art That Would Have Led One of Ordinary Skill To Modify the Prior Art Reference or To Combine Prior Art Reference Teachings To Arrive at the Claimed Invention

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Then, Office personnel must articulate the following:

(1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;

(2) a finding that there was reasonable expectation of success; and

(3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that "a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

The Courts have made clear that the teaching, suggestion, or motivation test is flexible and an explicit suggestion to combine the prior art is not necessary. The motivation to combine may be implicit and may be found in the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. *Id*. at 1366, 80 USPQ2d at 1649. "[A]n implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the 'improvement' is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient. Because the desire to enhance commercial opportunities by improving a product or process is universal-and even common-sensical-we have held that there exists in these situations a motivation to combine prior art references even absent any hint of suggestion in the references themselves. In such situations, the proper question is whether the ordinary artisan possesses knowledge and skills rendering him *capable* of combining the prior art references." *Id*. at 1368, 80 USPQ2d at 1651.

2143.01 Suggestion or Motivation To Modify the References [R-6]

I. *PRIOR ART **>SUGGESTION OF< THE DESIRABILITY OF THE CLAIMED INVENTION

**

Obviousness can * be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006) (discussing rationale underlying the motivation-suggestion-teaching *>test< as a guard against using hindsight in an obviousness analysis). **

In *In re Fulton*, 391 F.3d 1195, 73 USPQ2d 1141 (Fed. Cir. 2004), the claims of a utility patent application were directed to a shoe sole with increased traction having hexagonal projections in a "facing orientation." 391 F.3d at 1196-97, 73 USPQ2d at 1142. The Board combined a design patent having hexagonal projections in a facing orientation with a utility patent having other limitations of the independent claim. 391 F.3d at 1199, 73 USPQ2d at 1144. Applicant argued that the combination was improper because (1) the prior art did not suggest having the hexagonal projections in a facing (as opposed to a "pointing") orientation was the "most desirable" configuration for the projections, and (2) the prior art "taught away" by showing desirability of the "pointing orientation." 391 F.3d at 1200-01, 73 USPQ2d at 1145-46. The court stated that "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed…." *Id*. ** In affirming the Board's obviousness rejection, the court held that the prior art as a whole suggested the desirability of the combination of shoe sole limitations claimed, thus providing a motivation to combine, which need not be supported by a finding that the prior art suggested that the combination claimed by the applicant was the preferred, or most desirable combination over the other alternatives. *Id*.

In *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 69 USPQ2d 1686 (Fed. Cir. 2004), the patent claimed underpinning a slumping building foundation using a screw anchor attached to the foundation by a metal bracket. One prior art reference taught a screw anchor with a concrete bracket, and a second prior art reference disclosed a pier anchor with a metal bracket. The court found motivation to combine the references to arrive at the claimed invention in the "nature of the problem to be solved" because each reference was directed "to precisely the same problem of underpinning slumping foundations." *Id*. at 1276, 69 USPQ2d at 1690. The court also *rejected* the notion that "an express written motivation to combine must appear in prior art references…." *Id.* at 1276, 69 USPQ2d at 1690.

**

II. WHERE THE TEACHINGS OF THE PRIOR ART CONFLICT, THE EXAMINER MUST WEIGH THE SUGGESTIVE POWER OF EACH REFERENCE

The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art, and all teachings in the prior art must be considered to the extent that they are in analogous arts. Where the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another. *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991) (Prior art patent to Carlisle disclosed controlling and minimizing bubble oscillation for chemical explosives used in marine seismic exploration by spacing seismic sources close enough to allow the bubbles to intersect before reaching their maximum radius so the secondary pressure pulse was reduced. An article published several years later by Knudsen opined that the Carlisle technique does not yield appreciable improvement in bubble oscillation suppression. However, the article did not test the Carlisle technique under comparable conditions because Knudsen did not use Carlisle's spacing or seismic source. Furthermore, where the Knudsen model most closely approximated the patent technique there was a 30% reduction of the secondary pressure pulse. On these facts, the court found that the Knudsen article would not have deterred one of ordinary skill in the art from using the Carlisle patent teachings.).

III. FACT THAT REFERENCES CAN BE COMBINED OR MODIFIED **>MAY NOT BE< SUFFICIENT TO ESTABLISH PRIMA FACIE OBVIOUSNESS

The mere fact that references can be combined or modified does not render the resultant combination obvious unless **>the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007)("If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.").<

IV. *>MERE STATEMENT< THAT THE CLAIMED INVENTION IS WITHIN THE CAPABILITIES OF ONE OF ORDINARY SKILL IN THE ART IS NOT SUFFICIENT BY ITSELF TO ESTABLISH PRIMA FACIE OBVIOUSNESS

A statement that modifications of the prior art to meet the claimed invention would have been "'well within the ordinary skill of the art at the time the claimed invention was made'" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason

to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). **‘‘‘>[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’” *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).<

V. THE PROPOSED MODIFICATION CANNOT RENDER THE PRIOR ART UNSATISFACTORY FOR ITS INTENDED PURPOSE

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (Claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The court reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged.).

“Although statements limiting the function or capability of a prior art device require fair consideration, simplicity of the prior art is rarely a characteristic that weighs against obviousness of a more complicated device with added function.” *In re Dance*, 160 F.3d 1339, 1344, 48 USPQ2d 1635, 1638 (Fed. Cir. 1998) (Court held that claimed catheter for removing obstruction in blood vessels would have been obvious in view of a first reference which taught all of the claimed elements except for a “means for recovering fluid and debris” in combination with a second reference describing a catheter including that means. The court agreed that the first reference, which stressed simplicity of structure and taught emulsification of the debris, did not teach away from the addition of a channel for the recovery of the debris.).

VI. THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the “suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate.” 270 F.2d at 813, 123 USPQ at 352.).

2143.02 Reasonable Expectation of Success Is Required [R-9]

A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395 (2007); *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson’s-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

I. OBVIOUSNESS REQUIRES *A REASONABLE EXPECTATION OF SUCCESS

**>Where there is a reason to modify or combine the prior art to achieve the claimed invention, the claims may be rejected as *prima facie* obvious provided there is also< a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (Claims directed to a method of treating depression with amitriptyline (or nontoxic salts thereof) were rejected as *prima facie* obvious over prior art disclosures that

amitriptyline is a compound known to possess psychotropic properties and that imipramine is a structurally similar psychotropic compound known to possess antidepressive properties, in view of prior art suggesting the aforementioned compounds would be expected to have similar activity because the structural difference between the compounds involves a known bioisosteric replacement and because a research paper comparing the pharmacological properties of these two compounds suggested clinical testing of amitriptyline as an antidepressant. The court sustained the rejection, finding that the teachings of the prior art provide a sufficient basis for a reasonable expectation of success.); *Ex parte Blanc*, 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989) (Claims were directed to a process of sterilizing a polyolefinic composition with high-energy radiation in the presence of a phenolic polyester antioxidant to inhibit discoloration or degradation of the polyolefin. Appellant argued that it is unpredictable whether a particular antioxidant will solve the problem of discoloration or degradation. However, the Board found that because the prior art taught that appellant's preferred antioxidant is very efficient and provides better results compared with other prior art antioxidants, there would have been a reasonable expectation of success.).

II. AT LEAST SOME DEGREE OF PREDICTABILITY IS REQUIRED; APPLICANTS MAY PRESENT EVIDENCE SHOWING THERE WAS NO REASONABLE EXPECTATION OF SUCCESS

Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (Claims directed to a method for the commercial scale production of polyesters in the presence of a solvent at superatmospheric pressure were rejected as obvious over a reference which taught the claimed method at atmospheric pressure in view of a reference which taught the claimed process except for the presence of a solvent. The court reversed, finding there was no reasonable expectation that a process combining the prior art steps could be successfully scaled up in view of unchallenged evidence showing that the prior art processes individually could not be commercially scaled up successfully.). See also *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207-08, 18 USPQ2d 1016, 1022-23 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success.); *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.).

III. PREDICTABILITY IS DETERMINED AT THE TIME THE INVENTION WAS MADE

Whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made. *Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986) (Although an earlier case reversed a rejection because of unpredictability in the field of monoclonal antibodies, the court found "in this case at the time this invention was made, one of ordinary skill in the art would have been motivated to produce monoclonal antibodies specific for human fibroplast interferon using the method of [the prior art] with a reasonable expectation of success." 3 USPQ2d at 1016 (emphasis in original).).

2143.03 All Claim Limitations Must Be Considered> [R-6]

** "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under **35 U.S.C. 103**, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

>

I. < INDEFINITE LIMITATIONS MUST BE CONSIDERED

A claim limitation which is considered indefinite cannot be disregarded. If a claim is subject to more than one interpretation, at least one of which would render the claim unpatentable over the prior art, the examiner should reject the claim as indefinite under **35 U.S.C. 112**, second paragraph (see **MPEP § 706.03(d)**) and should reject the claim over the prior art based on the interpretation of the claim that renders the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. Pat. App. & Inter. 1984) (Claims on appeal were rejected on indefiniteness grounds only; the rejection was reversed and the case remanded to the examiner for consideration of pertinent prior art.). Compare *In re Wilson*, 424 F.2d 1382, 165 USPQ 494 (CCPA 1970) (if no reasonably definite meaning can be ascribed to certain claim language, the claim is indefinite,

not obvious) and *In re Steele*, 305 F.2d 859,134 USPQ 292 (CCPA 1962) (it is improper to rely on speculative assumptions regarding the meaning of a claim and then base a rejection under **35 U.S.C. 103** on these assumptions).

>

II. < LIMITATIONS WHICH DO NOT FIND SUPPORT IN THE ORIGINAL SPECIFICATION MUST BE CONSIDERED

When evaluating claims for obviousness under **35 U.S.C. 103**, all the limitations of the claims must be considered and given weight, including limitations which do not find support in the specification as originally filed (i.e., new matter). *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983) *aff'd mem*. 738 F.2d 453 (Fed. Cir. 1984) (Claim to a catalyst expressly excluded the presence of sulfur, halogen, uranium, and a combination of vanadium and phosphorous. Although the negative limitations excluding these elements did not appear in the specification as filed, it was error to disregard these limitations when determining whether the claimed invention would have been obvious in view of the prior art.).

2144 Supporting a Rejection Under 35 U.S.C. 103 [R-9]

>When considering obviousness, Office personnel are cautioned against treating any line of reasoning as a per se rule. This section discusses supporting a rejection under **35 U.S.C. 103** by reliance on scientific theory and legal precedent. In keeping with the flexible approach to obviousness under KSR, as well as the requirement for explanation, Office personnel may invoke legal precedent as a source of supporting rationale when warranted and appropriately supported. See **MPEP § 2144.04**. So, for example, automating a manual activity, making portable, making separable, reversing or duplicating parts, or purifying an old product may form the basis of a rejection. However, such rationales should not be treated as per se rules, but rather must be explained and shown to apply to the facts at hand. A similar caveat applies to any obviousness analysis. Simply stating the principle (e.g., "art recognized equivalent," "structural similarity") without providing an explanation of its applicability to the facts of the case at hand is generally not sufficient to establish a prima facie case of obviousness. <

I. RATIONALE MAY BE IN A REFERENCE, OR REASONED FROM COMMON KNOWLEDGE IN THE ART, SCIENTIFIC PRINCIPLES, ART-RECOGNIZED EQUIVALENTS, OR LEGAL PRECEDENT

The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present convincing line of reasoning supporting rejection); and *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning).

II. THE EXPECTATION OF SOME ADVANTAGE IS THE STRONGEST RATIONALE FOR COMBINING REFERENCES

The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Sernaker*, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). See also *Dystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick*, 464 F.3d 1356, 1368, 80 USPQ2d 1641, 1651 (Fed. Cir. 2006) ("Indeed, we have repeatedly held that an implicit motivation to combine exists not only when a suggestion may be gleaned from the prior art as a whole, but when the 'improvement' is technology-independent and the combination of references results in a product or process that is more desirable, for example because it is stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient. Because the desire to enhance commercial opportunities by improving a product or process is universal—and even common-sensical—we have held that there exists in these situations a motivation to combine prior art references even absent any hint of suggestion in the references themselves.").

III. LEGAL PRECEDENT CAN PROVIDE THE RATIONALE SUPPORTING OBVIOUSNESS ONLY

IF THE FACTS IN THE CASE ARE SUFFICIENTLY SIMILAR TO THOSE IN THE APPLICATION

The examiner must apply the law consistently to each application after considering all the relevant facts. If the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court. If the applicant has demonstrated the criticality of a specific limitation, it would not be appropriate to rely solely on the rationale used by the court to support an obviousness rejection. "The value of the exceedingly large body of precedent wherein our predecessor courts and this court have applied the law of obviousness to particular facts, is that there has been built a wide spectrum of illustrations and accompanying reasoning, that have been melded into a fairly consistent application of law to a great variety of facts." *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990).

IV. RATIONALE DIFFERENT FROM APPLICANT'S IS PERMISSIBLE

The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1323, 76 USPQ2d 1662, 1685 (Fed. Cir. 2005) ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) (discussed below); *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), *cert. denied*, 500 U.S. 904 (1991) (discussed below).>

In *In re Linter* the claimed invention was a laundry composition consisting essentially of a dispersant, cationic fabric softener, sugar, sequestering phosphate, and brightener in specified proportions. The claims were rejected over the combination of a primary reference which taught all the claim limitations except for the presence of sugar, and secondary references which taught the addition of sugar as a filler or weighting agent in compositions containing cationic fabric softeners. Appellant argued that in the claimed invention, the sugar is responsible for the compatibility of the cationic softener with the other detergent components. The court sustained the rejection, stating "The fact that appellant uses sugar for a different purpose does not alter the conclusion that its use in a prior art composition would be [sic, would have been] *prima facie* obvious from the purpose disclosed in the references." 173 USPQ at 562.

In *In re Dillon*, applicant claimed a composition comprising a hydrocarbon fuel and a sufficient amount of a tetra-orthoester of a specified formula to reduce the particulate emissions from the combustion of the fuel. The claims were rejected as obvious over a reference which taught hydrocarbon fuel compositions containing tri-orthoesters for dewatering fuels, in combination with a reference teaching the equivalence of tri-orthoesters and tetra-orthoesters as water scavengers in hydraulic (nonhydrocarbon) fluids. The Board affirmed the rejection finding "there was a 'reasonable expectation' that the tri- and tetra-orthoester fuel compositions would have similar properties based on 'close structural and chemical similarity' between the tri- and tetra-orthoesters and the fact that both the prior art and Dillon use these compounds 'as fuel additives'." 919 F.2d at 692, 16 USPQ2d at 1900. The court held "it is not necessary in order to establish a *prima facie* case of obviousness . . . that there be a suggestion or expectation from *the prior art* that the claimed [invention] will have the same or a similar utility as *one newly discovered by applicant*," and concluded that here a *prima facie* case was established because "[t]he art provided the motivation to make the claimed compositions in the expectation that they would have similar properties." 919 F.2d at 693, 16 USPQ2d at 1901 (emphasis in original).

See **MPEP § 2145**, paragraph II for case law pertaining to the presence of additional advantages or latent properties not recognized in the prior art.

2144.01 Implicit Disclosure

"[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968) (A process for catalytically producing carbon disulfide by reacting sulfur vapor and methane in the presence of charcoal at a temperature of "about 750-830°C" was found to be met by a reference which expressly taught the same process at 700°C because the reference recognized the possibility of using temperatures greater than 750°C. The reference disclosed that catalytic processes for converting methane with sulfur vapors into carbon disulfide at temperatures greater than 750°C (albeit without charcoal) was known, and that 700°C was "much lower than had previously proved feasible."); *In re Lamberti*, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA

1976) (Reference disclosure of a compound where the R-S-R¢ portion has "at least one methylene group attached to the sulfur atom" implies that the other R group attached to the sulfur atom can be other than methylene and therefore suggests asymmetric dialkyl moieties.).

2144.02 Reliance on Scientific Theory [R-6]

The rationale to support a rejection under **35 U.S.C. 103** may rely on logic and sound scientific principle. *In re Soli*, 317 F.2d 941, 137 USPQ 797 (CCPA 1963). However, when an examiner relies on a scientific theory, evidentiary support for the existence and meaning of that theory must be provided. *In re Grose*, 592 F.2d 1161, 201 USPQ 57 (CCPA 1979) (Court held that different crystal forms of zeolites would not have been structurally obvious one from the other because there was no chemical theory supporting such a conclusion. The known chemical relationship between structurally similar compounds (homologs, analogs, isomers) did not support a finding of *prima facie* obviousness of claimed zeolite over the prior art because a zeolite is not a compound but a mixture of compounds related to each other by a particular crystal structure.). **

2144.03 Reliance on Common Knowledge in the Art or "Well Known" Prior Art [R-6]

In *>certain< circumstances >where appropriate<, ** an examiner *>may< take official notice of facts not in the record or * rely on "common knowledge" in making a rejection, however such rejections should be judiciously applied.

PROCEDURE FOR RELYING ON COMMON KNOWLEDGE OR TAKING OFFICIAL NOTICE

The standard of review applied to findings of fact is the "substantial evidence" standard under the Administrative Procedure Act (APA). See *In re Gartside*, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). See also MPEP § **1216.01**. In light of recent Federal Circuit decisions as discussed below and the substantial evidence standard of review now applied to USPTO Board decisions, the following guidance is provided in order to assist the examiners in determining when it is appropriate to take official notice of facts without supporting documentary evidence or to rely on common knowledge in the art in making a rejection, and if such official notice is taken, what evidence is necessary to support the examiner's conclusion of common knowledge in the art.

A. Determine When It Is Appropriate To Take Official Notice Without Documentary Evidence To Support the Examiner's Conclusion

Official notice without documentary evidence to support an examiner's conclusion is permissible only in some circumstances. While "official notice" may be relied on, these circumstances should be rare when an application is under final rejection or action under 37 CFR **1.113**. Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. As noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute" (citing *In re Knapp Monarch Co*., 296 F.2d 230, 132 USPQ 6 (CCPA 1961)). In *Ahlert*, the court held that the Board properly took judicial notice that "it is old to adjust intensity of a flame in accordance with the heat requirement." See also *In re Fox*, 471 F.2d 1405, 1407, 176 USPQ 340, 341 (CCPA 1973) (the court took "judicial notice of the fact that tape recorders commonly erase tape automatically when new 'audio information' is recorded on a tape which already has a recording on it"). In appropriate circumstances, it might not be unreasonable to take official notice of the fact that it is desirable to make something faster, cheaper, better, or stronger without the specific support of documentary evidence. Furthermore, it might not be unreasonable for the examiner in a first Office action to take official notice of facts by asserting that certain limitations in a dependent claim are old and well known expedients in the art without the support of documentary evidence provided the facts so noticed are of notorious character and serve only to "fill in the gaps" which might exist in the evidentiary showing made by the examiner to support a particular ground of rejection. *In re Zurko*, 258 F.3d 1379, 1385, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001); *Ahlert*, 424 F.2d at 1092, 165 USPQ at 421.

It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art. *In re Ahlert*, 424 F.2d at 1091, 165 USPQ at 420-21. See also *In re Grose*, 592 F.2d 1161, 1167-68, 201 USPQ 57, 63 (CCPA 1979) ("[W]hen the PTO seeks to rely upon a chemical theory, in establishing a prima facie case of

obviousness, it must provide evidentiary support for the existence and meaning of that theory."); *In re Eynde*, 480 F.2d 1364, 1370, 178 USPQ 470, 474 (CCPA 1973) ("[W]e reject the notion that judicial or administrative notice may be taken of the state of the art. The facts constituting the state of the art are normally subject to the possibility of rational disagreement among reasonable men and are not amenable to the taking of such notice.").

It is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 ("[T]he Board cannot simply reach conclusions based on its own understanding or experience—or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings."). While the court explained that, "as an administrative tribunal the Board clearly has expertise in the subject matter over which it exercises jurisdiction," it made clear that such "expertise may provide sufficient support for conclusions [only] as to peripheral issues." *Id.* at 1385-86, 59 USPQ2d at 1697. As the court held in *Zurko*, an assessment of basic knowledge and common sense that is not based on any evidence in the record lacks substantial evidence support. *Id.* at 1385, 59 USPQ2d at 1697. **

B. If Official Notice Is Taken of a Fact, Unsupported by Documentary Evidence, the Technical Line of Reasoning Underlying a Decision To Take Such Notice Must Be Clear and Unmistakable

**In certain older cases, official notice has been taken of a fact that is asserted to be "common knowledge" without specific reliance on documentary evidence where the fact noticed was readily verifiable, such as when other references of record supported the noticed fact, or where there was nothing of record to contradict it. See *In re Soli*, 317 F.2d 941, 945-46, 137 USPQ 797, 800 (CCPA 1963) (accepting the examiner's assertion that the use of "a control is standard procedure throughout the entire field of bacteriology" because it was readily verifiable and disclosed in references of record not cited by the Office); *In re Chevenard*, 139 F.2d 711, 713, 60 USPQ 239, 241 (CCPA 1943) (accepting the examiner's finding that a brief heating at a higher temperature was the equivalent of a longer heating at a lower temperature where there was nothing in the record to indicate the contrary and where the applicant never demanded that the examiner produce evidence to support his statement). If such notice is taken, the basis for such reasoning must be set forth explicitly. The examiner must provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge. See *Soli*, 317 F.2d at 946, 37 USPQ at 801; *Chevenard*, 139 F.2d at 713, 60 USPQ at 241. The applicant should be presented with the explicit basis on which the examiner regards the matter as subject to official notice **>so as to adequately traverse the rejection< in the next reply after the Office action in which the common knowledge statement was made.

C. If Applicant Challenges a Factual Assertion as Not Properly Officially Noticed or Not Properly Based Upon Common Knowledge, the Examiner Must Support the Finding With Adequate Evidence

To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR **1.111**(b). See also *Chevenard*, 139 F.2d at 713, 60 USPQ at 241 ("[I]n the absence of any demand by appellant for the examiner to produce authority for his statement, we will not consider this contention."). A general allegation that the claims define a patentable invention without any reference to the examiner's assertion of official notice would be inadequate. If applicant adequately traverses the examiner's assertion of official notice, the examiner must provide documentary evidence in the next Office action if the rejection is to be maintained. See 37 CFR **1.104**(c)(2). See also *Zurko* , 258 F.3d at 1386, 59 USPQ2d at 1697 ("[T]he Board [or examiner] must point to some concrete evidence in the record in support of these findings" to satisfy the substantial evidence test). If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR **1.104**(d)(2).

If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate. If the traverse was inadequate, the examiner should include an explanation as to why it was inadequate.

D. Determine Whether the Next Office Action Should Be Made Final

If the examiner adds a reference in the next Office action after applicant's rebuttal, and the newly added reference is added only as directly corresponding evidence to

support the prior common knowledge finding, and it does not result in a new issue or constitute a new ground of rejection, the Office action may be made final. If no amendments are made to the claims, the examiner must not rely on any other teachings in the reference if the rejection is made final. If the newly cited reference is added for reasons other than to support the prior common knowledge statement and a new ground of rejection is introduced by the examiner that is not necessitated by applicant's amendment of the claims, the rejection may not be made final. See MPEP § **706.07(a)**.

E. Summary

Any rejection based on assertions that a fact is well-known or is common knowledge in the art without documentary evidence to support the examiner's conclusion should be judiciously applied. Furthermore, as noted by the court in *Ahlert*, any facts so noticed should be of notorious character and serve only to "fill in the gaps" in an insubstantial manner which might exist in the evidentiary showing made by the examiner to support a particular ground for rejection. It is never appropriate to rely solely on common knowledge in the art without evidentiary support in the record as the principal evidence upon which a rejection was based. See *Zurko*, 258 F.3d at 1386, 59 USPQ2d at 1697; *Ahlert*, 424 F.2d at 1092, 165 USPQ 421.

2144.04 Legal Precedent as Source of Supporting Rationale [R-6]

As discussed in **MPEP § 2144**, if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court. Examples directed to various common practices which the court has held normally require only ordinary skill in the art and hence are considered routine expedients are discussed below. If the applicant has demonstrated the criticality of a specific limitation, it would not be appropriate to rely solely on case law as the rationale to support an obviousness rejection.

I. AESTHETIC DESIGN CHANGES

In re Seid, 161 F.2d 229, 73 USPQ 431 (CCPA 1947) (Claim was directed to an advertising display device comprising a bottle and a hollow member in the shape of a human figure from the waist up which was adapted to fit over and cover the neck of the bottle, wherein the hollow member and the bottle together give the impression of a human body. Appellant argued that certain limitations in the upper part of the body, including the arrangement of the arms, were not taught by the prior art. The court found that matters relating to ornamentation only which have no mechanical function cannot be relied upon to patentably distinguish the claimed invention from the prior art.). But see ** *Ex parte Hilton*, 148 USPQ 356 (Bd. App. 1965) (Claims were directed to fried potato chips with a specified moisture and fat content, whereas the prior art was directed to french fries having a higher moisture content. While recognizing that in some cases the particular shape of a product is of no patentable significance, the Board held in this case the shape (chips) is important because it results in a product which is distinct from the reference product (french fries).).

II. ELIMINATION OF A STEP OR AN ELEMENT AND ITS FUNCTION

A. Omission of an Element and Its Function Is Obvious if the Function of the Element Is Not Desired

Ex parte Wu, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989) (Claims at issue were directed to a method for inhibiting corrosion on metal surfaces using a composition consisting of epoxy resin, petroleum sulfonate, and hydrocarbon diluent. The claims were rejected over a primary reference which disclosed an anticorrosion composition of epoxy resin, hydrocarbon diluent, and polybasic acid salts wherein said salts were taught to be beneficial when employed in a freshwater environment, in view of secondary references which clearly suggested the addition of petroleum sulfonate to corrosion inhibiting compositions. The Board affirmed the rejection, holding that it would have been obvious to omit the polybasic acid salts of the primary reference where the function attributed to such salt is not desired or required, such as in compositions for providing corrosion resistance in environments which do not encounter fresh water.). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965) (Omission of additional framework and axle which served to increase the cargo carrying capacity of prior art mobile fluid carrying unit would have been obvious if this feature was not desired.); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (deleting a prior art switch member and thereby eliminating its function was an obvious expedient).

B. Omission of an Element with Retention of the Element's Function Is an Indicia of Unobviousness

Note that the omission of an element and retention of its function is an indicia of unobviousness. *In re Edge*, 359 F.2d 896, 149 USPQ 556 (CCPA 1966) (Claims at issue were directed to a printed sheet having a thin layer of erasable metal bonded directly to the sheet wherein said thin layer obscured the original print until removal by

erasure. The prior art disclosed a similar printed sheet which further comprised an intermediate transparent and erasure-proof protecting layer which prevented erasure of the printing when the top layer was erased. The claims were found unobvious over the prior art because the although the transparent layer of the prior art was eliminated, the function of the transparent layer was retained since appellant's metal layer could be erased without erasing the printed indicia.).

III. AUTOMATING A MANUAL ACTIVITY

In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958) (Appellant argued that claims to a permanent mold casting apparatus for molding trunk pistons were allowable over the prior art because the claimed invention combined "old permanent-mold structures together with a timer and solenoid which automatically actuates the known pressure valve system to release the inner core after a predetermined time has elapsed." The court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.).

IV. CHANGES IN SIZE, SHAPE, OR SEQUENCE OF ADDING INGREDIENTS

A. Changes in Size/Proportion

In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (Claims directed to a lumber package "of appreciable size and weight requiring handling by a lift truck" where held unpatentable over prior art lumber packages which could be lifted by hand because limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) ("mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.).

In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

B. Changes in Shape

In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

C. Changes in Sequence of Adding Ingredients

Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render *prima facie* obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.).

V. MAKING PORTABLE, INTEGRAL, SEPARABLE, ADJUSTABLE, OR CONTINUOUS

A. Making Portable

In re Lindberg, 194 F.2d 732, 93 USPQ 23 (CCPA 1952) (Fact that a claimed device is portable or movable is not sufficient by itself to patentably distinguish over an otherwise old device unless there are new or unexpected results.).

B. Making Integral

In re Larson, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) (A claim to a fluid transporting vehicle was rejected as obvious over a prior art reference which differed from the prior art in claiming a brake drum integral with a clamping means, whereas the brake disc and clamp of the prior art comprise several parts rigidly secured together as a single unit. The court affirmed the rejection holding, among other reasons, "that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice."); but see *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983) (Claims were directed to a vibratory testing machine (a hard-bearing wheel balancer) comprising a holding structure, a base structure, and a supporting means which

form "a single integral and gaplessly continuous piece." Nortron argued that the invention is just making integral what had been made in four bolted pieces. The court found this argument unpersuasive and held that the claims were patentable because the prior art perceived a need for mechanisms to dampen resonance, whereas the inventor eliminated the need for dampening via the one-piece gapless support structure, showing insight that was contrary to the understandings and expectations of the art.).

C. Making Separable

In re Dulberg, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) (The claimed structure, a lipstick holder with a removable cap, was fully met by the prior art except that in the prior art the cap is "press fitted" and therefore not manually removable. The court held that "if it were considered desirable for any reason to obtain access to the end of [the prior art's] holder to which the cap is applied, it would be obvious to make the cap removable for that purpose.").

D. Making Adjustable

In re Stevens, 212 F.2d 197, 101 USPQ 284 (CCPA 1954) (Claims were directed to a handle for a fishing rod wherein the handle has a longitudinally adjustable finger hook, and the hand grip of the handle connects with the body portion by means of a universal joint. The court held that adjustability, where needed, is not a patentable advance, and because there was an art-recognized need for adjustment in a fishing rod, the substitution of a universal joint for the single pivot of the prior art would have been obvious.).

E. Making Continuous

In re Dilnot, 319 F.2d 188, 138 USPQ 248 (CCPA 1963) (Claim directed to a method of producing a cementitious structure wherein a stable air foam is introduced into a slurry of cementitious material differed from the prior art only in requiring the addition of the foam to be continuous. The court held the claimed continuous operation would have been obvious in light of the batch process of the prior art.).

VI. REVERSAL, DUPLICATION, OR REARRANGEMENT OF PARTS

A. Reversal of Parts

In re Gazda, 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious expedient.).

B. Duplication of Parts

In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) (Claims at issue were directed to a water-tight masonry structure wherein a water seal of flexible material fills the joints which form between adjacent pours of concrete. The claimed water seal has a "web" which lies in the joint, and a plurality of "ribs" projecting outwardly from each side of the web into one of the adjacent concrete slabs. The prior art disclosed a flexible water stop for preventing passage of water between masses of concrete in the shape of a plus sign (+). Although the reference did not disclose a plurality of ribs, the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.).

C. Rearrangement of Parts

In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (Claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice). However, "The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant's specification, to make the necessary changes in the reference device." *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984).

VII. PURIFYING AN OLD PRODUCT

Pure materials are novel *vis-à-vis* less pure or impure materials because there is a difference between pure and impure materials. Therefore, the issue is whether claims to a pure material are unobvious over the prior art. *In re Bergstrom*, 427 F.2d 1394, 166 USPQ 256 (CCPA 1970). Purer forms of known products may be patentable, but the mere purity of a product, by itself, does not render the product unobvious. *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989).

Factors to be considered in determining whether a purified form of an old product is obvious over the prior art include whether the claimed chemical compound or composition has the same utility as closely related materials in the prior art, and whether the prior art suggests the particular form or structure of the claimed material or suitable methods of obtaining that form or structure. *In re Cofer*, 354 F.2d 664, 148 USPQ 268 (CCPA 1966) (Claims to the free-flowing crystalline form of a compound were held unobvious over references disclosing the viscous liquid form of the same compound because the prior art of record did not suggest the claimed compound in crystalline form or how to obtain such crystals.).

See also *Ex parte Stern*, 13 USPQ2d 1379 (Bd. Pat. App. & Inter. 1987) (Claims to interleukin 2 (a protein with a molecular weight of over 12,000) purified to homogeneity were held unpatentable over references which recognized the desirability of purifying interleukin 2 to homogeneity in a view of a reference which taught a method of purifying proteins having molecular weights in excess of 12,000 to homogeneity wherein the prior art method was similar to the method disclosed by appellant for purifying interleukin 2.).

Compare *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (Claims were directed to human nerve growth factor b-NGF free from other proteins of human origin, and the specification disclosed making the claimed factor through the use of recombinant DNA technology. The claims were rejected as *prima facie* obvious in view of two references disclosing b-NGF isolated from human placental tissue. The Board applied case law pertinent to product-by-process claims, reasoning that the prior art factor appeared to differ from the claimed factor only in the method of obtaining the factor. The Board held that the burden of persuasion was on appellant to show that the claimed product exhibited unexpected properties compared with that of the prior art. The Board further noted that "no objective evidence has been provided establishing that no method was known to those skilled in this field whereby the claimed material might have been synthesized." 10 USPQ2d at 1926.).

2144.05 Obviousness of Ranges [R-5]

See **MPEP § 2131.03** for case law pertaining to rejections based on the anticipation of ranges under **35 U.S.C. 102** and **35 U.S.C. 102**/**103**.

I. OVERLAP OF RANGES

In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) (The prior art taught carbon monoxide concentrations of "about 1-5%" while the claim was limited to "more than 5%." The court held that "about 1-5%" allowed for concentrations slightly above 5% thus the ranges overlapped.); *In re Geisler*, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997) (Claim reciting thickness of a protective layer as falling within a range of "50 to 100 Angstroms" considered *prima facie* obvious in view of prior art reference teaching that "for suitable protection, the thickness of the protective layer should be not less than about 10 nm [i.e., 100 Angstroms]." The court stated that "by stating that 'suitable protection' is provided if the protective layer is 'about' 100 Angstroms thick, [the prior art reference] directly teaches the use of a thickness within [applicant's] claimed range."). Similarly, a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Court held as proper a rejection of a claim directed to an alloy of "having 0.8% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.).

"[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a primafacie case of obviousness." *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003). >See also *In re Harris*, 409 F.3d 1339, 74 USPQ2d 1951 (Fed. Cir. 2005)(claimed alloy held obvious over prior art alloy that taught ranges of weight percentages overlapping, and in most instances completely encompassing, claimed ranges; furthermore, narrower ranges taught by reference overlapped all but one range in claimed invention).< However, if the reference's disclosed range is so broad as to encompass a very large number of possible distinct compositions, this might present a situation analogous to the obviousness of a species when the prior art broadly discloses a genus. *Id.* See also *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992); MPEP § 2144.08.

A range can be disclosed in multiple prior art references instead of in a single prior art reference depending on the specific facts of the case. *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322, 73 USPQ2d 1225, 1228 (Fed. Cir. 2004). The patent claim at issue was directed to a weight plate having 3 elongated openings

that served as handles for transporting the weight plate. Multiple prior art patents each disclosed weight plates having 1, 2 or 4 elongated openings. 392 F.3d at 1319, 73 USPQ2d at 1226. The court stated that the claimed weight plate having 3 elongated openings fell within the "range" of the prior art and was thus presumed obvious. 392 F.3d at 1322, 73 USPQ2d at 1228. The court further stated that the "range" disclosed in multiple prior art patents is "a distinction without a difference" from previous range cases which involved a range disclosed in a single patent since the "prior art suggested that a larger number of elongated grips in the weight plates was beneficial… thus plainly suggesting that one skilled in the art look to the range appearing in the prior art." *Id*.

II. OPTIMIZATION OF RANGES

A. Optimization Within Prior Art Conditions or Through Routine Experimentation

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

B. Only Result-Effective Variables Can Be Optimized

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result-effective variable.). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (prior art suggested proportional balancing to achieve desired results in the formation of an alloy).

III. REBUTTAL OF PRIMA FACIE CASE OF OBVIOUSNESS

Applicants can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range. "The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See **MPEP § 716.02 - § 716.02(g)** for a discussion of criticality and unexpected results.

A *prima facie* case of obviousness may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention. *In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997) (Applicant argued that the prior art taught away from use of a protective layer for a reflective article having a thickness within the claimed range of "50 to 100 Angstroms." Specifically, a patent to Zehender, which was relied upon to reject applicant's claim, included a statement that the thickness of the protective layer "should be not less than about [100 Angstroms]." The court held that the patent did not teach away from the claimed invention. "Zehender suggests that there are benefits to be derived from keeping the protective layer as thin as possible, consistent with achieving adequate protection. A thinner coating reduces light absorption and minimizes manufacturing time and expense. Thus, while Zehender expresses a preference for a thicker protective layer of 200-300 Angstroms, at the same time it provides the motivation for one of ordinary skill in the art to focus on thickness levels at the bottom of Zehender's 'suitable'

range- about 100 Angstroms- and to explore thickness levels below that range. The statement in Zehender that '[i]n general, the thickness of the protective layer should be not less than about [100 Angstroms]' falls far short of the kind of teaching that would discourage one of skill in the art from fabricating a protective layer of 100 Angstroms or less. [W]e are therefore 'not convinced that there was a sufficient teaching away in the art to overcome [the] strong case of obviousness' made out by Zehender."). See **MPEP § 2145**, paragraph X.D., for a discussion of "teaching away" references.

Applicant can rebut a presumption of obviousness based on a claimed invention that falls within a prior art range by showing "(1) [t]hat the prior art taught away from the claimed invention...or (2) that there are new and unexpected results relative to the prior art." *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322, 73 USPQ2d 1225, 1228 (Fed. Cir. 2004). The court found that patentee offered neither evidence of teaching away of the prior art nor new and unexpected results of the claimed invention drawn to a weight plate having 3 elongated handle openings. 392 F.3d at 1323, 73 USPQ2d at 1229. The court then turned to considering substantial evidence of pertinent secondary factors such as commercial success, satisfaction of a long-felt need, and copying by others may also support patentability. *Id*. Nevertheless, the court found that *Iron Grip* failed to show evidence of commercial success, copying by others, or satisfaction of a long felt need for the following reasons: (A) *Iron Grip's* licensing of its patent to three competitors was insufficient to show nexus between the "merits of the invention and the licenses," and thus did not establish secondary consideration of commercial success; (B) in response to *Iron Grip's* argument that the competitor's production of a three-hole plate is evidence of copying, the court stated that "[n]ot every competing product that falls within the scope of a patent is evidence of copying" since "[o]therwise every infringement suit would automatically confirm the nonobviousness of the patent;" and (C) although *Iron Grip* offered as evidence that the absence of the three-grip plate on the market prior to its patent showed that the invention was nonobviousness, the court stated that "[a]bsent a showing of a long-felt need or the failure of others, the mere passage of time without the claimed invention is not evidence of nonobviousness." 392 F.3d at 1324-25, 73 USPQ2d at 1229-30.

2144.06 Art Recognized Equivalence for the Same Purpose [R-6]

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I. < COMBINING EQUIVALENTS KNOWN FOR THE SAME PURPOSE

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held *prima facie* obvious). **

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II. < SUBSTITUTING EQUIVALENTS KNOWN FOR THE SAME PURPOSE

In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958) (The mere fact that components are claimed as members of a Markush group cannot be relied upon to establish the equivalency of these components. However, an applicant's expressed recognition of an art-recognized or obvious equivalent may be used to refute an argument that such equivalency does not exist.); ** *Smith v. Hayashi*, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.).

An express suggestion to substitute one equivalent component or process for another is not necessary to

render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982).

2144.07 Art Recognized Suitability for an Intended Purpose [R-9]

The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) (Claims to a printing ink comprising a solvent having the vapor pressure characteristics of butyl carbitol so that the ink would not dry at room temperature but would dry quickly upon heating were held invalid over a reference teaching a printing ink made with a different solvent that was nonvolatile at room temperature but highly volatile when heated in view of an article which taught the desired boiling point and vapor pressure characteristics of a solvent for printing inks and a catalog teaching the boiling point and vapor pressure characteristics of butyl carbitol. "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301.).

See also *In re Leshin*, *>277< F.2d 197, 125 USPQ 416 (CCPA 1960) (selection of a known plastic to make a container of a type made of plastics prior to the invention was held to be obvious); *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988) (Claimed agricultural bagging machine, which differed from a prior art machine only in that the brake means were hydraulically operated rather than mechanically operated, was held to be obvious over the prior art machine in view of references which disclosed hydraulic brakes for performing the same function, albeit in a different environment.).

2144.08 Obviousness of Species When Prior Art Teaches Genus [R-6]

I. ** EXAMINATION OF CLAIMS DIRECTED TO SPECIES OF CHEMICAL COMPOSITIONS BASED UPON A SINGLE PRIOR ART REFERENCE

>When< a single prior art reference which discloses a genus encompassing the claimed species or subgenus but does not expressly disclose the particular claimed species or subgenus*>,< Office personnel should attempt to find additional prior art to show that the differences between the prior art primary reference and the claimed invention as a whole would have been obvious. Where such additional prior art is not found, Office personnel should **>consider the factors discussed below< to determine whether a single reference **35 U.S.C. 103 rejection would be appropriate. **

II. DETERMINE WHETHER THE CLAIMED SPECIES OR SUBGENUS WOULD HAVE BEEN OBVIOUS TO ONE OF ORDINARY SKILL IN THE PERTINENT ART AT THE TIME THE INVENTION WAS MADE

The patentability of a claim to a specific compound or subgenus embraced by a prior art genus should be analyzed no differently than any other claim for purposes of **35 U.S.C. 103**. "The section 103 requirement of unobviousness is no different in chemical cases than with respect to other categories of patentable inventions." *In re Papesch*, 315 F.2d 381, 385, 137 USPQ 43, 47 (CCPA 1963). A determination of patentability under **35 U.S.C. 103** should be made upon the facts of the particular case in view of the totality of the circumstances. See, e.g., *In re Dillon*, 919 F.2d 688, 692-93, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (*in banc*). Use of *per se* rules by Office personnel is improper for determining whether claimed subject matter would have been obvious under **35 U.S.C. 103**. See, e.g., *In re Brouwer*, 77 F.3d 422, 425, 37 USPQ2d 1663, 1666 (Fed. Cir. 1996); *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995); *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."); *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) (Federal Circuit has "decline[d] to extract from *Merck* [*& Co. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989)] the rule that... regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it."). See also *In re Deuel*, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995).

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A. Establishing a Prima Facie Case of Obviousness<

A proper obviousness analysis involves a three-step process. First, Office personnel should establish a *prima facie* case of unpatentability considering the factors set out by the Supreme Court in *Graham v. John Deere.* See, e.g., *In re Bell*, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) ("The PTO bears the burden of establishing a case of *prima facie* obviousness."); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956

(Fed. Cir. 1993); *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), requires that to make out a case of obviousness, one must:

(A) determine the scope and contents of the prior art;

(B) ascertain the differences between the prior art and the claims in issue;

(C) determine the level of >ordinary< skill in the pertinent art; and

(D) evaluate any evidence of secondary considerations. **If a *prima facie* case is established, the burden shifts to applicant to come forward with rebuttal evidence or argument to overcome the *prima facie* case. See, e.g., *Bell*, 991 F.2d at 783-84, 26 USPQ2d at 1531; *Rijckaert*, 9 F.3d at 1532, 28 USPQ2d at 1956; *Oetiker*, 977 F.2d at 1445, 24 USPQ2d at 1444 . Finally, Office personnel should evaluate the totality of the facts and all of the evidence to determine whether they still support a conclusion that the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made. *Id.*
**

1. Determine the Scope and Content of the Prior Art

As an initial matter, Office personnel should determine the scope and content of the relevant prior art. Each reference must qualify as prior art under **35 U.S.C. 102** (e.g., *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597 (Fed. Cir. 1987) ("Before answering *Graham's* 'content' inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. § 102.")) and should be **>analogous art. See MPEP § **2141.01(a)**<.

In the case of a prior art reference disclosing a genus, Office personnel should make findings as to:

(A) the structure of the disclosed prior art genus and that of any expressly described species or subgenus within the genus;

(B) any physical or chemical properties and utilities disclosed for the genus, as well as any suggested limitations on the usefulness of the genus, and any problems alleged to be addressed by the genus;

(C) the predictability of the technology; and

(D) the number of species encompassed by the genus taking into consideration all of the variables possible.

2. Ascertain the Differences Between the Closest Disclosed Prior Art Species or Subgenus of Record and the Claimed Species or Subgenus

Once the structure of the disclosed prior art genus and that of any expressly described species or subgenus within the genus are identified, Office personnel should compare it to the claimed species or subgenus to determine the differences. Through this comparison, the closest disclosed species or subgenus in the prior art reference should be identified and compared to that claimed. Office personnel should make explicit findings on the similarities and differences between the closest disclosed prior art species or subgenus of record and the claimed species or subgenus including findings relating to similarity of structure, chemical properties and utilities. In *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1537, 218 USPQ 871, 877 (Fed. Cir. 1983), the Court noted that "the question under 35 U.S.C. § 103 is not whether the differences [between the claimed invention and the prior art] would have been obvious" but "whether the claimed invention *as a whole* would have been obvious." (emphasis in original).

3. Determine the Level of Skill in the Art

Office personnel should evaluate the prior art from the standpoint of the hypothetical person having ordinary skill in the art at the time the claimed invention was made. See, *Ryko Mfg. Co. v. Nu-Star Inc.*, 950 F.2d 714, 718, 21 USPQ2d 1053, 1057 (Fed. Cir. 1991) ("The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry."); *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988) (evidence must be viewed from position of ordinary skill, not of an expert). In most cases, the only facts of record pertaining to the level of skill in the art will be found within the prior art reference. However, any additional evidence presented by applicant should be evaluated.

4. Determine Whether One of Ordinary Skill in the Art Would Have Been Motivated To Select the Claimed Species or Subgenus

In light of the findings made relating to the three *Graham* factors, Office personnel should determine whether >it would have been obvious to< one of ordinary skill in the relevant art ** to make the claimed invention as a whole, i.e., to select the claimed species or subgenus from the disclosed prior art genus. ** To address this key issue, Office personnel should consider all relevant prior art teachings, focusing on the following, where present.

(a) Consider the Size of the Genus

Consider the size of the prior art genus, bearing in mind that size alone cannot support an obviousness rejection. See , e.g. , *Baird*, 16 F.3d at 383, 29 USPQ2d at 1552 (observing that "it is not the mere number of compounds in this limited class which is significant here but, rather, the total circumstances involved"). There is no absolute correlation between the size of the prior art genus and a conclusion of obviousness. *Id.* Thus, the mere fact that a prior art genus contains a small number of members does not create a *per se* rule of obviousness. ** However, a genus may be so small that, when considered in light of the totality of the circumstances, it would anticipate the claimed species or subgenus. For example, it has been held that a prior art genus containing only 20 compounds and a limited number of variations in the generic chemical formula inherently anticipated a claimed species within the genus because "one skilled in [the] art would... envisage *each member*" of the genus. *In re Petering*, 301 F.2d 676, 681, 133 USPQ 275, 280 (CCPA 1962) (emphasis in original). More specifically, the court in *Petering* stated:

> A simple calculation will show that, excluding isomerism within certain of the R groups, the limited class we find in Karrer contains only 20 compounds. However, we wish to point out that it is not the mere number of compounds in this limited class which is significant here but, rather, the total circumstances involved, including such factors as the limited number of variations for R, only two alternatives for Y and Z, no alternatives for the other ring positions, and a large unchanging parent structural nucleus. With these circumstances in mind, it is our opinion that Karrer has described to those with ordinary skill in this art each of the various permutations here involved as fully as if he had drawn each structural formula or had written each name.

Id. (emphasis in original). *Accord In re Schaumann*, 572 F.2d 312, 316, 197 USPQ 5, 9 (CCPA 1978) (prior art genus encompassing claimed species which disclosed preference for lower alkyl secondary amines and properties possessed by the claimed compound constituted description of claimed compound for purposes of **35 U.S.C. 102(b)**). *C.f., In re Ruschig*, 343 F.2d 965, 974, 145 USPQ 274, 282 (CCPA 1965) (Rejection of claimed compound in light of prior art genus based on *Petering* is not appropriate where the prior art does not disclose a small recognizable class of compounds with common properties.).

