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2105 Patentable Subject Matter — Living Subject Matter [R–2]

The decision of the Supreme Court in *Diamond* v. *Chakrabarty*, 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 cannons 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.' V 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 non–naturally 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 & Kalo Co., 333 U.S.127 (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:

(1) That the Court did not limit its decision to genetically engineered living organisms,

(2) The Court enunciated a very broad interpretation of "manufacture" and "composition of matter" in Section 101 (Note esp. quotes 1, 2, and 3 above),

(3) The Court set forth several tests for weighing whether patentable subject matter under Section 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):

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

– "A non–naturally occurring manufacture or composition of matter — a product of human ingenuity — having a distinctive name, character, [and] use" is patentable subject matter.

– "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.' "

– "However, 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 machinery* (emphasis added) is a manufacture under Section 101."

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 belief that plants, even those artificially bred, were products of nature for purposes of the patent law . . . 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)."

The Office will decide the questions as to patentable subject matter under 35 U.S.C. 101 on a case–by–case basis following the tests set forth in *Chakrabarty*; e.g., that "a non–naturally occurring manufacture or composition of matter" is patentable, etc. It is inappropriate to try to attempt to set forth here in advance the exact parameters to be followed.

The standard of patentability has not and will not be lowered. The requirements of 35 U.S.C. 102 and 103 still apply. The tests outlined above simply mean that a rational basis will be present for any 35 U.S.C. 101 determination. In addition, the requirements of 35 U.S.C. 112 must also be met. In this regard, see MPEP § 608.01(p).

Following this analysis by the Supreme Court of the scope of 35 U.S.C. 101, the Board of Patent Appeals and Interferences has determined that plant subject matter or an animal may be protected under 35 U.S.C. 101. In *Ex Parte Hibberd*, 227 USPQ 443 (**>Bd. Pat. App. & Inter.< 1985) 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 (35 U.S.C. 161 – 164) or the Plant Variety Protection Act (7 U.S.C. 2321 et seq.). 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.

>If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter. 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.<

2106 Patentable Subject Matter – **>Computer–Related Inventions< [R–2]

**

>I. Introduction

These Examination Guidelines for Computer–Related Inventions ("Guidelines") are to assist Office personnel in the examination of applications drawn to computer–related inventions. "Computer–related inventions" include inventions implemented in a computer and inventions employing computer–readable media. The 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. These Guidelines have been 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 failure by Office personnel to follow the Guidelines is neither appealable nor petitionable.

The Guidelines alter the procedures Office personnel will follow when examining applications drawn to computer–related inventions and are equally applicable to claimed inventions implemented in either hardware or software. The Guidelines also clarify the Office's position on certain patentability standards related to this field of technology. Office personnel are to rely on these

Guidelines in the event of any inconsistent treatment of issues between these Guidelines and any earlier provided guidance from the Office.

The Freeman–Walter–Abele test (*In re Abele*, 684 F.2d 902, 905–07, 214 USPQ 682, 685–87 (CCPA 1982); *In re Walter*, 618 F.2d 758, 767, 205 USPQ 397, 406–07 (CCPA 1980); *In re Freeman*, 573 F.2d 1237, 1245, 197 USPQ 464, 471 (CCPA 1978)) may additionally be relied upon in analyzing claims directed solely to a process for solving a mathematical algorithm.

Office personnel have had difficulty in properly treating claims directed to methods of doing business. Claims should not be categorized as methods of doing business. Instead, such claims should be treated like any other process claims, pursuant to these Guidelines when relevant. See, e.g., *In re Toma*, 575 F.2d 872, 877–78, 197 USPQ 852, 857 (CCPA 1978); *In re Musgrave*, 431 F.2d 882, 893, 167 USPQ 280, 289–90 (CCPA 1970). See also *In re Schrader*, 22 F.3d 290, 297–98, 30 USPQ2d 1455, 1461–62 (Fed. Cir. 1994) (Newman, J., dissenting); *Paine, Webber, Jackson & Curtis, Inc.* v. *Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 564 F. Supp. 1358, 1368–69, 218 USPQ 212, 220 (D. Del. 1983).

The appendix which appears at the end of this section includes a flow chart of the process Office personnel will follow in conducting examinations for computer–related inventions.

II. 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, Office 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, Office 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, Office 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. (As the courts have repeatedly reminded the Office: "The goal is to answer the question " 'What did applicants invent?' " *Abele*, 684 F.2d at 907, 214 USPQ at 687. Accord, e.g., *Arrhythmia Research Tech.* v. *Corazonix Corp.*, 958 F.2d 1053, 1059, 22 USPQ2d 1033, 1038 (Fed. Cir. 1992).) Consequently, Office personnel will no longer begin examination by determining if a claim recites a "mathematical algorithm." Rather, they will review the complete specification, including the detailed description of the invention, any specific embodiments that have been disclosed, the claims and any specific utilities that have been asserted for the invention.

A. Identify and Understand Any Practical Application Asserted for the Invention

The subject matter sought to be patented must be a "useful" process, machine, manufacture, or composition of matter; i.e., it must have a practical application. 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 Ziegler*, 992 F.2d 1197, 1200–03, 26 USPQ2d 1600, 1603–06 (Fed. Cir. 1993)). 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.

The utility of an invention must be within the "technological" arts. See, e.g., *Musgrave*, 431 F.2d at 893, 167 USPQ at 289–90, cited with approval in *Schrader*, 22 F.3d at 297, 30 USPQ2d at 1461 (Newman, J., dissenting). (The definition of "technology" is the "application of science and engineering to the development of machines and procedures in order to enhance or improve human conditions, or at least to improve human efficiency in some respect." Computer Dictionary 384 (Microsoft Press, 2d ed. 1994).) A computer–related invention is within the technological arts. A practical application of a computer–related invention is statutory subject matter. This requirement can be discerned from the variously phrased prohibitions against the patenting of abstract ideas, laws of nature or natural phenomena. An invention that has a practical application in the techno-

logical arts satisfies the utility requirement. See, e.g., *In re Alappat*, 33 F.3d 1526, 1543, 31 USPQ2d 1545, 1556–57 (Fed. Cir. 1994) (in banc) (quoting *Diamond* v. *Diehr*, 450 U.S. 175, 192, 209 USPQ 1, 10 (1981)). See also *Alappat* at 1569, 31 USPQ2d at 1578–79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 114–19 (1854)); *Arrhythmia*, 958 F.2d at 1056, 22 USPQ2d at 1036; *Musgrave*, 431 F.2d at 893, 167 USPQ at 289–90 ("All that is necessary, in our view, to make a sequence of operational steps a statutory 'process' within 35 U.S.C. 101 is that it be in the technological arts so as to be in consonance with the Constitutional purpose to promote the progress of 'useful arts.' Const. Art. 1, sec. 8.").

The applicant is in the best position to explain why an invention is believed useful. Office personnel should therefore focus their efforts on pointing out statements made in the specification that identify all practical applications for the invention. Office personnel should rely on such statements throughout the examination when assessing the invention for compliance with all statutory criteria. An applicant may assert more than one practical application, but only one is necessary to satisfy the utility requirement. Office personnel should review the entire disclosure to determine the features necessary to accomplish at least one asserted practical application.

B. Review the Detailed Disclosure and Specific Embodiments of the Invention to Determine 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, Office personnel should begin their evaluation of a computer-related invention as follows:

- determine what the programmed computer does when it performs the processes dictated by the software (i.e., the functionality of the programmed computer) (*Arrhythmia*, 958 F.2d at 1057, 22 USPQ at 1036, "It is of course true that a modern digital computer manipulates data, usually in binary form, by performing mathematical operations, such as addition, subtraction, multiplication, division, or bit shifting, on the data. But this is only how the computer does what it does. Of importance is the significance of the data and their manipulation in the real world, i.e., what the computer is doing.");

- determine how the computer is to be configured to provide that functionality (i.e., what elements constitute the programmed computer and how those elements are configured and interrelated to provide the specified functionality); and

- if applicable, determine the relationship of the programmed computer to other subject matter outside the computer that constitutes the invention (e.g., machines, devices, materials, or process steps other than those that are part of or performed by the programmed computer). (Many computer-related inventions do not consist solely of a computer. Thus, Office personnel should identify those claimed elements of the computer-related invention that are not part of the programmed computer, and determine how those elements relate to the programmed computer. Office personnel should look for specific information that explains the role of the programmed computer in the overall process or machine and how the programmed computer is to be integrated with the other elements of the apparatus or used in the process.)

Patent applicants can assist the Office by preparing applications that clearly set forth these aspects of a computer-related 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. Office personnel must thoroughly analyze the language of a claim before determining if the claim complies with each statutory requirement for patentability.

Office 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. Product claims are claims that are directed to either machines, manufactures or compositions of matter. The discrete physical

structures may be comprised of hardware or a combination of hardware and software.

Office 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; i.e., whether or not the claimed invention is defined using means or step plus function language. The correlation step will ensure that Office 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.)

Office personnel must rely on the applicant's disclosure to properly determine the meaning of terms used in the claims. *Markman* v. *Westview Instruments*, 52 F.3d 967, 980, 34 USPQ2d 1321, 1330 (Fed. Cir.) (*in banc*), aff'd, ** U.S. **, 116 S. Ct. 1384 (1996). An applicant is entitled to be his or her own lexicographer, and in many instances will provide an explicit definition for certain terms used in the claims. 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. Office personnel should determine if the original disclosure provides a definition consistent with any assertions made by applicant. See, e.g., *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)). If an applicant does not define a term in the specification, that term will be given its "common meaning." *Paulsen* at 1480, 31 USPQ2d at 1674.

If the applicant asserts that a term has a meaning that conflicts with the term's art–accepted meaning, Office personnel should encourage the applicant to amend the claim to better reflect what applicant intends to claim as the invention. If the application becomes a patent, it becomes prior art against subsequent applications. Therefore, it is important for later search purposes to have the patentee employ commonly accepted terminology, particularly for searching text–searchable databases.

Office personnel must always remember to use the perspective of one of ordinary skill in the art. Claims and disclosures are not to be evaluated in a vacuum. If elements of an invention are well known in the art, the applicant does not have to provide a disclosure that describes those elements. In such a case the elements will be construed as encompassing any and every art–recognized hardware or combination of hardware and software technique for implementing the defined requisite functionalities.

Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. See, e.g., *In re Zletz*, 893 F.2d 319, 321–22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow. . . . The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed. . . . An 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.").

Where means plus function language is used to define the characteristics of a machine or manufacture invention, claim limitations must be interpreted to read on only the structures or materials disclosed in the specification and "equivalents thereof." (Two in banc decisions of the Federal Circuit have made clear that the Office is to interpret means plus function language according to 35 U.S.C. 112, sixth paragraph. In the first, *In re Donaldson*, 16 F.3d 1189, 1193, 29 USPQ2d 1845, 1848 (Fed. Cir. 1994), the court held:

> The plain and unambiguous meaning of paragraph six is that one construing means–plus–function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure. Paragraph six does not state or even suggest that the PTO is exempt from this mandate, and there is no legislative history indicating that Congress intended that the PTO should be. Thus, this court must accept the plain and precise language of paragraph six.

Consistent with *Donaldson*, in the second decision, *In re Alappat*, 33 F.3d at 1540, 31 USPQ2d at 1554, the Federal Circuit held:

> Given *Alappat*'s disclosure, it was error for the Board majority to interpret each of the means clauses in claim 15 so broadly as to "read on any and every means for performing the function" recited, as it said it was doing, and then to conclude that claim 15 is nothing more than a process claim wherein each means clause represents a step in that process. Contrary to suggestions by the Commissioner, this court's precedents do not support the Board's view that the particular apparatus claims at issue in this case may be viewed as nothing more than process claims.)

Disclosure may be express, implicit or inherent. Thus, at the outset, Office personnel must attempt to correlate claimed means to elements set forth in the written description. The written description includes the specification and the drawings. Office 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. Further guidance in interpreting the scope of equivalents is provided in MPEP § 2181 through § 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 impose that limitation. A broad interpretation of a claim by Office 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. Office 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. at 188–89, 209 USPQ at 9 ("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.").