(b) Consider the Express Teachings

If the prior art reference expressly teaches a particular reason to select the claimed species or subgenus, Office personnel should point out the express disclosure **>and explain why it would have been obvious to< one of ordinary skill in the art to select the claimed invention. An express teaching may be based on a statement in the prior art reference such as an art recognized equivalence. For example, see *Merck & Co. v. Biocraft Labs.*, 874 F.2d 804, 807, 10 USPQ2d 1843, 1846 (Fed. Cir. 1989) (holding claims directed to diuretic compositions comprising a specific mixture of amiloride and hydrochlorothiazide were obvious over a prior art reference expressly teaching that amiloride was a pyrazinoylguanidine which could be coadministered with potassium excreting diuretic agents, including hydrochlorothiazide which was a named example, to produce a diuretic with desirable sodium and potassium eliminating properties). See also, *In re Kemps*, 97 F.3d 1427, 1430, 40 USPQ2d 1309, 1312 (Fed. Cir. 1996) (holding **>it would have been obvious< to combine teachings of prior art to achieve claimed invention where one reference specifically refers to the other).

(c) Consider the Teachings of Structural Similarity

Consider any teachings of a "typical," "preferred," or "optimum" species or subgenus within the disclosed genus. If such a species or subgenus is structurally similar to that claimed, its disclosure may *>provide a reason for< one of ordinary skill in the art to choose the claimed species or subgenus from the genus, based on the reasonable expectation that structurally similar species usually have similar properties. See, e.g., *Dillon*, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also *Deuel*, 51 F.3d at 1558, 34 USPQ2d at 1214 ("Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties."). **

In making an obviousness determination, Office personnel should consider the number of variables which must be selected or modified, and the nature and significance of the differences between the prior art and the claimed invention. See, e.g., *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) (reversing obviousness rejection of novel dicamba salt with acyclic structure over broad prior art genus encompassing claimed salt, where disclosed examples of genus were dissimilar in structure, lacking an ether linkage or being cyclic); *In*

re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971) (the difference from the particularly preferred subgenus of the prior art was a hydroxyl group, a difference conceded by applicant "to be of little importance"). In the area of biotechnology, an exemplified species may differ from a claimed species by a conservative substitution ("the replacement in a protein of one amino acid by another, chemically similar, amino acid... [which] is generally expected to lead to either no change or only a small change in the properties of the protein." *Dictionary of Biochemistry and Molecular Biology* 97 (John Wiley & Sons, 2d ed. 1989)). The effect of a conservative substitution on protein function depends on the nature of the substitution and its location in the chain. Although at some locations a conservative substitution may be benign, in some proteins only one amino acid is allowed at a given position. For example, the gain or loss of even one methyl group can destabilize the structure if close packing is required in the interior of domains. James Darnell *et al.*, *Molecular Cell Biology* 51 (2d ed. 1990).

The closer the physical and chemical similarities between the claimed species or subgenus and any exemplary species or subgenus disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner to the genus. See, e.g., *Dillon*, 919 F.2d at 696, 16 USPQ2d at 1904 (and cases cited therein). *Cf. Baird*, 16 F.3d at 382-83, 29 USPQ2d at 1552 (disclosure of dissimilar species can provide teaching away).

Similarly, consider any teaching or suggestion in the reference of a preferred species or subgenus that is significantly different in structure from the claimed species or subgenus. Such a teaching may weigh against selecting the claimed species or subgenus and thus against a determination of obviousness. *Baird*, 16 F.3d at 382-83, 29 USPQ2d at 1552 (reversing obviousness rejection of species in view of large size of genus and disclosed "optimum" species which differed greatly from and were more complex than the claimed species); *Jones*, 958 F.2d at 350, 21 USPQ2d at 1943 (reversing obviousness rejection of novel dicamba salt with acyclic structure over broad prior art genus encompassing claimed salt, where disclosed examples of genus were dissimilar in structure, lacking an ether linkage or being cyclic). For example, teachings of preferred species of a complex nature within a disclosed genus may motivate an artisan of ordinary skill to make similar complex species and thus teach away from making simple species within the genus. *Baird*, 16 F.3d at 382, 29 USPQ2d at 1552. See also *Jones*, 958 F.2d at 350, 21 USPQ2d at 1943 (disclosed salts of genus held not sufficiently similar in structure to render claimed species *prima facie* obvious).

Concepts used to analyze the structural similarity of chemical compounds in other types of chemical cases are equally useful in analyzing genus-species cases. For example, a claimed tetra-orthoester fuel composition was held to be obvious in light of a prior art tri-orthoester fuel composition based on their structural and chemical similarity and similar use as fuel additives. *Dillon*, 919 F.2d at 692-93, 16 USPQ2d at 1900-02. Likewise, claims to amitriptyline used as an antidepressant were held obvious in light of the structural similarity to imipramine, a known antidepressant prior art compound, where both compounds were tricyclic dibenzo compounds and differed structurally only in the replacement of the unsaturated carbon atom in the center ring of amitriptyline with a nitrogen atom in imipramine. *In re Merck & Co.*, 800 F.2d 1091, 1096-97, 231 USPQ 375, 378-79 (Fed. Cir. 1986). Other structural similarities have been found to support a *prima facie* case of obviousness. See, e.g., *In re May*, 574 F.2d 1082, 1093-95, 197 USPQ 601, 610-11 (CCPA 1978) (stereoisomers); *In re Wilder*, 563 F.2d 457, 460, 195 USPQ 426, 429 (CCPA 1977) (adjacent homologs and structural isomers); *In re Hoch*, 428 F.2d 1341, 1344, 166 USPQ 406, 409 (CCPA 1970) (acid and ethyl ester); *In re Druey*, 319 F.2d 237, 240, 138 USPQ 39, 41 (CCPA 1963) (omission of methyl group from pyrazole ring). Generally, some teaching of a structural similarity will be necessary to suggest selection of the claimed species or subgenus. *Id.*

(d) Consider the Teachings of Similar Properties or Uses

Consider the properties and utilities of the structurally similar prior art species or subgenus. It is the properties and utilities that provide real world motivation for a person of ordinary skill to make species structurally similar to those in the prior art. *Dillon*, 919 F.2d at 697, 16 USPQ2d at 1905; *In re Stemniski*, 444 F.2d 581, 586, 170 USPQ 343, 348 (CCPA 1971). Conversely, lack of any known useful properties weighs against a finding of motivation to make or select a species or subgenus. *In re Albrecht*, 514 F.2d 1389, 1392, 1395-96, 185 USPQ 585, 587, 590 (CCPA 1975) (The prior art compound so irritated the skin that it could not be regarded as useful for the disclosed anesthetic purpose, and therefore a person skilled in the art would not have been motivated to make related compounds.); *Stemniski*, 444 F.2d at 586, 170 USPQ at 348 (close structural similarity alone is not sufficient to create a *prima facie* case of obviousness when the reference compounds lack utility, and thus there is no motivation to make related compounds.). However, the prior art need not disclose a newly discovered property in order for there to be a *prima facie* case of obviousness. *Dillon*, 919 F.2d at 697, 16 USPQ2d at 1904-05 (and cases cited therein). If the claimed invention and the

structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species, *e.g., id.* For example, based on a finding that a tri-orthoester and a tetra-orthoester behave similarly in certain chemical reactions, it has been held that one of ordinary skill in the relevant art would have been motivated to select either structure. 919 F.2d at 692, 16 USPQ2d at 1900-01. In fact, similar properties may normally be presumed when compounds are very close in structure. *Dillon,* 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also *In re Grabiak,* 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985) ("When chemical compounds have 'very close' structural similarities and similar utilities, without more a *prima facie* case may be made."). Thus, evidence of similar properties or evidence of any useful properties disclosed in the prior art that would be expected to be shared by the claimed invention weighs in favor of a conclusion that the claimed invention would have been obvious. *Dillon*, 919 F.2d at 697-98, 16 USPQ2d at 1905; *In re Wilder*, 563 F.2d 457, 461, 195 USPQ 426, 430 (CCPA 1977); *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

(e) Consider the Predictability of the Technology

Consider the predictability of the technology. See, e.g., *Dillon*, 919 F.2d at 692-97, 16 USPQ2d at 1901-05; *In re Grabiak*, 769 F.2d 729, 732-33, 226 USPQ 870, 872 (Fed. Cir. 1985). If the technology is unpredictable, it is less likely that structurally similar species will render a claimed species obvious because it may not be reasonable to infer that they would share similar properties. See, e.g. , *In re May*, 574 F.2d 1082, 1094, 197 USPQ 601, 611 (CCPA 1978) (*prima facie* obviousness of claimed analgesic compound based on structurally similar prior art isomer was rebutted with evidence demonstrating that analgesia and addiction properties could not be reliably predicted on the basis of chemical structure); *In re Schechter*, 205 F.2d 185, 191, 98 USPQ 144, 150 (CCPA 1953) (unpredictability in the insecticide field, with homologs, isomers and analogs of known effective insecticides having proven ineffective as insecticides, was considered as a factor weighing against a conclusion of obviousness of the claimed compounds). However, obviousness does not require absolute predictability, only a reasonable expectation of success, i.e., a reasonable expectation of obtaining similar properties. See , e.g. , *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

(f) Consider Any Other Teaching To Support the Selection of the Species or Subgenus

The categories of relevant teachings enumerated above are those most frequently encountered in a genus-species case, but they are not exclusive. Office personnel should consider the totality of the evidence in each case. In unusual cases, there may be other relevant teachings sufficient to support the selection of the species or subgenus and, therefore, a conclusion of obviousness.

5. Make Express Fact-Findings and Determine Whether They Support a Prima Facie Case of Obviousness

Based on the evidence as a whole (*In re Bell*, 991 F.2d 781,784, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993); *In re Kulling*, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1057 (Fed. Cir. 1990)), Office personnel should make express fact-findings relating to the *Graham* factors, focusing primarily on the prior art teachings discussed above. The fact-findings should specifically articulate what teachings or suggestions in the prior art would have motivated one of ordinary skill in the art to select the claimed species or subgenus. *Kulling*, 897 F.2d at 1149, 14 USPQ2d at 1058; *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1579 n.42, 1 USQP2d 1593, 1606 n.42 (Fed. Cir. 1987). Thereafter, it should be determined whether these findings, considered as a whole, support a *prima facie* case that the claimed invention would have been obvious to one of ordinary skill in the relevant art at the time the invention was made. **

2144.09 Close Structural Similarity Between Chemical Compounds (Homologs, Analogues, Isomers) [R-6]

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I. < REJECTION BASED ON CLOSE STRUCTURAL SIMILARITY IS FOUNDED ON THE EXPECTATION THAT COMPOUNDS SIMILAR IN STRUCTURE WILL HAVE SIMILAR PROPERTIES

A *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." *In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) (discussed in more detail below) and *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir.

1991) (discussed below and in **MPEP § 2144**) for an extensive review of the case law pertaining to obviousness based on close structural similarity of chemical compounds. See also **MPEP § 2144.08**, paragraph II.A.4.(c).

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II. < HOMOLOGY AND ISOMERISM ARE FACTS WHICH MUST BE CONSIDERED WITH ALL OTHER RELEVANT FACTS IN DETERMINING OBVIOUSNESS

Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by $-CH_2-$ groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers *prima facie* obvious).

Isomers having the same empirical formula but different structures are not necessarily considered equivalent by chemists skilled in the art and therefore are not necessarily suggestive of each other. *Ex parte Mowry*, 91 USPQ 219 (Bd. App. 1950) (claimed cyclohexylstyrene not *prima facie* obvious over prior art isohexylstyrene). Similarly, homologs which are far removed from adjacent homologs may not be expected to have similar properties. *In re Mills*, 281 F.2d 218, 126 USPQ 513 (CCPA 1960) (prior art disclosure of C_8 to C_{12} alkyl sulfates was not sufficient to render *prima facie* obvious claimed C_1 alkyl sulfate).

Homology and isomerism involve close structural similarity which must be considered with all other relevant facts in determining the issue of obviousness. *In re Mills*, 281 F.2d 218, 126 USPQ 513 (CCPA 1960); *In re Wiechert*, 370 F.2d 927, 152 USPQ 247 (CCPA 1967). Homology should not be automatically equated with *prima facie* obviousness because the claimed invention and the prior art must each be viewed "as a whole." *In re Langer*, 465 F.2d 896, 175 USPQ 169 (CCPA 1972) (Claims to a polymerization process using a sterically hindered amine were held unobvious over a similar prior art process because the prior art disclosed a large number of unhindered amines and only one sterically hindered amine (which differed from a claimed amine by 3 carbon atoms), and therefore the reference as a whole did not apprise the ordinary artisan of the significance of hindered amines as a class.).

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III. < PRESENCE OF A TRUE HOMOLOGOUS OR ISOMERIC RELATIONSHIP IS NOT CONTROLLING

Prior art structures do not have to be true homologs or isomers to render structurally similar compounds *prima facie* obvious. *In re Payne*, 606 F.2d 303, 203 USPQ 245 (CCPA 1979) (Claimed and prior art compounds were both directed to heterocyclic carbamoyloximino compounds having pesticidal activity. The only structural difference between the claimed and prior art compounds was that the ring structures of the claimed compounds had two carbon atoms between two sulfur atoms whereas the prior art ring structures had either one or three carbon atoms between two sulfur atoms. The court held that although the prior art compounds were not true homologs or isomers of the claimed compounds, the similarity between the chemical structures and properties is sufficiently close that one of ordinary skill in the art would have been motivated to make the claimed compounds in searching for new pesticides.).

See also *In re Mayne*, 104 F.3d 1339, 41 USPQ2d 1451 (Fed. Cir. 1997) (claimed protein was held to be obvious in light of structural similarities to the prior art, including known structural similarity of Ile and Lev); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (claimed and prior art compounds used in a method of treating depression would have been expected to have similar activity because the structural difference between the compounds involved a known bioisosteric replacement) (see **MPEP § 2144.08**, paragraph II.A.4(c) for a more detailed discussion of the facts in the *Mayne* and *Merck* cases); *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991) (The tri-orthoester fuel compositions of the prior art and the claimed tetra-orthoester fuel compositions would have been expected to have similar properties based on close structural and chemical similarity between the orthoesters and the fact that both the prior art and applicant used the orthoesters as fuel additives.) (See **MPEP § 2144** for a more detailed discussion of the facts in the *Dillon* case.).

Compare *In re Grabiak*, 769 F.2d 729, 226 USPQ 871 (Fed. Cir. 1985) (substitution of a thioester group for an ester group in an herbicidal safener compound was not suggested by the prior art); *In re Bell*, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993) (The established relationship between a nucleic acid and the protein it encodes in the genetic code does not render a gene *prima facie* obvious over its corresponding protein in the same way that closely related structures in chemistry may create a *prima facie* case because there are a vast number of nucleotide sequences that might encode for a specific

protein as a result of degeneracy in the genetic code (i.e., the fact that most amino acids are specified by more than one nucleotide sequence or codon).); *In re Deuel*, 51 F.3d 1552, 1558-59, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995) ("A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein." The existence of a general method of gene cloning in the prior art is not sufficient, without more, to render obvious a particular cDNA molecule.).

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IV. < PRESENCE OR ABSENCE OF PRIOR ART SUGGESTION OF METHOD OF MAKING A CLAIMED COMPOUND MAY BE RELEVANT IN DETERMINING PRIMA FACIE OBVIOUSNESS

"[T]he presence—or absence—of a suitably operative, obvious process for making a composition of matter may have an ultimate bearing on whether that composition is obvious—or nonobvious—under **35 U.S.C. 103**." *In re Maloney*, 411 F.2d 1321, 1323, 162 USPQ 98, 100 (CCPA 1969).

"[I]f the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on the close relationships between their structures and those of prior art compounds." *In re Hoeksema*, 399 F.2d 269, 274-75, 158 USPQ 597, 601 (CCPA 1968).

See *In re Payne*, 606 F.2d 303, 203 USPQ 245 (CCPA 1979) for a general discussion of circumstances under which the prior art suggests methods for making novel compounds which are of close structural similarity to compounds known in the prior art. **>It< may be proper to apply "methodology in rejecting product claims under **35 U.S.C. 103**, depending on the particular facts of the case, the manner and context in which methodology applies, and the overall logic of the rejection." *Ex parte Goldgaber*, 41 USPQ2d 1172, 1176 (Bd. Pat. App. & Inter. 1996).

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V. < PRESUMPTION OF OBVIOUSNESS BASED ON STRUCTURAL SIMILARITY IS OVERCOME WHERE THERE IS NO REASONABLE EXPECTATION OF SIMILAR PROPERTIES

The presumption of obviousness based on a reference disclosing structurally similar compounds may be overcome where there is evidence showing there is no reasonable expectation of similar properties in structurally similar compounds. *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (appellant produced sufficient evidence to establish a substantial degree of unpredictability in the pertinent art area, and thereby rebutted the presumption that structurally similar compounds have similar properties); *In re Schechter*, 205 F.2d 185, 98 USPQ 144 (CCPA 1953). See also *Ex parte Blattner*, 2 USPQ2d 2047 (Bd. Pat. App. & Inter. 1987) (Claims directed to compounds containing a 7-membered ring were rejected as *prima facie* obvious over a reference which taught 5- and 6-membered ring homologs of the claimed compounds. The Board reversed the rejection because the prior art taught that the compounds containing a 5-membered ring possessed the opposite utility of the compounds containing the 6-membered ring, undermining the examiner's asserted *prima facie* case arising from an expectation of similar results in the claimed compounds which contain a 7-membered ring.).

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VI. < IF PRIOR ART COMPOUNDS HAVE NO UTILITY, OR UTILITY ONLY AS INTERMEDIATES, CLAIMED STRUCTURALLY SIMILAR COMPOUNDS MAY NOT BE PRIMA FACIE OBVIOUS OVER THE PRIOR ART

If the prior art does not teach any specific or significant utility for the disclosed compounds, then the prior art is **>unlikely< to render structurally similar claims *prima facie* obvious **>in the absence of any reason< for one of ordinary skill in the art to make the reference compounds **>or< any structurally related compounds. *In re Stemniski*, 444 F.2d 581, 170 USPQ 343 (CCPA 1971).

**>See also< *In re Albrecht*, 514 F.2d 1389, 1396, 185 USPQ 585, 590 (CCPA 1975) (prior art reference studied the local anesthetic activity of various compounds, and taught that compounds structurally similar to those claimed were irritating to human skin and therefore "cannot be regarded as useful anesthetics." 514 F.2d at 1393, 185 USPQ at 587).

Similarly, if the prior art merely discloses compounds as intermediates in the production of a final product, one of ordinary skill in the art would not **>ordinarily< stop the reference synthesis and investigate the intermediate

compounds with an expectation of arriving at claimed compounds which have different uses. *In re Lalu*, 747 F.2d 703, 223 USPQ 1257 (Fed. Cir. 1984).

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VII. <PRIMA FACIE CASE REBUTTABLE BY EVIDENCE OF SUPERIOR OR UNEXPECTED RESULTS

A *prima facie* case of obviousness based on structural similarity is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) (Affidavit evidence which showed that claimed triethylated compounds possessed anti-inflammatory activity whereas prior art trimethylated compounds did not was sufficient to overcome obviousness rejection based on the homologous relationship between the prior art and claimed compounds.); *In re Wiechert*, 370 F.2d 927, 152 USPQ 247 (CCPA 1967) (a 7-fold improvement of activity over the prior art held sufficient to rebut *prima facie* obviousness based on close structural similarity).

However, a claimed compound may be obvious because it was suggested by, or structurally similar to, a prior art compound even though a particular benefit of the claimed compound asserted by patentee is not expressly disclosed in the prior art. It is the differences in fact in their respective properties which are determinative of nonobviousness. If the prior art compound does in fact possess a particular benefit, even though the benefit is not recognized in the prior art, applicant's recognition of the benefit is not in itself sufficient to distinguish the claimed compound from the prior art. *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991).

See **MPEP § 716.02** - **§ 716.02(g)** for a discussion of evidence alleging unexpectedly advantageous or superior results.

2145 Consideration of Applicant's Rebuttal Arguments [R-9]

If a *prima facie* case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the *prima facie* case. See, e.g., In re *Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990). Rebuttal evidence and arguments can be presented in the specification, *In re Soni* , 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995), by counsel, *In re Chu* , 66 F.3d 292, 299, 36 USPQ2d 1089, 1094-95 (Fed. Cir. 1995), or by way of an affidavit or declaration under **37 CFR 1.132**, e.g., *Soni*, 54 F.3d at 750, 34 USPQ2d at 1687; *In re Piasecki*, 745 F.2d 1468, 1474, 223 USPQ 785, 789-90 (Fed. Cir. 1984). However, arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., *In re Huang*, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

Office personnel should consider all rebuttal arguments and evidence presented by applicants. See, e.g., *Soni*, 54 F.3d at 750, 34 USPQ2d at 1687 (error not to consider evidence presented in the specification). *C.f., In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996) (error not to consider factual evidence submitted to counter a **35 U.S.C. 112** rejection); *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992) (Office personnel should consider declarations from those skilled in the art praising the claimed invention and opining that the art teaches away from the invention.); *Piasecki*, 745 F.2d at 1472, 223 USPQ at 788 ("[Rebuttal evidence] may relate to any of the *Graham* factors including the so-called secondary considerations.").

Rebuttal evidence may include evidence of "secondary considerations," such as "commercial success, long felt but unsolved needs, [and] failure of others." *Graham v. John Deere Co.*, 383 U.S. at 17, 148 USPQ at 467. See also, e.g., *In re Piasecki*, 745 F.2d 1468, 1473, 223 USPQ 785, 788 (Fed. Cir. 1984) (commercial success). Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. Rebuttal evidence may consist of a showing that the claimed compound possesses unexpected properties. *Dillon*, 919 F.2d at 692-93, 16 USPQ2d at 1901. A showing of unexpected results must be based on evidence, not argument or speculation. *In re Mayne*, 104 F.3d 1339, 1343-44, 41 USPQ2d 1451, 1455-56 (Fed. Cir. 1997) (conclusory statements that claimed compound possesses unusually low immune response or unexpected biological activity that is unsupported by comparative data held insufficient to overcome *prima facie* case of obviousness). Rebuttal evidence may include evidence that the claimed invention was copied by others. See, e.g., *In re GPAC*, 57 F.3d 1573, 1580, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995); *Hybritech Inc. v. Monoclonal Antibodies*, 802 F.2d 1367, 1380, 231 USPQ 81, 90 (Fed. Cir. 1986). It may also include evidence of the state of the art, the level of skill in the art, and the beliefs of those skilled in the art. See, e.g., *In re Oelrich*, 579 F.2d 86, 91-92, 198 USPQ 210, 214 (CCPA 1978) (Expert opinions regarding the level of skill in the art were probative of the Nonobviousness of the claimed invention.); *Piasecki*, 745 F.2d at 1471, 1473-74, 223 USPQ at 790 (Evidence of nontechnological nature is pertinent to the conclusion of obviousness. The

declarations of those skilled in the art regarding the need for the invention and its reception by the art were improperly discounted by the Board.); *Beattie*, 974 F.2d at 1313, 24 USPQ2d at 1042-43 (Seven declarations provided by music teachers opining that the art teaches away from the claimed invention must be considered, but were not probative because they did not contain facts and did not deal with the specific prior art that was the subject of the rejection.). For example, rebuttal evidence may include a showing that the prior art fails to disclose or render obvious a method for making the compound, which would preclude a conclusion of obviousness of the compound. A conclusion of obviousness requires that the reference(s) relied upon be enabling in that it put the public in possession of the claimed invention. The court in *In re Hoeksema*, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968), stated:

> Thus, upon careful reconsideration it is our view that if the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. [footnote omitted.] In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close relationships between their structures and those of prior art compounds.

The *Hoeksema* court further noted that once a prima facie case of obviousness is made by the PTO through citation of references, the burden is on the applicant to produce contrary evidence establishing that the reference being relied on would not enable a skilled artisan to produce the different compounds claimed. *Id*. at 274-75, 158 USPQ at 601. See also *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 295, 297, 227 USPQ 657, 666, 667 (Fed. Cir. 1985) (citing *Hoeksema* for the proposition above); *In re Grose*, 592 F.2d 1161, 1168, 201 USPQ 57, 63-64 (CCPA 1979) ("One of the assumptions underlying a prima facie obviousness rejection based upon a structural relationship between compounds, such as adjacent homologs, is that a method disclosed for producing one would provide those skilled in the art with a method for producing the other... Failure of the prior art to disclose or render obvious a method for making any composition of matter, whether a compound or a mixture of compounds like a zeolite, precludes a conclusion that the composition would have been obvious.").

Consideration of rebuttal evidence and arguments requires Office personnel to weigh the proffered evidence and arguments. Office personnel should avoid giving evidence no weight, except in rare circumstances. *Id.* See also *In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996). However, to be entitled to substantial weight, the applicant should establish a nexus between the rebuttal evidence and the claimed invention, i.e., objective evidence of nonobviousness must be attributable to the claimed invention. The Federal Circuit has acknowledged that applicant bears the burden of establishing nexus, stating:

> In the exparte process of examining a patent application, however, the PTO lacks the means or resources to gather evidence which supports or refutes the applicant's assertion that the sales constitute commercial success. C.f.Ex parte Remark, 15 USPQ2d 1498, 1503 ([BPAI] 1990) (evidentiary routine of shifting burdens in civil proceedings inappropriate in ex parte prosecution proceedings because examiner has no available means for adducing evidence). Consequently, the PTO must rely upon the applicant to provide hard evidence of commercial success.

In re Huang, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996). See also *GPAC*, 57 F.3d at 1580, 35 USPQ2d at 1121; *In re Paulsen*, 30 F.3d 1475, 1482, 31 USPQ2d 1671, 1676 (Fed. Cir. 1994) (Evidence of commercial success of articles not covered by the claims subject to the **35 U.S.C. 103** rejection was not probative of nonobviousness.). Additionally, the evidence must be reasonably commensurate in scope with the claimed invention. See, e.g., *In re Kulling*, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 777 (Fed. Cir. 1983). *In re Soni*, 54 F.3d 746, 34 USPQ2d 1684 (Fed. Cir. 1995) does not change this analysis. In *Soni*, the Court declined to consider the Office's argument that the evidence of nonobviousness was not commensurate in scope with the claim because it had not been raised by the examiner (54 F.3d at 751, 34 USPQ2d at 1688).

When considering whether proffered evidence is commensurate in scope with the claimed invention, Office personnel should not require the applicant to show unexpected results over the entire range of properties possessed by a chemical compound or composition. See, e.g., *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Evidence that the compound or composition possesses superior and unexpected properties in one of a spectrum of common properties can be sufficient to rebut a *prima facie* case of obviousness. *Id.*

For example, a showing of unexpected results for a single member of a claimed subgenus, or a narrow portion of a claimed range would be sufficient to rebut a *prima facie* case of obviousness if a skilled artisan "could ascertain a trend in the exemplified data that would allow him to reasonably extend the probative value thereof." *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Evidence of the unobviousness of a broad range can be proven by a narrower range when one skilled in the art could ascertain a trend that would allow him to reasonably extend the probative value thereof.). But see , *Grasselli*, 713 F.2d at 743, 218 USPQ at 778 (evidence of superior properties for sodium containing composition insufficient to establish the non-obviousness of broad claims for a catalyst with "an alkali metal" where it was well known in the catalyst art that different alkali metals were not interchangeable and applicant had shown unexpected results only for sodium containing materials); *In re Greenfield*, 571 F.2d 1185, 1189, 197 USPQ 227, 230 (CCPA 1978) (evidence of superior properties in one species insufficient to establish the nonobviousness of a subgenus containing hundreds of compounds); *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972) (one test not sufficient where there was no adequate basis for concluding the other claimed compounds would behave the same way). However, an exemplary showing may be sufficient to establish a reasonable correlation between the showing and the entire scope of the claim, when viewed by a skilled artisan. See, e.g., *Chupp*, 816 F.2d at 646, 2 USPQ2d at 1439; *Clemens*, 622 F.2d at 1036, 206 USPQ at 296. On the other hand, evidence of an unexpected property may not be sufficient regardless of the scope of the showing. Usually, a showing of unexpected results is sufficient to overcome a *prima facie* case of obviousness. See, e.g., *In re Albrecht*, 514 F.2d 1389, 1396, 185 USPQ 585, 590 (CCPA 1975). However, where the claims are not limited to a particular use, and where the prior art provides other motivation to select a particular species or subgenus, a showing of a new use may not be sufficient to confer patentability. See *Dillon*, 919 F.2d at 692, 16 USPQ2d at 1900-01. Accordingly, each case should be evaluated individually based on the totality of the circumstances.

Evidence pertaining to secondary considerations must be taken into account whenever present; however, it does not necessarily control the obviousness conclusion. See, e.g., *Pfizer, Inc. v. Apotex, Inc.* , 480 F.3d 1348, 1372, 82 USPQ2d 1321, 1339 (Fed. Cir. 2007) ("the record establish [ed] such a strong case of obviousness" that allegedly unexpectedly superior results were ultimately insufficient to overcome obviousness conclusion); *Leapfrog Enterprises Inc. v. Fisher-Price Inc.* , 485 F.3d 1157, 1162, 82 USPQ2d 1687, 1692 (Fed. Cir. 2007)("given the strength of the *prima facie* obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion" of obviousness); and *Newell Cos., Inc. v. Kenney Mfg. Co.* , 864 F.2d 757, 768, 9 USPQ2d 1417, 1426 (Fed. Cir. 1988). Office personnel should not evaluate rebuttal evidence for its "knockdown" value against the *prima facie* case, *Piasecki*, 745 F.2d at 1473, 223 USPQ at 788, or summarily dismiss it as not compelling or insufficient. If the evidence is deemed insufficient to rebut the *prima facie* case of obviousness, Office personnel should specifically set forth the facts and reasoning that justify this conclusion. See **MPEP § 716** - **§ 716.10** for a additional information pertaining to the evaluation of rebuttal evidence submitted under 37 CFR **1.132**.

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Many basic approaches that a practitioner may use to demonstrate nonobviousness also continue to apply in the post- *KSR* era. Since it is now clear that a strict teaching-suggestion-motivation approach is not the only way to establish a *prima facie* case of obviousness, it is true that practitioners have been required to shift the emphasis of their nonobviousness arguments to a certain degree. However, familiar lines of argument still apply, including teaching away from the claimed invention by the prior art, lack of a reasonable expectation of success, and unexpected results. Indeed, they may have even taken on added importance in view of the recognition in *KSR* of a variety of possible rationales.

The following cases exemplify the continued application of the principle that when evidence has been presented to rebut an obviousness rejection, it should not be evaluated simply for its "knockdown" value. Rather, all evidence must be reweighed to determine whether the claims are nonobvious.

Example 1:

The claims at issue in *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007), were directed to compositions comprising hematopoietic stem cells from umbilical cord or placental blood, and to methods of using such compositions for treatment of blood and immune system disorders. The composition claims required that the stem cells be present in an amount sufficient to effect hematopoietic reconstitution when administered to a human adult. The trial court had found that PharmaStem's patents were infringed and not invalid on obviousness or other grounds. On appeal, the Federal Circuit reversed the district court, determining that the claims were invalid for obviousness.

The Federal Circuit discussed the evidence presented at trial. It pointed out that the patentee, PharmaStem, had not invented an entirely new procedure or new composition. Rather, PharmaStem's own specification acknowledged that it was already known in the prior art that umbilical cord and placental blood-based compositions contained hematopoietic stem cells, and that hematopoietic stem cells were useful for the purpose of hematopoietic reconstitution. PharmaStem's contribution was to provide experimental proof that umbilical cord and placental blood could be used to effect hematopoietic reconstitution in mice. By extrapolation, one of ordinary skill in the art would have expected this reconstitution method to work in humans as well.

The court rejected PharmaStem's expert testimony that hematopoietic stem cells had not been proved to exist in cord blood prior to the experiments described in PharmaStem's patents. The court explained that the expert testimony was contrary to the inventors' admissions in the specification, as well as prior art teachings that disclosed stem cells in cord blood. In this case, PharmaStem's evidence of nonobviousness was outweighed by contradictory evidence.

Despite PharmaStem's useful experimental validation of hematopoietic reconstitution using hematopoietic stem cells from umbilical cord and placental blood, the Federal Circuit found that the claims at issue would have been obvious. There had been ample suggestion in the prior art that the claimed method would have worked. Absolute predictability is not a necessary prerequisite to a case of obviousness. Rather, a degree of predictability that one of ordinary skill would have found to be reasonable is sufficient. The Federal Circuit concluded that "[g]ood science and useful contributions do not necessarily result in patentability." *Id.* at 1364.

Example 2:

It was found to be an error in *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007), for the Board to fail to consider evidence submitted to rebut a prima facie case of obviousness.

The claimed invention was directed to an antivenom composition comprising F(ab) fragments used to treat venomous rattlesnake bites. The composition was created from antibody molecules that include three fragments, F(ab)2, F(ab) and F(c), which have separate properties and utilities. There have been commercially available antivenom products that consisted of whole antibodies and F(ab)2 fragments, but researchers had not experimented with antivenoms containing only F(ab) fragments because it was believed that their unique properties would prevent them from decreasing the toxicity of snake venom. The inventor, Sullivan, discovered that F(ab) fragments are effective at neutralizing the lethality of rattlesnake venom, while reducing the occurrence of adverse immune reactions in humans. On appeal of the examiner's rejection, the Board held that the claim was obvious because all the elements of the claimed composition were accounted for in the prior art, and that the composition taught by that prior art would have been expected by a person of ordinary skill in the art at the time the invention was made to neutralize the lethality of the venom of a rattlesnake.

Rebuttal evidence had not been considered by the Board because it considered the evidence to relate to the intended use of the claimed composition as an antivenom, rather than the composition itself. Appellant successfully argued that even if the Board had shown a prima facie case of obviousness, the extensive rebuttal evidence must be considered. The evidence included three expert declarations submitted to show that the prior art taught away from the claimed invention, an unexpected property or result from the use of F(ab) fragment antivenom, and why those having ordinary skill in the art expected antivenoms comprising F(ab) fragments to fail. The declarations related to more than the use of the claimed composition. While a statement of intended use may not render a known composition patentable, the claimed composition was not known, and whether it would have been obvious depends upon consideration of the rebuttal evidence. Appellant did not concede that the only distinguishing factor of its composition is the statement of intended use and extensively argued that its claimed composition exhibits the unexpected property of neutralizing the lethality of rattlesnake venom while reducing the occurrence of adverse immune reactions in humans. The Federal Circuit found that such a use and unexpected property cannot be ignored – the unexpected property is relevant and thus the declarations describing it should have been considered.

Nonobviousness can be shown when a person of ordinary skill in the art would not have reasonably predicted the claimed invention based on the prior art, and the resulting invention would not have been expected. All evidence must be considered when properly presented.

Example 3:

The case of *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357 (Fed. Cir. 2010), involved a disposable protective covering for the portion of a hearing aid that is inserted into the ear canal. The covering was such that it could be readily replaced by a user as needed.

At the district court, Shure had argued that Hearing Components' patents were obvious over one or more of three different combinations of prior art references. The jury disagreed, and determined that the claims were nonobvious. The district court upheld the jury verdict, stating that in view of the conflicting evidence presented by the parties as to the teachings of the references, motivation to combine, and secondary considerations, the nonobviousness verdict was sufficiently grounded in the evidence.

Shure appealed to the Federal Circuit, but the Federal Circuit agreed with the district court that the jury's nonobviousness verdict had been supported by substantial evidence. Although Shure had argued before the jury that the Carlisle reference taught an ear piece positioned inside the ear canal, Hearing Components' credible witness countered that only the molded duct and not the ear piece itself was taught by Carlisle as being inside the ear canal. On the issue of combining references, Shure's witness had given testimony described as "rather sparse, and lacking in specific details." Id. at 1364. In contradistinction, Hearing Components' witness "described particular reasons why one skilled in the art would not have been motivated to combine the references." Id. Finally, as to secondary considerations, the Federal Circuit determined that Hearing Components had shown a nexus between the commercial success of its product and the patent by providing evidence that "the licensing fee for a covered product was more than cut in half immediately upon expiration" of the patent.

Although the Hearing Components case involves substantial evidence of nonobviousness in a jury verdict, it is nevertheless instructive for Office personnel on the matter of weighing evidence. Office personnel routinely must consider evidence in the form of prior art references, statements in the specification, or declarations under 37 CFR 1.131 or 1.132. Other forms of evidence may also be presented during prosecution. Office personnel are reminded that evidence that has been presented in a timely manner should not be ignored, but rather should be considered on the record. However, not all evidence need be accorded the same weight. In determining the relative weight to accord to rebuttal evidence, considerations such as whether a nexus exists between the claimed invention and the proffered evidence, and whether the evidence is commensurate in scope with the claimed invention, are appropriate. The mere presence of some credible rebuttal evidence does not dictate that an obviousness rejection must always be withdrawn. See MPEP § 2145. Office personnel must consider the appropriate weight to be accorded to each piece of evidence. An obviousness rejection should be made or maintained only if evidence of obviousness outweighs evidence of nonobviousness. See MPEP § 706(I) ("The standard to be applied in all cases is the 'preponderance of the evidence' test. In other words, an examiner should reject a claim if, in view of the prior art and evidence of record, it is more likely than not that the claim is unpatentable."). MPEP § 716.01(d) provides further guidance on weighing evidence in making a determination of patentability.

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I. ARGUMENT DOES NOT REPLACE EVIDENCE WHERE EVIDENCE IS NECESSARY

Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See **MPEP § 2129** and **§ 2144.03** for a discussion of admissions as prior art.

The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a *prima facie* case of obviousness."). See **MPEP § 716.01(c)** for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

II. ARGUING ADDITIONAL ADVANTAGES OR LATENT PROPERTIES

Prima Facie Obviousness Is Not Rebutted by Merely Recognizing Additional Advantages or Latent Properties Present in the Prior Art

Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979) (Claims were directed to grooved carbon disc brakes wherein the grooves were provided to vent steam or vapor during a braking action. A prior art reference taught noncarbon disc brakes which were grooved for the purpose of cooling the faces of the braking members and eliminating dust. The court held the prior art references when combined would overcome the problems of dust and overheating solved by the prior art and would inherently overcome the steam or vapor cause of the problem relied upon for patentability by applicants. Granting a patent on the discovery of an unknown but inherent function (here venting steam or vapor) "would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art." 596 F.2d at 1022, 201 USPQ at 661.); *In re Baxter*

Travenol Labs., 952 F.2d 388, 21 USPQ2d 1281 (Fed. Cir. 1991) (Appellant argued that the presence of DEHP as the plasticizer in a blood collection bag unexpectedly suppressed hemolysis and therefore rebutted any *prima facie* showing of obviousness, however the closest prior art utilizing a DEHP plasticized blood collection bag inherently achieved same result, although this fact was unknown in the prior art.).

"The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985) (The prior art taught combustion fluid analyzers which used labyrinth heaters to maintain the samples at a uniform temperature. Although appellant showed an unexpectedly shorter response time was obtained when a labyrinth heater was employed, the Board held this advantage would flow naturally from following the suggestion of the prior art.). See also *Lantech Inc. v. Kaufman Co. of Ohio Inc.*, 878 F.2d 1446, 12 USPQ2d 1076, 1077 (Fed. Cir. 1989), *cert. denied*, 493 U.S. 1058 (1990) (unpublished — not citable as precedent) ("The recitation of an additional advantage associated with doing what the prior art suggests does not lend patentability to an otherwise unpatentable invention.").

In re Lintner, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) and *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990) discussed in **MPEP § 2144** are also pertinent to this issue.

See **MPEP § 716.02** - **§ 716.02(g)** for a discussion of declaratory evidence alleging unexpected results.

III. ARGUING THAT PRIOR ART DEVICES ARE NOT PHYSICALLY COMBINABLE

"The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.... Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). See also *In re Sneed*, 710 F.2d 1544, 1550, 218 USPQ 385, 389 (Fed. Cir. 1983) ("[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review."); and *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973) ("Combining the teachings of references does not involve an ability to combine their specific structures."). However, the claimed combination cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose. See **MPEP § 2143.01**.

IV. ARGUING AGAINST REFERENCES INDIVIDUALLY

One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

V. ARGUING ABOUT THE NUMBER OF REFERENCES COMBINED

Reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991) (Court affirmed a rejection of a detailed claim to a candy sucker shaped like a thumb on a stick based on thirteen prior art references.).

VI. ARGUING LIMITATIONS WHICH ARE NOT CLAIMED

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993) (Claims to a superconducting magnet which generates a "uniform magnetic field" were not limited to the degree of magnetic field uniformity required for Nuclear Magnetic Resonance (NMR) imaging. Although the specification disclosed that the claimed magnet may be used in an NMR apparatus, the claims were not so limited.); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571-72, 7 USPQ2d 1057, 1064-1065 (Fed. Cir.), *cert. denied*, 488 U.S. 892 (1988) (Various limitations on which appellant relied were not stated in the claims; the specification did not provide evidence indicating these limitations must be read into the claims to give meaning to the disputed terms.); *Ex parte McCullough*, 7 USPQ2d 1889, 1891 (Bd. Pat. App. & Inter. 1987) (Claimed electrode was rejected as obvious despite assertions that electrode functions differently than would be expected when used in nonaqueous battery since "although the demonstrated results may be germane to the patentability of a battery containing appellant's electrode, they are not germane to the patentability of the invention claimed on appeal.").

See **MPEP § 2111** - **§ 2116.01**, for additional case law relevant to claim interpretation.

VII. ARGUING ECONOMIC INFEASIBILITY

The fact that a combination would not be made by businessmen for economic reasons does not mean that a person of ordinary skill in the art would not make the combination because of some technological incompatibility. *In re Farrenkopf*, 713 F.2d 714, 219 USPQ 1 (Fed. Cir. 1983) (Prior art reference taught that addition of inhibitors to radioimmunoassay is the most convenient, but costliest solution to stability problem. The court held that the additional expense associated with the addition of inhibitors would not discourage one of ordinary skill in the art from seeking the convenience expected therefrom.).

VIII. ARGUING ABOUT THE AGE OF REFERENCES

"The mere age of the references is not persuasive of the unobviousness of the combination of their teachings, absent evidence that, notwithstanding knowledge of the references, the art tried and failed to solve the problem." *In re Wright*, 569 F.2d 1124, 1127, 193 USPQ 332, 335 (CCPA 1977) (100 year old patent was properly relied upon in a rejection based on a combination of references.). See also *Ex parte Meyer*, 6 USPQ2d 1966 (Bd. Pat. App. & Inter. 1988) (length of time between the issuance of prior art patents relied upon (1920 and 1976) was not persuasive of unobviousness).

IX. ARGUING THAT PRIOR ART IS NONANALOGOUS

See **MPEP § 2141.01(a)** for case law pertaining to analogous art.

X. ARGUING IMPROPER RATIONALES FOR COMBINING REFERENCES

A. Impermissible Hindsight

Applicants may argue that the examiner's conclusion of obviousness is based on improper hindsight reasoning. However, "[a]ny judgement on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). Applicants may also argue that the combination of two or more references is "hindsight" because "express" motivation to combine the references is lacking. However, there is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004). See MPEP § **2141** and § **2143** for guidance regarding establishment of a *prima facie* case of obviousness.

B. Obvious To Try Rationale

An applicant may argue the examiner is applying an improper "obvious to try" rationale in support of an obviousness rejection.

An "obvious to try" rationale may support a conclusion that a claim would have been obvious where one skilled in the art is choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success. " [A] person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007).

"The admonition that 'obvious to try' is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.... In others, what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (citations omitted) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.).

C. Lack of Suggestion To Combine References

A suggestion or motivation to combine references is an appropriate method for determining obviousness, however it is just one of a number of valid rationales for doing so. The Court in *KSR* identified several exemplary rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham*. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1395-97. See MPEP § **2141** and § **2143**.

D. References Teach Away from the Invention or Render Prior Art Unsatisfactory for Intended Purpose

In addition to the material below, see **MPEP § 2141.02** (prior art must be considered in its entirety, including disclosures that teach away from the claims) and **MPEP § 2143.01** (proposed modification cannot render the prior art unsatisfactory for its intended purpose or change the principle of operation of a reference).

1. The Nature of the Teaching Is Highly Relevant

A prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness; however, "the nature of the teaching is highly relevant and must be weighed in substance. A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (Claims were directed to an epoxy resin based printed circuit material. A prior art reference disclosed a polyester-imide resin based printed circuit material, and taught that although epoxy resin based materials have acceptable stability and some degree of flexibility, they are inferior to polyester-imide resin based materials. The court held the claims would have been obvious over the prior art because the reference taught epoxy resin based material was useful for applicant's purpose, applicant did not distinguish the claimed epoxy from the prior art epoxy, and applicant asserted no discovery beyond what was known to the art.).

Furthermore, "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed…." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

2. References Cannot Be Combined Where Reference Teaches Away from Their Combination

It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983) (The claimed catalyst which contained both iron and an alkali metal was not suggested by the combination of a reference which taught the interchangeability of antimony and alkali metal with the same beneficial result, combined with a reference expressly excluding antimony from, and adding iron to, a catalyst.).

3. Proceeding Contrary to Accepted Wisdom Is Evidence of Nonobviousness

The totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. *In re Hedges*, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986) (Applicant's claimed process for sulfonating diphenyl sulfone at a temperature above 127ºC was contrary to accepted wisdom because the prior art as a whole suggested using lower temperatures for optimum results as evidenced by charring, decomposition, or reduced yields at higher temperatures.).

Furthermore, "[k]nown disadvantages in old devices which would naturally discourage search for new inventions may be taken into account in determining obviousness." *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966).

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E. Applicability of KSR to All Technologies

At the time the *KSR* decision was handed down, some observers questioned whether the principles discussed were intended by the Supreme Court to apply to all fields of inventive endeavor. Arguments were made that because the technology at issue in KSR involved the relatively well-developed and predictable field of vehicle pedal assemblies, the decision was relevant only to such fields. The Federal Circuit has soundly repudiated such a notion, stating that *KSR* applies across technologies:

> This court also declines to cabin KSR to the "predictable arts" (as opposed to the "unpredictable art" of biotechnology). In fact, this record shows that one of skill in this advanced art would find these claimed "results" profoundly "predictable."

In re Kubin, 561 F.3d 1351, 1360 (Fed. Cir. 2009). Thus, Office personnel should not withdraw any rejection solely on the basis that the invention lies in a technological area ordinarily considered to be unpredictable.

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XI. FORM PARAGRAPHS

See **MPEP § 707.07**(f) for form paragraphs 7.37 through 7.38 which may be used where applicant's arguments are not persuasive or are moot.

2146 35 U.S.C. 103(c) [R-3]

35 U.S.C. 103 Conditions of patentability; non-obvious subject matter.

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(c) (1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of **section 102** of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

(2) For purposes of this subsection, subject matter developed by another person and a claimed invention shall be deemed to have been owned by the same person or subject to an obligation of assignment to the same person if — (A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

(B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement.

(3) For purposes of paragraph (2), the term "joint research agreement" means a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention.<

>Effective November 29, 1999, subject matter which was prior art under former **35 U.S.C. 103 via 35 U.S.C. 102(e) was disqualified as prior art against the claimed invention if that subject matter and the claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." This amendment to 35 U.S.C. **103**(c) was made pursuant to section 4807 of the American Inventors Protection Act of 1999 (AIPA); see Pub. L. 106-113, 113 Stat. 1501, 1501A-591 (1999). The changes to 35 U.S.C. **102**(e) in the Intellectual Property and High Technology Technical Amendments Act of 2002 (Pub. L. 107-273, 116 Stat. 1758 (2002)) did not affect the exclusion under 35 U.S.C. **103**(c) as amended on November 29, 1999. Subsequently, the Cooperative Research and Technology Enhancement Act of 2004 (CREATE Act) (Pub. L. 108-453, 118 Stat. 3596 (2004)) further amended 35 U.S.C. **103**(c) to provide that subject matter developed by another person shall be treated as owned by the same person or subject to an obligation of assignment to the same person for purposes of determining obviousness if three conditions are met:

(A) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made;

(B) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(C) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement (hereinafter "joint research agreement disqualification").