III. Conduct a Thorough Search of the Prior Art

Prior to classifying the claimed invention under 35 U.S.C. 101, Office 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 Office 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.

IV. 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

As the Supreme Court has held, Congress chose the expansive language of 35 U.S.C. 101 so as to include "anything under the sun that is made by man." *Diamond* v. *Chakrabarty*, 447 U.S. 303, 308–09, 206 USPQ 193, 197 (1980). Accordingly, 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.

(In *Diamond*, 477 U.S. at 308–309, 206 USPQ at 197, the court stated:

> 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. The relevant legislative history also supports a broad construction. The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]." Act of Feb. 21,

1793, 1, 1 Stat. 319. The Act embodied Jefferson's philosophy that "ingenuity should receive a liberal encouragement." 5 Writings of Thomas Jefferson 75–76 (Washington ed. 1871). 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 anything under the sun that is made by man." S. Rep. No. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess. 6 (1952).

This perspective has been embraced by the Federal Circuit:

> The plain and unambiguous meaning of 101 is that any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may be patented if it meets the requirements for patentability set forth in Title 35, such as those found in ' 102, 103, and 112. The use of the expansive term "any" in 101 represents Congress's intent not to place any restrictions on the subject matter for which a patent may be obtained beyond those specifically recited in 101 and the other parts of Title 35.... Thus, it is improper to read into 101 limitations as to the subject matter that may be patented where the legislative history does not indicate that Congress clearly intended such limitations. [*Alappat*, 33 F.3d at 1542, 31 USPQ2d at 1556.])

As cast, 35 U.S.C. 101 defines four categories of inventions that Congress deemed to be the appropriate subject matter of a patent; namely, processes, machines, manufactures and compositions of matter. The latter three categories define "things" 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.").

Federal courts have held that 35 U.S.C. 101 does have certain limits. First, the phrase "anything under the sun that is made by man" is limited by the text of 35 U.S.C. 101, meaning that one may only patent something that is a machine, manufacture, composition of matter or a process. See, e.g., *Alappat*, 33 F.3d at 1542, 31 USPQ2d at 1556; *In re Warmerdam*, 33 F.3d 1354, 1358, 31 USPQ2d 1754, 1757 (Fed. Cir. 1994). Second, 35 U.S.C. 101 requires that the subject matter sought to be patented be a "useful" invention. Accordingly, a complete definition of the scope of 35 U.S.C. 101, reflecting Congressional intent, is that any new and useful process, machine, manufacture or composition of matter under the sun that is made by man is the proper subject matter of a patent. Subject matter not within one of the four statutory invention categories or which is not "useful" in a patent sense is, accordingly, not eligible to be patented.

The subject matter courts have found to be outside the four statutory categories of invention is limited to abstract ideas, laws of nature and natural phenomena. While this is easily stated, determining whether an applicant is seeking to patent an abstract idea, a law of nature or a natural phenomenon has proven to be challenging. These three exclusions recognize that subject matter that is not a practical application or use of an idea, a law of nature or a natural phenomenon is not patentable. See, e.g., *Rubber–Tip Pencil Co.* v. *Howard*, 87 U.S. 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 (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."); *Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759 ("steps of 'locating' a medial axis, and 'creating' a bubble hierarchy ... describe nothing more than the manipulation of basic mathematical constructs, the paradigmatic 'abstract idea'").

Courts have expressed a concern over "preemption" of ideas, laws of nature or natural phenomena. 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."); *Funk Brothers Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 132, 76 USPQ 280, 282 (1948) (combination of six species of bacteria held to be nonstatutory subject matter). The concern over preemption serves to bolster and justify the prohibition against the patenting of such subject matter. In fact, such concerns are only relevant to claiming a scientific truth or principle. Thus, a claim to an "abstract idea" is nonstatutory because it does not represent a practical application of the idea, not because it would preempt the idea.

B. Classify the Claimed Invention as to Its Proper Statutory Category

To properly determine whether a claimed invention complies with the statutory invention requirements of 35 U.S.C. 101, Office personnel should classify each claim into one or more statutory or nonstatutory categories. If the claim falls into a nonstatutory category, that

should not preclude complete examination of the application for satisfaction of all other conditions of patentability. This classification is only an initial finding at this point in the examination process that will be again assessed after the examination for compliance with 35 U.S.C. 102, 103, and 112 is completed and before issuance of any Office action on the merits.

If the invention as set forth in the written description is statutory, but the claims define subject matter that is not, the deficiency can be corrected by an appropriate amendment of the claims. In such a case, Office personnel should reject the claims drawn to nonstatutory subject matter under 35 U.S.C. 101, but identify the features of the invention that would render the claimed subject matter statutory if recited in the claim.

1. Nonstatutory Subject Matter

Claims to computer-related inventions that are clearly nonstatutory fall into the same general categories as nonstatutory claims in other arts, namely natural phenomena such as magnetism, and abstract ideas or laws of nature which constitute "descriptive material." Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when encoded on a computer-readable medium. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.

Both types of "descriptive material" are nonstatutory when claimed as descriptive material *per se*. When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases. Compare *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure that increases computer efficiency held statutory) and *Warmerdam*, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having specific memory held statutory product-by-process claim) with *Warmerdam*, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory). When nonfunctional descriptive material is recorded on some computer-readable medium, it is not structurally and functionally interrelated to the medium but is merely carried by the medium. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory. Such a result would exalt form over substance. *In re Sarkar*, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978)("[E]ach invention must be evaluated as claimed; yet semantogenic considerations preclude a determination based solely on words appearing in the claims. In the final analysis under 101, the claimed invention, as a whole, must be evaluated for what it is.") (quoted with approval in *Abele*, 684 F.2d at 907, 214 USPQ at 687). See also *In re Johnson*, 589 F.2d 1070, 1077, 200 USPQ 199, 206 (CCPA 1978) ("form of the claim is often an exercise in drafting"). Thus, nonstatutory music does not become statutory by merely recording it on a compact disk. Protection for this type of work is provided under the copyright law.

Claims to processes that do nothing more than solve mathematical problems or manipulate abstract ideas or concepts are more complex to analyze and are addressed below. See sections IV.B.2(d) and IV.B.2(e).