These changes to 35 U.S.C. **103**(c) apply to all patents (including reissue patents) granted on or after December 10, 2004. The amendment to 35 U.S.C. **103**(c) made by the AIPA to change "subsection (f) or (g)" to "one of more of subsections (e), (f), or (g)" applies to applications filed on or after November 29, 1999. It is to be noted that, for all applications (including reissue applications), if the application is pending on or after December 10, 2004, the 2004 changes to 35 U.S.C. **103**(c), which effectively include the 1999 changes, apply; thus, the November 29, 1999 date of the prior revision to 35 U.S.C. **103**(c) is no longer relevant. In a reexamination proceeding, however, one must look at whether or not the patent being reexamined was granted on or after December 10, 2004 to determine whether 35 U.S.C. **103**(c), as amended by the CREATE Act, applies. For a reexamination proceeding of a patent granted prior to December 10, 2004 on an application filed on or after November 29, 1999, it is the 1999 changes to 35 U.S.C. **103**(c) that are applicable to the disqualifying commonly assigned/owned prior art provisions of 35 U.S.C. **103**(c). See MPEP § **706.02(l)(1)** for additional information regarding disqualified prior art under 35 U.S.C. **102**(e)/**103**. For a reexamination proceeding of a patent granted prior to December 10, 2004 on an application filed prior to November 29, 1999, neither the 1999 nor the 2004 changes to 35 U.S.C. **103**(c) are applicable. Therefore, only prior art under 35 U.S.C. **102**(f) or (g) used in a rejection under 35 U.S.C. **103**(a)

may be disqualified under the commonly assigned/owned prior art provision of 35 U.S.C. 103(c).

35 U.S.C. 103(c), as amended by the CREATE Act, applies only to subject matter which qualifies as prior art under 35 U.S.C. 102(e), (f), or (g), and which is being relied upon in a rejection under 35 U.S.C. 103. If the rejection is anticipation under 35 U.S.C. 102(e), (f), or (g), 35 U.S.C. 103(c) cannot be relied upon to disqualify the subject matter in order to overcome or prevent the anticipation rejection. Likewise, 35 U.S.C. 103(c) cannot be relied upon to overcome or prevent a double patenting rejection. See 37 CFR 1.78(c) and MPEP § 804.< See MPEP § 706.02(l) - § 706.02(l)(3).

2161 Three Separate Requirements for Specification Under 35 U.S.C. 112, First Paragraph

THE SPECIFICATION MUST INCLUDE A WRITTEN DESCRIPTION OF THE INVENTION, ENABLEMENT, AND BEST MODE OF CARRYING OUT THE CLAIMED INVENTION

The first paragraph of 35 U.S.C. 112 provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. [emphasis added].

This section of the statute requires that the specification include the following:

(A) A written description of the invention;

(B) The manner and process of making and using the invention (the enablement requirement); and

(C) The best mode contemplated by the inventor of carrying out his invention.

THE THREE REQUIREMENTS ARE SEPARATE AND DISTINCT FROM EACH OTHER

The written description requirement is separate and distinct from the enablement requirement. *In re Barker*, 559 F.2d 588, 194 USPQ 470 (CCPA 1977), *cert. denied*, 434 U.S. 1064 (1978); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991) (While acknowledging that some of its cases concerning the written description requirement and the enablement requirement are confusing, the Federal Circuit reaffirmed that under 35 U.S.C. 112, first paragraph, the written description requirement is separate and distinct from the enablement requirement and gave an example thereof.). An invention may be described without the disclosure being enabling (e.g., a chemical compound for which there is no disclosed or apparent method of making), and a disclosure could be enabling without describing the invention (e.g., a specification describing a method of making and using a paint composition made of functionally defined ingredients within broad ranges would be enabling for formulations falling within the description but would not describe any specific formulation). See *In re Armbruster*, 512 F.2d 676, 677, 185 USPQ 152, 153 (CCPA 1975) ("[A] specification which 'describes' does not necessarily also 'enable' one skilled in the art to make or use the claimed invention."). Best mode is a separate and distinct requirement from the enablement requirement. *In re Newton*, 414 F.2d 1400, 163 USPQ 34 (CCPA 1969).

2161.01 Computer Programming and 35 U.S.C. 112**, First Paragraph [R-9]

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The statutory requirements for computer-implemented inventions are the same as for all inventions, such as the subject matter eligibility and utility requirements under 35 U.S.C. 101 , the definiteness requirement of 35 U.S.C. 112, second paragraph, the three separate and distinct requirements of 35 U.S.C. 112, first paragraph, the novelty requirement of 35 U.S.C. 102, and nonobviousness requirement of 35 U.S.C. 103 . For determining whether claimed subject matter complies with the subject matter eligibility requirement of 35 U.S.C. 101 , examiners should consult MPEP §2106. For determining whether claimed subject matter complies with the utility requirement of 35 U.S.C. 101 , examiners should consult the "Guidelines for Examination of Applications for Compliance with the Utility Requirement" set forth in MPEP § 2107. For determining whether claimed subject matter complies with the written description requirement of 35 U.S.C. 112, first paragraph, examiners should consult the "Computer Programming and 35 U.S.C. 112, First Paragraph, Guidelines" set forth in MPEP §2161.01 and the "Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, 'Written Description' Requirement" set forth in MPEP §2163 . For determining whether claimed subject matter complies with the enablement requirement of 35 U.S.C. 112, first paragraph, examiners should consult the enablement guidelines set forth in MPEP §2164 et seq., including the "Examples of Enablement Issues – Computer Programming Cases" set forth in MPEP §2164.06(c) and "Enablement

Commensurate in Scope With the Claims" set forth in **MPEP §2164.08** . For determining whether the claims comply with the nonobviousness requirement of **35 U.S.C. 103** , examiners should use the "Examination Guidelines for Determining Obviousness Under **35 U.S.C. 103** " set forth in **MPEP §2141**. Nevertheless, computer-implemented inventions have certain unique examination issues, especially those that are claimed using functional language that is not limited to a specific structure. This section provides supplemental information to assist examiners in examining computer-implemented functional claim limitations. See **MPEP §2181**(II)(B) and **§2181**(IV) for information regarding means (or step) plus function limitations that invoke **35 U.S.C. 112**, sixth paragraph.

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I. **>DETERMINING WHETHER THERE IS ADEQUATE WRITTEN DESCRIPTION FOR A COMPUTER-IMPLEMENTED FUNCTIONAL CLAIM LIMITATION

The first paragraph of **35 U.S.C. 112** contains a written description requirement that is separate and distinct from the enablement requirement. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1340, 94 USPQ2d 1161, ___ (Fed. Cir. 2010) (*en banc*). To satisfy the written description requirement, the specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562-63, 19 USPQ2d 1111, ___ (Fed. Cir. 1991). Specifically, the specification must describe the claimed invention in a manner understandable to a person of ordinary skill in the art and show that the inventor actually invented the claimed invention. *Vas-Cath*, 935 F.2d at 1562-63; *Ariad*, 598 F.3d at 1351. The function of the written description requirement is to ensure that the inventor had possession of, as of the filing date of the application relied on, the specific subject matter later claimed by him or her; how the specification accomplishes this is not material. *In re Herschler*, 591 F.2d 693, 700-01, 200 USPQ 711, 717 (CCPA 1979) and further reiterated in *In re Kaslow*, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983). See also MPEP § 2163 - § 2163.04.

The written description requirement of **35 U.S.C. 112**, first paragraph applies to all claims including original claims that are part of the disclosure as filed. *Ariad*, 598 F.3d at 1349. As stated by the Federal Circuit, "[a]lthough many original claims will satisfy the written description requirement, certain claims may not." *Ariad*, 598 F.3d at 1349; see also *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1343-46, 76 USPQ2d 1724, ___ (Fed. Cir. 2005); *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, ___ (Fed. Cir. 1997). For instance, generic claim language in the original disclosure does not satisfy the written description requirement if it fails to support the scope of the genus claimed. *Ariad*, 598 F.3d at 1350; *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 968, 63 USPQ2d 1609, ___ (Fed. Cir. 2002) (holding that generic claim language appearing in ipsis verbis in the original specification did not satisfy the written description requirement because it failed to support the scope of the genus claimed); *Fiers v. Revel*, 984 F.2d 1164, 1170, 25 USPQ2d 1601, ___ (Fed. Cir. 1993) (rejecting the argument that "only similar language in the specification or original claims is necessary to satisfy the written description requirement"). For example, in *LizardTech*, the claim was directed to a method of compressing digital images using seamless discrete wavelet transformation ("DWT"). The court found that the claim covered all ways of performing DWT-based compression processes that lead to a seamless DWT because there were no limitations as to how the seamless DWT was to be accomplished. *LizardTech*, 424 F.3d at 1346 ("[T]he description of one method for creating a seamless DWT does not entitle the inventor . . . to claim any and all means for achieving that objective."). However, the specification provided only one method for creating a seamless DWT, and there was no evidence that the specification contemplated a more generic way of creating a seamless array of DWT coefficients. Therefore, the written description requirement was not satisfied in this case because the specification did not provide sufficient evidence that the inventor invented the generic claim. *LizardTech*, 424 F.3d at 1346.

In addition, original claims may fail to satisfy the written description requirement when the invention is claimed and described in functional language but the specification does not sufficiently identify how the invention achieves the claimed function. *Ariad*, 598 F.3d at 1349 ("[A]n adequate written description of a claimed genus requires more than a generic statement of an invention's boundaries.") (citing *Eli Lilly*, 119 F.3d at 1568). In *Ariad*, the court recognized the problem of using functional claim language without providing in the specification examples of species that achieve the claimed function:

> The problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing species that achieve that result. But the specification must demonstrate that

> the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus. *Ariad*, 598 F.3d at 1349.

The level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. *Ariad*, 598 F.3d at 1351; *Capon v. Eshhar*, 418 F.3d 1349, 1357-58, 76 USPQ2d 1078, ___ (Fed. Cir. 2005). Computer-implemented inventions are often disclosed and claimed in terms of their functionality. This is because writing computer programming code for software to perform specific functions is normally within the skill of the art once those functions have been adequately disclosed. *Fonar Corp. v. General Elec. Co.*, 107 F.3d 1543, 1549, 41 USPQ2d 1801, ___ (Fed. Cir. 1997). Nevertheless, for computer-implemented inventions, the determination of the sufficiency of disclosure will require an inquiry into both the sufficiency of the disclosed hardware as well as the disclosed software due to the interrelationship and interdependence of computer hardware and software. For instance, in *In re Hayes Microcomputer Products*, the written description requirement was satisfied because the specification disclosed the specific type of microcomputer used in the claimed invention as well as the necessary steps for implementing the claimed function. The disclosure was in sufficient detail such that one skilled in the art would know how to program the microprocessor to perform the necessary steps described in the specification. *In re Hayes Microcomputer Prods., Inc. Patent Litigation*, 982 F.2d 1527, 1533-34, 25 USPQ2d 1241, ___ (Fed. Cir. 1992). Two additional observations made by the Federal Circuit in *Hayes* are important. First, the Federal Circuit stressed that the written description requirement was satisfied because the particular steps, i.e., algorithm, necessary to perform the claimed function were "**described in the specification**." *Hayes*, 982 F.2d at 1534 (emphasis in original). Second, the Court acknowledged that the level of detail required for the written description requirement to be met is case specific. *Hayes*, 982 F.2d at 1534.

When examining computer-implemented functional claims, examiners should determine whether the specification discloses the computer and the algorithm (e.g., the necessary steps and/or flowcharts) that perform the claimed function in sufficient detail such that one of ordinary skill in the art can reasonably conclude that the inventor invented the claimed subject matter. Specifically, if one skilled in the art would know how to program the disclosed computer to perform the necessary steps described in the specification to achieve the claimed function and the inventor was in possession of that knowledge, the written description requirement would be satisfied. *Hayes*, 982 F.2d at 1534. If the specification does not provide a disclosure of the computer and algorithm in sufficient detail to demonstrate to one of ordinary skill in the art that the inventor possessed the invention including how to program the disclosed computer to perform the claimed function, a rejection under **35 U.S.C. 112**, first paragraph for lack of written description must be made. For more information regarding the written description requirement, see **MPEP §2161.01**-**§2163.07(b)**.

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II. BEST MODE

The purpose of the best mode requirement is to "restrain inventors from applying for patents while at the same time concealing from the public the preferred embodiments of their inventions which they have in fact conceived." *In re Gay*, 309 F.2d 769, 772, 135 USPQ 311, 315 (CCPA 1962). Only evidence of concealment, "whether accidental or intentional," is considered in judging the adequacy of the disclosure for compliance with the best mode requirement. *Spectra-Physics, Inc. v. Coherent, Inc.*,827 F.2d 1524, 1535, 3 USPQ 2d 1737, 1745 (Fed. Cir. 1987). That evidence, in order to result in affirmance of a best mode rejection, must tend to show that the quality of an applicant's best mode disclosure is so poor as to effectively result in concealment." *In re Sherwood*, 613 F.2d 809, 816-817, 204 USPQ 537, 544 (CCPA 1980). Also, see *White Consol. Indus. v. Vega Servo-Control Inc.*, 214 USPQ 796, 824 (S.D. Mich. 1982), *aff'd on related grounds*, 713 F.2d 788, 218 USPQ 961 (Fed. Cir. 1983). See also **MPEP § 2165** - **§ 2165.04**.

There are two factual inquiries to be made in determining whether a specification satisfies the best mode requirement. First, there must be a subjective determination as to whether at the time the application was filed, the inventor knew of a best mode of practicing the invention. Second, if the inventor had a best mode of practicing the invention in mind, there must be an objective determination as to whether that best mode was disclosed in sufficient detail to allow one skilled in the art to practice it. *Fonar Corp. v. General Electric Co.*, 107 F.3d 1543, 41 USPQ2d 1801, 1804 (Fed. Cir. 1997); *Chemcast Corp. v. Arco Industries*, 913 F.2d 923, 927-28, 16 USPQ2d 1033, 1036 (Fed. Cir. 1990). "As a general rule, where software constitutes part of a best mode of carrying out an invention, description of such a best mode is satisfied by a disclosure of the functions of the software. This is because, normally, writing code for such software is within the skill of the art, not requiring undue

experimentation, once its functions have been disclosed. . . . [F]low charts or source code listings are not a requirement for adequately disclosing the functions of software." *Fonar Corp.*, 107 F.3d at 1549, 41 USPQ2d at 1805 (citations omitted).

III. *>DETERMINING WHETHER THE FULL SCOPE OF A COMPUTER-IMPLEMENTED FUNCTIONAL CLAIM LIMITATION IS ENABLED

To satisfy the enablement requirement of **35 U.S.C. 112**, first paragraph, the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation." See, e.g., *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, ___ (Fed. Cir. 1993); *In re Wands*, 858 F.2d 731, 736-37, 8 USPQ2d 1400, ___ (Fed. Cir. 1988). In *In re Wands*, the court set forth the following factors to consider when determining whether undue experimentation is needed: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *Wands*, 858 F.2d at 737. The undue experimentation determination is not a single factual determination. Rather, it is a conclusion reached by weighing all the factual considerations. *Wands*, 858 F.2d at 737.

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When basing a rejection on the failure of the applicant's disclosure to meet the enablement provisions of the first paragraph of **35 U.S.C. 112**, USPTO personnel must establish on the record a reasonable basis for questioning the adequacy of the disclosure to enable a person of ordinary skill in the art to make and use the claimed invention without resorting to *undue experimentation*. See *In re Brown*, 477 F.2d 946, 177 USPQ 691 (CCPA 1973); *In re Ghiron*, 442 F.2d 985, 169 USPQ 723 (CCPA 1971). Once USPTO personnel have advanced a reasonable basis for questioning the adequacy of the disclosure, it becomes incumbent on the applicant to rebut that challenge and factually demonstrate that his or her application disclosure is in fact sufficient. See *In re Doyle*, 482 F.2d 1385, 1392, 179 USPQ 227, 232 (CCPA 1973); *In re Scarbrough*, 500 F.2d 560, 566, 182 USPQ 298, 302 (CCPA 1974); *In re Ghiron, supra*. See also **MPEP § 2106**, paragraph V.B.2 and § **2164** - § **2164.08(c)**.

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Functional claim language may render the claims broad when the claim is not limited to any particular structure for performing the claimed function. *In re Swinehart*, 439 F.2d 210, 213, 169 USPQ 226, ___ (CCPA 1971). Since such a claim covers all devices which perform the recited function, there is a concern regarding whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claim. *Swinehart*, 439 F.2d at 213; *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, ___ (Fed. Cir. 2003); *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, ___ (CCPA 1971). Applicants who present broad claim language must ensure the claims are fully enabled. Specifically, the scope of the claims must be less than or equal to the scope of the enablement provided by the specification. *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999, 85 USPQ2d 1826, ___ (Fed. Cir. 2008) ("The scope of the claims must be less than or equal to the scope of the enablement to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.") (quotation omitted).

For example, the claims in *Sitrick* were directed to "integrating" or "substituting" a user's audio signal or visual image into a pre-existing video game or movie. While the claims covered both video games and movies, the specification only taught the skilled artisan how to substitute and integrate user images into video games. The Federal Circuit held that the specification failed to enable the full scope of the claims because the skilled artisan could not substitute a user image for a preexisting character image in movies without undue experimentation. Specifically, the court recognized that one skilled in the art could not apply the teachings of the specification regarding video games to movies, because movies, unlike video games, do not have easily separable character functions. Because the specification did not teach how the substitution and integration of character functions for a user image would be accomplished in movies, the claims were not enabled. *Sitrick*, 516 F.3d at 999-1001.

Although the specification need not teach what is well known in the art, applicant cannot rely on the knowledge of one skilled in the art to supply information that is required to enable the novel aspect of the claimed invention, when the enabling knowledge is in fact not known in the art. *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 941, 94 USPQ2d 1823, ___ (Fed. Cir. 2010) ("ALZA was required to provide an adequate enabling disclosure in the specification; it cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification."); *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1283, 84 USPQ2d 1108, ___ (Fed. Cir. 2007) ("Although the knowledge of one skilled in the art is indeed relevant, the novel aspect of an

invention must be enabled in the patent."). The Federal Circuit has stated that "'[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.'" *Auto. Techs.*, 501 F.3d at 1283 (quoting Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, ___ (Fed. Cir. 1997)). The rule that a specification need not disclose what is well known in the art is "merely a rule of supplementation, not a substitute for a basic enabling disclosure." *Genentech*, 108 F.3d at 1366; see also *ALZA Corp.*, 603 F.3d at 940-41. Therefore, the specification must contain the information necessary to enable the novel aspects of the claimed invention. *ALZA Corp.*, 603 F.3d at 941; *Auto. Techs.*, 501 F.3d at 1283-84 ("[T]he 'omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required.'") (quoting *Genentech*, 108 F.3d at 1366). For instance, in *Auto. Techs.*, the claim limitation "means responsive to the motion of said mass" was construed to include both mechanical side impact sensors and electronic side impact sensors for performing the function of initiating an occupant protection apparatus. *Auto. Techs.*, 501 F.3d at 1282. The specification did not disclose any discussion of the details or circuitry involved in the electronic side impact sensor, and thus, it failed to apprise one of ordinary skill how to make and use the electronic sensor. Since the novel aspect of the invention was side impact sensors, the patentee could not rely on the knowledge of one skilled in the art to supply the missing information. *Auto. Techs.*, 501 F.3d at 1283.

A rejection under **35 U.S.C. 112**, first paragraph for lack of enablement must be made when the specification does not enable the full scope of the claim. USPTO personnel should establish a reasonable basis to question the enablement provided for the claimed invention and provide reasons for the uncertainty of the enablement. For more information regarding the enablement requirement, see MPEP §§ 2164.01(a)-2164.08(c), e.g., 2164.06(c) on examples of computer programming cases.<

2162 Policy Underlying 35 U.S.C. 112, First Paragraph

To obtain a valid patent, a patent application must be filed that contains a full and clear disclosure of the invention in the manner prescribed by **35 U.S.C. 112**, first paragraph. The requirement for an adequate disclosure ensures that the public receives something in return for the exclusionary rights that are granted to the inventor by a patent. The grant of a patent helps to foster and enhance the development and disclosure of new ideas and the advancement of scientific knowledge. Upon the grant of a patent in the U.S., information contained in the patent becomes a part of the information available to the public for further research and development, subject only to the patentee's right to exclude others during the life of the patent.

In exchange for the patent rights granted, **35 U.S.C. 112**, first paragraph, sets forth the minimum requirements for the quality and quantity of information that must be contained in the patent to justify the grant. As discussed in more detail below, the patentee must disclose in the patent sufficient information to put the public in possession of the invention and to enable those skilled in the art to make and use the invention. The applicant must not conceal from the public the best way of practicing the invention that was known to the patentee at the time of filing the patent application. Failure to fully comply with the disclosure requirements could result in the denial of a patent, or in a holding of invalidity of an issued patent.

2163 Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement [R-5]

The following Guidelines establish the policies and procedures to be followed by Office personnel in the evaluation of any patent application for compliance with the written description requirement of 35 U.S.C. **112**. These Guidelines are based on the Office's current understanding of the law and are believed to be fully consistent with binding precedent of the U.S. Supreme Court, as well as the U.S. Court of Appeals for the Federal Circuit and its predecessor courts.

The Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. They are designed to assist Office personnel in analyzing claimed subject matter for compliance with substantive law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.

These Guidelines are intended to form part of the normal examination process. Thus, where Office personnel establish a prima facie case of lack of written description for a claim, a thorough review of the prior art and examination on the merits for compliance with the other statutory requirements, including those of 35 U.S.C. **101**, **102**, **103**, and **112**, is to be conducted prior to completing an Office action which includes a rejection for lack of written description.

I. GENERAL PRINCIPLES GOVERNING COMPLIANCE WITH THE "WRITTEN DESCRIPTION" REQUIREMENT FOR APPLICATIONS

The first paragraph of 35 U.S.C. **112** requires that the "specification shall contain a written description of the invention *** * ***." This requirement is separate and distinct from the enablement requirement. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). See also *Univ. of Rochester v. G.D. Searle & Co*., 358 F.3d 916, 920-23, 69 USPQ2d 1886, 1890-93 (Fed. Cir. 2004) (discussing history and purpose of the written description requirement); *In re Curtis*, 354 F.3d 1347, 1357, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) ("conclusive evidence of a claim's enablement is not equally conclusive of that claim's satisfactory written description"). The written description requirement has several policy objectives. "[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997) , *cert. denied*, 523 U.S. 1089 (1998). *>"The 'written description' requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005). Further, the< written description requirement ** promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. However, a showing of possession alone does not cure the lack of a written description. *Enzo Biochem, Inc. v. Gen-Probe, Inc*., 323 F.3d 956, 969-70, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). Much of the written description case law addresses whether the specification as originally filed supports claims not originally in the application. The issue raised in the cases is most often phrased as whether the original application provides "adequate support" for the claims at issue or whether the material added to the specification incorporates "new matter" in violation of 35 U.S.C. **132**. The "written description" question similarly arises in the interference context, where the issue is whether the specification of one party to the interference can support the newly added claims corresponding to the count at issue, i.e., whether that party can "make the claim" corresponding to the interference count. See, e.g., *Martin v. Mayer*, 823 F.2d 500, 503, 3 USPQ2d 1333, 1335 (Fed. Cir. 1987). In addition, early opinions suggest the Patent and Trademark Office was unwilling to find written descriptive support when the only description was found in the claims; however, this viewpoint was rejected. See *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) (original claims constitute their own description); accord *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); *accord In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification. These early opinions did not address the quality or specificity of particularity that was required in the description, i.e., how much description is enough.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.* , 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly* , 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical* , 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). "Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'"*Enzo Biochem* , 323 F.3d at 963, 63 USPQ2d at 1613. An application specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of biological materials,

by specifically describing a deposit made in accordance with 37 CFR **1.801** *et seq.* See *Enzo Biochem*, 323 F.3d at 965, 63 USPQ2d at 1614 ("reference in the specification to a deposit may also satisfy the written description requirement with respect to a claimed material"); see also Deposit of Biological Materials for Patent Purposes, Final Rule, 54 FR 34,864 (August 22, 1989) ("The requirement for a specific identification is consistent with the description requirement of the first paragraph of 35 U.S.C. **112**, and to provide an antecedent basis for the biological material which either has been or will be deposited before the patent is granted." Id. at 34,876. "The description must be sufficient to permit verification that the deposited biological material is in fact that disclosed. Once the patent issues, the description must be sufficient to aid in the resolution of questions of infringement." Id. at 34,880.). Such a deposit is not a substitute for a written description of the claimed invention. The written description of the deposited material needs to be as complete as possible because the examination for patentability proceeds solely on the basis of the written description. See, e.g., *In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985). See also 54 FR at 34,880 ("As a general rule, the more information that is provided about a particular deposited biological material, the better the examiner will be able to compare the identity and characteristics of the deposited biological material with the prior art.").

A question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently (see, e.g., > *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1733 (Fed. Cir. 2005);< Enzo Biochem, 323 F.3d at 968, 63 USPQ2d at 1616 (Fed. Cir. 2002); *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398), a new or amended claim wherein a claim limitation has been added or removed, or a claim to entitlement of an earlier priority date or effective filing date under 35 U.S.C. **119**, **120**, or **365(c)**. Most typically, the issue will arise in the context of determining whether new or amended claims are supported by the description of the invention in the application as filed (see, e.g., *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989)), whether a claimed invention is entitled to the benefit of an earlier priority date or effective filing date under **35 U.S.C. 119**, **120**, or **365(c)** (see, e.g., *New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 63 USPQ2d 1843 (Fed. Cir. 2002); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998); Fiers v. Revel, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993); *In re Ziegler*, 992 F.2d 1197, 1200, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993)), or whether a specification provides support for a claim corresponding to a count in an interference (see, e.g., *Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1971)). Compliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991).

A. Original Claims

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims"). However, as discussed in paragraph I., *supra*, the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. For example, consider the claim "A gene comprising SEQ ID NO:1." A determination of what the claim as a whole covers may result in a conclusion that specific structures such as a promoter, a coding region, or other elements are included. Although all genes encompassed by this claim share the characteristic of comprising SEQ ID NO:1, there may be insufficient description of those specific structures (e.g., promoters, enhancers, coding regions, and other regulatory elements) which are also included.

The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. Cf. *In re Bell*, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993), and *In re Deuel*, 51 F.3d

1552, 34 USPQ2d 1210 (Fed. Cir. 1995) (holding that a process could not render the product of that process obvious under **35 U.S.C. 103**). The Federal Circuit has pointed out that under United States law, a description that does not render a claimed invention obvious cannot sufficiently describe the invention for the purposes of the written description requirement of 35 U.S.C. **112**. *Eli Lilly*, 119 F.3d at 1567, 43 USPQ2d at 1405. Compare *Fonar Corp. v. General Electric Co.*, 107 F.3d 1543, 1549, 41 USPQ2d 1801, 1805 (Fed. Cir. 1997) ("As a general rule, where software constitutes part of a best mode of carrying out an invention, description of such a best mode is satisfied by a disclosure of the functions of the software. This is because, normally, writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed. *** * *** Thus, flow charts or source code listings are not a requirement for adequately disclosing the functions of software.").

A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) (" *If* n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it.") (emphasis in original); *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) ("the specification does not clearly disclose to the skilled artisan that the inventors ... considered the ratio... to be part of their invention .... There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion").

B. New or Amended Claims

The proscription against the introduction of new matter in a patent application (35 U.S.C. **132** and **251**) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. See *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). See MPEP § **2163.06** through § **2163.07** for a more detailed discussion of the written description requirement and its relationship to new matter. The claims as filed in the original specification are part of the disclosure and, therefore, if an application as originally filed contains a claim disclosing material not found in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985). Thus, the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).

While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction. *In re Oda* , 443 F.2d 1200, 170 USPQ 268 (CCPA 1971). With respect to the correction of sequencing errors in applications disclosing nucleic acid and/or amino acid sequences, it is well known that sequencing errors are a common problem in molecular biology. See, e.g., Peter Richterich, Estimation of Errors in 'Raw' DNA Sequences: A Validation Study, 8 *Genome Research* 251-59 (1998). If an application as filed includes sequence information and references a deposit of the sequenced material made in accordance with the requirements of 37 CFR **1.801***et seq.* , amendment may be permissible. Deposits made after the application filing date cannot be relied upon to support additions to or correction of information in the application as filed. Corrections of minor errors in the sequence may be possible based on the argument that one of skill in the art would have resequenced the deposited material and would have immediately recognized the minor error. Deposits made after the filing date can only be relied upon to provide support for the correction of sequence information if applicant submits a statement in compliance with 37 CFR **1.804** stating that the biological material which is deposited is a biological material specifically defined in the application as filed.

Under certain circumstances, omission of a limitation can raise an issue regarding whether the inventor had possession of a broader, more generic invention. See, e.g., *PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1248, 64 USPQ2d 1344, 1353 (Fed. Cir. 2002) (Claim for a method of inhibiting sprout growth on tubers by treating them with spaced, sequential application of two chemicals was held invalid for lack of adequate written description where the specification indicated that invention was a method of applying a "composition," or mixture, of the two chemicals.); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998) (claims to a sectional sofa comprising, inter alia, a console and a control means were held invalid for failing to satisfy the written description requirement where the claims were broadened by removing the location of the control means); *Johnson Worldwide Associates v. Zebco Corp.*, 175 F.3d 985, 993, 50 USPQ2d 1607, 1613 (Fed. Cir. 1999) (In *Gentry Gallery*, the "court's determination that the patent disclosure did not support a broad meaning for the disputed claim terms was premised on clear statements in the written description that described the location of a claim element--the 'control means' --as 'the only possible location' and that variations were 'outside the stated purpose of the invention.' *Gentry Gallery*, 134 F.3d at 1479, 45 USPQ2d at 1503. *Gentry Gallery*, then, considers the situation where the patent's disclosure makes crystal clear that a particular (i.e., narrow) understanding of a claim term is an 'essential element of [the inventor's] invention.'"); *Tronzo v. Biomet*, 156 F.3d at 1158-59, 47 USPQ2d at 1833 (Fed. Cir. 1998) (claims to generic cup shape were not entitled to filing date of parent application which disclosed "conical cup" in view of the disclosure of the parent application stating the advantages and importance of the conical shape.). A claim that omits an element which applicant describes as an essential or critical feature of the invention originally disclosed does not comply with the written description requirement. See *Gentry Gallery*, 134 F.3d at 1480, 45 USPQ2d at 1503; *In re Sus*, 306 F.2d 494, 504, 134 USPQ 301, 309 (CCPA 1962) ("[O]ne skilled in this art would not be taught by the written description of the invention in the specification that any 'aryl or substituted aryl radical' would be suitable for the purposes of the invention but rather that only certain aryl radicals and certain specifically substituted aryl radicals [i.e., aryl azides] would be suitable for such purposes.") (emphasis in original). A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may also be subject to rejection under 35 U.S.C. **112**, para. 1, as not enabling, or under 35 U.S.C. **112**, para. 2. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976); *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976); and *In re Collier*, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968). See also MPEP § **2172.01**.

The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 USPQ2d at 1117.

II. METHODOLOGY FOR DETERMINING ADEQUACY OF WRITTEN DESCRIPTION

A. Read and Analyze the Specification for Compliance with 35 U.S.C. 112, para. 1

Office personnel should adhere to the following procedures when reviewing patent applications for compliance with the written description requirement of 35 U.S.C. **112**, para. 1. The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, *Wertheim*, 541 F.2d at 262, 191 USPQ at 96; however, with respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims. See MPEP § **714.02** and § **2163.06** ("Applicant should *** * *** specifically point out the support for any amendments made to the disclosure."); and MPEP § **2163.04** ("If applicant amends the claims and points out where and/or how the originally filed disclosure supports the amendment(s), and the examiner finds that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of the filing of the application, the examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims."). Consequently, rejection of an original claim for lack of written description should be rare. The inquiry into whether the description requirement is met is a question of fact that must be determined on a case-by-case basis. See *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ("Precisely how close [to the claimed invention] the description must come to comply with Sec. 112 must be left to case-by-case development."); *In re Wertheim*, 541 F.2d at 262, 191 USPQ at 96 (inquiry is primarily factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure).

1. For Each Claim, Determine What the Claim as a Whole Covers

Claim construction is an essential part of the examination process. Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description. See, e.g., *In re Morris*, 127 F.3d 1048, 1053-54, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). The entire claim must be considered, including the preamble language and the transitional phrase. "Preamble language" is that language in a claim appearing before the transitional phase, e.g., before "comprising," "consisting essentially of," or "consisting of." The transitional term "comprising" (and other comparable terms, e.g., "containing," and "including") is "open-ended" -it covers the expressly recited subject matter, alone or in combination with unrecited subject matter. See, e.g., *Genentech, Inc. v. Chiron Corp*., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim."); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves the "claim open for the inclusion of unspecified ingredients even in major amounts"). See also MPEP § 2111.03. "By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format." *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). For the purposes of searching for and applying prior art under 35 U.S.C. **102** and **103**, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also *AK Steel Corp. v. Sollac*, 344 F3.d 1234, 1239-1240, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003); *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also MPEP § **2111.03**. The claim as a whole, including all limitations found in the preamble (see *Pac-Tec Inc. v. Amerace Corp*., 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention)), the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

The examiner should evaluate each claim to determine if sufficient structures, acts, or functions are recited to make clear the scope and meaning of the claim, including the weight to be given the preamble. See, e.g., *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995) ("[A] claim preamble has the import that the claim as a whole suggests for it."); *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim."). The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. **112**, para. 1, for lack of adequate written description. Limitations may not, however, be imported into the claims from the specification.

2. Review the Entire Application to Understand How Applicant Provides Support for the Claimed Invention Including Each Element and/or Step

Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention. An element may be critical where those of skill in the art would require it to determine that applicant was in possession of the invention. Compare *Rasmussen*, 650 F.2d at 1215, 211 USPQ at 327 ("one skilled in the art who read Rasmussen's specification would understand that it is unimportant how the layers are adhered, so long as they are adhered") (emphasis in original), with *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) ("it is well established in our law that conception of a chemical compound requires that the inventor be able to define it

so as to distinguish it from other materials, and to describe how to obtain it"). The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed (see, e.g., *Wang Labs. v. Toshiba Corp*., 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993)) and should include a determination of the field of the invention and the level of skill and knowledge in the art. Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

3. Determine Whether There is Sufficient Written Description to Inform a Skilled Artisan That Applicant was in Possession of the Claimed Invention as a Whole at the Time the Application Was Filed

(a) Original claims

Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. See, e.g., *Purdue Pharma L.P. v. Faulding Inc*., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (the written description "inquiry is a factual one and must be assessed on a case-by-case basis"); see also *Pfaff v. Wells Electronics, Inc.*, 55 U.S. at 66, 119 S.Ct. at 311, 48 USPQ2d at 1646 ("The word 'invention' must refer to a concept that is complete, rather than merely one that is 'substantially complete.' It is true that reduction to practice ordinarily provides the best evidence that an invention is complete. But just because reduction to practice is sufficient evidence of completion, it does not follow that proof of reduction to practice is necessary in every case. Indeed, both the facts of the Telephone Cases and the facts of this case demonstrate that one can prove that an invention is complete and ready for patenting before it has actually been reduced to practice.").

A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose. *Cooper v. Goldfarb* , 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). See also *UMC Elecs. Co. v. United States* , 816 F.2d 647, 652, 2 USPQ2d 1465, 1468 (Fed. Cir. 1987) ("[T]here cannot be a reduction to practice of the invention * * * without a physical embodiment which includes all limitations of the claim."); *Estee Lauder Inc. v. L'Oreal, S.A.* , 129 F.3d 588, 593, 44 USPQ2d 1610, 1614 (Fed. Cir. 1997) ("[A] reduction to practice does not occur until the inventor has determined that the invention will work for its intended purpose."); *Mahurkar v. C.R. Bard, Inc* ., 79 F.3d 1572, 1578, 38 USPQ2d 1288, 1291 (Fed. Cir. 1996) (determining that the invention will work for its intended purpose may require testing depending on the character of the invention and the problem it solves). Description of an actual reduction to practice of a biological material may be shown by specifically describing a deposit made in accordance with the requirements of 37 CFR **1.801***et seq* . See especially 37 CFR **1.804** and **1.809**. See also paragraph I., *supra*.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., *Vas-Cath*, 935 F.2d at 1565, 19 USPQ2d at 1118 ("drawings alone may provide a 'written description' of an invention as required by Sec. 112*"); *In re Wolfensperger*, 302 F.2d 950, 133 USPQ 537 (CCPA 1962) (the drawings of applicant's specification provided sufficient written descriptive support for the claim limitation at issue); *Autogiro Co. of America v. United States*, 384 F.2d 391, 398, 155 USPQ 697, 703 (Ct. Cl. 1967) ("In those instances where a visual representation can flesh out words, drawings may be used in the same manner and with the same limitations as the specification."); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 ("In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus."). The description need only describe in detail that which is new or not conventional. See *Hybritech v. Monoclonal Antibodies*, 802 F.2d at 1384, 231 USPQ at 94; *Fonar Corp. v. General Electric Co.*, 107 F.3d at 1549, 41 USPQ2d at 1805 (source code description not

required). This is equally true whether the claimed invention is directed to a product or a process.

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. *Enzo Biochem*, 323 F.3d at 964, 63 USPQ2d at 1613. For example, the presence of a restriction enzyme map of a gene may be relevant to a statement that the gene has been isolated. One skilled in the art may be able to determine whether the gene disclosed is the same as or different from a gene isolated by another by comparing the restriction enzyme maps. In contrast, evidence that the gene could be digested with a nuclease would not normally represent a relevant characteristic since any gene would be digested with a nuclease. Similarly, isolation of an mRNA and its expression to produce the protein of interest is strong evidence of possession of an mRNA for the protein.

For some biomolecules, examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length. Although structural formulas provide a convenient method of demonstrating possession of specific molecules, other identifying characteristics or combinations of characteristics may demonstrate the requisite possession. >As explained by the Federal Circuit, "(1) examples are not necessary to support the adequacy of a written description; (2) the written description standard may be met … even where actual reduction to practice of an invention is absent; and (3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure." *Falkner v. Inglis*, 448 F.3d 1357, 1366, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006). See also *Capon v. Eshhar*, 418 F.3d at 1358, 76 USPQ2d at 1084 ("The Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes" where the genes were novel combinations of known DNA segments.).< For example, disclosure of an antigen fully characterized by its structure, formula, chemical name, physical properties, or deposit in a public depository provides an adequate written description of an antibody claimed by its binding affinity to that antigen. *Noelle v. Lederman*, 355 F.3d 1343, 1349, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (holding there is a lack of written descriptive support for an antibody defined by its binding affinity to an antigen that itself was not adequately described). Additionally, unique cleavage by particular enzymes, isoelectric points of fragments, detailed restriction enzyme maps, a comparison of enzymatic activities, or antibody cross-reactivity may be sufficient to show possession of the claimed invention to one of skill in the art. See *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966 ("written description" requirement may be satisfied by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention"). A definition by function alone "does not suffice" to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." *Eli Lilly*, 119 F.3 at 1568, 43 USPQ2d at 1406. See also *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)). An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) (The patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that "[w]ithout such disclosure, the claimed methods cannot be said to have been described.").

If a claim limitation invokes 35 U.S.C. **112**, para. 6, it must be interpreted to cover the corresponding structure, materials, or acts in the specification and "equivalents thereof." See 35 U.S.C. **112**, para. 6. See also *B. Braun Medical, Inc. v. Abbott Lab.*, 124 F.3d 1419, 1424, 43 USPQ2d 1896, 1899 (Fed. Cir. 1997). In considering whether there is 35 U.S.C. **112**, para. 1, support for a means- (or step) plus-function claim limitation, the examiner must consider not only the original disclosure contained in the summary and detailed description of the invention portions of the specification, but also the original claims, abstract, and drawings. A means- (or step-) plus-function claim limitation is adequately described under 35 U.S.C. **112**, para. 1, if: (1) The written description adequately links or associates adequately described particular structure, material, or acts to the function recited in a means- (or step-) plus-function claim limitation; or (2) it is clear based on the facts of the application that one skilled in the art would have known

what structure, material, or acts perform the function recited in a means- (or step-) plus-function limitation. Note also: A rejection under 35 U.S.C. **112**, para. 2, "cannot stand where there is adequate description in the specification to satisfy 35 U.S.C. **112**, first paragraph, regarding means-plus-function recitations that are not, per se, challenged for being unclear." *In re Noll*, 545 F.2d 141, 149, 191 USPQ 721, 727 (CCPA 1976). See Supplemental Examination Guidelines for Determining the Applicability of 35 U.S.C. **112**, para. 6, 65 Fed. Reg. 38510, June 21, 2000. See also MPEP § **2181**.

What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. >See also *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005)("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge…. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.").< If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient").

A claim which is limited to a single disclosed embodiment or species is analyzed as a claim drawn to a single embodiment or species, whereas a claim which encompasses two or more embodiments or species within the scope of the claim is analyzed as a claim drawn to a genus. See also MPEP § **806.04(e)**.

i) For Each Claim Drawn to a Single Embodiment or Species:

(A) Determine whether the application describes an actual reduction to practice of the claimed invention.

(B) If the application does not describe an actual reduction to practice, determine whether the invention is complete as evidenced by a reduction to drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.

(C) If the application does not describe an actual reduction to practice or reduction to drawings or structural chemical formula as discussed above, determine whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention.(1) Determine whether the application as filed describes the complete structure (or acts of a process) of the claimed invention as a whole. The complete structure of a species or embodiment typically satisfies the requirement that the description be set forth "in such full, clear, concise, and exact terms" to show possession of the claimed invention. **35 U.S.C. 112**, para. 1. Cf. *Fields v. Conover*, 443 F.2d 1386, 1392, 170 USPQ 276, 280 (CCPA 1971) (finding a lack of written description because the specification lacked the "full, clear, concise, and exact written description" which is necessary to support the claimed invention). If a complete structure is disclosed, the written description requirement is satisfied for that species or embodiment, and a rejection under 35 U.S.C. **112**, para. 1, for lack of written description must not be made.

(2) If the application as filed does not disclose the complete structure (or acts of a process) of the claimed invention as a whole, determine whether the specification discloses other relevant identifying characteristics sufficient to describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. For example, if the art has established a strong correlation between structure and function, one skilled in the art would be able to predict with a reasonable degree of confidence the structure of the claimed invention from a recitation of its function. Thus, the written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. In contrast, without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In this latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 (written description requirement not satisfied by merely providing "a result that one might achieve if one made that invention"); *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming a rejection for lack of written description because the specification does "little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). Compare *Fonar*, 107 F.3d at 1549, 41 USPQ2d at 1805 (disclosure of software function adequate in that art).

Whether the specification shows that applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and

knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. >The description needed to satisfy the requirements of 35 U.S.C. **112** "varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence." *Capon v. Eshhar*, 418 F.3d at 1357, 76 USPQ2d at 1084.< Patents and printed publications in the art should be relied upon to determine whether an art is mature and what the level of knowledge and skill is in the art. In most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised for * claims >present in the application when originally filed,< even if the specification discloses only a method of making the invention and the function of the invention. See, e.g., *In re Hayes Microcomputer Products, Inc. Patent Litigation*, 982 F.2d 1527, 1534-35, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992) ("One skilled in the art would know how to program a microprocessor to perform the necessary steps described in the specification. Thus, an inventor is not required to describe every detail of his invention. An applicant's disclosure obligation varies according to the art to which the invention pertains. Disclosing a microprocessor capable of performing certain functions is sufficient to satisfy the requirement of section **112**, first paragraph, when one skilled in the relevant art would understand what is intended and know how to carry it out.").

In contrast, for inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, more evidence is required to show possession. For example, disclosure of only a method of making the invention and the function may not be sufficient to support a product claim other than a product-by-process claim. See, e.g., *Fiers v. Revel*, 984 F.2d at 1169, 25 USPQ2d at 1605; *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021. Where the process has actually been used to produce the product, the written description requirement for a product-by-process claim is clearly satisfied; however, the requirement may not be satisfied where it is not clear that the acts set forth in the specification can be performed, or that the product is produced by that process. Furthermore, disclosure of a partial structure without additional characterization of the product may not be sufficient to evidence possession of the claimed invention. See, e.g., *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021 ("A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated.") (citations omitted). In such instances the alleged conception fails not merely because the field is unpredictable or because of the general uncertainty surrounding experimental sciences, but because the conception is incomplete due to factual uncertainty that undermines the specificity of the inventor's idea of the invention. *Burroughs Wellcome Co. v. Barr Laboratories Inc.*, 40 F.3d 1223, 1229, 32 USPQ2d 1915, 1920 (Fed. Cir. 1994). Reduction to practice in effect provides the only evidence to corroborate conception (and therefore possession) of the invention. *Id.*

Any claim to a species that does not meet the test described under at least one of (a), (b), or (c) must be rejected as lacking adequate written description under 35 U.S.C. **112**, para. 1.

ii) For each claim drawn to a genus:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial

variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]." See *Enzo Biochem*, 323 F.3d at 966, 63 USPQ2d at 1615; *Noelle v. Lederman*, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when … the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004)(Claims directed to PTFE dental floss with a friction-enhancing coating were not supported by a disclosure of a microcrystalline wax coating where there was no evidence in the disclosure or anywhere else in the record showing applicant conveyed that any other coating was suitable for a PTFE dental floss.) On the other hand, there may be situations where one species adequately supports a genus. See, e.g., *Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326-27 (disclosure of a single method of adheringly applying one layer to another was sufficient to support a generic claim to "adheringly applying" because one skilled in the art reading the specification would understand that it is unimportant how the layers are adhered, so long as they are adhered); *In re Herschler*, 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979) (disclosure of corticosteroid in DMSO sufficient to support claims drawn to a method of using a mixture of a "physiologically active steroid" and DMSO because "use of known chemical compounds in a manner auxiliary to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. Occasionally, a functional recitation of those known compounds in the specification may be sufficient as that description."); *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 285 (CCPA 1973) (the phrase "air or other gas which is inert to the liquid" was sufficient to support a claim to "inert fluid media" because the description of the properties and functions of the air or other gas segmentizing medium would suggest to a person skilled in the art that appellant's invention includes the use of "inert fluid" broadly.).

>The Federal Circuit has explained that a specification cannot always support expansive claim language and satisfy the requirements of 35 U.S.C. **112 "merely by clearly describing one embodiment of the thing claimed." *LizardTech v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1346, 76 USPQ2d 1731, 1733 (Fed. Cir. 2005). The issue is whether a person skilled in the art would understand applicant to have invented, and been in possession of, the invention as broadly claimed. In *LizardTech*, claims to a generic method of making a seamless discrete wavelet transformation (DWT) were held invalid under 35 U.S.C. **112**, first paragraph because the specification taught only one particular method for making a seamless DWT and there was no evidence that the specification contemplated a more generic method. See also< *Tronzo v. Biomet*, 156 F.3d at 1159, 47 USPQ2d at 1833 (Fed. Cir. 1998), >wherein< the disclosure of a species in the parent application did not suffice to provide written description support for the genus in the child application.

What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See, e.g., *Eli Lilly*. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species. Cf. *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. **112**, para. 1.

(b) New Claims, Amended Claims, or Claims Asserting Entitlement to the Benefit of an Earlier

Priority Date or Filing Date under 35 U.S.C. 119, 120, or 365(c)

The examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims. See *Wertheim*, 541 F.2d at 263, 191 USPQ at 97 ("[T]he PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims."). However, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP § 714.02 and § 2163.06 ("Applicant should * * * specifically point out the support for any amendments made to the disclosure.").

To comply with the written description requirement of 35 U.S.C. 112, para. 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. When an explicit limitation in a claim "is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation." *Hyatt v. Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998). See also *In re Wright*, 866 F.2d 422, 425, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989) (Original specification for method of forming images using photosensitive microcapsules which describes removal of microcapsules from surface and warns that capsules not be disturbed prior to formation of image, unequivocally teaches absence of permanently fixed microcapsules and supports amended language of claims requiring that microcapsules be "not permanently fixed" to underlying surface, and therefore meets description requirement of 35 U.S.C. 112.); *In re Robins*, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970) ("[W]here no explicit description of a generic invention is to be found in the specification[,] ... mention of representative compounds may provide an implicit description upon which to base generic claim language."); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads); *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) ("To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'") (citations omitted). Furthermore, each claim must include all elements which applicant has described as essential. See, e.g., *Johnson Worldwide Associates Inc. v. Zebco Corp.*, 175 F.3d at 993, 50 USPQ2d at 1613; *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d at 1479, 45 USPQ2d at 1503; *Tronzo v. Biomet*, 156 F.3d at 1159, 47 USPQ2d at 1833.

If the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description, or in the case of a claim for priority under 35 U.S.C. 119, 120, or 365(c), the claim for priority must be denied.

III. COMPLETE PATENTABILITY DETERMINATION UNDER ALL STATUTORY REQUIREMENTS AND CLEARLY COMMUNICATE FINDINGS, CONCLUSIONS, AND THEIR BASES

The above only describes how to determine whether the written description requirement of 35 U.S.C. 112, para. 1, is satisfied. Regardless of the outcome of that determination, Office personnel must complete the patentability determination under all the relevant statutory provisions of title 35 of the U.S. Code.

Once Office personnel have concluded analysis of the claimed invention under all the statutory provisions, including 35 U.S.C. 101, 112, 102, and 103, they should review all the proposed rejections and their bases to confirm their correctness. Only then should any rejection be imposed in an Office action. The Office action should clearly communicate the findings, conclusions, and reasons which support them. When possible, the Office action should offer helpful suggestions on how to overcome rejections.

A. For Each Claim Lacking Written Description Support, Reject the Claim Under 35 U.S.C. 112, para. 1, for Lack of Adequate Written Description

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not

recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97. In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should:

(A) Identify the claim limitation at issue; and

(B) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. A general allegation of "unpredictability in the art" is not a sufficient reason to support a rejection for lack of adequate written description.

When appropriate, suggest amendments to the claims which can be supported by the application's written description, being mindful of the prohibition against the addition of new matter in the claims or description. See *Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326.

B. Upon Reply by Applicant, Again Determine the Patentability of the Claimed Invention, Including Whether the Written Description Requirement Is Satisfied by Reperforming the Analysis Described Above in View of the Whole Record

Upon reply by applicant, before repeating any rejection under 35 U.S.C. **112**, para. 1, for lack of written description, review the basis for the rejection in view of the record as a whole, including amendments, arguments, and any evidence submitted by applicant. If the whole record now demonstrates that the written description requirement is satisfied, do not repeat the rejection in the next Office action. If the record still does not demonstrate that the written description is adequate to support the claim(s), repeat the rejection under 35 U.S.C. **112**, para. 1, fully respond to applicant's rebuttal arguments, and properly treat any further showings submitted by applicant in the reply. When a rejection is maintained, any affidavits relevant to the 112, para. 1, written description requirement, must be thoroughly analyzed and discussed in the next Office action. See *In re Alton*, 76 F.3d 1168, 1176, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996).

2163.01 Support for the Claimed Subject Matter in Disclosure

A written description requirement issue generally involves the question of whether the subject matter of a claim is supported by [conforms to] the disclosure of an application as filed. If the examiner concludes that the claimed subject matter is not supported [described] in an application as filed, this would result in a rejection of the claim on the ground of a lack of written description under **35 U.S.C. 112**, first paragraph or denial of the benefit of the filing date of a previously filed application. The claim should not be rejected or objected to on the ground of new matter. As framed by the court in *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981), the concept of new matter is properly employed as a basis for objection to amendments to the abstract, specification or drawings attempting to add new disclosure to that originally presented. While the test or analysis of description requirement and new matter issues is the same, the examining procedure and statutory basis for addressing these issues differ. See **MPEP § 2163.06**.

2163.02 Standard for Determining Compliance With the Written Description Requirement

The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).

Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual

reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. This conclusion will result in the rejection of the claims affected under **35 U.S.C.112**, first paragraph - description requirement, or denial of the benefit of the filing date of a previously filed application, as appropriate.

See MPEP § **2163** for examination guidelines pertaining to the written description requirement.

2163.03 Typical Circumstances Where Adequate Written Description Issue Arises

A description requirement issue can arise in a number of different circumstances where it must be determined whether the subject matter of a claim is supported in an application as filed. See MPEP § **2163** for examination guidelines pertaining to the written description requirement. While a question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently (see, e.g., *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997)), there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). Consequently, rejection of an original claim for lack of written description should be rare. Most typically, the issue will arise in the following circumstances:

I. AMENDMENT AFFECTING A CLAIM

An amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed. *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989). An amendment to the specification (e.g., a change in the definition of a term used both in the specification and claim) may indirectly affect a claim even though no actual amendment is made to the claim.

II. RELIANCE ON FILING DATE OF PARENT APPLICATION UNDER 35 U.S.C. 120

Under **35 U.S.C. 120**, the claims in a U.S. application are entitled to the benefit of the filing date of an earlier filed U.S. application if the subject matter of the claim is disclosed in the manner provided by **35 U.S.C. 112**, first paragraph in the earlier filed application. See, e.g., *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998); *In re Scheiber*, 587 F.2d 59, 199 USPQ 782 (CCPA 1978).

III. RELIANCE ON PRIORITY UNDER 35 U.S.C. 119

Under **35 U.S.C. 119** (a) or (e), the claims in a U.S. application are entitled to the benefit of a foreign priority date or the filing date of a provisional application if the corresponding foreign application or provisional application supports the claims in the manner required by **35 U.S.C. 112**, first paragraph. *In re Ziegler*, 992 F.2d 1197, 1200, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993); *Kawai v. Metlesics*, 480 F.2d 880, 178 USPQ 158 (CCPA 1973); *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

IV. SUPPORT FOR A CLAIM CORRESPONDING TO A COUNT IN AN INTERFERENCE

In an interference proceeding, the claim corresponding to a count must be supported by the specification in the manner provided by 35 U.S.C. **112**, first paragraph. *Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1971) (A broad generic disclosure to a class of compounds was not a sufficient written description of a specific compound within the class.). Furthermore, when a party to an interference seeks the benefit of an earlier-filed U.S. patent application, the earlier application must meet the requirements of 35 U.S.C. **112**, first paragraph for the

subject matter of the count. *Hyatt v. Boone*, 146 F.3d 1348, 1352, 47 USPQ2d 1128, 1130 (Fed. Cir. 1998).

2163.04 Burden on the Examiner with Regard to the Written Description Requirement [R-6]

The inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.

I. STATEMENT OF REJECTION REQUIREMENTS

In rejecting a claim, the examiner must set forth express findings of fact which support the lack of written description conclusion (see MPEP § **2163** for examination guidelines pertaining to the written description requirement). These findings should:

(A) Identify the claim *>limitation(s)< at issue; and

(B) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. A general allegation of "unpredictability in the art" is not a sufficient reason to support a rejection for lack of adequate written description. A simple statement such as "Applicant has not pointed out where the new (or amended) claim is supported, nor does there appear to be a written description of the claim limitation '____' in the application as filed." may be sufficient where the claim is a new or amended claim, the support for the limitation is not apparent, and applicant has not pointed out where the limitation is supported.>See *Hyatt v. Dudas*, 492 F.3d 1365, 1370, 83 USPQ2d 1373, 1376 (Fed. Cir. 2007) (holding that "[MPEP] § **2163.04** (I)(B) as written is a lawful formulation of the *prima facie* standard for a lack of written description rejection.").<

When appropriate, suggest amendments to the claims which can be supported by the application's written description, being mindful of the prohibition against the addition of new matter in the claims or description. See *Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326.

II. RESPONSE TO APPLICANT'S REPLY

Upon reply by applicant, before repeating any rejection under 35 U.S.C. **112**, para. 1, for lack of written description, review the basis for the rejection in view of the record as a whole, including amendments, arguments, and any evidence submitted by applicant. If the whole record now demonstrates that the written description requirement is satisfied, do not repeat the rejection in the next Office action. If the record still does not demonstrate that the written description is adequate to support the claim(s), repeat the rejection under 35 U.S.C. **112**, para. 1, fully respond to applicant's rebuttal arguments, and properly treat any further showings submitted by applicant in the reply. When a rejection is maintained, any affidavits relevant to the 35 U.S.C. **112**, para. 1, written description requirement, must be thoroughly analyzed and discussed in the next Office action. See *In re Alton*, 76 F.3d 1168, 1176, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996).

2163.05 Changes to the Scope of Claims [R-2]

The failure to meet the written description requirement of **35 U.S.C. 112**, first paragraph, commonly arises when the claims are changed after filing to either broaden or narrow the breadth of the claim limitations, or to alter a numerical range limitation or to use claim language which is not synonymous with the terminology used in the original disclosure. To comply with the written description requirement of 35 U.S.C. **112**, para. 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. **119**, **120**, or **365(c)**, each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. See MPEP § **2163** for examination guidelines pertaining to the written description requirement.

I. BROADENING CLAIM

Omission of a Limitation

Under certain circumstances, omission of a limitation can raise an issue regarding whether the inventor had possession of a broader, more generic invention. See, e.g., *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998) (claims to a sectional sofa comprising, *inter alia*, a console and a control means were held invalid for failing to satisfy the written description requirement where the claims were broadened by removing the location of the control means.); *Johnson Worldwide Associates v. Zebco Corp.*, 175 F.3d 985, 993,

50 USPQ2d 1607, 1613 (Fed. Cir. 1999) (In *Gentry Gallery*, the "court's determination that the patent disclosure did not support a broad meaning for the disputed claim terms was premised on clear statements in the written description that described the location of a claim element--the 'control means'--as 'the only possible location' and that variations were 'outside the stated purpose of the invention.' *Gentry Gallery*, 134 F.3d at 1479, 45 USPQ2d at 1503. *Gentry Gallery*, then, considers the situation where the patent's disclosure makes crystal clear that a particular (i.e., narrow) understanding of a claim term is an 'essential element of [the inventor's] invention.'"); *Tronzo v. Biomet*, 156 F.3d at 1158-59, 47 USPQ2d at 1833 (Fed. Cir. 1998) (claims to generic cup shape were not entitled to filing date of parent application which disclosed "conical cup" in view of the disclosure of the parent application stating the advantages and importance of the conical shape.); *In re Wilder*, 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984) (reissue claim omitting "in synchronism" limitation with respect to scanning means and indexing means was not supported by the original patent's disclosure in such a way as to indicate possession, as of the original filing date, of that generic invention.).

A claim that omits an element which applicant describes as an essential or critical feature of the invention originally disclosed does not comply with the written description requirement. See *Gentry Gallery*, 134 F.3d at 1480, 45 USPQ2d at 1503; *In re Sus*, 306 F.2d 494, 504, 134 USPQ 301, 309 (CCPA 1962) ("[O]ne skilled in this art would not be taught by the written description of the invention in the specification that any 'aryl or substituted aryl radical' would be suitable for the purposes of the invention but rather that only certain aryl radicals and certain specifically substituted aryl radicals [i.e., aryl azides] would be suitable for such purposes.") (emphasis in original). Compare *In re Peters*, 723 F.2d 891, 221 USPQ 952 (Fed. Cir. 1983) (In a reissue application, a claim to a display device was broadened by removing the limitations directed to the specific tapered shape of the tips without violating the written description requirement. The shape limitation was considered to be unnecessary since the specification, as filed, did not describe the tapered shape as essential or critical to the operation or patentability of the claim.). A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may also be subject to rejection under 35 U.S.C. **112**, para. 1, as not enabling, or under 35 U.S.C. **112**, para. 2. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976); *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976); and *In re Collier*, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968). See also MPEP § **2172.01**.

Addition of Generic Claim

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. >The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]." See *Enzo Biochem*, 323 F.3d at 966, 63 USPQ2d at 1615. "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when … the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) (Claims directed to PTFE dental floss with a friction-enhancing coating were not supported by a disclosure of a microcrystalline wax coating where there was no evidence in the disclosure or anywhere else in the record showing applicant conveyed that any other coating was suitable for a PTFE dental floss.)< On the other hand, there may be situations where one species adequately supports a genus. See, e.g., *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326-27 (CCPA 1981) (disclosure of a single method of adheringly applying one layer to another was sufficient to support a generic claim to "adheringly applying" because one skilled in the art reading the specification would understand that it is unimportant how the layers are adhered, so long as they are adhered); *In re Herschler*, 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979) (disclosure of corticosteriod in DMSO sufficient to support claims drawn to a method of using a mixture of a "physiologically active steroid" and DMSO because "use of known chemical compounds in a manner auxiliary to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. Occasionally, a functional recitation of those known compounds in the specification may be sufficient as that description."); *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 285 (CCPA 1973) (the phrase "air or other gas which is inert to the liquid" was sufficient to support a claim to "inert fluid media" because the description of the properties and functions of the air or other gas segmentizing medium would suggest to a person skilled in the art that appellant's invention includes the use of "inert fluid" broadly.). However, in *Tronzo v. Biomet*, 156 F.3d 1154, 1159, 47 USPQ2d 1829, 1833 (Fed. Cir. 1998), the disclosure of

a species in the parent application did not suffice to provide written description support for the genus in the child application. Similarly, see *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (generic and subgeneric claims in the U.S. application were not entitled to the benefit of foreign priority where the foreign application disclosed only two of the species encompassed by the broad generic claim and the subgeneric Markush claim that encompassed 21 compounds).

II. NARROWING OR SUBGENERIC CLAIM

The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of **35 U.S.C. 112**, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) (" *If* n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it.") (emphasis in original). In *Ex parte Ohshiro*, 14 USPQ2d 1750 (Bd. Pat. App. & Inter. 1989), the Board affirmed the rejection under **35 U.S.C. 112**, first paragraph, of claims to an internal combustion engine which recited "at least one of said piston and said cylinder (head) having a recessed channel." The Board held that the application which disclosed a cylinder head with a recessed channel and a piston without a recessed channel did not specifically disclose the "species" of a channeled piston.

While these and other cases find that recitation of an undisclosed species may violate the description requirement, a change involving subgeneric terminology may or may not be acceptable. Applicant was not entitled to the benefit of a parent filing date when the claim was directed to a subgenus (a specified range of molecular weight ratios) where the parent application contained a generic disclosure and a specific example that fell within the recited range because the court held that subgenus range was not described in the parent application. *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971). On the other hand, in *Ex parte Sorenson*, 3 USPQ2d 1462 (Bd. Pat. App. & Inter. 1987), the subgeneric language of "aliphatic carboxylic acid" and "aryl carboxylic acid" did not violate the written description requirement because species falling within each subgenus were disclosed as well as the generic carboxylic acid. See also *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ("Whatever may be the viability of an inductive-deductive approach to arriving at a claimed subgenus, it cannot be said that such a subgenus is necessarily described by a genus encompassing it and a species upon which it reads." (emphasis added)). Each case must be decided on its own facts in terms of what is reasonably communicated to those skilled in the art. *In re Wilder*, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984).

III. RANGE LIMITATIONS

With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In the decision in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of "25%- 60%" and specific examples of "36%" and "50%." A corresponding new claim limitation to "at least 35%" did not meet the description requirement because the phrase "at least" had no upper limit and caused the claim to read literally on embodiments outside the "25% to 60%" range, however a limitation to "between 35% and 60%" did meet the description requirement.

See also *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) ("[T]he specification does not clearly disclose to the skilled artisan that the inventors... considered the... ratio to be part of their invention.... There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion"). Compare *Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232-33 (Fed. Cir. 2000) (Description in terms of ranges of chemical properties which work in combination with ranges of other chemical properties to produce an automotive gasoline that reduces emissions was found to provide an adequate written description even though the exact chemical components of each combination were not disclosed and the specification did not disclose any distinct embodiments corresponding to any claim at issue. "[T]he Patent Act and this court's case law require only sufficient description to show one of

skill in the . . . art that the inventor possessed the claimed invention at the time of filing.").

2163.06 Relationship of Written Description Requirement to New Matter

Lack of written description is an issue that generally arises with respect to the subject matter of a claim. If an applicant amends or attempts to amend the abstract, specification or drawings of an application, an issue of new matter will arise if the content of the amendment is not described in the application as filed. Stated another way, information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter.

There are two statutory provisions that prohibit the introduction of new matter: **35 U.S.C. 132** - No amendment shall introduce new matter into the disclosure of the invention; and, similarly providing for a reissue application, **35 U.S.C. 251** - No new matter shall be introduced into the application for reissue.

I. TREATMENT OF NEW MATTER

If new subject matter is added to the disclosure, whether it be in the abstract, the specification, or the drawings, the examiner should object to the introduction of new matter under **35 U.S.C. 132** or **251** as appropriate, and require applicant to cancel the new matter. If new matter is added to the claims, the examiner should reject the claims under **35 U.S.C. 112**, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). The examiner should still consider the subject matter added to the claim in making rejections based on prior art since the new matter rejection may be overcome by applicant.

In an instance in which the claims have not been amended, *per se*, but the specification has been amended to add new matter, a rejection of the claims under **35 U.S.C. 112**, first paragraph should be made whenever any of the claim limitations are affected by the added material.

When an amendment is filed in reply to an objection or rejection based on **35 U.S.C. 112**, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure.

II. REVIEW OF NEW MATTER OBJECTIONS AND/OR REJECTIONS

A rejection of claims is reviewable by the Board of Patent Appeals and Interferences, whereas an objection and requirement to delete new matter is subject to supervisory review by petition under **37 CFR 1.181**. If both the claims and specification contain new matter either directly or indirectly, and there has been both a rejection and objection by the examiner, the issue becomes appealable and should not be decided by petition.

III. CLAIMED SUBJECT MATTER NOT DISCLOSED IN REMAINDER OF SPECIFICATION

The claims as filed in the original specification are part of the disclosure and therefore, if an application as originally filed contains a claim disclosing material not disclosed in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985). Form Paragraph 7.44 may be used where originally claimed subject matter lacks proper antecedent basis in the specification. See **MPEP § 608.01(o)**.

2163.07 Amendments to Application Which Are Supported in the Original Description [R-6]

Amendments to an application which are supported in the original description are NOT new matter.

I. REPHRASING

Mere rephrasing of a passage does not constitute new matter. Accordingly, a rewording of a passage where the same meaning remains intact is permissible. *In re Anderson*, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973). The mere inclusion of dictionary or art recognized definitions known at the time of filing an application would not be considered new matter. If there are multiple definitions for a term and a definition is added to the application, it must be clear from the application as filed that applicant intended a particular definition, in order to avoid an issue of new matter and/or lack of written description. See, e.g., *Scarring Corp. v. Megan, Inc.*, 222 F.3d 1347, 1352-53, 55 USPQ2d 1650, 1654 (Fed. Cir. 2000). In *Scarring*, the original disclosure drawn to recombinant DNA molecules utilized the term "leukocyte interferon." Shortly after the filing date, a scientific committee abolished the term in favor of "IFN-(a)," since the latter term more specifically identified a particular polypeptide and since the committee found that leukocytes also produced other types of interferon. The court held

that the subsequent amendment to the specification and claims substituting the term "IFN-(a)" for "leukocyte interferon" merely renamed the invention and did not constitute new matter. The claims were limited to cover only the interferon subtype coded for by the inventor's original deposits.

II. OBVIOUS ERRORS

An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction. *In re Odd*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971).

Where a foreign priority document under **35 U.S.C. 119** is of record in the U.S. application file, applicant may not rely on the disclosure of that document to support correction of an error in the pending U.S. application. *Ex parte* *>*Bondiou* <, 132 USPQ 356 (Bd. App. 1961). This prohibition applies regardless of the language of the foreign priority documents because a claim for priority is simply a claim for the benefit of an earlier filing date for subject matter that is common to two or more applications, and does not serve to incorporate the content of the priority document in the application in which the claim for priority is made. This prohibition does not apply where the U.S. application explicitly incorporates the foreign priority document by reference. For applications filed on or after September 21, 2004, where all or a portion of the specification or drawing(s) is inadvertently omitted from the U.S. application, a claim under 37 CFR **1.55** for priority of a prior-filed foreign application that is present on the filing date of the application is considered an incorporation by reference of the prior-filed foreign application as to the inadvertently omitted portion of the specification or drawing(s), subject to the conditions and requirements of 37 CFR **1.57**(a). See 37 CFR **1.57**(a) and MPEP § **201.17**.

Where a U.S. application as originally filed was in a non-English language and an English translation thereof was subsequently submitted pursuant to 37 CFR **1.52**(d), if there is an error in the English translation, applicant may rely on the disclosure of the originally filed non-English language U.S. application to support correction of an error in the English translation document.

2163.07(a) Inherent Function, Theory, or Advantage

By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

2163.07(b) Incorporation by Reference [R-3]

Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Replacing the identified material incorporated by reference with the actual text is not new matter. See >37 CFR **1.57** and<**MPEP § 608.01(p)** for Office policy regarding incorporation by reference. See MPEP § **2181** for the impact of incorporation by reference on the determination of whether applicant has complied with the requirements of 35 U.S.C. **112**, second paragraph when 35 U.S.C. **112**, sixth paragraph is invoked.

2164 The Enablement Requirement [R-2]

The enablement requirement refers to the requirement of **35 U.S.C. 112**, first paragraph that the specification describe how to make and how to use the invention. The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent.

The purpose of the requirement that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. >However, to comply with 35 U.S.C. **112**, first paragraph, it is not necessary to "enable one of ordinary skill in the art to make and use a perfected,

commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. Yieldup Int'l Corp*., 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (an invention directed to a general system to improve the cleaning process for semiconductor wafers was enabled by a disclosure showing improvements in the overall system).< Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. A patent claim is invalid if it is not supported by an enabling disclosure.

The enablement requirement of **35 U.S.C. 112**, first paragraph, is separate and distinct from the description requirement. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991) ("the purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'"). See also **MPEP § 2161**. Therefore, the fact that an additional limitation to a claim may lack descriptive support in the disclosure as originally filed does not necessarily mean that the limitation is also not enabled. In other words, the statement of a new limitation in and of itself may enable one skilled in the art to make and use the claim containing that limitation even though that limitation may not be described in the original disclosure. Consequently, such limitations must be analyzed for both enablement and description using their separate and distinct criteria.

Furthermore, when the subject matter is not in the specification portion of the application as filed but is in the claims, the limitation in and of itself may enable one skilled in the art to make and use the claim containing the limitation. When claimed subject matter is only presented in the claims and not in the specification portion of the application, the specification should be objected to for lacking the requisite support for the claimed subject matter using Form Paragraph 7.44. See **MPEP § 2163.06**. This is an objection to the specification only and enablement issues should be treated separately.

2164.01 Test of Enablement [R-5]

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies , Inc .*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). >Any part of the specification can support an enabling disclosure, even a background section that discusses, or even disparages, the subject matter disclosed therein. *Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 77 USPQ2d 1041 (Fed. Cir. 2005)(discussion of problems with a prior art feature does not mean that one of ordinary skill in the art would not know how to make and use this feature).< Determining enablement is a question of law based on underlying factual findings. *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984).

UNDUE EXPERIMENTATION

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

2164.01(a) Undue Experimentation Factors

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the

enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). In *Wands*, the court noted that there was no disagreement as to the facts, but merely a disagreement as to the interpretation of the data and the conclusion to be made from the facts. *In re Wands*, 858 F.2d at 736-40, 8 USPQ2d at 1403-07. The Court held that the specification was enabling with respect to the claims at issue and found that "there was considerable direction and guidance" in the specification; there was "a high level of skill in the art at the time the application was filed;" and "all of the methods needed to practice the invention were well known." 858 F.2d at 740, 8 USPQ2d at 1406. After considering all the factors related to the enablement issue, the court concluded that "it would not require undue experimentation to obtain antibodies needed to practice the claimed invention." *Id*., 8 USPQ2d at 1407.

It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. 858 F.2d at 737, 740, 8 USPQ2d at 1404, 1407.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. These factual considerations are discussed more fully in **MPEP § 2164.08** (scope or breadth of the claims), § **2164.05(a)** (nature of the invention and state of the prior art), § **2164.05(b)** (level of one of ordinary skill), § **2164.03** (level of predictability in the art and amount of direction provided by the inventor), § **2164.02** (the existence of working examples) and § **2164.06** (quantity of experimentation needed to make or use the invention based on the content of the disclosure).

2164.01(b) How to Make the Claimed Invention

As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of **35 U.S.C. 112** is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under **35 U.S.C. 112**. *Spectra-Physics, Inc. v. Coherent, Inc*., 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987).

Naturally, for unstable and transitory chemical intermediates, the "how to make" requirement does not require that the applicant teach how to make the claimed product in stable, permanent or isolatable form. *In re Breslow*, 616 F.2d 516, 521, 205 USPQ 221, 226 (CCPA 1980).

A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening.

The Court in *In re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

2164.01(c) How to Use the Claimed Invention

If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, **35 U.S.C. 112** is satisfied. *In re Johnson*,

282 F.2d 370, 373, 127 USPQ 216, 219 (CCPA 1960); *In re Hitchings*, 342 F.2d 80, 87, 144 USPQ 637, 643 (CCPA 1965). See also *In re Brana*, 51 F.2d 1560, 1566, 34 USPQ2d 1437, 1441 (Fed. Cir. 1993).

For example, it is not necessary to specify the dosage or method of use if it is known to one skilled in the art that such information could be obtained without undue experimentation. If one skilled in the art, based on knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation, this would be sufficient to satisfy **35 U.S.C. 112**, first paragraph. The applicant need not demonstrate that the invention is completely safe. See also **MPEP § 2107.01** and **§ 2107.03**.

When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (claiming a chimeric gene capable of being expressed in any cyanobacterium and thus defining the claimed gene by its use).

In contrast, when a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use. If multiple uses for claimed compounds or compositions are disclosed in the application, then an enablement rejection must include an explanation, sufficiently supported by the evidence, why the specification fails to enable each disclosed use. In other words, if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention.

2164.02 Working Example

Compliance with the enablement requirement of **35 U.S.C. 112**, first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved.

An applicant need not have actually reduced the invention to practice prior to filing. In *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987), as of Gould's filing date, no person had built a light amplifier or measured a population inversion in a gas discharge. The Court held that "The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." 822 F.2d at 1078, 3 USPQ2d at 1304 (quoting *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956)).

The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

Lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art. But because only an enabling disclosure is required, applicant need not describe all actual embodiments.

NONE OR ONE WORKING EXAMPLE

When considering the factors relating to a determination of non-enablement, if all the other factors point toward enablement, then the absence of working examples will not by itself render the invention non-enabled. In other words, lack of working examples or lack of evidence that the claimed invention works as described should never be the sole reason for rejecting the claimed invention on the grounds of lack of enablement. A single working example in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled. However, a rejection stating that enablement is limited to a particular scope may be appropriate.

The presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure, even though it is a factor to be considered along with all the other factors. To make a valid rejection, one must evaluate all the facts and evidence and state why one would not expect to be able to extrapolate that one example across the entire scope of the claims.

CORRELATION: IN VITRO/IN VIVO

The issue of "correlation" is related to the issue of the presence or absence of working examples. "Correlation" as used herein refers to the relationship between *in vitro* or *in vivo* animal model assays and a disclosed or a claimed method of use. An *in vitro* or *in vivo* animal model example in the specification, in effect, constitutes a "working example" if that example "correlates" with a disclosed or claimed method invention. If there is no correlation, then the examples do not constitute "working

examples." In this regard, the issue of "correlation" is also dependent on the state of the prior art. In other words, if the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate. Even with such evidence, the examiner must weigh the evidence for and against correlation and decide whether one skilled in the art would accept the model as reasonably correlating to the condition. *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (reversing the PTO decision based on finding that *in vitro* data did not support *in vivo* applications).

Since the initial burden is on the examiner to give reasons for the lack of enablement, the examiner must also give reasons for a conclusion of lack of correlation for an *in vitro* or *in vivo* animal model example. A rigorous or an invariable exact correlation is not required, as stated in *Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed. Cir. 1985):

> [B]ased upon the relevant evidence as a whole, there is a reasonable correlation between the disclosed *in vitro* utility and an *in vivo* activity, and therefore a rigorous correlation is not necessary where the disclosure of pharmacological activity is reasonable based upon the probative evidence. (Citations omitted.)

WORKING EXAMPLES AND A CLAIMED GENUS

For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation.

2164.03 Relationship of Predictability of the Art and the Enablement Requirement [R-2]

The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. >See, e.g., *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004) ("Nascent technology, however, must be enabled with a 'specific and useful teaching.' The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction. Thus, the public's end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology." (citations omitted)).<

The "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. In particular, the court in *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971), stated:

> [I]n the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof. [Footnote omitted.]

The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such

as mechanical or electrical elements. *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971). However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work.

2164.04 Burden on the Examiner Under *>the< Enablement Requirement [R-1]

Before any analysis of enablement can occur, it is necessary for the examiner to construe the claims. For terms that are not well-known in the art, or for terms that could have more than one meaning, it is necessary that the examiner select the definition that he/she intends to use when examining the application, based on his/her understanding of what applicant intends it to mean, and explicitly set forth the meaning of the term and the scope of the claim when writing an Office action. See *Genentech v. Wellcome Foundation*, 29 F.3d 1555, 1563-64, 31 USPQ2d 1161, 1167-68 (Fed. Cir. 1994).

In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of **35 U.S.C. 112**, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." 439 F.2d at 224, 169 USPQ at 370.

According to *In re Bowen*, 492 F.2d 859, 862-63, 181 USPQ 48, 51 (CCPA 1974), the minimal requirement is for the examiner to give reasons for the uncertainty of the enablement. This standard is applicable even when there is no evidence in the record of operability without undue experimentation beyond the disclosed embodiments. See also *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (citing *In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981)) (discussed in **MPEP § 2164.07** regarding the relationship of the enablement requirement to the utility requirement of **35 U.S.C. 101**).

While the analysis and conclusion of a lack of enablement are based on the factors discussed in **MPEP § 2164.01(a)** and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact. For example, doubt may arise about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation. In such a case, the examiner should specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation. See **MPEP § 2164.06(a)**. References should be supplied if possible to support a *prima facie* case of lack of enablement, but are not always required. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). However, specific technical reasons are always required.

In accordance with the principles of compact prosecution, if an enablement rejection is appropriate, the first Office action on the merits should present the best case with all the relevant reasons, issues, and evidence so that all such rejections can be withdrawn if applicant provides appropriate convincing arguments and/or evidence in

rebuttal. Providing the best case in the first Office action will also allow the second Office action to be made final should applicant fail to provide appropriate convincing arguments and/or evidence. Citing new references and/or expanding arguments in a second Office action could prevent that Office action from being made final. The principles of compact prosecution also dictate that if an enablement rejection is appropriate and the examiner recognizes limitations that would render the claims enabled, the examiner should note such limitations to applicant as early in the prosecution as possible.

In other words, the examiner should always look for enabled, allowable subject matter and communicate to applicant what that subject matter is at the earliest point possible in the prosecution of the application.

2164.05 Determination of Enablement Based on Evidence as a Whole

Once the examiner has weighed all the evidence and established a reasonable basis to question the enablement provided for the claimed invention, the burden falls on applicant to present persuasive arguments, supported by suitable proofs where necessary, that one skilled in the art would be able to make and use the claimed invention using the application as a guide. *In re Brandstadter*, 484 F.2d 1395, 1406-07, 179 USPQ 286, 294 (CCPA 1973). The evidence provided by applicant need not be conclusive but merely convincing to one skilled in the art.

Applicant may submit factual affidavits under **37 CFR 1.132** or cite references to show what one skilled in the art knew at the time of filing the application. A declaration or affidavit is, itself, evidence that must be considered. The weight to give a declaration or affidavit will depend upon the amount of factual evidence the declaration or affidavit contains to support the conclusion of enablement. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991) ("expert's opinion on the ultimate legal conclusion must be supported by something more than a conclusory statement"); *cf. In re Alton*, *76* F.3d 1168, 1174, 37 USPQ2d 1578, 1583 (Fed. Cir. 1996) (declarations relating to the written description requirement should have been considered).

Applicant should be encouraged to provide any evidence to demonstrate that the disclosure enables the claimed invention. In chemical and biotechnical applications, evidence actually submitted to the FDA to obtain approval for clinical trials may be submitted. However, considerations made by the FDA for approving clinical trials are different from those made by the PTO in determining whether a claim is enabled. See *Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir. 1994) ("Testing for full safety and effectiveness of a prosthetic device is more properly left to the [FDA]."). Once that evidence is submitted, it must be weighed with all other evidence according to the standards set forth above so as to reach a determination as to whether the disclosure enables the claimed invention.

To overcome a *prima facie* case of lack of enablement, applicant must demonstrate by argument and/or evidence that the disclosure, as filed, would have enabled the claimed invention for one skilled in the art at the time of filing. This does not preclude applicant from providing a declaration after the filing date which demonstrates that the claimed invention works. However, the examiner should carefully compare the steps, materials, and conditions used in the experiments of the declaration with those disclosed in the application to make sure that they are commensurate in scope; i.e., that the experiments used the guidance in the specification as filed and what was well known to one of skill in the art. Such a showing also must be commensurate with the scope of the claimed invention, i.e., must bear a reasonable correlation to the scope of the claimed invention.

The examiner must then weigh all the evidence before him or her, including the specification and any new evidence supplied by applicant with the evidence and/or sound scientific reasoning previously presented in the rejection and decide whether the claimed invention is enabled. The examiner should **never** make the determination based on personal opinion. The determination should always be based on the weight of all the evidence.

2164.05(a) Specification Must Be Enabling as of the Filing Date [R-2]

Whether the specification would have been enabling as of the filing date involves consideration of the nature of the invention, the state of the prior art, and the level of skill in the art. The initial inquiry is into the nature of the invention, i.e., the subject matter to which the claimed invention pertains. The nature of the invention becomes the backdrop to determine the state of the art and the level of skill possessed by one skilled in the art.

The state of the prior art is what one skilled in the art would have known, at the time the application was filed, about the subject matter to which the claimed invention pertains. The relative skill of those in the art refers to the skill of those in the art in relation to the subject matter to

which the claimed invention pertains at the time the application was filed. See **MPEP § 2164.05(b)**.

The state of the prior art provides evidence for the degree of predictability in the art and is related to the amount of direction or guidance needed in the specification as filed to meet the enablement requirement. The state of the prior art is also related to the need for working examples in the specification.

The state of the art for a given technology is not static in time. It is entirely possible that a disclosure filed on January 2, 1990, would not have been enabled. However, if the same disclosure had been filed on January 2, 1996, it might have enabled the claims. Therefore, the state of the prior art must be evaluated for each application based on its filing date.

35 U.S.C. 112 requires the specification to be enabling only to a person "skilled in the art to which it pertains, or with which it is most nearly connected." In general, the pertinent art should be defined in terms of the problem to be solved rather than in terms of the technology area, industry, trade, etc. for which the invention is used.

The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies , Inc .*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date. > *Chiron Corp. v. Genentech Inc*., 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004) ("a patent document cannot enable technology that arises after the date of application").< Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. *In re Gunn*, 537 F.2d 1123, 1128, 190 USPQ 402,405-06 (CCPA 1976); *In re Budnick*, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976) (In general, if an applicant seeks to use a patent to prove the state of the art for the purpose of the enablement requirement, the patent must have an issue date earlier than the effective filing date of the application.). While a later dated publication cannot supplement an insufficient disclosure in a prior dated application to make it enabling, applicant can offer the testimony of an expert based on the publication as evidence of the level of skill in the art at the time the application was filed. *Gould v. Quigg*, 822 F.2d 1074, 1077, 3 USPQ2d 1302, 1304 (Fed. Cir. 1987).

In general, the examiner should not use post-filing date references to demonstrate that the patent is non-enabling. Exceptions to this rule could occur if a later-dated reference provides evidence of what one skilled in the art would have known on or before the effective filing date of the patent application. *In re Hogan*, 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977). If individuals of skill in the art state that a particular invention is not possible years after the filing date, that would be evidence that the disclosed invention was not possible at the time of filing and should be considered. In *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513-14 (Fed. Cir. 1993) an article published 5 years after the filing date of the application adequately supported the examiner's position that the physiological activity of certain viruses was sufficiently unpredictable so that a person skilled in the art would not have believed that the success with one virus and one animal could be extrapolated successfully to all viruses with all living organisms. Claims not directed to the specific virus and the specific animal were held nonenabled.

2164.05(b) Specification Must Be Enabling to Persons Skilled in the Art

The relative skill of those in the art refers to the skill of those in the art in relation to the subject matter to which the claimed invention pertains at the time the application was filed. Where different arts are involved in the invention, the specification is enabling if it enables persons skilled in each art to carry out the aspect of the invention applicable to their specialty. *In re Naquin*, 398 F.2d 863, 866, 158 USPQ 317, 319 (CCPA 1968).

When an invention, in its different aspects, involves distinct arts, the specification is enabling if it enables those skilled in each art, to carry out the aspect proper to their specialty. "If two distinct technologies are relevant to an invention, then the disclosure will be adequate if a person of ordinary skill in each of the two technologies could practice the invention from the disclosures." *Technicon Instruments Corp. v. Alpkem Corp.*, 664 F. Supp. 1558, 1578, 2 USPQ2d 1729, 1742 (D. Ore. 1986), aff'd in part, vacated in part, rev'd in part, 837 F. 2d 1097 (Fed. Cir. 1987) (unpublished opinion), appeal after remand, 866 F. 2d 417, 9 USPQ 2d 1540 (Fed. Cir. 1989). In *Ex parte Zechnall*, 194 USPQ 461 (Bd. App. 1973), the Board stated "appellants' disclosure must be held sufficient if it would enable a person skilled in the electronic computer art, in cooperation with a person

skilled in the fuel injection art, to make and use appellants' invention." 194 USPQ at 461.

2164.06 Quantity of Experimentation

The quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). " 'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.'" *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Time and expense are merely factors in this consideration and are not the controlling factors. *United States v. Telectronics Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989).

In the chemical arts, the guidance and ease in carrying out an assay to achieve the claimed objectives may be an issue to be considered in determining the quantity of experimentation needed. For example, if a very difficult and time consuming assay is needed to identify a compound within the scope of a claim, then this great quantity of experimentation should be considered in the overall analysis. Time and difficulty of experiments are not determinative if they are merely routine. Quantity of examples is only one factor that must be considered before reaching the final conclusion that undue experimentation would be required. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

I. EXAMPLE OF REASONABLE EXPERIMENTATION

In *United States v. Telectronics, Inc*., 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989), the court reversed the findings of the district court for lack of clear and convincing proof that undue experimentation was needed. The court ruled that since one embodiment (stainless steel electrodes) and the method to determine dose/response was set forth in the specification, the specification was enabling. The question of time and expense of such studies, approximately $50,000 and 6-12 months standing alone, failed to show undue experimentation.

II. EXAMPLE OF UNREASONABLE EXPERIMENTATION

In *In re Ghiron*, 442 F.2d 985, 991-92, 169 USPQ 723, 727-28 (CCPA 1971), functional "block diagrams" were insufficient to enable a person skilled in the art to practice the claimed invention with only a reasonable degree of experimentation because the claimed invention required a "modification to prior art overlap computers," and because "many of the components which appellants illustrate as rectangles in their drawing necessarily are themselves complex assemblages . . . . It is common knowledge that many months or years elapse from the announcement of a new computer by a manufacturer before the first prototype is available. This does not bespeak of a routine operation but of extensive experimentation and development work. . . ."

2164.06(a) Examples of *>Enablement< Issues-Missing Information [R-1]

It is common that doubt arises about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation. In such a case, the examiner should specifically identify what information is missing and why the missing information is needed to provide enablement.

I. ELECTRICAL AND MECHANICAL DEVICES OR PROCESSES

For example, a disclosure of an electrical circuit apparatus, depicted in the drawings by block diagrams with functional labels, was held to be nonenabling in *In re Gunn*, 537 F.2d 1123, 1129, 190 USPQ 402, 406 (CCPA 1976). There was no indication in the specification as to whether the parts represented by boxes were "off the shelf" or must be specifically constructed or modified for applicant's system. Also there were no details in the specification of how the parts should be interconnected, timed and controlled so as to obtain the specific operations desired by the applicant. In *In re Donohue*, 550 F.2d 1269, 193 USPQ 136 (CCPA 1977), the lack of enablement was caused by lack of information in the specification about a single block labelled "LOGIC" in the drawings. See also *Union Pacific Resources Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 57 USPQ2d 1293 (Fed. Cir. 2001) (Claims directed to a method of determining the location of a horizontal borehole in the earth failed to comply with enablement requirement of 35 U.S.C. **112** because certain computer programming details used to perform claimed method were not disclosed in the specification, and the record showed that a person

of skill in art would not understand how to "compare" or "rescale" data as recited in the claims in order to perform the claimed method.).

In re Ghiron, 442 F.2d 985, 169 USPQ 723 (CCPA 1971), involved a method of facilitating transfers from one subset of program instructions to another which required modification of prior art "overlap mode" computers. The Board rejected the claims on the basis, *inter alia*, that the disclosure was insufficient to satisfy the requirements of **35 U.S.C. 112**, first paragraph and was affirmed. The Board focused on the fact that the drawings were "block diagrams, i.e., a group of rectangles representing the elements of the system, functionally labelled and interconnected by lines." 442 F.2d at 991, 169 USPQ at 727. The specification did not particularly identify each of the elements represented by the blocks or the relationship therebetween, nor did it specify particular apparatus intended to carry out each function. The Board further questioned whether the selection and assembly of the required components could be carried out routinely by persons of ordinary skill in the art.

An adequate disclosure of a device may require details of how complex components are constructed and perform the desired function. The claim before the court in *In re Scarbrough*, 500 F.2d 560, 182 USPQ 298 (CCPA 1974) was directed to a system which comprised several component parts (e.g., computer, timing and control mechanism, A/D converter, etc.) only by generic name and overall ultimate function. The court concluded that there was not an enabling disclosure because the specification did not describe how "complex elements known to perform broadly recited functions in different systems would be adaptable for use in Appellant's particular system with only a reasonable amount of experimentation" and that "an unreasonable amount of work would be required to arrive at the detailed relationships appellant says that he has solved." 500 F.2d at 566, 182 USPQ at 302.

II. MICROORGANISMS

Patent applications involving living biological products, such as microorganisms, as critical elements in the process of making the invention, present a unique question with regard to availability. The issue was raised in a case involving claims drawn to a fermentative method of producing two novel antibiotics using a specific microorganism and claims to the novel antibiotics so produced. *In re Argoudelis*, 434 F.2d 1390, 168 USPQ 99 (CCPA 1970). As stated by the court, "a unique aspect of using microorganisms as starting materials is that a sufficient description of how to obtain the microorganism from nature cannot be given." 434 F.2d at 1392, 168 USPQ at 102. It was determined by the court that availability of the biological product via a public depository provided an acceptable means of meeting the written description and the enablement requirements of **35 U.S.C. 112**, first paragraph.

To satisfy the enablement requirement a deposit must be made "prior to issue" but need not be made prior to filing the application. *In re Lundak*, 773 F.2d 1216, 1223, 227 USPQ 90, 95 (Fed. Cir. 1985).

The availability requirement of enablement must also be considered in light of the scope or breadth of the claim limitations. The Board of Appeals considered this issue in an application which claimed a fermentative method using microorganisms belonging to a species. Applicants had identified three novel individual strains of microorganisms that were related in such a way as to establish a new species of microorganism, a species being a broader classification than a strain. The three specific strains had been appropriately deposited. The issue focused on whether the specification enabled one skilled in the art to make any member of the species other than the three strains which had been deposited. The Board concluded that the verbal description of the species was inadequate to allow a skilled artisan to make any and all members of the claimed species. *Ex parte Jackson*, 217 USPQ 804, 806 (Bd. App. 1982).

See **MPEP § 2402** - **§ 2411.03** for a detailed discussion of the deposit rules. See **MPEP § 2411.01** for rejections under **35 U.S.C. 112** based on deposit issues.

III. DRUG CASES

See **MPEP § 2107** - **§ 2107.03** for a discussion of the utility requirement under **35 U.S.C. 112**, first paragraph, in drug cases.

2164.06(b) Examples of Enablement Issues — Chemical Cases

The following summaries should not be relied on to support a case of lack of enablement without carefully reading the case.

SEVERAL DECISIONS RULING THAT THE DISCLOSURE WAS NONENABLING

(A) In *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999), the court held that claims in two patents directed to genetic antisense technology (which aims to control gene expression in a particular organism), were invalid because the breadth of enablement was not commensurate in scope with the

claims. Both specifications disclosed applying antisense technology in regulating three genes in *E. coli*. Despite the limited disclosures, the specifications asserted that the "[t]he practices of this invention are generally applicable with respect to any organism containing genetic material which is capable of being expressed … such as bacteria, yeast, and other cellular organisms." The claims of the patents encompassed application of antisense methodology in a broad range of organisms. Ultimately, the court relied on the fact that (1) the amount of direction presented and the number of working examples provided in the specification were very narrow compared to the wide breadth of the claims at issue, (2) antisense gene technology was highly unpredictable, and (3) the amount of experimentation required to adapt the practice of creating antisense DNA from *E. coli* to other types of cells was quite high, especially in light of the record, which included notable examples of the inventor's own failures to control the expression of other genes in *E. coli* and other types of cells. Thus, the teachings set forth in the specification provided no more than a "plan" or "invitation" for those of skill in the art to experiment using the technology in other types of cells.

(B) In *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993), the 1983 application disclosed a vaccine against the RNA tumor virus known as Prague Avian Sarcoma Virus, a member of the Rous Associated Virus family. Using functional language, Wright claimed a vaccine "comprising an immunologically effective amount" of a viral expression product. *Id.*, at 1559, 27 USPQ2d at 1511. Rejected claims covered all RNA viruses as well as avian RNA viruses. The examiner provided a teaching that in 1988, a vaccine for another retrovirus (i.e., AIDS) remained an intractable problem. This evidence, along with evidence that the RNA viruses were a diverse and complicated genus, convinced the Federal Circuit that the invention was not enabled for either all retroviruses or even for avian retroviruses.

(C) In *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993), a 1985 application functionally claimed a method of producing protein in plant cells by expressing a foreign gene. The court stated: "[n]aturally, the specification must teach those of skill in the art 'how to make and use the invention as broadly as it is claimed.'" *Id.* at 1050, 29 USPQ2d at 2013. Although protein expression in dicotyledonous plant cells was enabled, the claims covered any plant cell. The examiner provided evidence that even as late as 1987, use of the claimed method in monocot plant cells was not enabled. *Id.* at 1051, 29 USPQ2d at 2014.

(D) In *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991), the court found that several claims were not supported by an enabling disclosure "[t]aking into account the relatively incomplete understanding of the biology of cyanobacteria as of appellants' filing date, as well as the limited disclosure by appellants of the particular cyanobacterial genera operative in the claimed invention...." The claims at issue were not limited to any particular genus or species of cyanobacteria and the specification mentioned nine genera and the working examples employed one species of cyanobacteria.

(E) In *In re Colianni*, 561 F.2d 220, 222-23, 195 USPQ 150, 152 (CCPA 1977), the court affirmed a rejection under **35 U.S.C. 112**, first paragraph, because the specification, which was directed to a method of mending a fractured bone by applying "sufficient" ultrasonic energy to the bone, did not define a "sufficient" dosage or teach one of ordinary skill how to select the appropriate intensity, frequency, or duration of the ultrasonic energy.

SEVERAL DECISIONS RULING THAT THE DISCLOSURE WAS ENABLING

(A) In *PPG Ind. v. Guardian Ind.*, 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996), the court ruled that even though there was a software error in calculating the ultraviolet transmittance data for examples in the specification making it appear that the production of a cerium oxide-free glass that satisfied the transmittance limitation would be difficult, the specification indicated that such glass could be made. The specification was found to indicate how to minimize the cerium content while maintaining low ultraviolet transmittance.

(B) In *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the court reversed the rejection for lack of enablement under **35 U.S.C. 112**, first paragraph, concluding that undue experimentation would not be required to practice the invention. The nature of monoclonal antibody technology is such that experiments first involve the entire attempt to make monoclonal hybridomas to determine which ones secrete antibody with the desired characteristics. The court found that the specification provided considerable direction and guidance on how to practice the claimed invention and presented working examples, that all of the methods needed to practice the invention were well known, and that there was a high level of skill in the art at the time the application was filed. Furthermore, the applicant carried out the entire procedure for making a monoclonal antibody against HBsAg three times and each time was successful in producing at least one antibody which fell within the scope of the claims.