(a) Functional Descriptive Material: "Data Structures" Representing Descriptive Material *Per Se* or Computer Programs Representing Computer Listings *Per Se*

Data structures not claimed as embodied in computer-readable media are descriptive material per se and are not statutory because they are neither physical "things" nor statutory processes. See, e.g., *Warmerdam*, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory). Such claimed data structures do not define any structural and functional interrelationships between the data structure and other claimed aspects of the invention which permit the data structure's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a data structure defines structural and functional interrelationships between the data structure and the medium which permit the data structure's functionality to be realized, and is thus statutory.

Similarly, computer programs claimed as computer listings per se, i.e., the descriptions or expressions of the programs, are not physical "things," nor are they statutory processes, as they are not "acts" being performed. Such claimed computer programs do not define any

structural and functional interrelationships between the computer program and other claimed aspects of the invention which permit the computer program's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a computer program defines structural and functional interrelationships between the computer program and the medium which permit the computer program's functionality to be realized, and is thus statutory. Accordingly, it is important to distinguish claims that define descriptive material per se from claims that define statutory inventions.

Computer programs are often recited as part of a claim. Office personnel should determine whether the computer program is being claimed as part of an otherwise statutory manufacture or machine. In such a case, the claim remains statutory irrespective of the fact that a computer program is included in the claim. The same result occurs when a computer program is used in a computerized process where the computer executes the instructions set forth in the computer program. Only when the claimed invention taken as a whole is directed to a mere program listing, i.e., to only its description or expression, is it descriptive material per se and hence nonstatutory.

Since a computer program is merely a set of instructions capable of being executed by a computer, the computer program itself is not a process and Office personnel should treat a claim for a computer program, without the computer-readable medium needed to realize the computer program's functionality, as nonstatutory functional descriptive material. When a computer program is claimed in a process where the computer is executing the computer program's instructions, Office personnel should treat the claim as a process claim. See Sections IV.B.2(b)-(e). When a computer program is recited in conjunction with a physical structure, such as a computer memory, Office personnel should treat the claim as a product claim. See Section IV.B.2(a).

(b) Nonfunctional Descriptive Material

Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C. 101. Thus, Office personnel should consider the claimed invention as a whole to determine whether the necessary functional interrelationship is provided.

Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Such "descriptive material" is not a process, machine, manufacture or composition of matter. (Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents. Computer Dictionary 210 (Microsoft Press, 2d ed. 1994).)

The policy that precludes the patenting of nonfunctional descriptive material would be easily frustrated if the same descriptive material could be patented when claimed as an article of manufacture. For example, music is commonly sold to consumers in the format of a compact disc. In such cases, the known compact disc acts as nothing more than a carrier for nonfunctional descriptive material. The purely nonfunctional descriptive material cannot alone provide the practical application for the manufacture.

Office personnel should be prudent in applying the foregoing guidance. Nonfunctional descriptive material may be claimed in combination with other functional descriptive material on a computer-readable medium to provide the necessary functional and structural interrelationship to satisfy the requirements of 35 U.S.C. 101. The presence of the claimed nonfunctional descriptive material is not necessarily determinative of nonstatutory subject matter. For example, a computer that recognizes a particular grouping of musical notes read from memory and upon recognizing that particular sequence, causes another defined series of notes to be played, defines a functional interrelationship among that data and the computing processes performed when utilizing that data, and as such is statutory because it implements a statutory process.

(c) Natural Phenomena Such as Electricity and Magnetism

Claims that recite nothing but the physical characteristics of a form of energy, such as a frequency, voltage, or the strength of a magnetic field, define energy or magnetism, per se, and as such are nonstatutory natural phe-

nomena. *O'Reilly* v. *Morse*, 56 U.S. (15 How.) at 112–114. However, a claim directed to a practical application of a natural phenomenon such as energy or magnetism is statutory. *Id.* at *114–119.*

2. Statutory Subject Matter

(a) Statutory Product Claims

(Products may be either machines, manufactures or compositions of matter.

A machine is:

a concrete thing, consisting of parts or of certain devices and combinations of devices.

Burr v. *Duryee*, 68 U.S. (1 Wall.) 531, 570 (1863).

A manufacture is:

the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties or combinations, whether by hand–labor or by machinery. *Diamond* v. *Chakrabarty*, 447 U.S. at 308, 206 USPQ at 196–97 (quoting *American Fruit Growers, Inc.* v. *Brogdex Co.*, 283 U.S. 1, 11 (1931).

A composition of matter is:

a composition[] of two or more substances [or] . . . a[] composite article[], whether . . . [it] be the result of chemical union, or of mechanical mixture, whether . . . [it] be [a] gas[], fluid[], powder[], or solid[]. *Diamond* v. *Chakrabarty*, 447 U.S. at 308, 206 USPQ at 197 (quoting *Shell Development Co.* v. *Watson*, 149 F. Supp. 279, 280, 113 USPQ 265, 266 (D.D.C. 1957), aff'd per curiam, 252 F.2d 861, 116 USPQ 428 (D.C. Cir. 1958).)

If a claim defines a useful machine or manufacture by identifying the physical structure of the machine or manufacture in terms of its hardware or hardware and software combination, it defines a statutory product. See, e.g., *Lowry*, 32 F.3d at 1583, 32 USPQ2d at 1034–35; *Warmerdam*, 33 F.3d at 1361–62, 31 USPQ2d at 1760.

A machine or manufacture claim may be one of two types: (1) a claim that encompasses any and every machine for performing the underlying process or any and every manufacture that can cause a computer to perform the underlying process, or (2) a claim that defines a specific machine or manufacture. When a claim is of the first type, Office personnel are to evaluate the underlying process the computer will perform in order to determine the patentability of the product.

(i) Claims that Encompass Any Machine or Manufacture Embodiment of a Process

Office personnel must treat each claim as a whole. The mere fact that a hardware element is recited in a claim does not necessarily limit the claim to a specific machine or manufacture. Cf. *In re Iwahashi*, 888 F.2d 1370, 1374–75, 12 USPQ2d 1908, 1911–12 (Fed. Cir. 1989), cited with approval in *Alappat*, 33 F.3d at 1544 n.24, 31 USPQ2d at 1558 n.24. If a product claim encompasses any and every computer implementation of a process, when read in light of the specification, it should be examined on the basis of the underlying process. Such a claim can be recognized as it will:

- define the physical characteristics of a computer or computer component exclusively as functions or steps to be performed on or by a computer, and
- encompass any and every product in the stated class (e.g., computer, computer–readable memory) configured in any manner to perform that process.