(C) In *In re Bundy*, 642 F.2d 430, 434, 209 USPQ 48, 51-52 (CCPA 1981), the court ruled that appellant's disclosure was sufficient to enable one skilled in the art to use the claimed analogs of naturally occurring prostaglandins even though the specification lacked any examples of specific dosages, because the specification taught that the novel prostaglandins had certain pharmacological properties and possessed activity similar to known E-type prostaglandins.

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2164.06(c) Examples of Enablement Issues – Computer Programming Cases [R-5]

To establish a reasonable basis for questioning the adequacy of a disclosure, the examiner must present a factual analysis of a disclosure to show that a person skilled in the art would not be able to make and use the claimed invention without resorting to undue experimentation.

In computer applications, it is not unusual for the claimed invention to involve two areas of prior art or more than one technology, e.g., an appropriately programmed computer and an area of application of said computer. *White Consol. Indus. v. Vega Servo-Control, Inc., 214 USPQ 796, 821 (S.D.Mich. 1982).* In regard to the "skilled in the art" standard, in cases involving both the art of computer programming, and another technology, the examiner must recognize that the knowledge of persons skilled in both technologies is the appropriate criteria for determining sufficiency. See *In re Naquin*, 398 F.2d 863, 158 USPQ 317 (CCPA 1968); *In re Brown*, 477 F.2d 946, 177 USPQ 691 (CCPA 1973); *White Consol. Indus.*, 214 USPQ at 822, *aff'd on related grounds*, 713 F.2d 788, 218 USPQ 961 (Fed. Cir. 1983).

In a typical computer application, system components are often represented in a "block diagram" format, i.e., a group of hollow rectangles representing the elements of the system, functionally labeled, and interconnected by lines. Such block diagram computer cases may be categorized into (A) systems which include but are more comprehensive than a computer and (B) systems wherein the block elements are totally within the confines of a computer.

I. BLOCK ELEMENTS MORE COMPREHENSIVE THAN A COMPUTER

The first category of such block diagram cases involves systems which include a computer as well as other system hardware and/or software components. In order to meet his or her burden of establishing a reasonable basis for questioning the adequacy of such disclosure, the examiner should initiate a factual analysis of the system by focusing on each of the individual block element components. More specifically, such an inquiry should focus on the diverse functions attributed to each block element as well as the teachings in the specification as to how such a component could be implemented. If based on such an analysis, the examiner can reasonably contend that more than routine experimentation would be required by one of ordinary skill in the art to implement such a component or components, that component or components should specifically be challenged by the examiner as part of a **35 U.S.C. 112**, first paragraph rejection. Additionally, the examiner should determine whether certain of the hardware or software components depicted as block elements are themselves complex assemblages which have widely differing characteristics and which must be precisely coordinated with other complex assemblages. Under such circumstances, a reasonable basis may exist for challenging such a functional block diagram form of disclosure. See *In re Ghiron*, 442 F.2d 985, 169 USPQ 723 (CCPA 1971) and *In re Brown, supra*. Moreover, even if the applicant has cited prior art patents or publications to demonstrate that particular block diagram hardware or software components are old, it should not always be considered as self-evident how such components are to be interconnected to function in a disclosed complex manner. See *In re Scarbrough*, 500 F.2d 560, 566, 182 USPQ 298, 301 (CCPA 1974) and *In re Forman*, 463 F.2d 1125, 1129, 175 USPQ 12, 16 (CCPA 1972). Furthermore, in complex systems including a digital computer, a microprocessor, or a complex control unit as one of many block diagram elements, timing between various system elements may be of the essence and without a timing chart relating the timed sequences for each element, an unreasonable amount of work may be required to come up with the detailed relationships an applicant alleges that he or she has solved. See *In re Scarbrough*, 500 F.2d at 566, 182 USPQ at 302.

For example, in a block diagram disclosure of a complex claimed system which includes a microprocessor and other system components controlled by the microprocessor, a mere reference to a prior art, commercially available microprocessor, without any description of the precise operations to be performed by the microprocessor, fails to disclose how such a microprocessor would be properly programmed to either perform any required calculations or to coordinate the other system components in the proper timed sequence to perform the functions disclosed and claimed. If, in such a system, a particular program is disclosed, such a program should be carefully reviewed to ensure that its scope is commensurate with the scope of the functions attributed to such a program in the claims. See *In re Brown*, 477 F.2d at 951, 177 USPQ at 695. If the disclosure fails to disclose any program and if more than routine experimentation would be required of one skilled in the art to generate such a program, the examiner clearly would have a reasonable basis for challenging the sufficiency of such a disclosure. The amount of experimentation that is considered routine will vary depending on the facts and circumstances of individual cases. No exact numerical standard has been fixed by the

courts, but the "amount of required experimentation must, however, be reasonable." *White Consol. Indus.*, 713 F.2d at 791, 218 USPQ at 963. One court apparently found that the amount of experimentation involved was reasonable where a skilled programmer was able to write a general computer program, implementing an embodiment form, within 4 hours. *Hirschfield v. Banner*, 462 F. Supp. 135, 142, 200 USPQ 276, 279 (D.D.C. 1978), *aff'd*, 615 F.2d 1368 (D.C. Cir. 1986), *cert. denied*, 450 U.S. 994 (1981). Another court found that, where the required period of experimentation for skilled programmers to develop a particular program would run to 1 to 2 man years, this would be "a clearly unreasonable requirement" (*White Consol. Indus.*, 713 F.2d at 791, 218 USPQ at 963).

II. BLOCK ELEMENTS WITHIN A COMPUTER

The second category of block diagram cases occurs most frequently in pure data processing applications where the combination of block elements is totally within the confines of a computer, there being no interfacing with external apparatus other than normal input/output devices. In some instances, it has been found that particular kinds of block diagram disclosures were sufficient to meet the enabling requirement of **35 U.S.C. 112**, first paragraph. See *In re Knowlton*, 481 F.2d 1357, 178 USPQ 486 (CCPA 1973), *In re Comstock*, 481 F.2d 905, 178 USPQ 616 (CCPA 1973). Most significantly, however, in both the *Comstock* and *Knowlton* cases, the decisions turned on the appellants' disclosure of (A) a reference to and reliance on an identified prior art computer system and (B) an operative computer program for the referenced prior art computer system. Moreover, in *Knowlton* the disclosure was presented in such a detailed fashion that the individual program's steps were specifically interrelated with the operative structural elements in the referenced prior art computer system. The court in *Knowlton* indicated that the disclosure did not merely consist of a sketchy explanation of flow diagrams or a bare group of program listings together with a reference to a proprietary computer in which they might be run. The disclosure was characterized as going into considerable detail in explaining the interrelationships between the disclosed hardware and software elements. Under such circumstances, the Court considered the disclosure to be concise as well as full, clear, and exact to a sufficient degree to satisfy the literal language of **35 U.S.C. 112**, first paragraph. It must be emphasized that because of the significance of the program listing and the reference to and reliance on an identified prior art computer system, absent either of these items, a block element disclosure within the confines of a computer should be scrutinized in precisely the same manner as the first category of block diagram cases discussed above.

Regardless of whether a disclosure involves block elements more comprehensive than a computer or block elements totally within the confines of a computer, USPTO personnel, when analyzing method claims, must recognize that the specification must be adequate to teach how to practice the claimed method. If such practice requires a particular apparatus, then the application must provide a sufficient disclosure of that apparatus if such is not already available. See *In re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971) and *In re Gunn*, 537 F.2d 1123, 1128, 190 USPQ 402, 406 (CCPA 1976). When USPTO personnel question the adequacy of computer system or computer programming disclosures, the reasons for finding the specification to be nonenabling should be supported by the record as a whole. In this regard, it is also essential for USPTO personnel to reasonably challenge evidence submitted by the applicant. For example, in *In re Naquin*, *supra*, an affiant's statement that the average computer programmer was familiar with the subroutine necessary for performing the claimed process, was held to be a statement of fact as it was unchallenged by USPTO personnel. In other words, unless USPTO personnel present a reasonable basis for challenging the disclosure in view of the record as a whole, a **35 U.S.C. 112**, first paragraph rejection in a computer system or computer programming application may not be sustained on appeal. See *In re Naquin*, *supra*, and *In re Morehouse*, 545 F.2d 162, 165-66, 192 USPQ 29, 32 (CCPA 1976).

While no specific universally applicable rule exists for recognizing an insufficiently disclosed application involving computer programs, an examining guideline to generally follow is to challenge the sufficiency of such disclosures which fail to include either the computer program itself or a reasonably detailed flowchart which delineates the sequence of operations the program must perform. In programming applications where the software disclosure only includes a flowchart, as the complexity of functions and the generality of the individual components of the flowchart increase, the basis for challenging the sufficiency of such a flowchart becomes more reasonable because the likelihood of more than routine experimentation being required to generate a working program from such a flowchart also increases.

As stated earlier, once USPTO personnel have advanced a reasonable basis or presented evidence to question the adequacy of a computer system or computer programming disclosure, the applicant must show that his or her specification would enable one of ordinary skill in the art to make and use the claimed invention without resorting to undue experimentation. In most cases, efforts to meet this burden involve submitting affidavits, referencing prior art patents or technical publications, presenting

arguments of counsel, or combinations of these approaches.

III. AFFIDAVIT PRACTICE (37 CFR 1.132)

In computer cases, affidavits must be critically analyzed. Affidavit practice at the outset usually involves analyzing the skill level and/or qualifications of the affiant, which should be of the person of ordinary skill in the art (hereinafter "routineer"). When an affiant's skill level is higher than that required by the routineer for a particular application, an examiner may challenge the affidavit since it would not be made by a routineer in the art, and therefore would not be probative as to the amount of experimentation required by a routineer in the art to implement the invention. An affiant having a skill level or qualifications above that of the routineer in the art would require less experimentation to implement the claimed invention than that for the routineer. Similarly, an affiant having a skill level or qualifications below that of the routineer in the art would require more experimentation to implement the claimed invention than that for the routineer in the art. In either situation, the standard of the routineer in the art would not have been met.

In computer systems or programming cases, the problems with a given affidavit, which relate to the sufficiency of disclosure issue, generally involve affiants submitting few facts to support their conclusions or opinions. Some affidavits may go so far as to present conclusions on the ultimate legal question of sufficiency. *In re Brandstadter,* 484 F.2d 1395 , 179 USPQ 286 (CCPA 1973), illustrates the extent of the inquiry into the factual basis underlying an affiant's conclusions or opinions. In *Brandstadter*, the invention concerned a stored program controller (computer) programmed to control the storing, retrieving, and forwarding of messages in a communications system. The disclosure consisted of broadly defined block diagrams of the structure of the invention and no flowcharts or program listings of the programs of the controller. The Court quoted extensively from the Examiner's Office Actions and Examiner's Answer in its opinion where it was apparent that the Examiner consistently argued that the disclosure was merely a broad system diagram in the form of labelled block diagrams along with statements of a myriad of desired results. Various affidavits were presented in which the affiants stated that all or some of the system circuit elements in the block diagrams were either well-known in the art or "could be constructed" by the skilled design engineer, that the controller was "capable of being programmed" to perform the stated functions or results desired, and that the routineer in the art "could design or construct or was able to program" the system. The Court did consider the affiants' statements as being some evidence on the ultimate legal question of enablement but concluded that the statements failed in their purpose since they recited conclusions or opinions with few facts to support or buttress these conclusions. With reference to the lack of a disclosed computer program or even a flowchart of the program to control the message switching system, the record contained no evidence as to the number of programmers needed, the number of man-hours and the level of skill of the programmers to produce the program required to practice the invention.

It should be noted also that it is not opinion evidence directed to the ultimate legal question of enablement, but rather factual evidence directed to the amount of time and effort and level of knowledge required for the practice of the invention from the disclosure alone which can be expected to rebut a *prima faci*e case of nonenablement. See *Hirschfield,* 462 F. Supp. at 143, 200 USPQ at 281. It has also been held that where an inventor described the problem to be solved to an affiant, thus enabling the affiant to generate a computer program to solve the problem, such an affidavit failed to demonstrate that the application alone would have taught a person of ordinary skill in the art how to make and use the claimed invention. See *In re Brown,* 477 F.2d at 951, 177 USPQ at 695. The Court indicated that it was not factually established that the applicant did not convey to the affiant vital and additional information in their several meetings in addition to that set out in the application. Also of significance for an affidavit to be relevant to the determination of enablement is that it must be probative of the level of skill of the routineer in the art as of the time the applicant filed his application. See *In re Gunn,* 537 F.2d 1123, 1128, 190 USPQ 402, 406 (CCPA 1976). In that case, each of the affiants stated what was known at the time he executed the affidavit, and not what was known at the time the applicant filed his application.

IV. REFERENCING PRIOR ART DOCUMENTS

The commercial availability of an identified prior art computer system is very pertinent to the issue of enablement. But in some cases, this approach may not be sufficient to meet the applicant's burden. Merely citing extracts from technical publications in an affidavit in order to satisfy the enablement requirement is not sufficient if it is not made clear that a person skilled in the art would know which, or what parts, of the cited circuits could be used to construct the claimed device or how they could be interconnected to act in combination to produce the required results. See *In re Forman,* 463 F.2d 1125, 1129, 175 USPQ 12, 16 (CCPA 1972). This analysis would appear to be less critical where the circuits comprising applicant's system are essentially standard components

of an identified prior art computer system and a standard device attached thereto.

Prior art patents are often relied on by applicants to show the state of the art for purposes of enablement. However, these patents must have an issue date earlier than the effective filing date of the application under consideration. See *In re Budnick*, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976). An analogous point was made in *In re Gunn, supra*, where the court indicated that patents issued after the filing date of the application under examination are not evidence of subject matter known to any person skilled in the art since their subject matter may have been known only to the patentees and the Patent and Trademark Office.

Merely citing prior art patents to demonstrate that the challenged components are old may not be sufficient proof since, even if each of the enumerated devices or labelled blocks in a block diagram disclosure were old, *per se*, this would not make it self-evident how each would be interconnected to function in a disclosed complex combination manner. Therefore, the specification in effect must set forth the integration of the prior art; otherwise, it is likely that undue experimentation, or more than routine experimentation would be required to implement the claimed invention. See *In re Scarbrough*, 500 F.2d 560, 565, 182 USPQ 298, 301 (CCPA 1974). The court also noted that any cited patents which are used by the applicant to demonstrate that particular box diagram hardware or software components are old must be analyzed as to whether such patents are germane to the instant invention and as to whether such patents provide better detail of disclosure as to such components than an applicant's own disclosure. Also, any patent or publication cited to provide evidence that a particular programming technique is well-known in the programming art does not demonstrate that one of ordinary skill in the art could make and use correspondingly disclosed programming techniques unless both programming techniques are of approximately the same degree of complexity. See *In re Knowlton*, 500 F.2d 566, 572, 183 USPQ 33, 37 (CCPA 1974).

V. ARGUMENTS OF COUNSEL

Arguments of counsel may be effective in establishing that an examiner has not properly met his or her burden or has otherwise erred in his or her position. However, it must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See *In re Budnick*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See *In re Knowlton*, 500 F.2d at 572, 183 USPQ at 37; *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979).<

2164.07 Relationship of Enablement Requirement to Utility Requirement of 35 U.S.C. 101

The requirement of **35 U.S.C. 112**, first paragraph as to how to use the invention is different from the utility requirement of **35 U.S.C. 101**. The requirement of **35 U.S.C. 101** is that some specific, substantial, and credible use be set forth for the invention. On the other hand, **35 U.S.C. 112**, first paragraph requires an indication of how the use (required by **35 U.S.C. 101**) can be carried out, i.e., how the invention can be used.

If an applicant has disclosed a specific and substantial utility for an invention and provided a credible basis supporting that utility, that fact alone does not provide a basis for concluding that the claims comply with all the requirements of **35 U.S.C. 112**, first paragraph. For example, if an applicant has claimed a process of treating a certain disease condition with a certain compound and provided a credible basis for asserting that the compound is useful in that regard, but to actually practice the invention as claimed a person skilled in the relevant art would have to engage in an undue amount of experimentation, the claim may be defective under **35 U.S.C. 112**, but not **35 U.S.C. 101**. To avoid confusion during examination, any rejection under **35 U.S.C. 112**, first paragraph, based on grounds other than "lack of utility" should be imposed separately from any rejection imposed due to "lack of utility" under **35 U.S.C. 101** and **35 U.S.C. 112**, first paragraph.

I. WHEN UTILITY REQUIREMENT IS NOT SATISFIED

A. Not Useful or Operative

If a claim fails to meet the utility requirement of **35 U.S.C. 101** because it is shown to be nonuseful or inoperative, then it necessarily fails to meet the how-to-use aspect of the enablement requirement of **35 U.S.C. 112**, first paragraph. As noted in *In re Fouche*, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971), if "compositions are in fact useless, appellant's specification cannot have taught how to use them." 439 F.2d at 1243, 169 USPQ at 434. The examiner should make both rejections (i.e., a rejection under **35 U.S.C. 112**, first paragraph and a rejection under

35 U.S.C. 101) where the subject matter of a claim has been shown to be nonuseful or inoperative.

The 35 U.S.C. 112, first paragraph, rejection should indicate that because the invention as claimed does not have utility, a person skilled in the art would not be able to use the invention as claimed, and as such, the claim is defective under 35 U.S.C. 112, first paragraph. A 35 U.S.C. 112, first paragraph, rejection should not be imposed or maintained unless an appropriate basis exists for imposing a rejection under 35 U.S.C. 101. In other words, Office personnel should not impose a 35 U.S.C. 112, first paragraph, rejection grounded on a "lack of utility" basis unless a 35 U.S.C. 101 rejection is proper. In particular, the factual showing needed to impose a rejection under 35 U.S.C. 101 must be provided if a 35 U.S.C. 112, first paragraph, rejection is to be imposed on "lack of utility" grounds. See MPEP § 2107 - § 2107.03 for a more detailed discussion of the utility requirements of 35 U.S.C. 101 and 112, first paragraph.

B. Burden on the Examiner

When the examiner concludes that an application is describing an invention that is nonuseful, inoperative, or contradicts known scientific principles, the burden is on the examiner to provide a reasonable basis to support this conclusion. Rejections based on 35 U.S.C. 112, first paragraph and 35 U.S.C. 101 should be made.

Examiner Has Initial Burden To Show That One of Ordinary Skill in the Art Would Reasonably Doubt the Asserted Utility

The examiner has the initial burden of challenging an asserted utility. Only after the examiner has provided evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince one of ordinary skill in the art of the invention's asserted utility. *In re Swartz*, 232 F.3d 862, 863, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000); *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (citing *In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981)).

C. Rebuttal by Applicant

If a rejection under 35 U.S.C. 101 has been properly imposed, along with a corresponding rejection under 35 U.S.C. 112, first paragraph, the burden shifts to the applicant to rebut the *prima facie* showing. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). There is no predetermined amount or character of evidence that must be provided by an applicant to support an asserted utility. Rather, the character and amount of evidence needed to support an asserted utility will vary depending on what is claimed (*Ex parte Ferguson*, 117 USPQ 229, 231 (Bd. App. 1957)), and whether the asserted utility appears to contravene established scientific principles and beliefs. *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967 *); In re Chilowsky*, 229 F.2d 457, 462, 108 USPQ 321, 325 (CCPA 1956). Furthermore, the applicant does not have to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt." *In re Irons*, 340 F.2d 974, 978, 144 USPQ 351, 354 (CCPA 1965). Instead, evidence will be sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true. See MPEP § 2107.02 for a more detailed discussion of consideration of a reply to a *prima facie* rejection for lack of utility and evaluation of evidence related to utility.

II. WHEN UTILITY REQUIREMENT IS SATISFIED

In some instances, the use will be provided, but the skilled artisan will not know how to effect that use. In such a case, no rejection will be made under 35 U.S.C. 101, but a rejection will be made under 35 U.S.C. 112, first paragraph. As pointed out in *Mowry v. Whitney*, 81 U.S. (14 Wall.) 620 (1871), an invention may in fact have great utility, i.e., may be "a highly useful invention," but the specification may still fail to "enable any person skilled in the art or science" to use the invention. 81 U.S. (14 Wall.) at 644.

2164.08 Enablement Commensurate in Scope With the Claims [R-2]

All questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim is enabled. Accordingly, the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims. >See, e.g., *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003)(When a range is claimed, there must be reasonable enablement of the scope of the range. Here, the claims at issue encompassed amounts of silicon as high as 10% by weight, however the specification included statements clearly and strongly warning that a silicon content above 0.5% by weight in an aluminum coating causes coating problems. Such statements indicate that higher amounts will not work in the claimed invention.).< The examiner should determine what each claim recites and what the subject matter is when the claim is considered as a whole, not when its parts are analyzed

individually. No claim should be overlooked. With respect to dependent claims, **35 U.S.C. 112**, fourth paragraph, should be followed. This paragraph states that "a claim in a dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers" and requires the dependent claim to further limit the subject matter claimed.

The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. > *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003);< *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003) (alleged "pioneer status" of invention irrelevant to enablement determination).

The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of the enablement involves two stages of inquiry. The first is to determine how broad the claim is with respect to the disclosure. The entire claim must be considered. The second inquiry is to determine if one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation.

How a teaching is set forth, by specific example or broad terminology, is not important. *In re Marzocchi*, 439 F.2d 220, 223-24 169 USPQ 367, 370 (CCPA 1971). A rejection of a claim under **35 U.S.C. 112** as broader than the enabling disclosure is a first paragraph enablement rejection and not a second paragraph definiteness rejection. Claims are not rejected as broader than the enabling disclosure under **35 U.S.C. 112** for noninclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. *In re Skrivan*, 427 F.2d 801, 806, 166 USPQ 85, 88 (CCPA 1970). One does not look to the claims but to the specification to find out how to practice the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1558, 220 USPQ 303, 316-17 (Fed. Cir. 1983); *In re Johnson*, 558 F.2d 1008, 1017, 194 USPQ 187, 195 (CCPA 1977). In *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976), the court stated:

> [T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

When analyzing the enabled scope of a claim, the teachings of the specification must not be ignored because claims are to be given their broadest reasonable interpretation that is consistent with the specification. "That claims are interpreted in light of the specification does not mean that everything in the specification must be read into the claims." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957, 220 USPQ 592, 597 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984).

The record must be clear so that the public will have notice as to the patentee's scope of protection when the patent issues. If a reasonable interpretation of the claim is broader than the description in the specification, it is necessary for the examiner to make sure the full scope of the claim is enabled. Limitations and examples in the specification do not generally limit what is covered by the claims.

The breadth of the claims was a factor considered in *Amgen v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991). In the *Amgen* case, the patent claims were directed to a purified DNA sequence encoding polypeptides which are analogs of erythropoietin (EPO). The Court stated that:

> Amgen has not enabled preparation of DNA sequences sufficient to support its all-encompassing claims. . . . [D]espite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling

> disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. . . . This disclosure might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen's desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them.

927 F.2d at 1213-14, 18 USPQ2d at 1027. However, when claims are directed to any purified and isolated DNA sequence encoding a specifically named protein where the protein has a specifically identified sequence, a rejection of the claims as broader than the enabling disclosure is generally not appropriate because one skilled in the art could readily determine any one of the claimed embodiments.

See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (The evidence did not show that a skilled artisan would have been able to carry out the steps required to practice the full scope of claims which encompass "any and all live, non-pathogenic vaccines, and processes for making such vaccines, which elicit immunoprotective activity in any animal toward any RNA virus." (original emphasis)); *In re Goodman*, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993) (The specification did not enable the broad scope of the claims for producing mammalian peptides in plant cells because the specification contained only an example of producing gamma-interferon in a dicot species, and there was evidence that extensive experimentation would have been required for encoding mammalian peptide into a monocot plant at the time of filing); *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (Where applicant claimed a composition suitable for the treatment of arthritis having a potency of "at least" a particular value, the court held that the claim was not commensurate in scope with the enabling disclosure because the disclosure was not enabling for compositions having a slightly higher potency. Simply because applicant was the first to achieve a composition beyond a particular threshold potency did not justify or support a claim that would dominate every composition that exceeded that threshold value.); *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (Given the relatively incomplete understanding in the biotechnological field involved, and the lack of a reasonable correlation between the narrow disclosure in the specification and the broad scope of protection sought in the claims, a rejection under **35 U.S.C. 112**, first paragraph for lack of enablement was appropriate.).

If a rejection is made based on the view that the enablement is not commensurate in scope with the claim, the examiner should identify the subject matter that is considered to be enabled.

2164.08(a) Single Means Claim

A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under **35 U.S.C. 112**, first paragraph. *In re Hyatt*, 708 F.2d 712, 714-715, 218 USPQ 195, 197 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to *Hyatt* is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor.

2164.08(b) Inoperative Subject Matter

The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984) (prophetic examples do not make the disclosure nonenabling).

Although, typically, inoperative embodiments are excluded by language in a claim (e.g., preamble), the scope of the claim may still not be enabled where undue experimentation is involved in determining those embodiments that are operable. A disclosure of a large number of operable embodiments and the identification of a single inoperative embodiment did not render a claim broader than the enabled scope because undue experimentation was not involved in determining those embodiments that were operable. *In re Angstadt*, 537 F.2d 498, 502-503, 190 USPQ 214, 218 (CCPA 1976). However, claims reading on significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative. *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984); *In*

re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

2164.08(c) Critical Feature Not Claimed

A feature which is taught as critical in a specification and is not recited in the claims should result in a rejection of such claim under the enablement provision section of **35 U.S.C. 112**. See *In re Mayhew*, 527 F.2d 1229, 1233, 188 USPQ 356, 358 (CCPA 1976). In determining whether an unclaimed feature is critical, the entire disclosure must be considered. Features which are merely preferred are not to be considered critical. *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976).

Limiting an applicant to the preferred materials in the absence of limiting prior art would not serve the constitutional purpose of promoting the progress in the useful arts. Therefore, an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality.

2165 The Best Mode Requirement [R-9]

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I. Requirement for a Disclosure of the Best Mode

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A third requirement of the first paragraph of **35 U.S.C. 112** is that:

> The specification. . . shall set forth the best mode contemplated by the inventor of carrying out his invention.

"The best mode requirement creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for practicing the claimed invention." *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 963, 58 USPQ2d 1865, 1874 (Fed. Cir. 2001).

The best mode requirement is a safeguard against the desire on the part of some people to obtain patent protection without making a full disclosure as required by the statute. The requirement does not permit inventors to disclose only what they know to be their second-best embodiment, while retaining the best for themselves. *In re Nelson*, 280 F.2d 172, 126 USPQ 242 (CCPA 1960).

Determining compliance with the best mode requirement requires a two-prong inquiry. First, it must be determined whether, at the time the application was filed, the inventor possessed a best mode for practicing the invention. This is a subjective inquiry which focuses on the inventor's state of mind at the time of filing. Second, if the inventor did possess a best mode, it must be determined whether the written description disclosed the best mode such that a person skilled in the art could practice it. This is an objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art. *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 963, 58 USPQ2d 1865, 1874 (Fed. Cir. 2001).** All applicants are required to disclose for the claimed subject matter the best mode contemplated by the inventor even though applicant may not have been the discoverer of that mode. *Benger Labs. Ltd. v. R.K. Laros Co.*, 209 F. Supp. 639, 135 USPQ 11 (E.D. Pa. 1962).

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Failure to disclose the best mode need not rise to the level of active concealment or grossly inequitable conduct in order to support a rejection **. Where an inventor knows of a specific material that will make possible the successful reproduction of the effects claimed by the patent, but does not disclose it, speaking instead in terms of broad categories, the best mode requirement has not been satisfied. *Union Carbide Corp. v. Borg-Warner*, 550 F.2d 555, 193 USPQ 1 (6th Cir. 1977).

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II. IMPACT OF FAILURE TO DISCLOSE THE BEST MODE PURSUANT TO THE AIA

Section 15 of the Leahy-Smith America Invents Act (AIA), Public Law 112-29, 125 Stat. 284 (Sept. 16, 2011), did not eliminate the requirement in **35 U.S.C. 112** , first paragraph, for a disclosure of the best mode, but effective September 16, 2011, it amended **35 U.S.C. 282** (the provision that sets forth defenses in a patent validity or infringement proceeding) to provide that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable. As this change is applicable only in patent validity or infringement proceedings, it does not alter current patent examining practices as set forth above for evaluation of an application for compliance with the best mode requirement of **35 U.S.C. 112** .

Prior to September 16, 2011, for an invention claimed in a later-filed application to receive the benefit of the filing date of an earlier-filed application, **35 U.S.C. 119(e)** and **120** required that the invention claimed in the later-filed application be disclosed in the earlier-filed application in the manner provided by **35 U.S.C. 112** , first paragraph. Section 15 of the Leahy-Smith America Invents Act also amended **35 U.S.C. 119(e)** and **120** to modify this requirement such that the disclosure in the earlier filed application must be made in the manner provided by **35 U.S.C. 112** , first paragraph, "other than the requirement to disclose the best mode." This change should not noticeably impact patent examining procedure. **MPEP § 201.08** provides that there is no need to determine whether the earlier-filed application contains a disclosure of the invention claimed in the later filed application in compliance with **35 U.S.C. 112** , first paragraph, unless the filing date of the earlier-filed application is actually necessary (e.g., to overcome a reference). Examiners should consult with their supervisors if it appears that an earlier-filed application does not disclose the best mode for carrying out a claimed invention and the filing date of the earlier-filed application is actually necessary.

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2165.01 Considerations Relevant to Best Mode [R-9]

I. DETERMINE WHAT IS THE INVENTION

Determine what the invention is — the invention is defined in the claims. The specification need not set forth details not relating to the essence of the invention. *In re Bosy*, 360 F.2d 972, 149 USPQ 789 (CCPA 1966). See also *Northern Telecom Ltd. v. Samsung Electronics Co.*, 215 F.3d 1281, 55 USPQ2d 1065 (Fed. Cir. 2000) (Unclaimed matter that is unrelated to the operation of the claimed invention does not trigger the best mode requirement); *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 966, 58 USPQ2d 1865, 1877 (Fed. Cir. 2001) ("[P]atentee's failure to disclose an unclaimed preferred mode for accomplishing a routine detail does not violate the best mode requirement because one skilled in the art is aware of alternative means for accomplishing the routine detail that would still produce the best mode of the claimed invention.").

II. SPECIFIC EXAMPLE IS NOT REQUIRED

There is no statutory requirement for the disclosure of a specific example — a patent specification is not intended nor required to be a production specification. *In re Gay*, 309 F.2d 768, 135 USPQ 311 (CCPA 1962).

The absence of a specific working example is not necessarily evidence that the best mode has not been disclosed, nor is the presence of one evidence that it has. Best mode may be represented by a preferred range of conditions or group of reactants. *In re Honn*, 364 F.2d 454, 150 USPQ 652 (CCPA 1966).

III. DESIGNATION AS BEST MODE IS NOT REQUIRED

There is no requirement in the statute that applicants point out which of their embodiments they consider to be their best; that the disclosure includes the best mode contemplated by applicants is enough to satisfy the statute. *Ernsthausen v. Nakayama*, 1 USPQ2d 1539 (Bd. Pat. App. & Inter. 1985).

IV. UPDATING BEST MODE IS NOT REQUIRED

There is no requirement to update in the context of a foreign priority application under **35 U.S.C. 119**, *Standard Oil Co. v. Montedison, S.p.A.*, 494 F.Supp. 370, 206 USPQ 676 (D.Del. 1980) (better catalyst developed between Italian priority and U.S. filing dates)**. >Furthermore, it is not necessary to udpate the best mode in applications claiming the benefit of an earlier filing date under **35 U.S.C. 119(e)** or **120**, which indicate that the disclosure in the earlier filed application must be made in the manner provided by **35 U.S.C. 112** , first paragraph, "other than the requirement to disclose the best mode." See **MPEP § 2165**, paragraph II. <

V. DEFECT IN BEST MODE CANNOT BE CURED BY NEW MATTER

If the best mode contemplated by the inventor at the time of filing the application is not disclosed, such a defect cannot be cured by submitting an amendment seeking to put into the specification something required to be there when the patent application was originally filed. *In re Hay*, 534 F.2d 917, 189 USPQ 790 (CCPA 1976).

Any proposed amendment of this type (adding a specific mode of practicing the invention not described in the application as filed) should be treated as new matter. New matter under **35 U.S.C. 132** and **251** should be objected to and coupled with a requirement to cancel the new matter.

2165.02 Best Mode Requirement Compared to Enablement Requirement

The best mode requirement is a separate and distinct requirement from the enablement requirement of the first

paragraph of **35 U.S.C. 112**. *In re Newton*, 414 F.2d 1400, 163 USPQ 34 (CCPA 1969).

The best mode provision of **35 U.S.C. 112** is not directed to a situation where the application fails to set forth any mode — such failure is equivalent to nonenablement. *In re Glass*, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974).

The enablement requirement looks to placing the subject matter of the claims generally in the possession of the public. If, however, the applicant develops specific instrumentalities or techniques which are recognized by the applicant at the time of filing as the best way of carrying out the invention, then the best mode requirement imposes an obligation to disclose that information to the public as well. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 3 USPQ 2d 1737 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987).

2165.03 Requirements for Rejection for Lack of Best Mode [R-1]

ASSUME BEST MODE IS DISCLOSED UNLESS THERE IS EVIDENCE TO THE CONTRARY

The examiner should assume that the best mode is disclosed in the application, unless evidence is presented that is inconsistent with that assumption. It is extremely rare that a best mode rejection properly would be made in *ex parte* prosecution. The information that is necessary to form the basis for a rejection based on the failure to set forth the best mode is rarely accessible to the examiner, but is generally uncovered during discovery procedures in interference, litigation, or other *inter partes* proceedings.

EXAMINER MUST DETERMINE WHETHER THE INVENTOR KNEW THAT ONE MODE WAS BETTER THAN ANOTHER, AND IF SO, WHETHER THE DISCLOSURE IS ADEQUATE TO ENABLE ONE OF ORDINARY SKILL IN THE ART TO PRACTICE THE BEST MODE

According to the approach used by the court in *Chemcast Corp. v. Arco Industries*, 913 F.2d 923, 16 USPQ2d 1033 (Fed. Cir. 1990), a proper best mode analysis has two components:

(A) >Determine whether, at the time the application was filed, the inventor knew of a mode of practicing the claimed invention that the inventor considered to be better than any other.<The first component is a subjective inquiry because it focuses on the inventor's state of mind at the time the application was filed. Unless the examiner has evidence that the inventors had information in their possession(1) at the time the application was filed

(2) that a mode was considered to be better than any others by the inventors,

there is no reason to address the second component and there is no proper basis for a best mode rejection. If the facts satisfy the first component, then, and only then, is the following second component analyzed:

(B) Compare what was known in (A) with what was disclosed - is the disclosure adequate to enable one skilled in the art to practice the best mode?

Assessing the adequacy of the disclosure in this regard is largely an objective inquiry that depends on the level of skill in the art. Is the information contained in the specification disclosure sufficient to enable a person skilled in the relevant art to make and use the best mode?

A best mode rejection is proper only when the first inquiry can be answered in the affirmative, and the second inquiry answered in the negative with reasons to support the conclusion that the specification is nonenabling with respect to the best mode.

2165.04 Examples of Evidence of Concealment [R-3]

In determining the adequacy of a best mode disclosure, only evidence of concealment (accidental or intentional) is to be considered. That evidence must tend to show that the quality of an applicant's best mode disclosure is so poor as to effectively result in concealment.

I. EXAMPLES — BEST MODE REQUIREMENT SATISFIED

In one case, even though the inventor had more information in his possession concerning the contemplated best mode than was disclosed (a known computer program) the specification was held to delineate the best mode in a manner sufficient to require only the application of routine skill to produce a workable digital computer program. *In re Sherwood*, 613 F.2d 809, 204 USPQ 537 (CCPA 1980).

In another case, the claimed subject matter was a time controlled thermostat, but the application did not disclose the specific Quartzmatic motor which was used in a commercial embodiment. The Court concluded that failure to disclose the commercial motor did not amount to concealment since similar clock motors were widely available and widely advertised. There was no evidence that the specific Quartzmatic motor was superior except possibly in price. *Honeywell v. Diamond*, 208 USPQ 452 (D.D.C. 1980).

There was held to be no violation of the best mode requirement even though the inventor did not disclose the only mode of calculating the stretch rate for plastic rods that he used because that mode would have been employed by those of ordinary skill in the art at the time the application was filed. *W.L. Gore & Assoc., Inc. v. Garlock Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983).

>There was no best mode violation where the patentee failed to disclose in the specification "[k]nown ways to perform a known operation" to practice the claimed invention. "Known ways of performing a known operation cannot be deemed intentionally concealed absent evidence of intent to deliberately withhold that information." *High Concrete Structures Inc. v. New Enter. Stone & Lime Co.*, 377 F.3d 1379, 1384, 71 USPQ2d 1948, 1951 (Fed. Cir. 2004). The unintentional failure to disclose in the specification the use of a crane to support the patented frame in order to carry out the method of loading and tilting the frame was held not to defeat the best mode requirement because one of ordinary skill in the art would understand and use a crane to move heavy loads. *Id.* "The best mode requirement of [35 U.S.C.] §**112** is not violated by unintentional omission of information that would be readily known to persons in the field of the invention." *Id.*<

There was no best mode violation where there was no evidence that the monoclonal antibodies used by the inventors differed from those obtainable according to the processes described in the specification. It was not disputed that the inventors obtained the antibodies used in the invention by following the procedures in the specification, that these were the inventors' preferred procedures, and that the data reported in the specification was for the antibody that the inventors had actually used. *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ 2d 1001 (Fed. Cir. 1991).

Where an organism was created by the insertion of genetic material into a cell obtained from generally available sources, all that was required to satisfy the best mode requirement was an adequate description of the means for carrying out the invention, not deposit of the cells. As to the observation that no scientist could ever duplicate exactly the cell used by applicants, the court observed that the issue is whether the disclosure is adequate, not that an exact duplication is necessary. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ 2d 1016 (Fed. Cir. 1991).

There was held to be no violation of the best mode requirement where the Solicitor argued that concealment could be inferred from the disclosure in a specification that each analog is "surprisingly and unexpectedly more useful than one of the corresponding prostaglandins . . . for at least one of the pharmacological purposes." It was argued that appellant must have had test results to substantiate this statement and this data should have been disclosed. The court concluded that no withholding could be inferred from general statements of increased selectivity and narrower spectrum of potency for these novel analogs, conclusions which could be drawn from the elementary pharmacological testing of the analogs. *In re Bundy*, 642 F.2d 430, 435, 209 USPQ 48, 52 (CCPA 1981).

II. EXAMPLES — BEST MODE REQUIREMENT NOT SATISFIED

The best mode requirement was held to be violated where inventors of a laser failed to disclose details of their preferred TiCuSil brazing method which were not contained in the prior art and were contrary to criteria for the use of TiCuSil as contained in the literature. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 3 USPQ 2d 1737 (Fed. Cir. 1987).

The best mode requirement was violated because an inventor failed to disclose whether to use a specific surface treatment that he knew was necessary to the satisfactory performance of his invention, even though how to perform the treatment itself was known in the art. The argument that the best mode requirement may be met solely by reference to what was known in the prior art was rejected as incorrect. *Dana Corp. v. IPC Ltd. Partnership*, 860 F.2d 415, 8 USPQ2d 1692 (Fed. Cir. 1988).

2171 Two Separate Requirements for Claims Under 35 U.S.C. 112, Second Paragraph

The second paragraph of **35 U.S.C. 112** is directed to requirements for the claims:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

There are two separate requirements set forth in this paragraph:

(A) the claims must set forth the subject matter that applicants regard as their invention; and

(B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

The first requirement is a subjective one because it is dependent on what the applicants for a patent regard as their invention. The second requirement is an objective one because it is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite — i.e., whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art.

Although an essential purpose of the examination process is to determine whether or not the claims define an invention that is both novel and nonobvious over the prior art, another essential purpose of patent examination is to determine whether or not the claims are precise, clear, correct, and unambiguous. The uncertainties of claim scope should be removed, as much as possible, during the examination process.

The inquiry during examination is patentability of the invention as applicant regards it. If the claims do not particularly point out and distinctly claim that which applicants regard as their invention, the appropriate action by the examiner is to reject the claims under **35 U.S.C. 112**, second paragraph. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). If a rejection is based on **35 U.S.C. 112**, second paragraph, the examiner should further explain whether the rejection is based on indefiniteness or on the failure to claim what applicants regard as their invention. *Ex parte Ionescu*, 222 USPQ 537, 539 (Bd. App. 1984).

2172 Subject Matter Which Applicants Regard as Their Invention

I. FOCUS FOR EXAMINATION

A rejection based on the failure to satisfy this requirement is appropriate only where applicant has stated, somewhere other than in the application as filed, that the invention is something different from what is defined by the claims. In other words, the invention set forth in the claims must be presumed, in the absence of evidence to the contrary, to be that which applicants regard as their invention. *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971).

II. EVIDENCE TO THE CONTRARY

Evidence that shows that a claim does not correspond in scope with that which applicant regards as applicant's invention may be found, for example, in contentions or admissions contained in briefs or remarks filed by applicant, *Solomon v. Kimberly-Clark Corp.* , 216 F.3d 1372, 55 USPQ2d 1279 (Fed. Cir. 2000); *In re Prater* , 415 F.2d 1393, 162 USPQ 541 (CCPA 1969), or in affidavits filed under **37 CFR 1.132**, *In re Cormany*, 476 F.2d 998, 177 USPQ 450 (CCPA 1973). The content of applicant's specification is not used as evidence that the scope of the claims is inconsistent with the subject matter which applicants regard as their invention. As noted in *In re Ehrreich*, 590 F.2d 902, 200 USPQ 504 (CCPA 1979), agreement, or lack thereof, between the claims and the specification is properly considered only with respect to **35 U.S.C. 112**, first paragraph; it is irrelevant to compliance with the second paragraph of that section.

III. SHIFT IN CLAIMS PERMITTED

The second paragraph of **35 U.S.C. 112** does not prohibit applicants from changing what they regard as their invention during the pendency of the application. *In re Saunders*, 444 F.2d 599, 170 USPQ 213 (CCPA 1971) (Applicant was permitted to claim and submit comparative evidence with respect to claimed subject matter which originally was only the preferred embodiment within much broader claims (directed to a method).). The fact that claims in a continuation application were directed to originally disclosed subject matter which applicants had not regarded as part of their invention when the parent application was filed was held not to prevent the continuation application from receiving benefits of the filing date of the parent application under **35 U.S.C. 120**. *In re Brower*, 433 F.2d 813, 167 USPQ 684 (CCPA 1970).

2172.01 Unclaimed Essential Matter [R-1]

A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under **35 U.S.C. 112**, first paragraph, as not enabling. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). See also **MPEP § 2164.08(c)**. Such essential matter may include missing elements, steps or necessary structural cooperative relationships of elements described by the applicant(s) as necessary to practice the invention.

In addition, a claim which fails to interrelate essential elements of the invention as defined by applicant(s) in the specification may be rejected under **35 U.S.C. 112**, second paragraph, for failure to point out and distinctly claim the invention. See *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976); *In re Collier*, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968). >But see *Ex parte Nolden*, 149 USPQ 378, 380 (Bd. Pat. App. 1965) ("[I]t is not essential to a patentable combination that there be interdependency between the elements of the claimed device or that all the elements operate concurrently toward the desired result"); *Ex parte Huber*, 148 USPQ 447,

448-49 (Bd. Pat. App. 1965) (A claim does not necessarily fail to comply with 35 U.S.C. 112, second paragraph where the various elements do not function simultaneously, are not directly functionally related, do not directly intercooperate, and/or serve independent purposes.).<

2173 Claims Must Particularly Point Out and Distinctly Claim the Invention [R-9]

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Optimizing patent quality by providing clear notice to the public of the boundaries of the inventive subject matter protected by a patent grant fosters innovation and competitiveness. Accordingly, providing high quality patents is one of the agency's guiding principles. The Office recognizes that issuing patents with clear and definite claim language is a key component to enhancing the quality of patents and raising confidence in the patent process.

35 U.S.C. 112, second paragraph requires that a patent application specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his or her invention. In patent examining parlance, the claim language must be "definite" to comply with 35 U.S.C. 112, second paragraph. Conversely, a claim that does not comply with this requirement of 35 U.S.C. 112, second paragraph is "indefinite."

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The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.

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It is of utmost importance that patents issue with definite claims that clearly and precisely inform persons skilled in the art of the boundaries of protected subject matter. Therefore, claims that do not meet this standard must be rejected under 35 U.S.C. 112 , second paragraph as indefinite. Such a rejection requires that the applicant respond by explaining why the language is definite or by amending the claim, thus making the record clear regarding the claim boundaries prior to issuance. As an indefiniteness rejection requires the applicant to respond by explaining why the language is definite or by amending the claim, such rejections must clearly identify the language that causes the claim to be indefinite and thoroughly explain the reasoning for the rejection.

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2173.01 **>Interpreting the Claims< [R-9]

A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification. See MPEP § 2111.01. Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought.

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I. BROADEST REASONABLE INTERPRETATION

The first step to examining a claim to determine if the language is definite is to fully understand the subject matter of the invention disclosed in the application and to ascertain the boundaries of that subject matter encompassed by the claim. During examination, a claim must be given its broadest reasonable interpretation consistent with the specification as it would be interpreted by one of ordinary skill in the art. Because the applicant has the opportunity to amend claims during prosecution, giving a claim its broadest reasonable interpretation will reduce the possibility that the claim, once issued, will be interpreted more broadly than is justified. In re *Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984); *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989) ("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow."). The focus of the inquiry regarding the meaning of a claim should be what would be reasonable from the perspective of one of ordinary skill in the art. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010); *In re Buszard*, 504 F.3d 1364 (Fed. Cir. 2007). In *Buszard*, the claim was directed to a flame retardant composition comprising a flexible polyurethane foam reaction mixture. *Buszard*, 504 F.3d at 1365. The Federal Circuit found that the Board's interpretation that equated a "flexible" foam with a crushed "rigid" foam was not reasonable. *Buszard*, 504 F.3d at 1367. Persuasive argument was presented that persons experienced in the field of polyurethane foams

know that a flexible mixture is different than a rigid foam mixture. *Buszard*, 504 F.3d at 1366. See MPEP § 2111 for a full discussion of broadest reasonable interpretation.

Under a broadest reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification. The plain meaning of a term means the ordinary and customary meaning given to the term by those of ordinary skill in the art at the time of the invention. The ordinary and customary meaning of a term may be evidenced by a variety of sources, including the words of the claims themselves, the specification, drawings, and prior art. However, the best source for determining the meaning of a claim term is the specification - the greatest clarity is obtained when the specification serves as a glossary for the claim terms. The presumption that a term is given its ordinary and customary meaning may be rebutted by the applicant by clearly setting forth a different definition of the term in the specification. *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997) (the USPTO looks to the ordinary use of the claim terms taking into account definitions or other "enlightenment" contained in the written description); But c.f. *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1369 (Fed. Cir. 2004) ("We have cautioned against reading limitations into a claim from the preferred embodiment described in the specification, even if it is the only embodiment described, absent clear disclaimer in the specification."). When the specification sets a clear path to the claim language, the scope of the claims is more easily determined and the public notice function of the claims is best served. See MPEP § 2111.01 for a full discussion of the plain meaning of claim language.

II. DETERMINE WHETHER OR NOT EACH CLAIM LIMITATION INVOKES 35 U.S.C. 112, sixth paragraph

As part of the claim interpretation analysis, examiners should determine whether each limitation invokes **35 U.S.C. 112**, sixth paragraph or not. If the claim limitation invokes **35 U.S.C. 112**, sixth paragraph, the claim limitation must "be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." **35 U.S.C. 112**, sixth paragraph; see also In re Donaldson Co., 16 F.3d 1189, 1193 (Fed. Cir. 1994) (en banc) ("[W]e hold that paragraph six applies regardless of the context in which the interpretation of means-plus-function language arises, i.e., whether as part of a patentability determination in the PTO or as part of a validity or infringement determination in a court."). See MPEP § 2181(I) for more information regarding the determination of whether a limitation invokes **35 U.S.C. 112**, sixth paragraph, and means-plus-function claim limitations.