Office personnel are reminded that finding a product claim to encompass any and every product embodiment of a process invention simply means that the Office will presume that the product claim encompasses any and every hardware or hardware platform and associated software implementation that performs the specified set of claimed functions. Because this is interpretive and nothing more, it does not provide any information as to the patentability of the applicant's underlying process or the product claim.

When Office personnel have reviewed the claim as a whole and found that it is not limited to a specific machine or manufacture, they shall identify how each claim limitation has been treated and set forth their reasons in support of their conclusion that the claim encompasses any and every machine or manufacture embodiment of a process. This will shift the burden to applicant to demonstrate why the claimed invention should be limited to a specific machine or manufacture.

If a claim is found to encompass any and every product embodiment of the underlying process, and if the underlying process is statutory, the product claim should be classified as a statutory product. By the same token, if the underlying process invention is found to be nonstatutory, Office personnel should classify the "product" claim as a "nonstatutory product." If the product claim is classified as being a nonstatutory product on the basis of the underlying process, Office personnel should empha-

size that they have considered all claim limitations and are basing their finding on the analysis of the underlying process.

(ii) Product Claims — Claims Directed to Specific Machines and Manufactures

If a product claim does not encompass any and every computer-implementation of a process, then it must be treated as a specific machine or manufacture. Claims that define a computer-related invention as a specific machine or specific article of manufacture must define the physical structure of the machine or manufacture in terms of its hardware or hardware and "specific software." ("Specific software" is defined as a set of instructions implemented in a specific program code segment. See Computer Dictionary 78 (Microsoft Press, 2d ed. 1994) for definition of "code segment.") The applicant may define the physical structure of a programmed computer or its hardware or software components in any manner that can be clearly understood by a person skilled in the relevant art. Generally a claim drawn to a particular programmed computer should identify the elements of the computer and indicate how those elements are configured in either hardware or a combination of hardware and specific software.

To adequately define a specific computer memory, the claim must identify a general or specific memory and the specific software which provides the functionality stored in the memory.

A claim limited to a specific machine or manufacture, which has a practical application in the technological arts, is statutory. In most cases, a claim to a specific machine or manufacture will have a practical application in the technological arts.

(iii) Hypothetical Machine Claims Which Illustrate Claims of the Types Described in Sections IV.B.2(a)(i) and (ii)

Two applicants present a claim to the following process:

> A process for determining and displaying the structure of a chemical compound comprising:
> (a) solving the wavefunction parameters for the compound to determine the structure of a compound; and
> (b) displaying the structure of the compound determined in step (a).

Each applicant also presents a claim to the following apparatus:

> A computer system for determining the three dimensional structure of a chemical compound comprising:
> (a) means for determining the three dimensional structure of a compound; and
> (b) means for creating and displaying an image representing a three-dimensional perspective of the compound.

In addition, each applicant provides the noted disclosures to support the claims:

	Applicant A	Applicant B
Disclosure	The disclosure describes specific software, i.e., specific program code segments, that are to be employed to configure a general purpose microprocessor to create specific logic circuits. These circuits are indicated to be the "means" corresponding to the claimed means limitations.	The disclosure states that it would be a matter of routine skill to select an appropriate conventional computer system and implement the claimed process on that computer system. The disclosure does not have specific disclosure that corresponds to the two "means" limitations recited in the claim (i.e., no specific software or logic circuit). The disclosure does have an explanation of how to solve the wavefunction equations of a chemical compound, and indicates that the solutions of those wavefunction equations can be employed to determine the physical structure of the corresponding compound.
Result	Claim defines specific computer, patentability stands independently from process claim.	Claim encompasses any computer embodiment of process claim; patentability stands or falls with process claim.
Explanation	Disclosure identifies the specific machine capable of performing the indicated functions.	Disclosure does not provide an information to distinguish the "implementation" of the process on a computer from the factors that will govern the patentability determination of the process *per se*. As such, the patentability of this apparatus claim will stand or fall with that of the process claim.

(b) Statutory Process Claims

A claim that requires one or more acts to be performed defines a process. However, not all processes are statutory under 35 U.S.C. 101. To be statutory, a claimed computer-related process must either: (1) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in (i) below), or (2) be limited by the language in the claim to a practical application within the technological arts (discussed in (ii) below). See *Diamond* v. *Diehr*, 450 U.S. at 183–84, 209 USPQ at 6 (quoting *Cochrane* v. *Deener*, 94 U.S. 780, 787–88 (1877)) ("A [statutory] 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. . . . The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence."). See also *Alappat*, 33 F.3d at 1543, 31 USPQ2d at 1556–57 (quoting *Diamond* v. *Diehr*, 450 U.S. at 192, 209 USPQ at 10). See also *id.* at 1569, 31 USPQ2d at 1578–79 (Newman, J., concurring) ("unpatentability of the principle does not defeat

patentability of its practical applicants") (citing *O'Reilly v. Morse*, 56 U.S. (15 How.) at 114–19). The claimed practical application must be a further limitation upon the claimed subject matter if the process is confined to the internal operations of the computer. If a physical transformation occurs outside the computer, it is not necessary to claim the practical application. A disclosure that permits a skilled artisan to practice the claimed invention, i.e., to put it to a practical use, is sufficient. On the other hand, it is necessary to claim the practical application if there is no physical transformation or if the process merely manipulates concepts or converts one set of numbers into another.

A claimed process is clearly statutory if it results in a physical transformation outside the computer, i.e., falls into one or both of the following specific categories ("safe harbors").

(i) Safe Harbors

– **Independent Physical Acts (Post–Computer Process Activity)**

A process is statutory if it requires physical acts to be performed outside the computer independent of and following the steps to be performed by a programmed computer, where those acts involve the manipulation of tangible physical objects and result in the object having a different physical attribute or structure. *Diamond v. Diehr*, 450 U.S. at 187, 209 USPQ at 8. Thus, if a process claim includes one or more post–computer process steps that result in a physical transformation outside the computer (beyond merely conveying the direct result of the computer operation, see Section IV.B.2(d)(iii)), the claim is clearly statutory.

Examples of this type of statutory process include the following:

– A method of curing rubber in a mold which relies upon updating process parameters, using a computer processor to determine a time period for curing the rubber, using the computer processor to determine when the time period has been reached in the curing process and then opening the mold at that stage.

– A method of controlling a mechanical robot which relies upon storing data in a computer that represents various types of mechanical movements of the robot, using a computer processor to calculate positioning of the robot in relation to given tasks to be performed by the robot, and controlling the robot's movement and position based on the calculated position.

– **Manipulation of Data Representing Physical Objects or Activities (Precomputer Process Activity)**

Another statutory process is one that requires the measurements of physical objects or activities to be transformed outside of the computer into computer data (*In re Gelnovatch*, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979) (data–gathering step did not measure physical phenomenon)), where the data comprises signals corresponding to physical objects or activities external to the computer system, and where the process causes a physical transformation of the signals which are intangible representations of the physical objects or activities. *Schrader*, 22 F.3d at 294, 30 USPQ2d at 1459 citing with approval *Arrhythmia*, 958 F.2d at 1058–59, 22 USPQ2d at 1037–38; *Abele*, 684 F.2d at 909, 214 USPQ at 688; *In re Taner*, 681 F.2d 787, 790, 214 USPQ 678, 681 (CCPA 1982).

Examples of this type of claimed statutory process include the following:

– A method of using a computer processor to analyze electrical signals and data representative of human cardiac activity by converting the signals to time segments, applying the time segments in reverse order to a high pass filter means, using the computer processor to determine the amplitude of the high pass filter's output, and using the computer processor to compare the value to a predetermined value. In this example the data is an intangible representation of physical activity, i.e., human cardiac activity. The transformation occurs when heart activity is measured and an electrical signal is produced. This process has real world value in predicting vulnerability to ventricular tachycardia immediately after a heart attack.

– A method of using a computer processor to receive data representing Computerized Axial Tomography ("CAT") scan images of a patient, performing a calculation to determine the difference between a local value at a data point and an average value of the data in a region surrounding the point, and displaying the difference as a gray scale for each point in the image, and displaying the resulting image. In this example the data is an intangible rep-

resentation of a physical object; i.e., portions of the anatomy of a patient. The transformation occurs when the condition of the human body is measured with X−rays and the X−rays are converted into electrical digital signals that represent the condition of the human body. The real world value of the invention lies in creating a new CAT scan image of body tissue without the presence of bones.

– A method of using a computer processor to conduct seismic exploration, by imparting spherical seismic energy waves into the earth from a seismic source, generating a plurality of reflected signals in response to the seismic energy waves at a set of receiver positions in an array, and summing the reflection signals to produce a signal simulating the reflection response of the earth to the seismic energy. In this example, the electrical signals processed by the computer represent reflected seismic energy. The transformation occurs by converting the spherical seismic energy waves into electrical signals which provide a geophysical representation of formations below the earth's surface. Geophysical exploration of formations below the surface of the earth has real world value.

If a claim does not clearly fall into one or both of the safe harbors, the claim may still be statutory if it is limited by the language in the claim to a practical application in the technological arts.

(ii) Computer−Related Processes Limited to a Practical Application in the Technological Arts

There is always some form of physical transformation within a computer because a computer acts on signals and transforms them during its operation and changes the state of its components during the execution of a process. Even though such a physical transformation occurs within a computer, such activity is not determinative of whether the process is statutory because such transformation alone does not distinguish a statutory computer process from a nonstatutory computer process. What is determinative is not how the computer performs the process, but what the computer does to achieve a practical application. See *Arrhythmia*, 958 F.2d at 1057, 22 USPQ2d at 1036.

A process that merely manipulates an abstract idea or performs a purely mathematical algorithm is nonstatutory despite the fact that it might inherently have some usefulness. (In *Sarkar*, 588 F.2d at 1335, 200 USPQ at 139, the court explained why this approach must be followed:

> No mathematical equation can be used, as a practical matter, without establishing and substituting values for the variables expressed therein. Substitution of values dictated by the formula has thus been viewed as a form of mathematical step. If the steps of gathering and substituting values were alone sufficient, every mathematical equation, formula, or algorithm having any practical use would be per se subject to patenting as a "process" under 101. Consideration of whether the substitution of specific values is enough to convert the disembodied ideas present in the formula into an embodiment of those ideas, or into an application of the formula, is foreclosed by the current state of the law.)

For such subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts. See *Alappat*, 33 F.3d at 1543, 31 USPQ2d at 1556−57 (quoting *Diamond* v. *Diehr*, 450 U.S. at 192, 209 USPQ at 10). See also *Alappat* at 1569, 31 USPQ2d at 1578−79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing *O'Reilly* v. *Morse*, 56 U.S. (15 How.) at 114−19). For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory.

Examples of this type of claimed statutory process include the following:

– A computerized method of optimally controlling transfer, storage and retrieval of data between cache and hard disk storage devices such that the most frequently used data is readily available.

– A method of controlling parallel processors to accomplish multi−tasking of several computing tasks to maximize computing efficiency. See, e.g., *In re Bernhart*, 417 F.2d 1395, 1400, 163 USPQ 611, 616 (CCPA 1969).

– A method of making a word processor by storing an executable word processing application program in a general purpose digital computer's memory, and executing the stored program to impart word processing functionality to the general purpose digital computer by changing the state of the computer's arithmetic logic unit when program instructions of the word processing program are executed.

– A digital filtering process for removing noise from a digital signal comprising the steps of calculating a mathematical algorithm to produce a correction signal and subtracting the correction signal from the digital signal to remove the noise.

(c) Nonstatutory Process Claims

If the "acts" of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

In practical terms, claims define nonstatutory processes if they:

– consist solely of mathematical operations without some claimed practical application (i.e., executing a "mathematical algorithm"); or

– simply manipulate abstract ideas, e.g., a bid (*Schrader*, 22 F.3d at 293–94, 30 USPQ2d at 1458–59) or a bubble hierarchy (*Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application.