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2173.02 **>Determining Whether Claim Language is Definite < [R-9]

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During prosecution, applicant has an opportunity and a duty to amend ambiguous claims to clearly and precisely define the metes and bounds of the claimed invention. The claim places the public on notice of the scope of the patentee's right to exclude. See, e.g., *Johnson & Johnston Assoc. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002)(en banc). As the Federal Circuit stated in *Halliburton Energy Services*:

> We note that the patent drafter is in the best position to resolve the ambiguity in the patent claims, and it is highly desirable that patent examiners demand that applicants do so in appropriate circumstances so that the patent can be amended during prosecution rather than attempting to resolve the ambiguity in litigation. *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1255 (Fed. Cir. 2008).

A decision on whether a claim is indefinite under **35 U.S.C. 112**, second paragraph requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1350 (Fed. Cir. 2010); *Orthokinetics, Inc. v. Safety Travel Chairs*, Inc., 806 F.2d 1565 (Fed. Cir. 1986). In *Orthokinetics*, a claim directed to a wheel chair included the phrase "so dimensioned as to be insertable through the space between the doorframe of an automobile and one of the seats thereof." *Orthokinetics*, 806 F.2d at 1568. The court found the phrase to be as accurate as the subject matter permits, since automobiles are of various sizes. *Orthokinetics*, 806 F.2d at 1576. "As long as those of ordinary skill in the art realized the dimensions could be easily obtained, § 112, 2d para. requires nothing more." *Orthokinetics*, 806 F.2d at 1576. Claim terms are typically given their ordinary and customary meaning as understood by one of ordinary skill in the pertinent art, and the generally understood meaning of particular terms may vary from art to art. Therefore, it is important to analyze claim terms in view of the application's specification from the perspective of those skilled in the relevant art since a particular term used in one patent or application may not have the same meaning when used in a different application. *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1318 (Fed. Cir. 2005).

I. CLAIMS UNDER EXAMINATION ARE EVALUATED WITH A DIFFERENT STANDARD THAN PATENTED CLAIMS TO DETERMINE WHETHER THE LANGUAGE IS DEFINITE

Patented claims enjoy a presumption of validity and are not given the broadest reasonable interpretation during court proceedings involving infringement and validity, and can be interpreted based on a fully developed prosecution record. Accordingly, when possible, courts construe patented claims in favor of finding a valid interpretation. A court will not find a patented claim indefinite unless it is "insolubly ambiguous." See, e.g., *Exxon Research and Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001); see also *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004) ("The requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles….Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite."). In other words, the validity of a claim will be preserved if some meaning can be gleaned from the language.

In contrast, no presumption of validity attaches before the issuance of a patent. The Office is not required or even permitted to interpret claims when examining patent applications in the same manner as the courts, which, post-issuance, operate under the presumption of validity. *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997); *In re Zletz*, 893 F.2d 319, 321-22 (Fed. Cir. 1989). The Office must construe claims in the broadest reasonable manner during prosecution in an effort to establish a clear record of what applicant intends to claim. In deciding whether a pending claim particularly points out and distinctly claims the subject matter, a lower threshold of ambiguity is applied during prosecution. *Ex parte Miyazaki*, 89 USPQ2d 1207, 1212 (Bd. Pat. App. & Int. 2008) (precedential); *In re Am. Acad. of Sci. Tech Center*, 367 F.3d 1359, 1369 (Fed. Cir. 2004) ("However, the Board is required to use a different standard for construing claims than that used by district courts."). The lower threshold is applied because the patent record is in development and not fixed. As such, applicant has the ability to provide explanation and/or amend the claims to ensure that the meaning of the language is clear and definite prior to issuance. *Burlington Indus. Inc. v. Quigg*, 822 F.2d 1581, 1583 (Fed. Cir. 1987) ("Issues of judicial claim construction such as arise after patent issuance, for example during infringement litigation, have no place in prosecution of pending claims before the PTO, when any ambiguity or excessive breadth may be corrected by merely changing the claim.").

During examination, after applying the broadest reasonable interpretation to the claim, if the metes and bounds of the claimed invention are not clear, the claim is indefinite and should be rejected. *Zletz*, 893 F.2d at 322. For example, if the language of a claim, given its broadest reasonable interpretation, is such that a person of ordinary skill in the relevant art would read it with more than one reasonable interpretation, then a rejection under **35 U.S.C. 112**, second paragraph is appropriate. Examiners, however, are cautioned against confusing claim breadth with claim indefiniteness. A broad claim is not indefinite merely because it encompasses a wide scope of subject matter provided the scope is clearly defined. Instead, a claim is indefinite when the boundaries of the protected subject matter are not clearly delineated and the scope is unclear. For example, a genus claim that covers multiple species is broad, but is not indefinite because of its breadth, which is otherwise clear. But a genus claim that could be interpreted in such a way that it is not clear which species are covered would be indefinite (e.g., because there is more than one reasonable interpretation of what species are included in the claim). See MPEP § 2173.05(h)(I), for more information regarding the determination of whether a Markush claim satisfies the requirements of **35 U.S.C. 112**, second paragraph.

II. THRESHOLD REQUIREMENTS OF CLARITY AND PRECISION

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The examiner's focus during examination of claims for compliance with the requirement for definiteness of **35 U.S.C. 112**, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. **112**, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. **112**, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. See, e.g., *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). See also *In re Larsen*, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished) (The preamble of the *Larsen* claim recited only a hanger and a loop but the body of the claim positively recited a linear member. The court observed that the totality of all the limitations of the claim and their interaction with each other must be considered to ascertain the inventor's contribution to the art. Upon review of the claim in its entirety, the court concluded that the claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. **112** paragraph 2.).

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Accordingly, a claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible. *Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004) (holding that the disputed claim term "surrender value protected investment credits" which was not defined or used in the specification was discernible and hence not indefinite because "the components of the term have well recognized meanings, which allow the reader to infer the meaning of the entire phrase with reasonable confidence").

If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. **112**, second paragraph, would be appropriate. See *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993). However, if the language used by applicant satisfies the statutory requirements of 35 U.S.C. **112**, second paragraph, but the examiner merely wants the applicant to improve the clarity or precision of the language used, the claim must not be rejected under 35 U.S.C. **112**, second paragraph, rather, the examiner should suggest improved language to the applicant.

For example, a claim recites "a suitable liquid such as the filtrate of the contaminated liquid to be filtered and solids of a filtering agent such as perlite, cellulose powder, etc." The mere use of the phrase "such as" in the claim does not by itself render the claim indefinite. Office policy is not to employ *per se* rules to make technical rejections. Examples of claim language which have been held to be indefinite set forth in MPEP § **2173.05(d)** are fact specific and should not be applied as *per se* rules. The test for definiteness under 35 U.S.C. **112**, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). If one skilled in the art is able to ascertain in the example above, the meaning of the terms "suitable liquid" and "solids of a filtering agent" in light of the specification, 35 U.S.C. **112**, second paragraph, is satisfied. If upon review of the claim as a whole in light of the specification, the examiner determines that a rejection under 35 U.S.C. **112**, second paragraph, is not appropriate in the above-noted example, but is of the opinion that the clarity and the precision of the language can be improved by the deletion of the phrase "such as" in the claim, the examiner may make such a suggestion to the applicant. If applicant does not accept the examiner's suggestion, the examiner should not pursue the issue.

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III. RESOLVING INDEFINITE CLAIM LANGUAGE

A. Examiner Must Establish a Clear Record

Examiners are urged to carefully carry out their responsibilities to see that the application file contains a complete and accurate picture of the Office's consideration of the patentability of an application. See MPEP § 1302.14(I). In order to provide a complete application file history and to enhance the clarity of the prosecution history record, an examiner should provide clear explanations of all actions taken during prosecution of the application. See MPEP § 707.07(f). Thus, when a rejection under **35 U.S.C. 112**, second paragraph, is appropriate based on the examiner's determination that a claim term or phrase is indefinite, the examiner should clearly communicate in an Office action any findings and

reasons which support the rejection and avoid a mere conclusion that the claim term or phrase is indefinite. See MPEP § 706.03, 707.07(g).

MPEP § 2173.05 provides numerous examples of rationales that may support a rejection under **35 U.S.C. 112**, second paragraph, such as functional claim limitations, relative terminology/terms of degree, lack of antecedent basis, etc. Only by providing a complete explanation in the Office action as to the basis for determining why a particular term or phrase used in the claim is "vague and indefinite" will the examiner enhance the clarity of the prosecution history record.

B. An Office Action Should Provide a Sufficient Explanation

The Office action must set forth the specific term or phrase that is indefinite and why the metes and bounds are unclear. Since a rejection requires the applicant to respond by explaining why claim language is definite or by amending the claim, the Office action should provide enough information for the applicant to prepare a meaningful response. "Because claims delineate the patentee's right to exclude, the patent statute requires that the scope of the claims be sufficiently definite to inform the public of the bounds of the protected invention, i.e., what subject matter is covered by the exclusive rights of the patent." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008). Thus, claims are given their broadest reasonable interpretation during prosecution "to facilitate sharpening and clarifying the claims at the application stage" when claims are readily changed. *In re Buszard*, 504 F.3d 1364, 1366 (Fed. Cir. 2007); see also *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984); *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989).

To comply with **35 U.S.C. 112**, second paragraph, applicants are required to make the terms that are used to define the invention clear and precise, so that the metes and bounds of the subject matter that will be protected by the patent grant can be ascertained. See MPEP § 2173.05(a)(I). It is important that a person of ordinary skill in the art be able to interpret the metes and bounds of the claims so as to understand how to avoid infringement of the patent that ultimately issues from the application being examined. See MPEP § 2173.02(II) (citing *Morton Int 'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993)); see also *Halliburton Energy Servs.*, 514 F.3d at 1249 ("Otherwise, competitors cannot avoid infringement, defeating the public notice function of patent claims."). Examiners should bear in mind that "[a]n essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process." *Zletz*, 893 F.2d at 322.

Accordingly, when rejecting a claim as indefinite under **35 U.S.C. 112**, second paragraph, the examiner should provide enough information in the Office action to permit applicant to make a meaningful response, as the indefiniteness rejection requires the applicant to explain or provide evidence as to why the claim language is not indefinite or amend the claim. For example, the examiner should point out the specific term or phrase that is indefinite, explain in detail why such term or phrase renders the metes and bounds of the claim scope unclear and, whenever practicable, indicate how the indefiniteness issues may be resolved to overcome the rejection. See **MPEP § 707.07(d)**.

The focus during the examination of claims for compliance with the requirement for definiteness under **35 U.S.C. 112**, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. See MPEP § 2173.02(II). If the language used by applicant satisfies the statutory requirement of **35 U.S.C. 112**, second paragraph, but the examiner merely wants the applicant to improve the clarity or precision of the language used, the examiner should suggest improved claim language to the applicant and not make a rejection under **35 U.S.C. 112**, second paragraph. See, e.g., *In re Skvorecz* , 580 F.3d 1262, 1268-69 (Fed. Cir. 2009). Furthermore, when the examiner determines that more information is necessary to ascertain the meaning of a claim term, a requirement for information under **37 CFR 1.105** is appropriate. See **MPEP § 704.10** regarding requirements for information.

It is highly desirable to have applicants resolve ambiguity by amending the claims during prosecution of the application rather than attempting to resolve the ambiguity in subsequent litigation of the issued patent. *Halliburton Energy Servs.*, 514 F.3d at 1255. Likewise, if the applicant traverses a rejection under **35 U.S.C. 112**, second paragraph, with or without the submission of an amendment, and the examiner considers applicant's arguments to be persuasive, the examiner should indicate in the next Office communication that the previous rejection under **35 U.S.C. 112**, second paragraph, has been withdrawn and provide an explanation as to what prompted the change in the examiner's position (e.g., by making specific reference to portions of applicant's remarks).

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By providing an explanation as to the action taken, the examiner will enhance the clarity of the prosecution history record. As noted by the Supreme Court in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*., 535 U.S. 722, 122 S.Ct. 1831, 1838, 62 USPQ2d 1705, 1710 (2002), a clear and complete prosecution file record is important in that "[p]rosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process." In *Festo*, the court held that "a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel." With respect to amendments made to comply with the requirements of 35 U.S.C. **112**, the court stated that "[i]f a § **112** amendment is truly cosmetic, then it would not narrow the patent's scope or raise an estoppel. On the other hand, if a § **112** amendment is necessary and narrows the patent's scope—even if only for the purpose of better description—estoppel may apply." *Id*., at 1840, 62 USPQ2d at 1712. The court further stated that "when the court is unable to determine the purpose underlying a narrowing amendment—and hence a rationale for limiting the estoppel to the surrender of particular equivalents—the court should presume that the patentee surrendered all subject matter between the broader and the narrower language…the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question." *Id*., at 1842, 62 USPQ2d at 1713. Thus, whenever possible, the examiner should make the record clear by providing explicit reasoning for making or withdrawing any rejection related to 35 U.S.C. **112**, second paragraph.

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C. Provide Claim Interpretation in Reasons for Allowance When Record is Unclear

Pursuant to **37 CFR 1.104(e)**, if the examiner believes that the record of the prosecution as a whole does not make clear his or her reasons for allowing a claim or claims, the examiner may set forth such reasoning in reasons for allowance. Further, prior to allowance, the examiner may also specify allowable subject matter and provide reasons for indicating such allowable subject matter in an Office communication. See MPEP § 1302.14(I). One of the primary purposes of **37 CFR 1.104(e)** is to improve the quality and reliability of issued patents by providing a complete file history which should clearly reflect the reasons why the application was allowed. Such information facilitates evaluation of the scope and strength of a patent by the patentee and the public and may help avoid or simplify subsequent litigation of an issued patent. See **MPEP § 1302.14(I)**. In meeting the need for the application file history to speak for itself, it is incumbent upon the examiner in exercising his or her responsibility to the public to see that the file history is complete. See **MPEP § 1302.14(I)**.

For example, when allowing a claim based on a claim interpretation which might not be readily apparent from the record of the prosecution as a whole, the examiner should set forth in reasons for allowance the claim interpretation that he or she applied in determining that the claim is allowable over the prior art. See **MPEP § 1302.14(II)(G)**. This is especially the case where the application is allowed after an interview. The examiner should ensure, however, that statements of reasons for allowance do not place unwarranted interpretations, whether broad or narrow, upon the claims. See **MPEP § 1302.14(I)**.

D. Open Lines of Communication with the Applicant – When Indefiniteness Is the Only Issue, Attempt Resolution through an Interview before Resorting to a Rejection

Examiners are reminded that interviews can be an effective examination tool and are encouraged to initiate an interview with the applicant or applicant's representative at any point during the pendency of an application, if the interview can help further prosecution, shorten pendency, or provide a benefit to the examiner or applicant.. Issues of claim interpretation and clarity of scope may lend themselves to resolution through an examiner interview. For example, the examiner may initiate an interview to discuss, among other issues, the broadest reasonable interpretation of a claim, the meaning of a particular claim limitation, and the scope and clarity of preamble language, functional language, intended use language, and means-plus-function limitations, etc.

An interview can serve to develop and clarify such issues and lead to a mutual understanding between the examiner and the applicant, potentially eliminating the need for the examiner to resort to making a rejection under **35 U.S.C. 112**, second paragraph. The examiner is reminded that the substance of any interview, whether in person, by video conference, or by telephone must be made of record in the application, whether or not an agreement was reached at the interview. See **MPEP § 713.04**; see also **37 CFR 1.2** ("The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt."). Examples of **35 U.S.C. 112** issues that should be made of record after the interview include: why the discussed claim term is or is not sufficiently clear; why the discussed claim term is or is not inconsistent with the specification; why the discussed claim term does or does not invoke **35 U.S.C.**

112, sixth paragraph (and if it does, the identification of corresponding structure in the specification for a 35 U.S.C. 112, sixth paragraph limitation); and any claim amendments discussed that would resolve identified ambiguities.

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2173.03 **>Correspondence Between Specification and Claims < [R-9]

**>The specification should ideally serve as a glossary to the claim terms so that the examiner and the public can clearly ascertain the meaning of the claim terms. Correspondence between the specification and claims is required by 37 CFR 1.75(d)(1), which provides that claim terms must find clear support or antecedent basis in the specification so that the meaning of the terms may be ascertainable by reference to the specification. To meet the definiteness requirement under 35 U.S.C. 112, second paragraph, the exact claim terms are not required to be used in the specification as long as the specification provides the needed guidance on the meaning of the terms (e.g., by using clearly equivalent terms) so that the meaning of the terms is readily discernable to a person of ordinary skill in the art. See, e.g., *Bancorp Servs., L.L.C. v. Hartford Life Ins. Co.* , 359 F.3d 1367, 1373 (Fed. Cir. 2004). Nevertheless, glossaries of terms used in the claims are a helpful device for ensuring adequate definition of terms used in claims. Express definitions of claim terms can eliminate the need for any "time-consuming and difficult inquiry into indefiniteness." *Bancorp* , 359 F.3d at 1373. Therefore, applicants are encouraged to use glossaries as a best practice in patent application preparation. If the specification does not provide the needed support or antecedent basis for the claim terms, the specification should be objected to under 37 CFR 1.75(d)(1). See MPEP §§ 608.01(o) and 2181(IV). Applicant will be required to make appropriate amendment to the description to provide clear support or antecedent basis for the claim terms provided no new matter is introduced, or amend the claim.

A claim, although clear on its face, may also be indefinite when a conflict or inconsistency between the claimed subject matter and the specification disclosure renders the scope of the claim uncertain as inconsistency with the specification disclosure or prior art teachings may make an otherwise definite claim take on an unreasonable degree of uncertainty. *In re Moore*, 439 F.2d 1232, 1235-36 (CCPA 1971); *In re Cohn*, 438 F.2d 989, 169 USPQ 95 (CCPA 1971); *In re Hammack*, 427 F.2d 1378, 166 USPQ 204 (CCPA 1970). For example, a claim with a limitation of "the clamp means including a clamp body and first and second clamping members, the clamping members being supported by the clamp body" was determined to be indefinite because the terms "first and second clamping members" and "clamp body" were found to be vague in light of the specification which showed no "clamp member" structure being "supported by the clamp body." *In re Anderson*, 1997 U.S. App. Lexis 167 (Fed. Cir. Jan. 6, 1997) (unpublished). In *Cohn*, a claim was directed to a process of treating an aluminum surface with an alkali silicate solution and included a further limitation that the surface has an "opaque" appearance. *Cohn*, 438 F.2d at 993. The specification, meanwhile, associated the use of an alkali silicate with a glazed or porcelain-like finish, which the specification distinguished from an opaque finish. *Cohn*, 438 F.2d at 993. Noting that no claim may be read apart from and independent of the supporting disclosure on which it is based, the court found that the claim was internally inconsistent based on the description, definitions and examples set forth in the specification relating to the appearance of the surface after treatment, and therefore indefinite. Cohn, 438 F.2d at 993. <

2173.04 Breadth Is Not Indefiniteness [R-9]

Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph. >See *Ultimax Cement Mfg. v. CTS Cement Mfg.*, 587 F.3d 1339, 1352 (Fed. Cir. 2010) (finding that "a claim to a formula containing over 5000 possible combinations is not necessarily ambiguous if it sufficiently notifies the public of the scope of the claims.").<

Undue breadth of the claim may be addressed under different statutory provisions, depending on the reasons for concluding that the claim is too broad. If the claim is too broad because it does not set forth that which applicants regard as their invention as evidenced by statements outside of the application as filed, a rejection under 35 U.S.C. 112, second paragraph, would be appropriate. If the claim is too broad because it is not supported by the original description or by an enabling disclosure, a rejection under 35 U.S.C. 112, first paragraph, would be appropriate. If the claim is too broad

because it reads on the prior art, a rejection under either 35 U.S.C. 102 or 103 would be appropriate.

2173.05 Specific Topics Related to Issues Under 35 U.S.C. 112, Second Paragraph [R-1]

The following sections are devoted to a discussion of specific topics where issues under 35 U.S.C. 112, second paragraph, have been addressed. These sections are not intended to be an exhaustive list of the issues that can arise under 35 U.S.C. 112, second paragraph, but are intended to provide guidance in areas that have been addressed with some frequency in recent examination practice. The court and Board decisions cited are representative. As with all appellate decisions, the results are largely dictated by the facts in each case. The use of the same language in a different context may justify a different result.

>See MPEP § 2181 for guidance in determining whether an applicant has complied with the requirements of 35 U.S.C. 112, second paragraph, when 35 U.S.C. 112, sixth paragraph, is invoked.<

2173.05(a) New Terminology [R-3]

I. THE MEANING OF EVERY TERM SHOULD BE APPARENT

The meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. Applicants need not confine themselves to the terminology used in the prior art, but are required to make clear and precise the terms that are used to define the invention whereby the metes and bounds of the claimed invention can be ascertained. During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969). See also MPEP § 2111 - § 2111.01. When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

II. THE REQUIREMENT FOR CLARITY AND PRECISION MUST BE BALANCED WITH THE LIMITATIONS OF THE LANGUAGE

Courts have recognized that it is not only permissible, but often desirable, to use new terms that are frequently more precise in describing and defining the new invention. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Although it is difficult to compare the claimed invention with the prior art when new terms are used that do not appear in the prior art, this does not make the new terms indefinite.

New terms are often used when a new technology is in its infancy or is rapidly evolving. The requirements for clarity and precision must be balanced with the limitations of the language and the science. If the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the statute (35 U.S.C. 112, second paragraph) demands no more. *Shatterproof Glass Corp. v. Libbey Owens Ford Co.*, 758 F.2d 613, 225 USPQ 634 (Fed. Cir. 1985) (interpretation of "freely supporting" in method claims directed to treatment of a glass sheet); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986) (interpretation of a limitation specifying a numerical value for antibody affinity where the method of calculation was known in the art at the time of filing to be imprecise). This does not mean that the examiner must accept the best effort of applicant. If the proposed language is not considered as precise as the subject matter permits, the examiner should provide reasons to support the conclusion of indefiniteness and is encouraged to suggest alternatives that are free from objection.

III. TERMS USED CONTRARY TO THEIR ORDINARY MEANING MUST BE CLEARLY REDEFINED IN THE WRITTEN DESCRIPTION

Consistent with the well-established axiom in patent law that a patentee or applicant is free to be his or her own lexicographer, a patentee or applicant may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings if the written description clearly redefines the terms. See, e.g., *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999) ("While we have held many times that a patentee can act as his own lexicographer to specifically define terms of a claim contrary to their ordinary meaning," in such a situation the written description must clearly redefine a claim term "so as to put a reasonable competitor or one reasonably skilled in the art on notice that the patentee intended to so redefine

that claim term."); *Hormone Research Foundation Inc. v. Genentech Inc.*, 904 F.2d 1558, 15 USPQ2d 1039 (Fed. Cir. 1990). Accordingly, when there is more than one definition for a term, it is incumbent upon applicant to make clear which definition is being relied upon to claim the invention. Until the meaning of a term or phrase used in a claim is clear, a rejection under **35 U.S.C. 112**, second paragraph is appropriate. In applying the prior art, the claims should be construed to encompass all definitions that are consistent with applicant's use of the term. See *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202, 64 USPQ2d 1812, 1818 (Fed. Cir. 2002). It is appropriate to compare the meaning of terms given in technical dictionaries in order to ascertain the accepted meaning of a term in the art. *In re Barr*, 444 F.2d 588, 170 USPQ 330 (CCPA 1971). >See also MPEP § **2111.01**.<

2173.05(b) Relative Terminology [R-9]

The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under **35 U.S.C. 112**, second paragraph. *Seattle Box Co., Inc. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

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I. TERMS OF DEGREE

When a term of degree is used in the claim, the examiner should determine whether the specification provides some standard for measuring that degree. *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1367 (Fed. Cir. 2010); *Enzo Biochem, Inc., v. Applera Corp.*, 599 F.3d 1325, 1332 (Fed. Cir. 2010); *Seattle Box Co., Inc. v. Indus. Crating & Packing, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 1984). If the specification does not provide some standard for measuring that degree, a determination must be made as to whether one of ordinary skill in the art could nevertheless ascertain the scope of the claim (e.g., a standard that is recognized in the art for measuring the meaning of the term of degree). The claim is not indefinite if the specification provides examples or teachings that can be used to measure a degree even without a precise numerical measurement (e.g., a figure that provides a standard for measuring the meaning of the term of degree). See, e.g., *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1346 (Fed. Cir. 2007); *Exxon Research and Eng'g Co. v. United States*, 265 F.3d 1371, 1381 (Fed. Cir. 2001). During prosecution, an applicant may also overcome an indefiniteness rejection by submitting a declaration under 37 CFR 1.132 showing examples that meet the claim limitation and examples that do not. *Enzo Biochem*, 599 F.3d at 1335 (noting that applicant overcame an indefiniteness rejection over "not interfering substantially" claim language by submitting a declaration under 37 CFR 1.132 listing eight specific linkage groups that applicant declared did not substantially interfere with hybridization or detection).

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Even if the specification uses the same term of degree as in the claim, a rejection may be proper if the scope of the term is not understood when read in light of the specification. While, as a general proposition, broadening modifiers are standard tools in claim drafting in order to avoid reliance on the doctrine of equivalents in infringement actions, when the scope of the claim is unclear a rejection under **35 U.S.C. 112**, second paragraph, is proper. See *In re Wiggins*, 488 F. 2d 538, 541, 179 USPQ 421, 423 (CCPA 1973).

When relative terms are used in claims wherein the improvement over the prior art rests entirely upon size or weight of an element in a combination of elements, the adequacy of the disclosure of a standard is of greater criticality.

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II. REFERENCE TO AN OBJECT THAT IS VARIABLE MAY RENDER A CLAIM INDEFINITE

A claim may be rendered indefinite by reference to an object that is variable. For example, the Board has held that a limitation in a claim to a bicycle that recited "said front and rear wheels so spaced as to give a wheelbase that is between 58 percent and 75 percent of the height of the rider that the bicycle was designed for" was indefinite because the relationship of parts was not based on any known standard for sizing a bicycle to a rider, but on a rider of unspecified build. *Ex parte Brummer*, 12 USPQ2d 1653 (Bd. Pat. App. & Inter. 1989). On the other hand, a claim limitation specifying that a certain part of a pediatric wheelchair be "so dimensioned as to be insertable through the space between the doorframe of an automobile and one of the seats" was held to be definite. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986). The court stated that the phrase "so dimensioned" is as accurate as the subject matter permits, noting that the patent law does not require that all possible lengths corresponding to the spaces in hundreds of different automobiles be listed in the patent, let alone that they be listed in the claims.

A. "About"

In determining the range encompassed by the term "about", one must consider the context of the term as it is used in the specification and claims of the application. *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1326, 81 USPQ2d 1427, 1432 (Fed. Cir. 2007). In *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch. However, the court held that claims reciting "at least about" were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

B. "Essentially"

The phrase "a silicon dioxide source that is essentially free of alkali metal" was held to be definite because the specification contained guidelines and examples that were considered sufficient to enable a person of ordinary skill in the art to draw a line between unavoidable impurities in starting materials and essential ingredients. *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (CCPA 1983). The court further observed that it would be impractical to require applicants to specify a particular number as a cutoff between their invention and the prior art.

C. "Similar"

The term "similar" in the preamble of a claim that was directed to a nozzle "for high-pressure cleaning units or similar apparatus" was held to be indefinite since it was not clear what applicant intended to cover by the recitation "similar" apparatus. *Ex parte Kristensen*, 10 USPQ2d 1701 (Bd. Pat. App. & Inter. 1989).

A claim in a design patent application which read: "The ornamental design for a feed bunk or similar structure as shown and described." was held to be indefinite because it was unclear from the specification what applicant intended to cover by the recitation of "similar structure." *Ex parte Pappas*, 23 USPQ2d 1636 (Bd. Pat. App. & Inter. 1992).

D. "Substantially"

The term "substantially" is often used in conjunction with another term to describe a particular characteristic of the claimed invention. It is a broad term. *In re Nehrenberg*, 280 F.2d 161, 126 USPQ 383 (CCPA 1960). The court held that the limitation "to substantially increase the efficiency of the compound as a copper extractant" was definite in view of the general guidelines contained in the specification. *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). The court held that the limitation "which produces substantially equal E and H plane illumination patterns" was definite because one of ordinary skill in the art would know what was meant by "substantially equal." *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988).

E. "Type"

The addition of the word "type" to an otherwise definite expression (e.g., Friedel-Crafts catalyst) extends the scope of the expression so as to render it indefinite. *Ex parte Copenhaver*, 109 USPQ 118 (Bd. App. 1955). Likewise, the phrase "ZSM-5-type aluminosilicate zeolites" was held to be indefinite because it was unclear what "type" was intended to convey. The interpretation was made more difficult by the fact that the zeolites defined in the dependent claims were not within the genus of the type of zeolites defined in the independent claim. *Ex parte Attig*, 7 USPQ2d 1092 (Bd. Pat. App. & Inter. 1986).

F. Other Terms

The phrases "relatively shallow," "of the order of," "the order of about 5mm," and "substantial portion" were held to be indefinite because the specification lacked some standard for measuring the degree intended and, therefore, properly rejected as indefinite under **35 U.S.C. 112**, second paragraph. *Ex parte Oetiker*, 23 USPQ2d 1641 (Bd. Pat. App. & Inter. 1992).

The term "or like material" in the context of the limitation "coke, brick, or like material" was held to render the claim indefinite since it was not clear how the materials other than coke or brick had to resemble the two specified materials to satisfy the limitations of the claim. *Ex parte Caldwell*, 1906 C.D. 58 (Comm'r Pat. 1906).

The terms "comparable" and "superior" were held to be indefinite in the context of a limitation relating the characteristics of the claimed material to other materials - "properties that are superior to those obtained with

comparable" prior art materials. *Ex parte Anderson*, 21 USPQ2d 1241 (Bd. Pat. App. & Inter. 1991). It was not clear from the specification which properties had to be compared and how comparable the properties would have to be to determine infringement issues. Further, there was no guidance as to the meaning of the term "superior."

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III. SUBJECTIVE TERMS

When a subjective term is used in the claim, the examiner should determine whether the specification supplies some standard for measuring the scope of the term, similar to the analysis for a term of degree. Some objective standard must be provided in order to allow the public to determine the scope of the claim. A claim that requires the exercise of subjective judgment without restriction may render the claim indefinite. In re Musgrave, 431 F.2d 882, 893 (CCPA 1970). Claim scope cannot depend solely on the unrestrained, subjective opinion of a particular individual purported to be practicing the invention. *Datamize LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350, 75 USPQ2d 1801, 1807 (Fed. Cir. 2005).

For example, in *Datamize*, the invention was directed to a computer interface screen with an "aesthetically pleasing look and feel." *Datamize*, 417 F.3d at 1344-45. The meaning of the term "aesthetically pleasing" depended solely on the subjective opinion of the person selecting features to be included on the interface screen. Nothing in the intrinsic evidence (e.g., the specification) provided any guidance as to what design choices would result in an "aesthetically pleasing" look and feel. *Datamize*, 417 F.3d at 1352. The claims were held indefinite because the interface screen may be "aesthetically pleasing" to one user but not to another. *Datamize*, 417 F.3d at 1350.

During prosecution, the applicant may overcome a rejection by providing evidence that the meaning of the term can be ascertained by one of ordinary skill in the art when reading the disclosure, or by amending the claim to remove the subjective term.

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2173.05(c) Numerical Ranges and Amounts Limitations

Generally, the recitation of specific numerical ranges in a claim does not raise an issue of whether a claim is definite.

I. NARROW AND BROADER RANGES IN THE SAME CLAIM

Use of a narrow numerical range that falls within a broader range in the same claim may render the claim indefinite when the boundaries of the claim are not discernible. Description of examples and preferences is properly set forth in the specification rather than in a single claim. A narrower range or preferred embodiment may also be set forth in another independent claim or in a dependent claim. If stated in a single claim, examples and preferences lead to confusion over the intended scope of the claim. In those instances where it is not clear whether the claimed narrower range is a limitation, a rejection under **35 U.S.C. 112**, second paragraph should be made. The Examiner should analyze whether the metes and bounds of the claim are clearly set forth. Examples of claim language which have been held to be indefinite are (A) "a temperature of between 45 and 78 degrees Celsius, preferably between 50 and 60 degrees Celsius"; and (B) "a predetermined quantity, for example, the maximum capacity."

While a single claim that includes both a broad and a narrower range may be indefinite, it is not improper under 35 U.S.C. **112**, second paragraph, to present a dependent claim that sets forth a narrower range for an element than the range set forth in the claim from which it depends. For example, if claim 1 reads "A circuit … wherein the resistance is 70-150 ohms." and claim 2 reads "The circuit of claim 1 wherein the resistance is 70-100 ohms.", then claim 2 should not be rejected as indefinite.

II. OPEN-ENDED NUMERICAL RANGES

Open-ended numerical ranges should be carefully analyzed for definiteness. For example, when an independent claim recites a composition comprising "at least 20% sodium" and a dependent claim sets forth specific amounts of nonsodium ingredients which add up to 100%, apparently to the exclusion of sodium, an ambiguity is created with regard to the "at least" limitation (unless the percentages of the nonsodium ingredients are based on the weight of the nonsodium ingredients). On the other hand, the court held that a composition claimed to have a theoretical content greater than 100% (i.e., 20-80% of A, 20-80% of B and 1-25% of C) was not indefinite simply because the claims may be read in theory to include compositions that are impossible in fact to formulate. It was observed that subject matter which cannot exist in fact can neither anticipate nor infringe a claim. *In re Kroekel*, 504 F.2d 1143, 183 USPQ 610 (CCPA 1974).

In a claim directed to a chemical reaction process, a limitation required that the amount of one ingredient in the reaction mixture should "be maintained at less than 7 mole percent" based on the amount of another ingredient. The examiner argued that the claim was indefinite because the limitation sets only a maximum amount and is inclusive of substantially no ingredient resulting in termination of any reaction. The court did not agree because the claim was clearly directed to a reaction process which did not warrant distorting the overall meaning of the claim to preclude performing the claimed process. *In re Kirsch*, 498 F.2d 1389, 182 USPQ 286 (CCPA 1974).

Some terms have been determined to have the following meanings in the factual situations of the reported cases: the term "up to" includes zero as a lower limit, *In re Mochel*, 470 F.2d 638, 176 USPQ 194 (CCPA 1974); and "a moisture content of not more than 70% by weight" reads on dry material, *Ex parte Khusid*, 174 USPQ 59 (Bd. App. 1971).

III. "EFFECTIVE AMOUNT"

The common phrase "an effective amount" may or may not be indefinite. The proper test is whether or not one skilled in the art could determine specific values for the amount based on the disclosure. See *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). The phrase "an effective amount . . . for growth stimulation" was held to be definite where the amount was not critical and those skilled in the art would be able to determine from the written disclosure, including the examples, what an effective amount is. *In re Halleck*, 422 F.2d 911, 164 USPQ 647 (CCPA 1970). The phrase "an effective amount" has been held to be indefinite when the claim fails to state the function which is to be achieved and more than one effect can be implied from the specification or the relevant art. *In re Fredericksen* 213 F.2d 547, 102 USPQ 35 (CCPA 1954). The more recent cases have tended to accept a limitation such as "an effective amount" as being definite when read in light of the supporting disclosure and in the absence of any prior art which would give rise to uncertainty about the scope of the claim. In *Ex parte Skuballa*, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989), the Board held that a pharmaceutical composition claim which recited an "effective amount of a compound of claim 1" without stating the function to be achieved was definite, particularly when read in light of the supporting disclosure which provided guidelines as to the intended utilities and how the uses could be effected.

2173.05(d) Exemplary Claim Language ("for example," "such as") [R-1]

Description of examples or preferences is properly set forth in the specification rather than the claims. If stated in the claims, examples and preferences >may< lead to confusion over the intended scope of a claim. In those instances where it is not clear whether the claimed narrower range is a limitation, a rejection under **35 U.S.C. 112**, second paragraph should be made. The examiner should analyze whether the metes and bounds of the claim are clearly set forth. Examples of claim language which have been held to be indefinite because the intended scope of the claim was unclear are:

(A) "R is halogen, for example, chlorine";

(B) "material such as rock wool or asbestos" *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1949);

(C) "lighter hydrocarbons, such, for example, as the vapors or gas produced" *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949); and

(D) "normal operating conditions such as while in the container of a proportioner" *Ex parte Steigerwald*, 131 USPQ 74 (Bd. App. 1961).

>The above examples of claim language which have been held to be indefinite are fact specific and should not be applied as *per se* rules. See MPEP § **2173.02** for guidance regarding when it is appropriate to make a rejection under 35 U.S.C. **112**, second paragraph.<

2173.05(e) Lack of Antecedent Basis [R-5]

A claim is indefinite when it contains words or phrases whose meaning is unclear. The lack of clarity could arise where a claim refers to "said lever" or "the lever," where the claim contains no earlier recitation or limitation of a lever and where it would be unclear as to what element the limitation was making reference. Similarly, if two different levers are recited earlier in the claim, the recitation of "said lever" in the same or subsequent claim would be unclear where it is uncertain which of the two levers was intended. A claim which refers to "said aluminum lever," but recites only "a lever" earlier in the claim, is indefinite because it is uncertain as to the lever to which reference is made. Obviously, however, the failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite. > *Energizer Holdings Inc. v. Int'l Trade Comm'n, 435 F.3d 1366, 77 USPQ2d 1625 (Fed. Cir. 2006)(holding that "anode gel"*

provided by implication the antecedent basis for "zinc anode");< Ex parte Porter, 25 USPQ2d 1144, 1145 (Bd. Pat. App. & Inter. 1992) ("controlled stream of fluid" provided reasonable antecedent basis for "the controlled fluid"). Inherent components of elements recited have antecedent basis in the recitation of the components themselves. For example, the limitation "the outer surface of said sphere" would not require an antecedent recitation that the sphere has an outer surface. See *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354, 1359, 61 USPQ2d 1216, 1218-19 (Fed. Cir 2001) (holding that recitation of "an ellipse" provided antecedent basis for "an ellipse having a major diameter" because "[t]here can be no dispute that mathematically an inherent characteristic of an ellipse is a major diameter").

EXAMINER SHOULD SUGGEST CORRECTIONS TO ANTECEDENT PROBLEMS

Antecedent problems in the claims are typically drafting oversights that are easily corrected once they are brought to the attention of applicant. The examiner's task of making sure the claim language complies with the requirements of the statute should be carried out in a positive and constructive way, so that minor problems can be identified and easily corrected, and so that the major effort is expended on more substantive issues. However, even though indefiniteness in claim language is of semantic origin, it is not rendered unobjectionable simply because it could have been corrected. *In re Hammack*, 427 F.2d 1384 n.5, 166 USPQ 209 n.5 (CCPA 1970).

A CLAIM TERM WHICH HAS NO ANTECEDENT BASIS IN THE DISCLOSURE IS NOT NECESSARILY INDEFINITE

The mere fact that a term or phrase used in the claim has no antecedent basis in the specification disclosure does not mean, necessarily, that the term or phrase is indefinite. There is no requirement that the words in the claim must match those used in the specification disclosure. Applicants are given a great deal of latitude in how they choose to define their invention so long as the terms and phrases used define the invention with a reasonable degree of clarity and precision.

A CLAIM IS NOT PER SE INDEFINITE IF THE BODY OF THE CLAIM RECITES ADDITIONAL ELEMENTS WHICH DO NOT APPEAR IN THE PREAMBLE

The mere fact that the body of a claim recites additional elements which do not appear in the claim's preamble does not render the claim indefinite under **35 U.S.C. 112**, second paragraph. See *In re Larsen*, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished) (The preamble of the *Larsen* claim recited only a hanger and a loop but the body of the claim positively recited a linear member. The examiner rejected the claim under **35 U.S.C. 112**, second paragraph, because the omission from the claim's preamble of a critical element (i.e., a linear member) renders that claim indefinite. The court reversed the examiner's rejection and stated that the totality of all the limitations of the claim and their interaction with each other must be considered to ascertain the inventor's contribution to the art. Upon review of the claim in its entirety, the court concluded that the claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. **112**, paragraph 2.).

2173.05(f) Reference to Limitations in Another Claim

A claim which makes reference to a preceding claim to define a limitation is an acceptable claim construction which should not necessarily be rejected as improper or confusing under **35 U.S.C. 112**, second paragraph. For example, claims which read: "The product produced by the method of claim 1." or "A method of producing ethanol comprising contacting amylose with the culture of claim 1 under the following conditions ....." are not indefinite under **35 U.S.C. 112**, second paragraph, merely because of the reference to another claim. See also *Ex parte Porter*, 25 USPQ2d 1144 (Bd. Pat. App. & Inter. 1992) where reference to "the nozzle of claim 7" in a method claim was held to comply with **35 U.S.C. 112**, second paragraph. However, where the format of making reference to limitations recited in another claim results in confusion, then a rejection would be proper under **35 U.S.C. 112**, second paragraph.

2173.05(g) Functional Limitations [R-9]

>A claim term is functional when it recites a feature "by what it does rather than by what it is" (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 212, 169 USPQ 226, 229 (CCPA 1971). In fact, **35 U.S.C. 112, sixth paragraph, expressly authorizes a form of functional claiming (means-plus-function claim limitations discussed in **MPEP § 2181**) . Functional language may also be employed to limit the claims without using the means-plus-function format. See, e.g., *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1363 (Fed. Cir. 1999). Unlike means-plus-function claim language that applies

only to purely functional limitations, *Phillips v. AWH Corp*, 415 F.3d 1303, 1311 (Fed. Cir. 2005) (en banc) ("Means-plus-function claiming applies only to purely functional limitations that do not provide the structure that performs the recited function."), functional claiming often involves the recitation of some structure followed by its function. For example, in *In re Schreiber*, the claims were directed to a conical spout (the structure) that "allow[ed] several kernels of popped popcorn to pass through at the same time" (the function). *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997). As noted by the court in *Schreiber*, "[a] patent applicant is free to recite features of an apparatus either structurally or functionally." *Schreiber*, 128 F.3d at 1478. <

A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. In *Innova/Pure Water Inc. v. Safari Water Filtration Sys. Inc.*, 381 F.3d 1111, 1117-20, 72 USPQ2d 1001, 1006-08 (Fed. Cir. 2004), the court noted that the claim term "operatively connected" is "a general descriptive claim term frequently used in patent drafting to reflect a functional relationship between claimed components," that is, the term "means the claimed components must be connected in a way to perform a designated function." "In the absence of modifiers, general descriptive terms are typically construed as having their full meaning." *Id*. at 1118, 72 USPQ2d at 1006. In the patent claim at issue, "subject to any clear and unmistakable disavowal of claim scope, the term 'operatively connected' takes the full breath of its ordinary meaning, i.e., 'said tube [is] operatively connected to said cap' when the tube and cap are arranged in a manner capable of performing the function of filtering." *Id.* at 1120, 72 USPQ2d at 1008.

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Notwithstanding the permissible instances, the use of functional language in a claim may fail "to provide a clear-cut indication of the scope of the subject matter embraced by the claim" and thus be indefinite. *In re Swinehart*, 439 F.2d 210, 213 (CCPA 1971). For example, when claims merely recite a description of a problem to be solved or a function or result achieved by the invention, the boundaries of the claim scope may be unclear. *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1255 (Fed. Cir. 2008) (noting that the Supreme Court explained that a vice of functional claiming occurs "when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty") (quoting *General Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 371 (1938)); see also *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 234 (1942) (holding indefinite claims that recited substantially pure carbon black "in the form of commercially uniform, comparatively small, rounded smooth aggregates having a spongy or porous exterior"). Further, without reciting the particular structure, materials or steps that accomplish the function or achieve the result, all means or methods of resolving the problem may be encompassed by the claim. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc). Unlimited functional claim limitations that extend to all means or methods of resolving a problem may not be adequately supported by the written description or may not be commensurate in scope with the enabling disclosure, both of which are required by **35 U.S.C. 112**, first paragraph. *In re Hyatt*, 708 F.2d 712, 714 (Fed. Cir. 1983); *Ariad*, 598 F.3d at 1340. For instance, a single means claim covering every conceivable means for achieving the stated result was held to be invalid under **35 U.S.C. 112**, first paragraph because the court recognized that the specification, which disclosed only those means known to the inventor, was not commensurate in scope with the claim. *Hyatt*, 708 F.2d at 714-715. For more information regarding the written description requirement and enablement requirement under **35 U.S.C. 112**, first paragraph, see MPEP §§ 2161-2164.08(c).

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Whether or not the functional limitation complies with **35 U.S.C. 112**, second paragraph, is a different issue from whether the limitation is properly supported under **35 U.S.C. 112**, first paragraph, or is distinguished over the prior art. A few examples are set forth below to illustrate situations where the issue of whether a functional limitation complies with **35 U.S.C. 112**, second paragraph, was considered.

It was held that the limitation used to define a radical on a chemical compound as "incapable of forming a dye with said oxidizing developing agent" although functional, was perfectly acceptable because it set definite boundaries on the patent protection sought. *In re Barr*, 444 F.2d 588, 170 USPQ *>330<(CCPA 1971).

In a claim that was directed to a kit of component parts capable of being assembled, the Court held that limitations such as "members adapted to be positioned" and "portions . . . being resiliently dilatable whereby said housing may be slidably positioned" serve to precisely define present structural attributes of interrelated component parts of the claimed assembly. *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976).

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When a claim limitation employs functional language, the examiner's determination of whether the limitation is sufficiently definite will be highly dependent on context (e.g., the disclosure in the specification and the knowledge of a person of ordinary skill in the art). *Halliburton Energy Servs.*, 514 F.3d at 1255. For example, a claim that included the term "fragile gel" was found to be indefinite because the definition of the term in the specification was functional, i.e., the fluid is defined by what it does rather than what it is ("ability of the fluid to transition quickly from gel to liquid, and the ability of the fluid to suspend drill cuttings at rest"), and it was ambiguous as to the requisite degree of the fragileness of the gel, the ability of the gel to suspend drill cuttings (i.e., gel strength), and/or some combination of the two. *Halliburton Energy Servs*., 514 F.3d at 1255-56. In another example, the claims directed to a tungsten filament for electric incandescent lamps were held invalid for including a limitation that recited "comparatively large grains of such size and contour as to prevent substantial sagging or offsetting during a normal or commercially useful life for such a lamp or other device." *General Elec. Co.*, 304 U.S. at 370-71, 375. The Court observed that the prior art filaments also "consisted of comparatively large crystals" but they were "subject to offsetting" or shifting, and the court further found that the phrase "of such size and contour as to prevent substantial sagging and offsetting during a normal or commercially useful life for a lamp or other device" did not adequately define the structural characteristics of the grains (e.g., the size and contour) to distinguish the claimed invention from the prior art. *General Elec. Co.*, 304 U.S. at 370. Similarly, a claim was held invalid because it recited "sustantially (sic) pure carbon black in the form of commercially uniform, comparatively small, rounded smooth aggregates having a spongy or porous exterior." *United Carbon Co.*, 317 U.S. at 234. In the latter example, the Court observed various problems with the limitation: "commercially uniform" meant only the degree of uniformity buyers desired; "comparatively small" did not add anything because no standard for comparison was given; and "spongy" and "porous" are synonyms that the Court found unhelpful in distinguishing the claimed invention from the prior art. *United Carbon Co.*, 317 U.S. at 233.

In comparison, a claim limitation reciting "transparent to infrared rays" was held to be definite because the specification showed that a substantial amount of infrared radiation was always transmitted even though the degree of transparency varied depending on certain factors. *Swinehart*, 439 F.2d at 214. Likewise, the claims in another case were held definite because applicant provided "a general guideline and examples sufficient to enable a person of ordinary skill in the art to determine whether a process uses a silicon dioxide source 'essentially free of alkali metal' to make a reaction mixture 'essentially free of alkali metal' to produce a zeolitic compound 'essentially free of alkali metal.'" *In re Marosi*, 710 F.2d 799, 803 (Fed. Cir. 1983).