A claimed process that consists solely of mathematical operations is nonstatutory whether or not it is performed on a computer. Courts have recognized a distinction between types of mathematical algorithms, namely, some define a "law of nature" in mathematical terms and others merely describe an "abstract idea." See, e.g., *In re Meyer*, 688 F.2d 789, 794–95, 215 USPQ 193, 197 (CCPA 1982) ("Scientific principles, such as the relationship between mass and energy, and laws of nature, such as the acceleration of gravity, namely, a = 32 ft./sec.^{2}, can be represented in mathematical format. However, some mathematical algorithms and formulae do not represent scientific principles or laws of nature; they represent ideas or mental processes and are simply logical vehicles for communicating possible solutions to complex problems. The presence of a mathematical algorithm or formula in a claim is merely an indication that a scientific principle, law of nature, idea or mental process may be the subject matter claimed and, thus, justify a rejection of that claim under 35 U.S.C 101; but the presence of a mathematical algorithm or formula is only a signpost for further analysis."). Cf. *Alappat*, 33 F.3d at 1543 n.19, 31 USPQ2d at 1556 n.19 in which the Federal Circuit recognized the confusion:

> The Supreme Court has not been clear . . . as to whether such subject matter is excluded from the scope of 101 because it represents laws of nature, natural phenomena, or abstract ideas. See *Diehr*, 450 U.S. at 186 (viewed mathematical algorithm as a law of nature); *Gottschalk* v. *Benson*, 409 U.S. 63, 71–72 (1972) (treated mathematical algorithm as an "idea"). The Supreme Court also has not been clear as to exactly what kind of mathematical subject matter may not be patented. The Supreme Court has used, among others, the terms "mathematical algorithm," "mathematical formula," and "mathematical equation" to describe types of mathematical subject matter not entitled to patent protection standing alone. The Supreme Court has not set forth, however, any consistent or clear explanation of what it intended by such terms or how these terms are related, if at all.

Certain mathematical algorithms have been held to be nonstatutory because they represent a mathematical definition of a law of nature or a natural phenomenon. For example, a mathematical algorithm representing the formula $E = mc^2$ is a "law of nature" — it defines a "fundamental scientific truth" (i.e., the relationship between energy and mass). To comprehend how the law of nature relates to any object, one invariably has to perform certain steps (e.g., multiplying a number representing the mass of an object by the square of a number representing the speed of light). In such a case, a claimed process which consists solely of the steps that one must follow to solve the mathematical representation of $E = mc^2$ is indistinguishable from the law of nature and would "preempt" the law of nature. A patent cannot be granted on such a process.

Other mathematical algorithms have been held to be nonstatutory because they merely describe an abstract idea. An "abstract idea" may simply be any sequence of mathematical operations that are combined to solve a mathematical problem. The concern addressed by holding such subject matter nonstatutory is that the mathematical operations merely describe an idea and do not define a process that represents a practical application of the idea.

Accordingly, when a claim reciting a mathematical algorithm is found to define nonstatutory subject matter the basis of the 35 U.S.C. 101 rejection must be that, when taken as a whole, the claim recites a law of nature, a natural phenomenon, or an abstract idea.

(d) Certain Claim Language Related to Mathematical Operation Steps of a Process

(i) Intended Use or Field of Use Statements

Claim language that simply specifies an intended use or field of use for the invention generally will not limit the scope of a claim, particularly when only presented in the claim preamble. Thus, Office personnel should be careful to properly interpret such language. *Walter*, 618 F.2d at 769, 205 USPQ at 409 (Because none of the claimed steps were explicitly or implicitly limited to their application in seismic prospecting activities, the court held that "[a]lthough the claim preambles relate the claimed invention to the art of seismic prospecting, the claims themselves are not drawn to methods of or apparatus for seismic prospecting; they are drawn to improved mathematical methods for interpreting the results of seismic prospecting."). Cf. *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1558. When such language is treated as nonlimiting, Office personnel should expressly identify in the Office action the claim language that constitutes the intended use or field of use statements and provide the basis for their findings. This will shift the burden to applicant to demonstrate why the language is to be treated as a claim limitation.

(ii) Necessary Antecedent Step to Performance of a Mathematical Operation or Independent Limitation on a Claimed Process

In some situations, certain acts of "collecting" or "selecting" data for use in a process consisting of one or more mathematical operations will not further limit a claim beyond the specified mathematical operation step(s). Such acts merely determine values for the variables used in the mathematical formulae used in making the calculations. *Walter*, 618 F.2d at 769–70, 205 USPQ at 409. In other words, the acts are dictated by nothing other than the performance of a mathematical operation. *Sarker*, 588 F.2d at 1335, 200 USPQ at 139.

If a claim requires acts to be performed to create data that will then be used in a process representing a practical application of one or more mathematical operations, those acts must be treated as further limiting the claim beyond the mathematical operation(s) *per se*. Such acts are data gathering steps not dictated by the algorithm but by other limitations which require certain antecedent steps and as such constitute an independent limitation on the claim.

Examples of acts that independently limit a claimed process involving mathematical operations include:

- a method of conducting seismic exploration which requires generating and manipulating signals from seismic energy waves before "summing" the values represented by the signals (*Taner*, 681 F.2d at 788, 214 USPQ at 679); and

- a method of displaying X–ray attenuation data as a signed gray scale signal in a "field" using a particular algorithm, where the antecedent steps require generating the data using a particular machine (e.g., a computer tomography scanner). *Abele*, 684 F.2d at 908, 214 USPQ at 687 ("The specification indicates that such attenuation data is available only when an X–ray beam is produced by a CAT scanner, passed through an object, and detected upon its exit. Only after these steps have been completed is the algorithm performed, and the resultant modified data displayed in the required format.").