Examiners should consider the following factors when examining claims that contain functional language to determine whether the language is ambiguous: (1) whether there is a clear cut indication of the scope of the subject matter covered by the claim; (2) whether the language sets forth well-defined boundaries of the invention or only states a problem solved or a result obtained; and (3) whether one of ordinary skill in the art would know from the claim terms what structure or steps are encompassed by the claim. These factors are examples of points to be considered when determining whether language is ambiguous and are not intended to be all inclusive or limiting. Other factors may be more relevant for particular arts. The primary inquiry is whether the language leaves room for ambiguity or whether the boundaries are clear and precise.

During prosecution, applicant may resolve the ambiguities of a functional limitation in a number of ways. For example: (1) "the ambiguity might be resolved by using a quantitative metric (e.g., numeric limitation as to a physical property) rather than a qualitative functional feature" (see *Halliburton Energy Servs.*, 514 F.3d at 1255-56); (2) applicant could demonstrate that the "specification provide[s] a formula for calculating a property along with examples that meet the claim limitation and examples that do not" (see *Halliburton Energy Servs.*, at 1256 (citing *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1341 (Fed. Cir. 2003))); (3) applicant could demonstrate that the specification provides a general guideline and examples sufficient to teach a person skilled in the art when the claim limitation was satisfied (see Marosi, 710 F.2d at 803); or (4) applicant could amend the claims to recite the particular structure that accomplishes the function.

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2173.05(h) Alternative Limitations [R-9]

I. MARKUSH GROUPS

Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. **> A "Markush" claim recites a list of alternatively useable species. *In re Harnisch*, 631 F.2d 716, 719-20 (CCPA 1980); *Ex parte Markush*, 1925 Dec. Comm'r Pat. 126, 127 (1924). A

Markush claim is commonly formatted as: "selected from the group consisting of A, B, and C;" however, the phrase "Markush claim" means any claim that recites a list of alternatively useable species regardless of format. <

Ex parte Markush sanctions claiming a genus expressed as a group consisting of certain specified materials. Inventions in metallurgy, refractories, ceramics, pharmacy, pharmacology and biology are most frequently claimed under the Markush formula but purely mechanical features or process steps may also be claimed by using the Markush style of claiming. See *Ex parte Head*, 214 USPQ 551 (Bd. App. 1981); *In re Gaubert*, 524 F.2d 1222, 187 USPQ 664 (CCPA 1975); * *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980). It is improper to use the term "comprising" instead of "consisting of." *Ex parte Dotter*, 12 USPQ 382 (Bd. App. 1931).

The use of Markush claims of diminishing scope should not, in itself, be considered a sufficient basis for objection to or rejection of claims. However, if such a practice renders the claims indefinite or if it results in undue multiplicity, an appropriate rejection should be made.

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A Markush claim may encompass a large number of alternative species, but is not necessarily indefinite under **35 U.S.C. 112**, second paragraph for such breadth. In re Gardner, 427 F.2d 786, 788 (CCPA 1970) ("Breadth is not indefiniteness."). In certain circumstances, however, a Markush group may be so expansive that persons skilled in the art cannot determine the metes and bounds of the claimed invention. For example, a Markush group that encompasses a massive number of distinct alternative species may be indefinite under **35 U.S.C. 112**, second paragraph if one skilled in the art cannot determine the metes and bounds of the claim due to an inability to envision all of the members of the Markush group. In such a circumstance, an examiner may reject the claim for indefiniteness under **35 U.S.C. 112**, second paragraph.

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Similarly, the double inclusion of an element by members of a Markush group is not, in itself, sufficient basis for objection to or rejection of claims. Rather, the facts in each case must be evaluated to determine whether or not the multiple inclusion of one or more elements in a claim renders that claim indefinite. The mere fact that a compound may be embraced by more than one member of a Markush group recited in the claim does not necessarily render the scope of the claim unclear. For example, the Markush group, "selected from the group consisting of amino, halogen, nitro, chloro and alkyl" should be acceptable even though "halogen" is generic to "chloro."

The materials set forth in the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. However, when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property. While in the past the test for Markush-type claims was applied as liberally as possible, present practice which holds that claims reciting Markush groups are not generic claims (**MPEP § 803**) may subject the groups to a more stringent test for propriety of the recited members. Where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by a consideration of the compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression.

When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if "wherein R is a material selected from the group consisting of A, B, C and D" is a proper limitation, then "wherein R is A, B, C or D" shall also be considered proper.

Subgenus Claim

Genus, subgenus, and Markush-type claims, if properly supported by the disclosure, are all acceptable ways for applicants to claim their inventions. They provide different ways to present claims of different scope. Examiners should therefore not reject Markush-type claims merely because there are genus claims that encompass the Markush-type claims.

See also **MPEP § 608.01(p)** and **§ 715.03**.

See **MPEP § 803.02** for restriction practice re Markush-type claims.

II. "OR" TERMINOLOGY

Alternative expressions using "or" are acceptable, such as "wherein R is A, B, C, or D." The following phrases were each held to be acceptable and not in violation of **35 U.S.C. 112**, second paragraph in *In re Gaubert*, 524 F.2d 1222, 187 USPQ 664 (CCPA 1975): "made entirely or in part of"; "at least one piece"; and "iron, steel or any other magnetic material."

III. "OPTIONALLY"

An alternative format which requires some analysis before concluding whether or not the language is indefinite involves the use of the term "optionally." In *Ex parte Cordova*, 10 USPQ2d 1949 (Bd. Pat. App. & Inter. 1989) the language "containing A, B, and optionally C" was considered acceptable alternative language because there was no ambiguity as to which alternatives are covered by the claim. A similar holding was reached with regard to the term "optionally" in *Ex parte Wu*, 10 USPQ2d 2031 (Bd. Pat. App. & Inter. 1989). In the instance where the list of potential alternatives can vary and ambiguity arises, then it is proper to make a rejection under **35 U.S.C. 112**, second paragraph, and explain why there is confusion.

2173.05(i) Negative Limitations

The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of **35 U.S.C. 112**, second paragraph. Some older cases were critical of negative limitations because they tended to define the invention in terms of what it was not, rather than pointing out the invention. Thus, the court observed that the limitation "R is an alkenyl radical other than 2-butenyl and 2,4-pentadienyl" was a negative limitation that rendered the claim indefinite because it was an attempt to claim the invention by excluding what the inventors did not invent rather than distinctly and particularly pointing out what they did invent. *In re Schechter*, 205 F.2d 185, 98 USPQ 144 (CCPA 1953).

A claim which recited the limitation "said homopolymer being free from the proteins, soaps, resins, and sugars present in natural Hevea rubber" in order to exclude the characteristics of the prior art product, was considered definite because each recited limitation was definite. *In re Wakefield*, 422 F.2d 897, 899, 904, 164 USPQ 636, 638, 641 (CCPA 1970). In addition, the court found that the negative limitation "incapable of forming a dye with said oxidized developing agent" was definite because the boundaries of the patent protection sought were clear. *In re Barr*, 444 F.2d 588, 170 USPQ 330 (CCPA 1971).

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under **35 U.S.C. 112**, first paragraph, as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support. *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993). See **MPEP § 2163** - **§ 2163.07(b)** for a discussion of the written description requirement of **35 U.S.C. 112**, first paragraph.

2173.05(j) Old Combination [R-6]

A CLAIM SHOULD NOT BE REJECTED ON THE GROUND OF OLD COMBINATION

With the passage of the 1952 Patent Act, the courts and the Board have taken the view that a rejection based on the principle of old combination is NO LONGER VALID. Claims should be considered proper so long as they comply with the provisions of **35 U.S.C. 112**, second paragraph.

A rejection on the basis of old combination was based on the principle applied in *Lincoln Engineering Co. v. Stewart-Warner Corp.*, 303 U.S. 545, 37 USPQ 1 (1938). The principle was that an inventor who made an improvement or contribution to but one element of a generally old combination, should not be able to obtain a patent on the entire combination including the new and improved element. A rejection required the citation of a single reference which broadly disclosed a combination of the claimed elements functionally cooperating in substantially the same manner to produce substantially the same results as that of the claimed combination. The case of *In re Hall*, 208 F.2d 370, 100 USPQ 46 (CCPA 1953) illustrates an application of this principle.

The court pointed out in *In re *>Bernhart<*, 417 F.2d 1395, 163 USPQ 611 (CCPA 1969) that the statutory language (particularly point out and distinctly claim) is the only proper basis for an old combination rejection, and in applying the rejection, that language determines what an applicant has a right and obligation to do. A majority opinion of the Board of Appeals held that Congress removed the underlying rationale of *Lincoln Engineering* in the 1952 Patent Act, and thereby effectively legislated that decision out of existence. *Ex parte Barber*, 187 USPQ 244 (Bd. App. 1974). Finally,

the Court of Appeals for the Federal Circuit, in *Radio Steel and Mfg. Co. v. MTD Products, Inc.*, 731 F.2d 840, 221 USPQ 657 (Fed. Cir. 1984), followed the *>*Bernhart*< case, and ruled that a claim was not invalid under *Lincoln Engineering* because the claim complied with the requirements of **35 U.S.C. 112**, second paragraph. Accordingly, a claim should not be rejected on the ground of old combination.

2173.05(k) Aggregation [R-1]

>A claim should not be rejected on the ground of "aggregation." *In re Gustafson*, 331 F.2d 905, 141 USPQ 585 (CCPA 1964) (an applicant is entitled to know whether the claims are being rejected under 35 U.S.C. **101, **102**, **103**, or **112**); *In re Collier*, 397 F.2d 1003, 1006, 158 USPQ 266, 268 (CCPA 1968) ("[A] rejection for 'aggregation' is non-statutory.").

If a claim omits essential matter or fails to interrelate essential elements of the invention as defined by applicant(s) in the specification, see MPEP § **2172.01**.<

2173.05(m) Prolix

Examiners should reject claims as prolix only when they contain such long recitations or unimportant details that the scope of the claimed invention is rendered indefinite thereby. Claims are rejected as prolix when they contain long recitations that the metes and bounds of the claimed subject matter cannot be determined.

2173.05(n) Multiplicity [R-2]

37 CFR 1.75 Claim(s).

(a) The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery.

(b) More than one claim may be presented provided they differ substantially from each other and are not unduly multiplied.

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Where, in view of the nature and scope of applicant's invention, applicant presents an unreasonable number of claims which ** are repetitious and multiplied, the net result of which is to confuse rather than to clarify, a rejection on undue multiplicity based on 35 U.S.C. **112**, second paragraph, may be appropriate. As noted by the court in *In re Chandler*, 319 F.2d 211, 225, 138 USPQ 138, 148 (CCPA 1963), "applicants should be allowed reasonable latitude in stating their claims in regard to number and phraseology employed. The right of applicants to freedom of choice in selecting phraseology which truly points out and defines their inventions should not be abridged. Such latitude, however, should not be extended to sanction that degree of repetition and multiplicity which beclouds definition in a maze of confusion. The rule of reason should be practiced and applied on the basis of the relevant facts and circumstances in each individual case." See also *In re Flint*, 411 F.2d 1353, 1357, 162 USPQ 228, 231 (CCPA 1969). Undue multiplicity rejections based on 35 U.S.C. **112**, second paragraph, should be applied judiciously and should be rare.

If an undue multiplicity rejection under 35 U.S.C. **112**, second paragraph, is appropriate, the examiner should contact applicant by telephone explaining that the claims are unduly multiplied and will be rejected under 35 U.S.C. **112**, second paragraph. Note MPEP § **408**. The examiner should also request that applicant select a specified number of claims for purpose of examination. If applicant is willing to select, by telephone, the claims for examination, an undue multiplicity rejection on all the claims based on 35 U.S.C. **112**, second paragraph, should be made in the next Office action along with an action on the merits on the selected claims. If applicant refuses to comply with the telephone request, an undue multiplicity rejection of all the claims based on 35 U.S.C. **112**, second paragraph, should be made in the next Office action. Applicant's reply must include a selection of claims for purpose of examination, the number of which may not be greater than the number specified by the examiner. In response to applicant's reply, if the examiner adheres to the undue multiplicity rejection, it should be repeated and the selected claims will be examined on the merits. This procedure preserves applicant's right to have the rejection on undue multiplicity reviewed by the Board of Patent Appeals and Interferences.

Also, it is possible to reject one claim on an allowed claim if they differ only by subject matter old in the art. This ground of rejection is set forth in *Ex parte Whitelaw*, 1915 C.D. 18, 219 O.G. 1237 (Comm'r Pat. 1914). The *Ex parte Whitelaw* doctrine is restricted to cases where the claims are unduly multiplied or are substantial duplicates. *Ex parte Kochan*, 131 USPQ 204, 206 (Bd. App. 1961).

2173.05(o) Double Inclusion

There is no *per se* rule that "double inclusion" is improper in a claim. *In re Kelly*, 305 F.2d 909, 916, 134 USPQ 397, 402 (CCPA 1962) ("Automatic reliance upon a 'rule against double inclusion' will lead to as many unreasonable interpretations as will automatic reliance upon a 'rule allowing double inclusion'. The governing

consideration is not *double inclusion*, but rather is what is a reasonable construction of the language of the claims."). Older cases, such as *Ex parte White*, 759 O.G. 783 (Bd. App. 1958) and *Ex parte Clark*, 174 USPQ 40 (Bd. App. 1971) should be applied with care, according to the facts of each case.

The facts in each case must be evaluated to determine whether or not the multiple inclusion of one or more elements in a claim gives rise to indefiniteness in that claim. The mere fact that a compound may be embraced by more than one member of a Markush group recited in the claim does not lead to any uncertainty as to the scope of that claim for either examination or infringement purposes. On the other hand, where a claim directed to a device can be read to include the same element twice, the claim may be indefinite. *Ex parte Kristensen*, 10 USPQ2d 1701 (Bd. Pat. App. & Inter. 1989).

2173.05(p) Claim Directed to Product-By- Process or Product and Process [R-9]

There are many situations where claims are permissively drafted to include a reference to more than one statutory class of invention.

I. PRODUCT-BY-PROCESS

A product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper. *In re Luck*, 476 F.2d 650, 177 USPQ 523 (CCPA 1973); *In re Pilkington*, 411 F.2d 1345, 162 USPQ 145 (CCPA 1969); *In re Steppan*, 394 F.2d 1013, 156 USPQ 143 (CCPA 1967). A claim to a device, apparatus, manufacture, or composition of matter may contain a reference to the process in which it is intended to be used without being objectionable under **35 U.S.C. 112**, second paragraph, so long as it is clear that the claim is directed to the product and not the process.

An applicant may present claims of varying scope even if it is necessary to describe the claimed product in product-by-process terms. *Ex parte Pantzer*, 176 USPQ 141 (Bd. App. 1972).

II. PRODUCT AND PROCESS IN THE SAME CLAIM

A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under **35 U.S.C. 112**, second paragraph. **>See *In re Katz Interactive Call Processing Patent Litigation*, 639 F.3d 1303 (Fed. Cir. 2011). In *Katz*, a claim directed to "A system with an interface means for providing automated voice messages…to certain of said individual callers, *wherein said certain of said individual callers digitally enter data*" was determined to be indefinite because the italicized claim limitation is not directed to the system, but rather to actions of the individual callers, which creates confusion as to when direct infringement occurs. *In re Katz*, 639 F.3d at 1318 (citing *IPXL Holdings v. Amazon.com, Inc.*, 430 F.2d 1377, 1384, 77 USPQ2d 1140, 1145 (Fed. Cir. 2005), in which a system claim that recited "an input means" and required a user to use the input means was found to be indefinite because it was unclear "whether infringement … occurs when one creates a system that allows the user [to use the input means], or whether infringement occurs when the user actually uses the input means.");< *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990) (claim directed to an automatic transmission workstand and the method of using it held ambiguous and properly rejected under **35 U.S.C. 112**, second paragraph).

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2173.05(q) "Use" Claims

Attempts to claim a process without setting forth any steps involved in the process generally raises an issue of indefiniteness under **35 U.S.C. 112**, second paragraph. For example, a claim which read: "A process for using monoclonal antibodies of claim 4 to isolate and purify human fibroblast interferon." was held to be indefinite because it merely recites a use without any active, positive steps delimiting how this use is actually practiced. *Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986).

Other decisions suggest that a more appropriate basis for this type of rejection is **35 U.S.C. 101**. In *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967), the Board held the following claim to be an improper definition of a process: "The use of a high carbon austenitic iron alloy having a proportion of free carbon as a vehicle brake part subject to stress by sliding friction." In *Clinical Products Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966), the district court held the following claim was definite, but that it was not a proper process claim under **35 U.S.C. 101**: "The use of a sustained release therapeutic agent in the body of ephedrine absorbed upon polystyrene sulfonic acid."

Although a claim should be interpreted in light of the specification disclosure, it is generally considered improper to read limitations contained in the specification into the claims. See *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969) and *In re Winkhaus*, 527 F.2d 637, 188 USPQ 129 (CCPA 1975), which discuss the

premise that one cannot rely on the specification to impart limitations to the claim that are not recited in the claim.

A "USE" CLAIM SHOULD BE REJECTED UNDER ALTERNATIVE GROUNDS BASED ON 35 U.S.C 101 AND 112

In view of the split of authority as discussed above, the most appropriate course of action would be to reject a "use" claim under alternative grounds based on **35 U.S.C. 101** and 112.

BOARD HELD STEP OF "UTILIZING" WAS NOT INDEFINITE

It is often difficult to draw a fine line between what is permissible, and what is objectionable from the perspective of whether a claim is definite. In the case of *Ex parte Porter*, 25 USPQ2d 1144 (Bd. Pat. App. & Inter. 1992), the Board held that a claim which clearly recited the step of "utilizing" was not indefinite under **35 U.S.C. 112**, second paragraph. (Claim was to "A method for unloading nonpacked, nonbridging and packed, bridging flowable particle catalyst and bead material from the opened end of a reactor tube which comprises utilizing the nozzle of claim 7.").

2173.05(r) Omnibus Claim

Some applications are filed with an omnibus claim which reads as follows: A device substantially as shown and described. This claim should be rejected under **35 U.S.C. 112**, second paragraph, because it is indefinite in that it fails to point out what is included or excluded by the claim language. See *Ex parte Fressola*, 27 USPQ2d 1608 (Bd. Pat. App. & Inter. 1993), for a discussion of the history of omnibus claims and an explanation of why omnibus claims do not comply with the requirements of **35 U.S.C. 112**, second paragraph.

Such a claim can be rejected using Form Paragraph 7.35. See **MPEP § 706.03(d)**.

For cancellation of such a claim by examiner's amendment, see **MPEP § 1302.04(b)**.

2173.05(s) Reference to Figures or Tables

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the recitation of the same element or group of elements in the claims. See **MPEP § 608.01(m)**.

2173.05(t) Chemical Formula

Claims to chemical compounds and compositions containing chemical compounds often use formulas that depict the chemical structure of the compound. These structures should not be considered indefinite nor speculative in the absence of evidence that the assigned formula is in error. The absence of corroborating spectroscopic or other data cannot be the basis for finding the structure indefinite. See *Ex parte Morton*, 134 USPQ 407 (Bd. App. 1961), and *Ex parte Sobin*, 139 USPQ 528 (Bd. App. 1962).

A claim to a chemical compound is not indefinite merely because a structure is not presented or because a partial structure is presented. For example, the claim language at issue in *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) referred to a chemical compound as a "polypeptide of at least 24 amino acids having the following sequence." A rejection under **35 U.S.C. 112**, second paragraph, for failure to identify the entire structure was reversed and the court held: "While the absence of such a limitation obviously broadens the claim and raises questions of sufficiency of disclosure, it does not render the claim indefinite." Chemical compounds may be claimed by a name that adequately describes the material to one skilled in the art. See *Martin v. Johnson*, 454 F.2d 746, 172 USPQ 391 (CCPA 1972). A compound of unknown structure may be claimed by a combination of physical and chemical characteristics. See *Ex parte Brian*, 118 USPQ 242 (Bd. App. 1958). A compound may also be claimed in terms of the process by which it is made without raising an issue of indefiniteness.

2173.05(u) Trademarks or Trade Names in a Claim

The presence of a trademark or trade name in a claim is not, *per se*, improper under **35 U.S.C. 112**, second paragraph, but the claim should be carefully analyzed to determine how the mark or name is used in the claim. It is important to recognize that a trademark or trade name is used to identify a source of goods, and not the goods

themselves. Thus a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. See definitions of trademark and trade name in **MPEP § 608.01(v)**. A list of some trademarks is found in Appendix I.

If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the **35 U.S.C. 112**, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name.

If a trademark or trade name appears in a claim and is not intended as a limitation in the claim, the question of why it is in the claim should be addressed. Does its presence in the claim cause confusion as to the scope of the claim? If so, the claim should be rejected under **35 U.S.C. 112**, second paragraph.

2173.05(v) Mere Function of Machine

Process or method claims are not subject to rejection by U.S. Patent and Trademark Office examiners under **35 U.S.C. 112**, second paragraph, solely on the ground that they define the inherent function of a disclosed machine or apparatus. *In re Tarczy-Hornoch*, 397 F.2d 856, 158 USPQ 141 (CCPA 1968). The court in *Tarczy-Hornoch* held that a process claim, otherwise patentable, should not be rejected merely because the application of which it is part discloses apparatus which will inherently carry out the recited steps.

2173.06 **>Practice Compact Prosecution < [R-9]

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I. INTERPRET THE CLAIM AND APPLY ART WITH AN EXPLANATION OF HOW AN INDEFINITE TERM IS INTERPRETED

The goal of examination is to clearly articulate any rejection early in the prosecution process so that the applicant has the chance to provide evidence of patentability and otherwise reply completely at the earliest opportunity. See MPEP § 706. Under the principles of compact prosecution, the examiner should review each claim for compliance with every statutory requirement for patentability in the initial review of the application and identify all of the applicable grounds of rejection in the first Office action to avoid unnecessary delays in the prosecution of the application. See 37 CFR 1.104(a)(1) ("On taking up an application for examination or a patent in a reexamination proceeding, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention. The examination shall be complete with respect both to compliance of the application . . . with the applicable statutes and rules and to the patentability of the invention as claimed, as well as with respect to matters of form, unless otherwise indicated.").

Thus, when the examiner determines that a claim term or phrase renders the claim indefinite, the examiner should make a rejection based on indefiniteness under **35 U.S.C. 112**, second paragraph, as well as a rejection(s) in view of the prior art under 35 U.S.C. 102 or 103 that renders the prior art applicable based on the examiner's interpretation of the claim. When making a rejection over prior art in these circumstances, it is important that the **examiner state on the record how the claim term or phrase is being interpreted** with respect to the prior art applied in the rejection. By rejecting each claim on all reasonable grounds available, the examiner can avoid piecemeal examination. See MPEP § 707.07(g) ("Piecemeal examination should be avoided as much as possible. The examiner ordinarily should reject each claim on all valid grounds available . . . .").

II. PRIOR ART REJECTION OF CLAIM REJECTED AS INDEFINITE

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All words in a claim must be considered in judging the patentability of a claim against the prior art. *In re Wilson*, 424 F.2d 1382, 165 USPQ 494 (CCPA 1970). The fact that terms may be indefinite does not make the claim obvious over the prior art. When the terms of a claim are considered to be indefinite, at least two approaches to the examination of an indefinite claim relative to the prior art are possible.

First, where the degree of uncertainty is not great, and where the claim is subject to more than one interpretation and at least one interpretation would render the claim unpatentable over the prior art, an appropriate course of action would be for the examiner to enter two rejections: (A) a rejection based on indefiniteness under **35 U.S.C. 112**, second paragraph; and (B) a rejection over the prior art based on the interpretation of the claims which renders

the prior art applicable. See, e.g., *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984). When making a rejection over prior art in these circumstances, it is important for the examiner to point out how the claim is being interpreted. Second, where there is a great deal of confusion and uncertainty as to the proper interpretation of the limitations of a claim, it would not be proper to reject such a claim on the basis of prior art. As stated in *In re Steele*, 305 F.2d 859, 134 USPQ 292 (CCPA 1962), a rejection under **35 U.S.C. 103** should not be based on considerable speculation about the meaning of terms employed in a claim or assumptions that must be made as to the scope of the claims.

The first approach is recommended from an examination standpoint because it avoids piecemeal examination in the event that the examiner's **35 U.S.C. 112**, second paragraph rejection is not affirmed, and may give applicant a better appreciation for relevant prior art if the claims are redrafted to avoid the **35 U.S.C. 112**, second paragraph rejection.

2174 Relationship Between the Requirements of the First and Second Paragraphs of 35 U.S.C. 112

The requirements of the first and second paragraphs of **35 U.S.C. 112** are separate and distinct. If a description or the enabling disclosure of a specification is not commensurate in scope with the subject matter encompassed by a claim, that fact alone does not render the claim imprecise or indefinite or otherwise not in compliance with **35 U.S.C. 112**, second paragraph; rather, the claim is based on an insufficient disclosure (**35 U.S.C. 112**, first paragraph) and should be rejected on that ground. *In re Borkowski*, 422 F.2d 904, 164 USPQ 642 (CCPA 1970). If the specification discloses that a particular feature or element is critical or essential to the practice of the invention, failure to recite or include that particular feature or element in the claims may provide a basis for a rejection based on the ground that those claims are not supported by an enabling disclosure. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). In *Mayhew*, the examiner argued that the only mode of operation of the process disclosed in the specification involved the use of a cooling zone at a particular location in the processing cycle. The claims were rejected because they failed to specify either a cooling step or the location of the step in the process. The court was convinced that the cooling bath and its location were essential, and held that claims which failed to recite the use of a cooling zone, specifically located, were not supported by an enabling disclosure (**35 U.S.C. 112**, first paragraph).

In addition, if a claim is amended to include an invention that is not described in the application as filed, a rejection of that claim under **35 U.S.C. 112**, first paragraph, as being directed to subject matter that is not described in the specification as filed may be appropriate. *In re Simon*, 302 F.2d 737, 133 USPQ 524 (CCPA 1962). In *Simon*, which involved a reissue application containing claims to a reaction product of a composition, applicant presented claims to a reaction product of a composition comprising the subcombination A+B+C, whereas the original claims and description of the invention were directed to a composition comprising the combination A+B+C+D+E. The court found no significant support for the argument that ingredients D+E were not essential to the claimed reaction product and concluded that claims directed to the reaction product of a subcombination A+B+C were not described (**35 U.S.C. 112**, first paragraph) in the application as filed. See also *In re Panagrossi*, 277 F.2d 181, 125 USPQ 410 (CCPA 1960).

2181 Identifying a 35 U.S.C. 112, Sixth Paragraph Limitation [R-9]

This section sets forth guidelines for the examination of **35 U.S.C. 112**, sixth paragraph, "means or step plus function" limitations in a claim. These guidelines are based on the Office's current understanding of the law and are believed to be fully consistent with binding precedent of the Supreme Court, the Federal Circuit and the Federal Circuit's predecessor courts. These guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law.

The Court of Appeals for the Federal Circuit, in its *en banc* decision *In re Donaldson Co.*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994), decided that a "means-or-step-plus-function" limitation should be interpreted in a manner different than patent examining practice had previously dictated. The *Donaldson* decision affects only the manner in which the scope of a "means or step plus function" limitation in accordance with **35 U.S.C. 112**, sixth paragraph, is interpreted during examination. *Donaldson* does not directly affect the manner in which any other section of the patent statutes is interpreted or applied.

When making a determination of patentability under **35 U.S.C. 102** or **103**, past practice was to interpret a "means or step plus function" limitation by giving it the "broadest reasonable interpretation." Under the PTO's long-standing practice this meant interpreting such a limitation as reading on any prior art means or step which performed the function specified in the claim without regard for whether the prior art means or step was equivalent to the corresponding structure, material or acts

described in the specification. However, in *Donaldson*, the Federal Circuit stated:

> Per our holding, the "broadest reasonable interpretation" that an examiner may give means-plus-function language is that statutorily mandated in paragraph six. Accordingly, the PTO may not disregard the structure disclosed in the specification corresponding to such language when rendering a patentability determination.

I. **>DETERMINING WHETHER A CLAIM LIMITATION INVOKES< 35 U.S.C. 112, SIXTH PARAGRAPH

The USPTO must apply 35 U.S.C. **112**, sixth paragraph in appropriate cases, and give claims their broadest reasonable interpretation, in light of and consistent with the written description of the invention in the application. See *Donaldson*, 16 F.3d at 1194, 29 USPQ2d at 1850 (stating that 35 U.S.C. **112**, sixth paragraph "merely sets a limit on how broadly the PTO may construe means-plus-function language under the rubric of reasonable interpretation.'"). The Federal Circuit has held that applicants (and reexamination patentees) before the USPTO have the opportunity and the obligation to define their inventions precisely during proceedings before the PTO. See *In re Morris*, 127 F.3d 1048, 1056–57, 44 USPQ2d 1023, 1029–30 (Fed. Cir. 1997) (35 U.S.C. **112**, second paragraph places the burden of precise claim drafting on the applicant); *In re Zletz*, 893 F.2d 319, 322, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (manner of claim interpretation that is used by courts in litigation is not the manner of claim interpretation that is applicable during prosecution of a pending application before the PTO); *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1425, 44 USPQ2d 1103, 1107 (Fed. Cir. 1997) (patentee who had a clear opportunity to negotiate broader claims during prosecution but did not do so, may not seek to expand the claims through the doctrine of equivalents, for it is the patentee, not the public, who must bear the cost of failure to seek protection for this foreseeable alteration of its claimed structure).

> If a claim limitation recites a term and associated functional language, the examiner should determine whether the claim limitation invokes **35 U.S.C. 112, sixth paragraph. The claim limitation is presumed to invoke **35 U.S.C. 112**, sixth paragraph when it explicitly uses the phrase "means for" or "step for" and includes functional language. That presumption is overcome when the limitation further includes the structure necessary to perform the recited function. *TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259-60 (Fed. Cir. 2008) ("Sufficient structure exists when the claim language specifies the exact structure that performs the function in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure."); see also *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1376 (Fed. Cir. 2003).

By contrast, a claim limitation that does not use the phrase "means for" or "step for" will trigger the rebuttable presumption that **35 U.S.C. 112**, sixth paragraph does not apply. See, e.g., *Phillips v. AWH Corp.*, 415 F.3d 1303, 1311 (Fed. Cir. 2005) (en banc); *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1369 (Fed. Cir. 2002); *Personalized Media Commc'ns, LLC v. ITC*, 161 F.3d 696, 703-04 (Fed. Cir. 1998). This presumption is a strong one that is not readily overcome. *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1358 (2004); *Inventio AG v. Thyssenkrupp Elevator Americas Corp.*, 649 F.3d 1350, 1356, 99 USPQ2d 1112, 1117 (Fed. Cir. 2011). This strong presumption may be overcome if the claim limitation is shown to use a non-structural term that is "a nonce word or a verbal construct that is not recognized as the name of structure" but is merely a substitute for the term "means for," associated with functional language. *Lighting World*, 382 F.3d at 1360.

Accordingly, examiners will apply **35 U.S.C. 112**, sixth paragraph to a claim limitation< if it meets the following 3-prong analysis:

(A) **>the claim limitation uses the phrase "means for" or "step for" or a non-structural term (a term that is simply a substitute for the term "means for")<;

(B) the >phrase< "means for" or "step for" >or the non-structural term< must be modified by functional language; and

(C) the phrase "means for" or "step for" >or the non-structural term< must not be modified by sufficient structure, material, or acts for achieving the specified function.

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A. The Claim Limitation Uses the Phrase "Means For" Or "Step For" Or A Non-Structural Term (A Term That Is Simply A Substitute for the Term "Means For")

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With respect to the first prong of this analysis, a claim element that does not include the phrase "means for" or "step for" will not be *>presumed< to invoke 35 U.S.C. **112**, sixth paragraph. *>When the claim limitation does not use the phrase "means for," examiners should determine whether the presumption that 35 U.S.C. 112, paragraph 6 does not apply is overcome if the claim limitation uses a non-structural term (a term that is simply

a substitute for the term "means for"). The following is a list of non-structural terms that may invoke 35 U.S.C. 112, paragraph 6: **"mechanism for," "module for," "device for," "unit for," "component for," "element for," "member for," "apparatus for," "machine for," or "system for."** *Welker Bearing Co., v. PHD, Inc.*, 550 F.3d 1090, 1096 (Fed. Cir. 2008); *Massachusetts Inst. of Tech. v. Abacus Software*, 462 F.3d 1344, 1354 (Fed. Cir. 2006); *Personalized Media*, 161 F.3d at 704; *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1214-1215 (Fed. Cir. 1998). This list is not exhaustive, and other non-structural terms may invoke 35 U.S.C. 112, paragraph 6.

However, 35 U.S.C. 112, paragraph 6 will not apply if persons of ordinary skill in the art reading the specification understand the term to be the name for the structure that performs the function, even when the term covers a broad class of structures or identifies the structures by their function (e.g., "filters," "brakes," "clamp," "screwdriver," and "locks"). *Lighting World*, 382 F.3d at 1360; *Apex Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364, 1372-73 (Fed. Cir. 2003); *CCS Fitness*, 288 F.3d at 1369; *Watts v. XL Sys. Inc.*, 232 F.3d 877, 880-81 (Fed. Cir. 2000); *Personalized Media*, 161 F.3d at 704; *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed. Cir. 1996) ("Many devices take their names from the functions they perform.") The term is not required to denote a specific structure or a precise physical structure to avoid the application of 35 U.S.C. 112, paragraph 6. See *Watts*, 232 F.3d at 880; *Inventio AG v. Thyssenkrupp Elevator Americas Corp.*, 649 F.3d 1350 (Fed. Cir. 2011)(The court concluded the claim terms "modernizing device" and "computing unit" when read in light of the specification connoted sufficient, definite structure to one of skill in the art to preclude application of 35 U.S.C. 112, sixth paragraph). The following are examples of structural terms that have been found **not** to invoke 35 U.S.C. 112, paragraph 6: "circuit," "detent mechanism," "digital detector," "reciprocating member," "connector assembly," "perforation," "sealingly connected joints," and "eyeglass hanger member." *Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1321 (Fed. Cir. 2004); *Apex*, 325 F.3d at 1373; *Greenberg*, 91 F.3d at 1583-84; *Personalized Media*, 161 F.3d at 704-05; *CCS Fitness*, 288 F.3d at 1369-70; *Lighting World*, 382 F.3d at 1358-63; *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531 (Fed. Cir. 1996); *Watts*, 232 F.3d at 881; *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1318-19 (Fed. Cir. 1999).

If the examiner has not interpreted a claim limitation as invoking 35 U.S.C. 112, sixth paragraph and <an applicant wishes to have the claim limitation treated under 35 U.S.C. **112**, sixth paragraph, applicant must either: (A) amend the claim to include the phrase "means for" or "step for" **>; or (B) rebut the presumption that 35 U.S.C. **112**, sixth paragraph does not apply by showing that the claim limitation is written as a function to be performed and does not recite sufficient structure, material, or acts.< See *Watts v. XL Systems, Inc.*, 232 F.3d 877, 56 USPQ2d 1836 (Fed. Cir. 2000) (Claim limitations were held not to invoke **35 U.S.C. 112**, sixth paragraph, because the absence of the term "means" raised the presumption that the limitations were not in means-plus-function form and the applicant did not rebut that presumption.); see also *Masco Corp. v. United States*, 303 F.3d 1316, 1327, 64 USPQ2d 1182, 1189 (Fed. Cir. 2002) ("[W]here a method claim does not contain the term 'step[s] for,' a limitation of that claim cannot be construed as a step-plus-function limitation without a showing that the limitation contains no act.").

Some of the following examples illustrate situations where the phrase "means for" or "step for" was not used but either the Board or courts nevertheless determined that the claim limitation fell within the scope of 35 U.S.C. **112**, sixth paragraph. Note that the examples are fact specific and should not be applied as *per se* rules. See *Signtech USA, Ltd. v. Vutek, Inc.*, 174 F.3d 1352, 1356, 50 USPQ2d 1372, 1374– 75 (Fed. Cir.1999) ("ink delivery means positioned on …" invokes 35 U.S.C. **112**, sixth paragraph since the phrase "ink delivery means" is equivalent to "means for ink delivery"); **; *Seal-Flex, Inc. v. Athletic Track and Court Construction*, 172 F.3d 836, 850, 50 USPQ2d 1225, 1234 (Fed. Cir. 1999) (Radar, J., concurring) ("claim elements without express step-plus-function language may nevertheless fall within **112** 6 if they merely claim the underlying function without recitation of acts for performing that function…In general terms, the underlying function' of a method claim element corresponds to *what* that element ultimately accomplishes in relationship to what the other elements of the claim and the claim as a whole accomplish. Acts,' on the other hand, correspond to *how* the function is accomplished…If the claim element uses the phrase step for,' then § **112**, 6 is presumed to apply…On the other hand, the term step' alone and the phrase steps of' tend to show that § **112**, 6 does not govern that limitation."); *Personalized Media Communications LLC v. ITC*, 161 F.3d 696, 703–04, 48 USPQ2d 1880, 1886–87 (Fed. Cir. 1998); *Mas-Hamilton Group v. LaGard Inc.*, 156 F.3d 1206, 1213, 48 USPQ2d 1010, 1016 (Fed. Cir. 1998) ("lever moving element for moving the lever" and "movable link member for holding the lever…and for releasing the lever" were construed as means-plus-function limitations invoking 35 U.S.C. **112**, sixth paragraph since the claimed limitations were described in terms of their function not their mechanical structure); *Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1463, 45 USPQ2d 1545, 1550 (Fed. Cir.

1998) (“use of the word means ‘gives rise to a presumption that the inventor used the term advisedly to invoke the statutory mandates for means-plus-function clauses’”)*>. However, compare *Al-Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308, 1317-19, 50 USPQ2d 1161, 1166-67 (Fed. Cir. 1999) (although the claim elements “eyeglass hanger member” and “eyeglass contacting member” include a function, these claim elements do not invoke 35 U.S.C. **112**, sixth paragraph because the claims themselves contain sufficient structural limitations for performing these functions);< *O.I. Corp. v. Tekmar*, 115 F.3d 1576, 1583, 42 USPQ2d 1777, 1782 (Fed. Cir. 1997) (method claim that paralleled means-plus-function apparatus claim but lacked “step for” language did not invoke 35 U.S.C. **112**, sixth paragraph). Thus, absent **>a determination that a claim limitation invokes **35 U.S.C. 112**, sixth paragraph<, the broadest reasonable interpretation will not be limited to “corresponding structure…and equivalents thereof.” *Morris*, 127 F.3d at 1055, 44 USPQ2d at 1028 (“no comparable mandate in the patent statute that relates the claim scope of non-§ **112** paragraph 6 claims to particular matter found in the specification”).

> When applicant uses the phrase “means for” or “step for” in the preamble, a rejection under **35 U.S.C. 112**, second paragraph may be appropriate when it is unclear whether the preamble is reciting a means (or step) plus function limitation or whether the preamble is merely stating the intended use of the claimed invention. If applicant uses a structural or non-structural term with the word “for” in the preamble, the examiner should not construe such phrase as reciting a means-plus-function limitation.<

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B. The Phrase “Means For” Or “Step For” Or the Non-Structural Term Must Be Modified By Functional Language

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With respect to the second prong of this analysis, it must be clear that the element in the claims is set forth, at least in part, by the function it performs as opposed to the specific structure, material, or acts that perform the function. See *York Prod., Inc. v. Central Tractor Farm & Family Center*, 99 F.3d 1568, 1574, 40 USPQ2d 1619, 1624 (Fed. Cir. 1996) (holding that a claim limitation containing the term “means” does not invoke 35 U.S.C. **112**, sixth paragraph, if the claim limitation does not link the term “means” to a specific function). *Caterpillar Inc. v. Detroit Diesel Corp.*, 41 USPQ2d 1876, 1882 (N.D. Ind. 1996) (35 U.S.C. **112**, sixth paragraph, “applies to functional method claims where the element at issue sets forth a step for reaching a particular result, but not the specific technique or procedure used to achieve the result .”); *O.I. Corp.*, 115 F.3d at 1582-83, 42 USPQ2d at 1782 (With respect to process claims, “[35 U.S.C. **112**, sixth paragraph] is implicated only when steps *plus function* without acts are present…If we were to construe every process claim containing steps described by an ‘ing’ verb, such as passing, heating, reacting, transferring, etc., into a step-plus-function, we would be limiting process claims in a manner never intended by Congress.” (Emphasis in original).). >See also *Baran v. Medical Device Techs., Inc.*, 616 F.3d 1309, 1317 (Fed. Cir. 2010) (the claimed function may include the functional language that precedes the phrase “means for.”)< However, “the fact that a particular mechanism…is defined in functional terms is not sufficient to convert a claim element containing that term into a ‘means for performing a specified function’ within the meaning of section **112**(6).” *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583, 39 USPQ2d 1783, 1786 (Fed. Cir. 1996) (“detent mechanism” defined in functional terms was not intended to invoke 35 U.S.C. **112**, sixth paragraph). See also *Al-Site Corp. v. VSI International Inc.*, 174 F.3d 1308, 1318, 50 USPQ2d 1161, 1166–67 (Fed. Cir. 1999) (although the claim elements “eyeglass hanger member” and “eyeglass contacting member” include a function, these claim elements do not invoke 35 U.S.C. **112**, sixth paragraph, because the claims themselves contain sufficient structural limitations for performing those functions). Also, a statement of function appearing only in the claim preamble is generally insufficient to invoke 35 U.S.C. **112**, sixth paragraph. *O.I. Corp.*, 115 F.3d at 1583, 42 USPQ2d at 1782 (“[A] statement in a preamble of a result that necessarily follows from performing a series of steps does not convert each of those steps into step- plus-function clauses. The steps of ‘passing’ are not individually associated in the claims with functions performed by the steps of passing.”).

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C. The Phrase “Means For” Or “Step For” Or the Non-Structural Term Must Not Be Modified By Sufficient Structure, Material, or Acts for Achieving the Specified Function

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With respect to the third prong of this analysis, >the phrase “means for” or “step for” or the non-structural term recited in the claim must not be modified by sufficient structure, material, or acts for achieving the specified function. See< *Seal-Flex*, 172 F.3d at 849, 50 USPQ2d at 1234 (Radar, J., concurring) (“Even when a claim element uses language that generally falls under the step-plus-function format, however, **112** ¶ 6 still does not apply when the claim limitation itself recites sufficient acts for performing the specified function.”); *Envirco*

Corp. v. Clestra Cleanroom, Inc., 209 F.3d 1360, 54 USPQ2d 1449 (Fed. Cir. 2000) (holding "second baffle means" does not invoke 35 U.S.C. **112**, sixth paragraph, because the word "baffle" itself imparts structure and the claim further recites the structure of the baffle); *Rodime PLC v. Seagate Technology, Inc.*, 174 F.3d 1294, 1303–04, 50 USPQ2d 1429, 1435–36 (Fed. Cir. 1999) (holding "positioning means for moving" does not invoke 35 U.S.C. **112**, sixth paragraph, because the claim further provides a list of the structure underlying the means and the detailed recitation of the structure for performing the moving function removes this element from the purview of 35 U.S.C. **112**, sixth paragraph); *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531, 41 USPQ2d 1001, 1006 (Fed. Cir. 1996) (holding "perforation means…for tearing" does not invoke 35 U.S.C. **112**, sixth paragraph, because the claim describes the structure supporting the tearing function (i.e., perforation)). In other cases, the Federal Circuit has held otherwise. See *Unidynamics Corp. v. Automatic Prod. Int'l*, 157 F.3d 1311, 1319, 48 USPQ2d 1099, 1104 (Fed. Cir. 1998) (holding "spring means" does invoke 35 U.S.C. **112**, sixth paragraph).

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Examiners will apply **35 U.S.C. 112**, sixth paragraph to a claim limitation that uses a non-structural term associated with functional language, unless the non-structural term is (1) preceded by a structural modifier, defined in the specification as a particular structure or known by one skilled in the art, that denotes the type of structural device (e.g., "filters"), or (2) modified by sufficient structure or material for achieving the claimed function.

A limitation will not invoke **35 U.S.C. 112**, sixth paragraph if there is a structural modifier that further describes the non-structural term. For example, although a non-structural term like "mechanism" standing alone may invoke **35 U.S.C. 112**, sixth paragraph when coupled with a function, it will not invoke **35 U.S.C. 112**, sixth paragraph when it is preceded by a structural modifier (e.g., "detent mechanism"). *Greenberg*, 91 F.3d at 1583 (holding that the term "detent mechanism" did not to invoke **35 U.S.C. 112**, sixth paragraph because the structural modifier "detent" denotes a type of structural device with a generally understood meaning in the mechanical arts). By contrast, a non-structural term (e.g., "mechanism," "element," "member") coupled with a function may invoke **35 U.S.C. 112**, sixth paragraph when it is preceded by a non-structural modifier that does not have any generally understood structural meaning in the art (e.g., "colorant selection mechanism," "lever moving element," or "movable link member"). *Massachusetts Inst. of Tech.*, 462 F.3d at 1354; *Mas-Hamilton*, 156 F.3d at 1214-1215.

To determine whether a word, term, or phrase coupled with a function denotes structure, examiners should check whether: (1) the specification provides a description sufficient to inform one of ordinary skill in the art that the term denotes structure; (2) general and subject matter specific dictionaries provide evidence that the term has achieved recognition as a noun denoting structure; and (3) the prior art provides evidence that the term has an art-recognized structure to perform the claimed function. *Ex parte Rodriguez*, 92 USPQ2d 1395, 1404 (Bd. Pat. App. & Int. 2009) (precedential).

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During examination, however, applicants have the opportunity and the obligation to define their inventions precisely, including whether a claim limitation invokes 35 U.S.C. **112**, sixth paragraph. Thus, if the phrase "means for" or "step for" >or non-structural term< is modified by sufficient structure, material or acts for achieving the specified function, the USPTO will not apply 35 U.S.C. **112**, sixth paragraph, until such modifying language is deleted from the claim limitation.

It is necessary to decide on an element by element basis whether 35 U.S.C. **112**, sixth paragraph, applies. Not all terms in a means-plus-function or step-plus-function clause are limited to what is disclosed in the written description and equivalents thereof, since 35 U.S.C. **112**, sixth paragraph, applies only to the interpretation of the means or step that performs the recited function. See, e.g., *IMS Technology Inc. v. Haas Automation Inc.*, 206 F.3d 1422, 54 USPQ2d 1129 (Fed. Cir. 2000) (the term "data block" in the phrase "means to sequentially display data block inquiries" was not the means that caused the sequential display, and its meaning was not limited to the disclosed embodiment and equivalents thereof.). Each claim must be independently reviewed to determine the applicability of 35 U.S.C. **112**, sixth paragraph, even where the application contains substantially similar process and apparatus claims. *O.I. Corp.*, 115 F.3d at 1583-1584, 42 USPQ2d at 1782 ("We understand that the steps in the method claims are essentially in the same language as the limitations in the apparatus claim, albeit without the 'means for' qualification…Each claim must be independently reviewed in order to determine if it is subject to the requirements of section **112**, ¶ 6. Interpretation of claims would be confusing indeed if claims that are not means- or step- plus function were to be interpreted as if they were, only because they use language similar to that used in other claims that are subject to this provision.").

Where a claim limitation meets the 3-prong analysis and is being treated under 35 U.S.C. 112, sixth paragraph, the examiner will include a statement in the Office action that the claim limitation is being treated under 35 U.S.C. 112, sixth paragraph. **>See MPEP § 2181, subsection VI, below. If a claim limitation uses< the phrase "means for" or "step for," ** but the examiner determines that either the second prong or the third prong of the 3-prong analysis is not met, then in these situations, the examiner must include a statement in the Office action explaining the reasons why a claim limitation which uses the phrase "means for" or "step for" is not being treated under 35 U.S.C. 112, sixth paragraph.

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In the event that it is unclear whether the claim limitation falls within the scope of 35 U.S.C. 112, sixth paragraph, a rejection under 35 U.S.C. 112, second paragraph may be appropriate.

II. DESCRIPTION NECESSARY TO SUPPORT A CLAIM LIMITATION WHICH INVOKES 35 U.S.C. 112, SIXTH PARAGRAPH

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure…described in the specification and equivalents thereof." "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112." *In re Donaldson Co*., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc).

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A. The Corresponding Structure Must Be Disclosed In the Specification Itself in A Way That One Skilled In the Art Will Understand What Structure Will Perform the Recited Function

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The proper test for meeting the definiteness requirement is that the corresponding structure (or material or acts) of a means (or step)-plus-function limitation must be disclosed in the specification itself in a way that one skilled in the art will understand what structure (or material or acts) will perform the recited function. See *Atmel Corp. v. Information Storage Devices, Inc*., 198 F.3d 1374, 1381, 53 USPQ2d 1225, 1230 (Fed. Cir. 1999). In *Atmel*, the patentee claimed an apparatus that included a "high voltage generating means" limitation, thereby invoking 35 U.S.C. 112, sixth paragraph. The specification incorporated by reference a non-patent document from a technical journal, which described a particular high voltage generating circuit. The Federal Circuit concluded that the title of the article in the specification may, by itself, be sufficient to indicate to one skilled in the art the precise structure of the means for performing the recited function, and it remanded the case to the district court "to consider the knowledge of one skilled in the art that indicated, based on unrefuted testimony, that the specification disclosed sufficient structure corresponding to the high-voltage means limitation." *Id*. at 1382, 53 USPQ2d at 1231.

The disclosure of the structure (or material or acts) may be implicit or inherent in the specification if it would have been clear to those skilled in the art what structure (or material or acts) corresponds to the means (or step)-plus-function claim limitation. See *Id*. at 1380, 53 USPQ2d at 1229; *In re Dossel*, 115 F.3d 942, 946-47, 42 USPQ2d 1881, 1885 (Fed. Cir. 1997). If there is no disclosure of structure, material or acts for performing the recited function, the claim fails to satisfy the requirements of 35 U.S.C. 112, second paragraph. >"[A] bare statement that known techniques or methods can be used does not disclose structure" in the context of a means plus function limitation. *Biomedino, LLC v. Waters Technology Corp* ., 490 F.3d 946, 952, 83 USPQ2d 1118, 1123 (Fed. Cir. 2007)(Disclosure that an invention "may be controlled by known differential pressure, valving and control equipment" was not a disclosure of any structure corresponding to the claimed "control means for operating [a] valving " and the claim was held indefinite.). See also< *Budde v. Harley-Davidson, Inc*., 250 F.3d 1369, 1376, 58 USPQ2d 1801, 1806 (Fed. Cir. 2001); *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc*., 296 F.3d 1106, 1115-18, 63 USPQ2d 1725, 1731-34 (Fed. Cir. 2002) (Court interpreted the language of the "third monitoring means for monitoring the ECG signal…for activating …" to require the same means to perform both functions and the only entity referenced in the specification that could possibly perform both functions is the physician. The court held that excluding the physician, no structure accomplishes the claimed dual functions. Because no structure disclosed in the embodiments of the invention actually performs the claimed dual functions, the specification lacks corresponding structure as required by 35 U.S.C. 112, sixth paragraph, and fails to comply with 35 U.S.C. 112, second paragraph.).

Whether a claim reciting an element in means- (or step-) plus-function language fails to comply with 35 U.S.C. 112, second paragraph, because the specification does not disclose adequate structure (or material or acts) for

performing the recited function is closely related to the question of whether the specification meets the description requirement in 35 U.S.C. **112**, first paragraph. See *In re Noll*, 545 F.2d 141, 149, 191 USPQ 721, 727 (CCPA 1976) (unless the means-plus-function language is itself unclear, a claim limitation written in means-plus- function language meets the definiteness requirement in 35 U.S.C. **112**, second paragraph, so long as the specification meets the written description requirement in 35 U.S.C. **112**, first paragraph). ***> *In Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 521 F.3d 1328, 1336-37 (Fed. Cir. 2008), the court stated:

> Enablement of a device requires only the disclosure of sufficient information so that a person of ordinary skill in the art could make and use the device. A section 112 paragraph 6 disclosure, however, serves the very different purpose of limiting the scope of the claim to the particular structure disclosed, together with equivalents. … For example, in *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1380 (Fed. Cir. 1999), the court embraced the proposition that 'consideration of the understanding of one skilled in the art in no way relieves the patentee of adequately disclosing sufficient structure in the specification.' It is not enough for the patentee simply to state or later argue that persons of ordinary skill in the art would know what structures to use to accomplish the claimed function. The court in *Biomedino, LLC v. Waters Technologies Corp.*, 490 F.3d 946, 953 (Fed. Cir. 2007), put the point this way: 'The inquiry is whether one of skill in the art would understand the specification itself to disclose a structure, not simply whether that person would be capable of implementing that structure.'

The< invocation of 35 U.S.C. **112**, sixth paragraph, does not exempt an applicant from compliance with 35 U.S.C. **112**, first and second paragraphs. See *Donaldson*, 16 F.3d at 1195, 29 USPQ2d at 1850; ***> *In re Knowlton*, 481 F.2d 1357, 1366, 178 USPQ 486, 493 (CCPA 1973) ("[The sixth paragraph of section 112] cannot be read as creating an exception either to the description requirement of the first paragraph … or to the definiteness requirement found in the second paragraph of section 112. Means-plus-function language can be used in the claims, but the claims must still accurately define the invention.").<

Under certain limited circumstances, the written description does not have to explicitly describe the structure (or material or acts) corresponding to a means- (or step-) plus-function limitation to particularly point out and distinctly claim the invention as required by 35 U.S.C. **112**, second paragraph. See *Dossel*, 115 F.3d at 946, 42 USPQ2d at 1885. Under proper circumstances, drawings may provide a written description of an invention as required by 35 U.S.C. **112**. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1565, 19 USPQ2d 1111, 1118 (Fed. Cir. 1991). *>Further<, disclosure of structure corresponding to a means-plus-function limitation may be implicit in the written description if it would have been clear to those skilled in the art what structure must perform the function recited in the means-plus-function limitation. See *Atmel Corp. v. Information Storage Devices Inc.*, 198 F.3d 1374, 1379, 53 USPQ2d 1225, 1228 (Fed. Cir. 1999) (stating that the "one skilled in the art" analysis should apply in determining whether sufficient structure has been disclosed to support a means-plus-function limitation and that the USPTO's recently issued proposed Supplemental Guidelines are consistent with the court's holding on this point); *Dossel*, 115 F.3d at 946–47, 42 USPQ2d at 1885 ("Clearly, a unit which receives digital data, performs complex mathematical computations and outputs the results to a display must be implemented by or on a general or special purpose computer (although it is not clear why the written description does not simply state 'computer' or some equivalent phrase.)").

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B. Computer-Implemented Means-Plus-Function Limitations

For a computer-implemented means-plus-function claim limitation invoking **35 U.S.C. 112**, sixth paragraph, a general purpose computer is usually sufficient for the corresponding structure for performing a general computing function (e.g., "means for storing data"), but the corresponding structure for performing a specific function is required to be more than simply a general purpose computer or microprocessor. In *In re Katz Interactive Call Processing Patent Litigation*, 639 F.3d 1303, 1316 (Fed. Cir. 2011), the court stated:

> Those cases involved specific functions that would need to be implemented by programming a general purpose computer to convert it into a special purpose computer capable of performing those specified functions. … By contrast, in the seven claims identified above, *Katz* has not claimed a specific function performed by a special purpose computer, but has simply recited the claimed functions of 'processing,' 'receiving,' and 'storing.' Absent a possible narrower construction of the terms 'processing,' 'receiving,' and 'storing,' discussed below, those functions can be achieved by any general purpose computer without special programming. As such, it was not necessary to

> disclose more structure than the general purpose processor that performs those functions. Those seven claims do not run afoul of the rule against purely functional claiming, because the functions of 'processing,' 'receiving,' and 'storing' are coextensive with the structure disclosed, i.e., a general purpose processor.).

To claim a means for performing a specific computer-implemented function and then to disclose only a general purpose computer as the structure designed to perform that function amounts to pure functional claiming. *Aristocrat*, 521 F.3d 1328 at 1333. In this instance, the structure corresponding to a **35 U.S.C. 112**, sixth paragraph claim limitation for a computer-implemented function must include the algorithm needed to transform the general purpose computer or microprocessor disclosed in the specification. *Aristocrat*, 521 F.3d at 1333; *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1340 (Fed. Cir. 2008); *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1349 (Fed. Cir. 1999). The corresponding structure is not simply a general purpose computer by itself but the special purpose computer as programmed to perform the disclosed algorithm. *Aristocrat*, 521 F.3d at 1333. Thus, the specification must sufficiently disclose an algorithm to transform a general purpose microprocessor to the special purpose computer. *Aristocrat*, 521 F.3d at 1338 ("Aristocrat was not required to produce a listing of source code or a highly detailed description of the algorithm to be used to achieve the claimed functions in order to satisfy **35 U.S.C. 112** P 6. It was required, however, to at least disclose the algorithm that transforms the general purpose microprocessor to a 'special purpose computer programmed to perform the disclosed algorithm.' *WMS Gaming*, 184 F.3d at 1349.") An algorithm is defined, for example, as "a finite sequence of steps for solving a logical or mathematical problem or performing a task." Microsoft Computer Dictionary, Microsoft Press, 5th edition, 2002. Applicant may express the algorithm in any understandable terms including as a mathematical formula, in prose, in a flow chart, or "in any other manner that provides sufficient structure." *Finisar*, 523 F.3d at 1340; see also *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003); *In re Dossel*, 115 F.3d 942, 946-47 (Fed. Cir.1997); *Typhoon Touch Inc. v. Dell Inc.*, 659 F.3d 1376, 1385 (Fed. Cir. 2011); *In re Aoyama*, 656 F.3d 1293, 1306 (Fed. Cir. 2011).

A rejection under **35 U.S.C. 112**, second paragraph is appropriate if the specification discloses no corresponding algorithm associated with a computer or microprocessor. *Aristocrat*, 521 F.3d at 1337-38. For example, mere reference to a general purpose computer with appropriate programming without providing an explanation of the appropriate programming, or simply reciting "software" without providing detail about the means to accomplish the software function, would not be an adequate disclosure of the corresponding structure to satisfy the requirements of **35 U.S.C. 112**, second paragraph. *Aristocrat*, 521 F.3d at 1334; *Finisar*, 523 F.3d at 1340-41. In addition, merely referencing a specialized computer (e.g., a "bank computer"), some undefined component of a computer system (e.g., "access control manager"), "logic," "code," or elements that are essentially a black box designed to perform the recited function, will not be sufficient because there must be some explanation of how the computer or the computer component performs the claimed function. *Blackboard, Inc. v. Desire2Learn, Inc.*, 574 F.3d 1371, 1383-1385 (Fed. Cir. 2009); *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1366-67 (Fed. Cir. 2008); *Rodriguez*, 92 USPQ2d at 1405-06.

In several Federal Circuit cases, the patentees argued that the requirement for the disclosure of an algorithm can be avoided if one of ordinary skill in the art is capable of writing the software to convert a general purpose computer to a special purpose computer to perform the claimed function. See, e.g., *Blackboard*, 574 F.3d at 1385; *Biomedino*, 490 F.3d at 952; *Atmel Corp.*, 198 F.3d at 1380. Such argument was found to be unpersuasive because the understanding of one skilled in the art does not relieve the patentee of the duty to disclose sufficient structure to support means-plus-function claim terms. *Blackboard*, 574 F.3d at 1385 ("A patentee cannot avoid providing specificity as to structure simply because someone of ordinary skill in the art would be able to devise a means to perform the claimed function."); *Atmel Corp.*, 198 F.3d at 1380 ("[C]onsideration of the understanding of one skilled in the art in no way relieves the patentee of adequately disclosing sufficient structure in the specification."). The specification must explicitly disclose the algorithm for performing the claimed function, and simply reciting the claimed function in the specification will not be a sufficient disclosure for an algorithm which, by definition, must contain a sequence of steps. *Blackboard*, 574 F.3d at 1384 (stating that language that simply describes the function to be performed describes an outcome, not a means for achieving that outcome); Microsoft Computer Dictionary, Microsoft Press, 5th edition, 2002; see also *Encyclopaedia Britannica, Inc. v. Alpine Elecs., Inc.*, 355 Fed. Appx. 389, 394-95, 2009 U.S. App. Lexis. 26358, 10-16 (Fed. Cir. 2009) (holding that implicit or inherent disclosure of a class of algorithms for performing the claimed functions is not sufficient, and the purported "one-step" algorithm is not an algorithm at all) (unpublished).

If the specification explicitly discloses an algorithm, the sufficiency of the disclosure of the algorithm must be determined in light of the level of ordinary skill in the art. *Aristocrat*, 521 F.3d at 1337; *AllVoice Computing PLC v. Nuance Commc'ns, Inc.*, 504 F.3d 1236, 1245 (Fed. Cir. 2007); Intel Corp., 319 F.3d at 1366-67 (knowledge of a person of ordinary skill in the art can be used to make clear how to implement a disclosed algorithm). The examiner should determine whether one skilled in the art would know how to program the computer to perform the necessary steps described in the specification (i.e., the invention is enabled), and that the inventor was in possession of the invention (i.e., the invention meets the written description requirement). Thus, the specification must sufficiently disclose an algorithm to transform a general purpose microprocessor to a special purpose computer so that a person of ordinary skill in the art can implement the disclosed algorithm to achieve the claimed function. *Aristocrat*, 521 F.3d at 1338.

Often the supporting disclosure for a computer-implemented invention discusses the implementation of the functionality of the invention through hardware, software, or a combination of both. In this situation, a question can arise as to which mode of implementation supports the means-plus-function limitation. The language of **35 U.S.C. 112**, sixth paragraph requires that the recited "means" for performing the specified function shall be construed to cover the corresponding "structure or material" described in the specification and equivalents thereof. Therefore, by choosing to use a means-plus-function limitation and invoke **35 U.S.C. 112**, sixth paragraph, applicant limits that claim limitation to the disclosed structure, i.e., implementation by hardware or the combination of hardware and software, and equivalents thereof. Therefore, the examiner should not construe the limitation as covering pure software implementation.

However, if there is no corresponding structure disclosed in the specification (i.e., the limitation is only supported by software and does not correspond to an algorithm and the computer or microprocessor programmed with the algorithm), the limitation should be deemed indefinite as discussed above, and the claim should be rejected under **35 U.S.C. 112**, second paragraph. It is important to remember that claims must be interpreted as a whole; so, a claim that includes a means-plus-function limitation that corresponds to software per se (and is thus indefinite for lacking structural support in the specification) is not necessarily directed as a whole to software per se unless the claim lacks other structural limitations.

C. The Supporting Disclosure Clearly Links or Associate the Disclosed Structure, Material, or Acts to the Claimed Function

The structure disclosed in the written description of the specification is the corresponding structure only if the written description of the specification or the prosecution history **clearly links or associates** that structure to the function recited in a means-plus-function claim limitation under **35 U.S.C. 112**, sixth paragraph. See *B. Braun Medical Inc., v. Abbott Laboratories*, 124 F.3d 1419, 1424, 43 USPQ2d 1896, 1900 (Fed. Cir. 1997). The requirement that a particular structure be clearly linked with the claimed function in order to qualify as corresponding structure is the quid pro quo for the convenience of employing **35 U.S.C. 112**, sixth paragraph, and is also supported by the requirement of **35 U.S.C. 112**, second paragraph, that an invention must be particularly pointed out and distinctly claimed. See *Medical Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1211, 68 USPQ2d 1263, 1268. For a means (or step) plus function claim limitation that invokes **35 U.S.C. 112**, sixth paragraph, a rejection under **35 U.S.C. 112**, second paragraph, is appropriate if one of ordinary skill in the art cannot identify what structure, material, or acts disclosed in the written description of the specification perform the claimed function.

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III. DETERMINING 35 U.S.C. 112 SECOND PARAGRAPH COMPLIANCE WHEN 35 U.S.C. 112 SIXTH PARAGRAPH IS INVOKED

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Once the examiner determines that a claim limitation is a means-plus-function limitation invoking **35 U.S.C. 112**, sixth paragraph, the examiner should determine the claimed function and then review the written description of the specification to determine whether the corresponding structure, material, or acts that perform the claimed function are disclosed. Note that drawings may provide a written description of an invention as required by **35 U.S.C. 112**. See *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1565 (Fed. Cir. 1991). The corresponding structure, material, or acts may be disclosed in the original drawings, figures, tables, or sequence listing. However, the corresponding structure, material, or acts cannot include any structure, material, or acts disclosed only in the material incorporated by reference or a prior art reference. See *Pressure Prods. Med. Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1317 (Fed. Cir. 2010) (stating, "Simply mentioning prior art references in a patent does not suffice as a specification description to give the patentee outright claim to all of the structures disclosed in those references."); *Atmel Corp. v. Info.*

Storage Devices, Inc., 198 F.3d 1374, 1381 (Fed. Cir. 1999). The disclosure must be reviewed from the point of view of one skilled in the relevant art to determine whether that person would understand the written description to disclose the corresponding structure, material, or acts. *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008); *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1211-12 (Fed. Cir. 2003). To satisfy the definiteness requirement under **35 U.S.C. 112**, second paragraph, the written description must clearly link or associate the corresponding structure, material, or acts to the claimed function. *Telcordia Techs., Inc. v. Cisco Systems, Inc.*, 612 F.3d 1365, 1376 (Fed. Cir. 2010). A rejection under **35 U.S.C. 112**, second paragraph is appropriate if the written description fails to link or associate the disclosed structure, material, or acts to the claimed function, or if there is no disclosure (or insufficient disclosure) of structure, material, or acts for performing the claimed function. *Donaldson*, 16 F.3d at 1195. A bare statement that known techniques or methods can be used would not be a sufficient disclosure to support a means-plus-function limitation. *Biomedino, LLC v. Waters Techs. Corp.*, 490 F.3d 946, 953 (Fed. Cir. 2007).

A rejection under **35 U.S.C. 112**, second paragraph may be appropriate in the following situations when examining means-plus-function claim limitations under **35 U.S.C. 112**, sixth paragraph:

(1) when it is unclear whether a claim limitation invokes **35 U.S.C. 112**, sixth paragraph;

(2) when **35 U.S.C. 112**, sixth paragraph is invoked and there is no disclosure or there is insufficient disclosure of structure, material, or acts for performing the claimed function; and/or

(3) when **35 U.S.C. 112**, sixth paragraph is invoked and the supporting disclosure fails to clearly link or associate the disclosed structure, material, or acts to the claimed function.

When the examiner cannot identify the corresponding structure, material, or acts, a rejection under **35 U.S.C. 112**, second paragraph should be made. In some cases, a requirement for information under 37 CFR 1.105 may be made to require the identification of the corresponding structure, material, or acts. See MPEP § 704.11(a) (Example R). If a requirement for information under 37 CFR 1.105 is made and the applicant states that he or she lacks such information or the reply does not identify the corresponding structure, material, or acts, a rejection under **35 U.S.C. 112**, second paragraph should be made. For more information, see MPEP § 704.12 ("Replies to requirements for information must be complete and filed within the time period set including any extensions. Failure to reply within the time period set will result in the abandonment of the application.")

If the written description sets forth the corresponding structure, material, or acts in compliance with **35 U.S.C. 112**, second paragraph, the claim limitation must "be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." **35 U.S.C. 112**, sixth paragraph. However, functional limitations that are not recited in the claim, or structural limitations from the written description that are unnecessary to perform the claimed function, cannot be imported into the claim. *Welker Bearing*, 550 F.3d at 1097; *Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1233 (Fed. Cir. 2001).

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The following guidance is provided to determine whether applicant has complied with the requirements of 35 U.S.C. **112**, second paragraph, when 35 U.S.C. **112**, sixth paragraph, is invoked:

(A) If the corresponding structure, material or acts are described in the specification in specific terms (e.g., an emitter-coupled voltage comparator) and one skilled in the art could identify the structure, material or acts from that description, then the requirements of 35 U.S.C. **112**, second and sixth paragraphs and are satisfied. See *Atmel*, 198 F.3d at 1382, 53 USPQ2d 1231.

(B) If the corresponding structure, material or acts are described in the specification in broad generic terms and the specific details of which are incorporated by reference to another document (e.g., attachment means disclosed in U.S. Patent No. X, which is hereby incorporated by reference, or a comparator as disclosed in the IBM article, which is hereby incorporated by reference), Office personnel must review the description in the specification, without relying on any material from the incorporated document, and apply the "one skilled in the art" analysis to determine whether one skilled in the art could identify the corresponding structure (or material or acts) for performing the recited function to satisfy the definiteness requirement of 35 U.S.C. **112**, second paragraph. See *Default Proof Credit Card System, Inc. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 75 USPQ2d 1116 (Fed. Cir. 2005) ("The inquiry under [35 U.S.C.] § 112, ¶ 2, does not turn on whether a patentee has 'incorporated by reference' material into the specification relating to structure, but instead asks first 'whether structure is described in the specification, and, if so, whether one skilled in the art would identify the structure from that description'").(1) If one skilled in the art would be able to identify the structure, material or acts from the description in the specification for performing the recited function, then the requirements of 35 U.S.C. **112**, second paragraph, are satisfied. See *Dossel*, 115 F.3d at 946-47,

42 USPQ2d at 1885 (The function recited in the means-plus-function limitation involved "reconstructing" data. The issue was whether the structure underlying this "reconstructing" function was adequately described in the written description to satisfy 35 U.S.C. 112, second paragraph. The court stated that "[n]either the written description nor the claims uses the magic word 'computer,' nor do they quote computer code that may be used in the invention. Nevertheless, when the written description is combined with claims 8 and 9, the disclosure satisfies the requirements of Section 112, Para. 2." The court concluded that based on the specific facts of the case, one skilled in the art would recognize the structure for performing the "reconstructing" function since "a unit which receives digital data, performs complex mathematical computations and outputs the results to a display must be implemented by or on a general or special purpose computer."). See also *Intel Corp. v. VIA Technologies, Inc*, 319 F.3d 1357, 1366, 65 USPQ2d 1934, 1941 (Fed. Cir. 2003) (The "core logic" structure that was modified to perform a particular program was held to be adequate corresponding structure for a claimed function although the specification did not disclose internal circuitry of the core logic to show exactly how it must be modified.)

(2) If one skilled in the art would not be able to identify the structure, material or acts from description in the specification for performing the recited function, then applicant will be required to amend the specification to include the material incorporated by reference and to clearly link or associate the structure, material or acts to the function recited in the claim. Applicant should not be required to insert the subject matter described in the entire referenced document into the specification. To maintain a concise specification, applicant should only include the relevant portions of the referenced document that correspond to the means (or step)-plus-function limitation. See *Atmel*, 198 F.3d at 1382, 53 USPQ2d at 1230 ("All one needs to do…is to recite some structure corresponding to the means in the specification…so that one can readily ascertain what the claim means and comply with the particularity requirement of Para. 2.").

IV. DETERMINING WHETHER 35 U.S.C. 112, FIRST PARAGRAPH SUPPORT EXISTS

The claims must still be analyzed to determine whether there exists corresponding adequate support for such claim under 35 U.S.C. 112, first paragraph. In considering whether there is 35 U.S.C. 112, first paragraph support for the claim limitation, the examiner must consider not only the original disclosure contained in the summary and detailed description of the invention portions of the specification, but also the original claims, abstract, and drawings. See *In re Mott*, 539 F.2d 1291, 1299, 190 USPQ 536, 542–43 (CCPA 1976) (claims); *In re Anderson*, 471 F.2d 1237, 1240, 176 USPQ 331, 333 (CCPA 1973) (claims); *Hill-Rom Co. v. Kinetic Concepts, Inc.*, 209 F.3d 1337, 54 USPQ2d 1437 (Fed. Cir. 2000) (unpublished) (abstract); *In re Armbruster*, 512 F.2d 676, 678–79, 185 USPQ 152, 153–54 (CCPA 1975) (abstract); *Anderson*, 471 F.2d at 1240, 176 USPQ at 333 (abstract); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d at 1564, 19 USPQ2d at 1117 (drawings); *In re Wolfensperger*, 302 F.2d 950, 955–57, 133 USPQ 537, 541– 43 (CCPA 1962) (drawings).

37 CFR 1.75(d)(1) provides, in part, that "the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." In the situation in which the written description only implicitly or inherently sets forth the structure, materials, or acts corresponding to a means- (or step-) plus-function, and the examiner concludes that one skilled in the art would recognize what structure, materials, or acts perform the function recited in a means- (or step-) plus-function, the examiner should either: (A) have the applicant clarify the record by amending the written description such that it expressly recites what structure, materials, or acts perform the function recited in the claim element; or (B) state on the record what structure, materials, or acts perform the function recited in the means- (or step-) plus-function limitation. Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to a means- (or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the USPTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP § 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, or acts perform the function recited in the claim element. See 35 U.S.C. 112, sixth paragraph ("An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." (emphasis added)); see also *B. Braun Medical*, 124 F.3d at 1424, 43 USPQ2d at 1900 (holding that "pursuant to this provision [35 U.S.C. 112, sixth paragraph], structure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim. This duty to link or associate structure to function is the *quid pro quo* for the convenience of employing 112, paragraph 6."); *Medical Instrumentation and Diagnostic Corp. v. Elekta AB*, 344 F.3d 1205, 1218, 68 USPQ2d 1263, 1268 (Fed. Cir. 2003)(Although one of skill in the art would have been able to write a software

program for digital to digital conversion, such software did not fall within the scope of "means for converting" images as claimed because nothing in the specification or prosecution history clearly linked or associated such software with the function of converting images into a selected format.); *Wolfensperger*, 302 F.2d at 955, 133 USPQ at 542 (just because the disclosure provides support for a claim element does not mean that the USPTO cannot enforce its requirement that the terms and phrases used in the claims find clear support or antecedent basis in the written description).

V. SINGLE MEANS CLAIMS

Donaldson does not affect the holding of *In re Hyatt*, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983) to the effect that a single means claim does not comply with the enablement requirement of **35 U.S.C. 112**, first paragraph. As *Donaldson* applies only to an interpretation of a limitation drafted to correspond to **35 U.S.C. 112**, sixth paragraph, which by its terms is limited to "an element in a claim to a combination," it does not affect a limitation in a claim which is not directed to a combination. See also MPEP § **2164.08(a)**.

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VI. ENSURE THAT THE RECORD IS CLEAR

The examiner should specify in the Office action that a claim limitation has been interpreted under the provisions of **35 U.S.C. 112**, sixth paragraph. When claim terms other than "means for" are determined to invoke **35 U.S.C. 112**, sixth paragraph, the reasons why the claim was interpreted as invoking **35 U.S.C. 112**, sixth paragraph, should also be clearly stated in the Office action. For example, the Office action can include a statement that a certain claim limitation is expressed in functional terms coupled to a non-structural word (e.g., "module for,") that does not connote structure and therefore invokes treatment under **35 U.S.C. 112**, sixth paragraph. When the examiner has determined that **35 U.S.C. 112**, sixth paragraph applies, the examiner may also specify what the specification identifies as the corresponding structure.

Additionally, if the corresponding structure for the claimed function is not clearly identifiable in the specification, the Office action should, nevertheless, attempt to identify what structure is most closely associated with the means-plus-function limitation to facilitate a prior art search. This is especially true when there may be confusion as to which disclosed implementation of the invention supports the limitation, as explained in section II.B above.

When allowing a claim that was treated under **35 U.S.C. 112**, sixth paragraph, the examiner should indicate that the claim was interpreted under the provisions of **35 U.S.C. 112**, sixth paragraph in reasons for allowance if such an explanation has not previously been made of record. As noted above, the indication should also clarify the associated structure if not readily apparent in the specification.

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2182 Scope of the Search and Identification of the Prior Art [R-2]

As noted in **MPEP § 2181**, in *In re Donaldson Co.*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994) the Federal Circuit recognized that it is important to retain the principle that claim language should be given its broadest reasonable interpretation. This principle is important because it helps insure that the statutory presumption of validity attributed to each claim of an issued patent is warranted by the search and examination conducted by the examiner. It is also important from the standpoint that the scope of protection afforded by patents issued prior to *Donaldson* are not unnecessarily limited by the latest interpretation of this statutory provision. Finally, it is important from the standpoint of avoiding the necessity for a patent specification to become a catalogue of existing technology. The specification need not describe the equivalents of the structures, material, or acts corresponding to the means- (or step-) plus-function claim element. See *In re Noll*, 545 F.2d 141, 149-50, 191 USPQ 721, 727 (CCPA 1976) ("The meaning of 'equivalents' is well understood in patent law, … and an applicant need not describe in his specification the full range of equivalents of his invention.") (citation omitted). A patent specification need not teach, and preferably omits, what is well known in the art. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).

The *Donaldson* decision thus does not substantially alter examining practice and procedure relative to the scope of the search. Both before and after *Donaldson*, the application of a prior art reference to a means or step plus function limitation requires that the prior art element perform the identical function specified in the claim. However, if a prior art reference teaches identity of function to that specified in a claim, then under *Donaldson* an examiner carries the initial burden of proof for showing that the prior art structure or step is the same as or equivalent to the structure, material, or acts described in the specification which has been identified as corresponding to the claimed means or step plus function.

The "means or step plus function" limitation should be interpreted in a manner consistent with the specification disclosure. >The Federal Circuit explained the two step analysis involved in construing means-plus-function limitations in *Golight Inc. v. Wal-Mart Stores Inc.*, 355 F.3d 1327, 1333-34, 69 USPQ2d 1481, 1486 (Fed. Cir. 2004):

> The first step in construing a means-plus-function claim limitation is to define the particular function of the claim limitation. *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1376 [58 USPQ2d 1801, 1806] (Fed. Cir. 2001). "The court must construe the function of a means-plus-function limitation to include the limitations contained in the claim language, and only those limitations." *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1113 [63 USPQ2d 1725, 1730] (Fed. Cir. 2002)…. The next step in construing a means-plus-function claim limitation is to look to the specification and identify the corresponding structure for that function. "Under this second step, 'structure disclosed in the specification is "corresponding" structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim.'" *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1210 [68 USPQ2d 1263, 1267] (Fed. Cir. 2003) (quoting *B. Braun Med. Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 [43 USPQ2d 1896, 1900] (Fed. Cir. 1997)).<

If the specification defines what is meant by the limitation for the purposes of the claimed invention, the examiner should interpret the limitation as having that meaning. If no definition is provided, some judgment must be exercised in determining the scope of the limitation. See, e.g., *B. Braun Medical, Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424, 43 USPQ2d 1896, 1900 (Fed. Cir. 1997) ("We hold that, pursuant to [**35 U.S.C. 112**, sixth paragraph], structure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim. This duty to link or associate structure to function is the *quid pro quo* for the convenience of employing **112**, paragraph 6." The court refused to interpret a means-plus-function limitation as corresponding to a disclosed valve seat structure, as argued by patentee, since there was no indication in the specification or prosecution history that this structure corresponds to the recited function, and there was an explicitly clear association between that function and a traverse cross section bar structure disclosed in the specification.).

2183 Making a Prima Facie Case of Equivalence [R-9]

If the examiner finds that a prior art element

(A) performs the function specified in the claim,

(B) is not excluded by any explicit definition provided in the specification for an equivalent, and

(C) is an equivalent of the means- (or step-) plus-function limitation,

the examiner should provide an explanation and rationale in the Office action as to why the prior art element is an equivalent. >See *In re Bond*, 910 F.2d 831, 833, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990) ("The disclosed and prior art structures are not identical, but the claim may nonetheless be anticipated. … However, the Board made no finding that the delay means of claim 1 and that embodied in the Curtis device are structurally equivalent. Accordingly, its decision as to the anticipation of claim 1 is deficient and must be vacated.")<

Factors that will support a conclusion that the prior art element is an equivalent are:

(A) the prior art element performs the identical function specified in the claim in substantially the same way, and produces substantially the same results as the corresponding element disclosed in the specification. *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000) (An internal adhesive sealing the inner surfaces of an envelope pocket was not held to be equivalent to an adhesive on a flap which attached to the outside of the pocket. Both the claimed invention and the accused device performed the same function of closing the envelope. But the accused device performed it in a substantially different way (by an internal adhesive on the inside of the pocket) with a substantially different result (the adhesive attached the inner surfaces of both sides of the pocket)); *Odetics Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267, 51 USPQ2d 1225, 1229-30 (Fed. Cir. 1999); *Lockheed Aircraft Corp. v. United States*, 193 USPQ 449, 461 (Ct. Cl. 1977). The concepts of equivalents as set forth in *Graver Tank & Mfg. Co. v. Linde Air Products*, 339 U.S. 605, 85 USPQ 328 (1950) are relevant to any "equivalents" determination. *Polumbo v. Don-Joy Co.*, 762 F.2d 969, 975 n.4, 226 USPQ 5, 8-9 n.4 (Fed. Cir. 1985).

(B) a person of ordinary skill in the art would have recognized the interchangeability of the element shown in the prior art for the corresponding element disclosed in the specification. *Caterpillar Inc. v. Deere & Co.*, 224 F.3d 1374, 56 USPQ2d 1305 (Fed. Cir. 2000); *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1316, 50 USPQ2d 1161, 1165 (Fed. Cir. 1999); *Chiuminatta Concrete*

Concepts, Inc. v. Cardinal Indus. Inc., 145 F.3d 1303, 1309, 46 USPQ2d 1752, 1757 (Fed. Cir. 1998); *Lockheed Aircraft Corp. v. United States*, 193 USPQ 449, 461 (Ct. Cl. 1977 *); Data Line Corp. v. Micro Technologies, Inc.*, 813 F.2d 1196, 1 USPQ2d 2052 (Fed. Cir. 1987).

(C) there are insubstantial differences between the prior art element and the corresponding element disclosed in the specification. *IMS Technology, Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1436, 54 USPQ2d 1129, 1138 (Fed. Cir. 2000); *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 117 S. Ct. 1040, 41 USPQ2d 1865, 1875 (1997); *Valmont Industries, Inc. v. Reinke Mfg. Co.*, 983 F.2d 1039, 25 USPQ2d 1451 (Fed. Cir. 1993). See also *Caterpillar Inc. v. Deere & Co.*, 224 F.3d 1374, 56 USPQ2d 1305 (Fed. Cir. 2000) (A structure lacking several components of the overall structure corresponding to the claimed function and also differing in the number and size of the parts may be insubstantially different from the disclosed structure. The limitation in a means-plus-function claim is the overall structure corresponding to the claimed function. The individual components of an overall structure that corresponds to the claimed function are not claim limitations. Also, potential advantages of a structure that do not relate to the claimed function should not be considered in an equivalents determination under 35 U.S.C. **112**, sixth paragraph).

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A showing of at least one of the above-noted factors by the examiner should be sufficient to support a conclusion that the prior art element is an equivalent. The examiner should then conclude that the claimed limitation is met by the prior art element. In addition to the conclusion that the prior art element is an equivalent, examiners should also demonstrate, where appropriate, why it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute applicant's described structure, material, or acts for that described in the prior art reference. See *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). The burden then shifts to applicant to show that the element shown in the prior art is not an equivalent of the structure, material or acts disclosed in the application. *In re Mulder*, 716 F.2d 1542, 219 USPQ 189 (Fed. Cir. 1983). No further analysis of equivalents is required of the examiner until applicant disagrees with the examiner's conclusion, and provides reasons why the prior art element should not be considered an equivalent. See also, *In re Walter*, 618 F.2d 758, 768, 205 USPQ 397, 407-08 (CCPA 1980) (a case treating **35 U.S.C. 112**, sixth paragraph, in the context of a determination of statutory subject matter and noting "If the functionally-defined disclosed means and their equivalents are so broad that they encompass any and every means for performing the recited functions . . . the burden must be placed on the applicant to demonstrate that the claims are truly drawn to specific apparatus distinct from other apparatus capable of performing the identical functions"); *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 229 (CCPA 1971) (a case in which the court treated as improper a rejection under **35 U.S.C. 112**, second paragraph, of functional language, but noted that "where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristics relied on"); and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980) (a case indicating that the burden of proof can be shifted to the applicant to show that the subject matter of the prior art does not possess the characteristic relied on whether the rejection is based on inherency under **35 U.S.C. 102** or obviousness under **35 U.S.C. 103**).

See **MPEP § 2184** when determining whether the applicant has successfully met the burden of proving that the prior art element is not equivalent to the structure, material or acts described in the applicant's specification.

IF NONEQUIVALENCE SHOWN, EXAMINER MUST CONSIDER OBVIOUSNESS

However, even where the applicant has met that burden of proof and has shown that the prior art element is not equivalent to the structure, material or acts described in the applicant's specification, the examiner must still make a **35 U.S.C. 103** analysis to determine if the claimed means or step plus function is obvious from the prior art to one of ordinary skill in the art. Thus, while a finding of nonequivalence prevents a prior art element from anticipating a means or step plus function limitation in a claim, it does not prevent the prior art element from rendering the claim limitation obvious to one of ordinary skill in the art. Because the exact scope of an "equivalent" may be uncertain, it would be appropriate to apply a **35 U.S.C. 102**/103 rejection where the balance of the claim limitations are anticipated by the prior art relied on. A similar approach is authorized in the case of product-by-process claims because the exact identity of the claimed product or the prior art product cannot be determined by the examiner. *In re Brown*, 450 F.2d 531, 173 USPQ 685 (CCPA 1972). In addition, although it is normally the best practice to rely on only the best prior art references in rejecting a claim, alternative grounds of rejection may be appropriate where the prior art shows elements that are different from each other, and different from the specific structure, material or acts described in

the specification, yet perform the function specified in the claim.

2184 Determining Whether an Applicant Has Met the Burden of Proving Nonequivalence After a Prima Facie Case Is Made [R-9]

The specification need not describe the equivalents of the structures, material, or acts corresponding to the means-(or step-) plus-function claim element. See *In re Noll*, 545 F.2d 141, 149-50, 191 USPQ 721, 727 (CCPA 1976) (the meaning of equivalents is well understood in patent law, and an applicant need not describe in his specification the full range of equivalents of his invention) (citation omitted). *Cf. Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986) ("a patent need not teach, and preferably omits, what is well known in the art"). Where, however, the specification is silent as to what constitutes equivalents and the examiner has made out a *prima facie* case of equivalence, the burden is placed upon the applicant to show that a prior art element which performs the claimed function is not an equivalent of the structure, material, or acts disclosed in the specification. See *In re Mulder*, 716 F.2d 1542, 1549, 219 USPQ 189, 196 (Fed. Cir. 1983).

If the applicant disagrees with the inference of equivalence drawn from a prior art reference, the applicant may provide reasons why the applicant believes the prior art element should not be considered an equivalent to the specific structure, material or acts disclosed in the specification. Such reasons may include, but are not limited to:

(A) Teachings in the specification that particular prior art is not equivalent;

(B) Teachings in the prior art reference itself that may tend to show nonequivalence; or

(C) **37 CFR 1.132** affidavit evidence of facts tending to show nonequivalence.

I. TEACHINGS IN APPLICANT'S SPECIFICATION

When the applicant relies on teachings in applicant's own specification, the examiner must make sure that the applicant is interpreting the "means or step plus function" limitation in the claim in a manner which is consistent with the disclosure in the specification. If the specification defines what is meant by "equivalents" to the disclosed embodiments for the purpose of the claimed means or step plus function, the examiner should interpret the limitation as having that meaning. If no definition is provided, some judgment must be exercised in determining the scope of "equivalents." Generally, an "equivalent" is interpreted as embracing more than the specific elements described in the specification for performing the specified function, but less than any element that performs the function specified in the claim. See, e.g., *NOMOS Corp. v. BrainLAB USA Inc.*, 357 F.3d, 1364, 1368, 69 USPQ2d 1853, 1856 (Fed. Cir. 2004) (only one embodiment is described, therefore the corresponding structure is limited to that embodiment and equivalents thereof). To interpret "means plus function" limitations as limited to a particular means set forth in the specification would nullify the provisions of **35 U.S.C. 112** requiring that the limitation shall be construed to cover the structure described in the specification and equivalents thereof. *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1574, 225 USPQ 236, 238 (Fed. Cir. 1985).

The scope of equivalents embraced by a claim limitation is dependent on the interpretation of an "equivalent." The interpretation will vary depending on how the element is described in the supporting specification. The claim may or may not be limited to particular structure, material or acts (e.g., steps) as opposed to any and all structure, material or acts performing the claimed function, depending on how the specification treats that question. See, e.g., *Ishida Co. v. Taylor*, 221 F.3d 1310, 55 USPQ2d 1449 (Fed. Cir. 2000) (The court construed the scope of a means-plus-function claim element where the specification disclosed two structurally very different embodiments for performing the claimed function by looking separately to each embodiment to determine corresponding structures. The court declined to adopt a single claim construction encompassing both embodiments since it would be so broad as to describe systems both with and without the fundamental structural features of each embodiment.).

If the disclosure is so broad as to encompass any and all structure, material or acts for performing the claimed function, the claims must be read accordingly when determining patentability. When this happens the limitation otherwise provided by "equivalents" ceases to be a limitation on the scope of the claim in that an equivalent would be any structure, material or act other than the ones described in the specification that perform the claimed function. For example, this situation will often be found in cases where (A) the claimed invention is a combination of elements, one or more of which are selected from elements that are old, *per se*, or (B) apparatus claims are treated as indistinguishable from method claims. See, for example, *In re Meyer*, 688 F.2d 789, 215 USPQ 193 (CCPA 1982); *In re Abele*, 684 F.2d 902, 909, 214 USPQ 682, 688 (CCPA 1982); *In re Walter*, 618 F.2d 758, 767, 205 USPQ 397, 406-07 (CCPA 1980); *In re Maucorps*, 609 F.2d 481, 203 USPQ 812 (CCPA 1979); *In re Johnson*, 589 F.2d 1070, 200 USPQ

199 (CCPA 1978); and *In re Freeman*, 573 F.2d 1237, 1246, 197 USPQ 464, 471 (CCPA 1978).

On the other end of the spectrum, the "equivalents" limitation as applied to a claim may also operate to constrict the claim scope to the point of covering virtually only the disclosed embodiments. This can happen in circumstances where the specification describes the invention only in the context of a specific structure, material or act that is used to perform the function specified in the claim.

II. FACTORS TO BE CONSIDERED IN DECIDING EQUIVALENCE

When deciding whether an applicant has met the burden of proof with respect to showing nonequivalence of a prior art element that performs the claimed function, the following factors may be considered. First, unless an element performs the identical function specified in the claim, it cannot be an equivalent for the purposes of **35 U.S.C. 112**, sixth paragraph. *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 4 USPQ2d 1737 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 961 (1988).

Second, while there is no litmus test for an "equivalent" that can be applied with absolute certainty and predictability, there are several indicia that are sufficient to support a conclusion that one element is or is not an "equivalent" of a different element in the context of **35 U.S.C. 112**, sixth paragraph. **>Indicia that will support a conclusion that one element is or is not an equivalent of another are set forth in **MPEP § 2183**.

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III. MERE ALLEGATIONS OF NONEQUIVALENCE ARE NOT SUFFICIENT

In determining whether arguments or **37 CFR 1.132** evidence presented by an applicant are persuasive that the element shown in the prior art is not an equivalent, the examiner should consider and weigh as many of the above-indicated or other indicia as are presented by applicant, and should determine whether, on balance, the applicant has met the burden of proof to show nonequivalence. However, under no circumstance should an examiner accept as persuasive a bare statement or opinion that the element shown in the prior art is not an equivalent embraced by the claim limitation. Moreover, if an applicant argues that the "means" or "step" plus function language in a claim is limited to certain specific structural or additional functional characteristics (as opposed to "equivalents" thereof) where the specification does not describe the invention as being only those specific characteristics, the claim should not be allowed until the claim is amended to recite those specific structural or additional functional characteristics. Otherwise, a claim could be allowed having broad functional language which, in reality, is limited to only the specific structure or steps disclosed in the specification. This would be contrary to public policy of granting patents which provide adequate notice to the public as to a claim's true scope.

IV. APPLICANT MAY AMEND CLAIMS

Finally, as in the past, applicant has the opportunity during proceedings before the Office to amend the claims so that the claimed invention meets all the statutory criteria for patentability. An applicant may choose to amend the claim by further limiting the function so that there is no longer identity of function with that taught by the prior art element, or the applicant may choose to replace the claimed means plus function limitation with specific structure, material or acts that are not described in the prior art.

2185 Related Issues Under 35 U.S.C. 112, First or Second Paragraphs [R-6]

Interpretation of claims as set forth in **MPEP § 2181** may create some uncertainty as to what applicant regards as the invention. If this issue arises, it should be addressed in a rejection under **35 U.S.C. 112**, second paragraph. While **35 U.S.C. 112**, sixth paragraph, permits a particular form of claim limitation, it cannot be read as creating an exception either to the description, enablement or best mode requirements of the first paragraph or the definiteness requirement of the second paragraph of **35 U.S.C. 112**. *In re Knowlton*, 481 F.2d 1357, 178 USPQ 486 (CCPA 1973).

If a "means or step plus function" limitation recited in a claim is not supported by corresponding structure, material or acts in the specification disclosure, the following rejections should be considered:

(A) under **35 U.S.C. 112**, first paragraph, as not being supported by an enabling disclosure because the person skilled in the art would not know how to make and use the invention without a description of elements to perform the function. The description of an apparatus with block diagrams describing the function, but not the structure, of the apparatus is not fatal under the enablement requirement of **35 U.S.C. 112**, first paragraph, as long as the structure is conventional and can be determined without an undue amount of experimentation. *In re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971);

(B) under **35 U.S.C. 112**, second paragraph, as being indefinite. See > *Biomedino, LLC v. Waters Technology Corp.*, 490 F.3d 946, 952, 83 USPQ2d 1118, 1123 (Fed. Cir. 2007), < *In re Dossel*, 115 F.3d 942, 946, 42 USPQ2d 1881, 1884 (Fed. Cir. 1997) and **MPEP § 2181**; and

(C) under **35 U.S.C. 102** or **103** where the prior art anticipates or renders obvious the claimed subject matter including the means or step that performs the function specified in the claim, the theory being that since there is no corresponding structure, etc., in the specification to limit the means or step plus function limitation, an equivalent is any element that performs the specified function.

2186 Relationship to the Doctrine of Equivalents

The doctrine of equivalents arises in the context of an infringement action. If an accused product or process does not literally infringe a patented invention, the accused product or process may be found to infringe under the doctrine of equivalents. The essential objective inquiry is: "Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention?" *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 117 S. Ct. 1040, 41 USPQ2d 1865, 1875 (1997). In determining equivalence, "[a]n analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute plays a role substantially different from the claimed element." 41 USPQ2d at 1875.

35 U.S.C. 112, sixth paragraph, permits "means or step plus function" limitations in claims to combinations, "with the proviso that application of the broad literal language of such claims must be limited to only those means that are 'equivalent' to the actual means shown in the patent specification. This is an application of the doctrine of equivalents in a restrictive role, narrowing the application of broad literal claim elements." 41 USPQ2d at 1870. Accordingly, decisions involving the doctrine of equivalents should be considered, but should not unduly influence a determination under **35 U.S.C. 112**, sixth paragraph, during *ex parte* examination.

2190 Prosecution Laches [R-5]

The Federal Circuit affirmed a rejection of claims in a patent application on the ground that applicant had forfeited his right to a patent under the doctrine of prosecution history laches for unreasonable and undue delay in prosecution. *In re Bogese*, 303 F.3d 1362, 1369, 64 USPQ2d 1448, 1453 (Fed. Cir. 2002) (Applicant "filed twelve continuation applications over an eight-year period and did not substantively advance prosecution when required and given an opportunity to do so by the PTO."). >While there are no firm guidelines for determining when laches is triggered, it applies only in egregious cases of unreasonable and unexplained delay in prosecution. For example, where there are "multiple examples of repetitive filings that demonstrate a pattern of unjustified delayed prosecution," laches may be triggered. *Symbol Tech. Inc. v. Lemelson Med., Educ., & Research Found.*, 422 F.3d 1378, 1385, 76 USPQ2d 1354, 1360 (Fed. Cir. 2005)(Court discussed difference between legitimate reasons for refiling patent applications and refilings for the business purpose of delaying the issuance of previously allowed claims.).< An examiner should obtain approval from the TC Director before making a rejection on the grounds of prosecution history laches.