Examples of steps that do not independently limit one or more mathematical operation steps include:

- "perturbing" the values of a set of process inputs, where the subject matter "perturbed" was a number and the act of "perturbing" consists of substituting the numerical values of variables (*Gelnovatch*, 595 F.2d at 41 n.7, 201 USPQ at 145 n.7 ("Appellants' claimed step of perturbing the values of a set of process inputs (step 3), in addition to being a mathematical operation, appears to be a data–gathering step of the type we have held insufficient to change a nonstatutory method of calculation into a statutory process.... In this instance, the perturbed process inputs are not even measured values of physical phenomena, but are instead derived by numerically changing the values in the previous set of process inputs.")); and

- selecting a set of arbitrary measurement point values (*Sarkar*, 588 F.2d at 1331, 200 USPQ at 135).

Such steps do not impose independent limitations on the scope of the claim beyond those required by the mathematical operation limitation.

(iii) Post–Mathematical Operation Step Using Solution or Merely Conveying Result of Operation

In some instances, certain kinds of post–solution "acts" will not further limit a process claim beyond the performance of the preceding mathematical operation

step even if the acts are recited in the body of a claim. If, however, the claimed acts represent some "significant use" of the solution, those acts will invariably impose an independent limitation on the claim. A "significant use" is any activity which is more than merely outputting the direct result of the mathematical operation. Office personnel are reminded to rely on the applicant's characterization of the significance of the acts being assessed to resolve questions related to their relationship to the mathematical operations recited in the claim and the invention as a whole. See *Sarkar*, 588 F.2d at 1332 n.6, 200 USPQ at 136 n.6 ("post–solution" construction that was being modeled by the mathematical process not considered in deciding 35 U.S.C. 101 question because applicant indicated that such construction was not a material element of the invention). Thus, if a claim requires that the direct result of a mathematical operation be evaluated and transformed into something else, Office personnel cannot treat the subsequent steps as being indistinguishable from the performance of the mathematical operation and thus not further limiting on the claim. For example, acts that require the conversion of a series of numbers representing values of a wavefunction equation for a chemical compound into values representing an image that conveys information about the three–dimensional structure of the compound and the displaying of the three–dimensional structure cannot be treated as being part of the mathematical operations.

Office personnel should be especially careful when reviewing claim language that requires the performance of "post–solution" steps to ensure that claim limitations are not ignored.

Examples of steps found not to independently limit a process involving one or more mathematical operation steps include:

- step of "updating alarm limits" found to constitute changing the number value of a variable to represent the result of the calculation (*Parker* v. *Flook*, 437 U.S. 584, 585, 198 USPQ 193, 195 (1978));
- final step of magnetically recording the result of a calculation (*Walter*, 618 F.2d at 770, 205 USPQ at 409 ("If 101 could be satisfied by the mere recordation of the results of a nonstatutory process on some record medium, even the most unskilled patent draftsman could provide for such a step."));
- final step of "equating" the process outputs to the values of the last set of process inputs found to constitute storing the result of calculations (*Gelnovatch*, 595 F.2d at 41 n.7, 201 USPQ at 145 n.7);
- final step of displaying result of a calculation "as a shade of gray rather than as simply a number" found to not constitute distinct step where the data were numerical values that did not represent anything (*Abele*, 684 F.2d at 909, 214 USPQ at 688 ("This claim presents no more than the calculation of a number and display of the result, albeit in a particular format. The specification provides no greater meaning to 'data in a field' than a matrix of numbers regardless of by what method generated. Thus, the algorithm is neither explicitly nor implicitly applied to any certain process. Moreover, that the result is displayed as a shade of gray rather than as simply a number provides no greater or better information, considering the broad range of applications encompassed by the claim.")); and
- step of "transmitting electrical signals representing" the result of calculations (*In re De Castelet*, 562 F.2d 1236, 1244, 195 USPQ 439, 446 (CCPA 1977) ("That the computer is instructed to transmit electrical signals, representing the results of its calculations, does not constitute the type of 'post solution activity' found in *Flook*, [437 U.S. 584, 198 USPQ 193 (1978)], and does not transform the claim into one for a process merely using an algorithm. The final transmitting step constitutes nothing more than reading out the result of the calculations.")).

(e) Manipulation of Abstract Ideas Without a Claimed Practical Application

A process that consists solely of the manipulation of an abstract idea without any limitation to a practical application is nonstatutory. See, e.g., *Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759. See also *Schrader*, 22 F.3d at 295, 30 USPQ2d at 1459. Office personnel have the burden to establish a *prima facie* case that the claimed invention taken as a whole is directed to the manipulation of abstract ideas without a practical application.

In order to determine whether the claim is limited to a practical application of an abstract idea, Office personnel must analyze the claim as a whole, in light of the specification, to understand what subject matter is being manipulated and how it is being manipulated. During this procedure, Office personnel must evaluate any statements of intended use or field of use, any data gathering step and any post-manipulation activity. See section IV.B.2(d) above for how to treat various types of claim language. Only when the claim is devoid of any limitation to a practical application in the technological arts should it be rejected under 35 U.S.C. 101. Further, when such a rejection is made, Office personnel must expressly state how the language of the claims has been interpreted to support the rejection.

V. Evaluate Application for Compliance with 35 U.S.C. 112

Office personnel should begin their evaluation of an application's compliance with 35 U.S.C. 112 by considering the requirements of 35 U.S.C. 112, second paragraph. The second paragraph contains two separate and distinct requirements: (1) that the claim(s) set forth the subject matter applicants regard as the invention, and (2) that the claim(s) particularly point out and distinctly claim the invention. An application will be deficient under 35 U.S.C. 112, second paragraph when (1) evidence including admissions, other than in the application as filed, shows applicant has stated that he or she regards the invention to be different from what is claimed, or when (2) the scope of the claims is unclear.

After evaluation of the application for compliance with 35 U.S.C. 112, second paragraph, Office personnel should then evaluate the application for compliance with the requirements of 35 U.S.C. 112, first paragraph. The first paragraph contains three separate and distinct requirements: (1) adequate written description, (2) enablement, and (3) best mode. An application will be deficient under 35 U.S.C. 112, first paragraph when the written description is not adequate to identify what the applicant has invented, or when the disclosure does not enable one skilled in the art to make and use the invention as claimed without undue experimentation. 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.

If deficiencies are discovered with respect to 35 U.S.C. 112, Office personnel must be careful to apply the appropriate paragraph of 35 U.S.C. 112.

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

1. Claims Setting Forth the Subject Matter Applicant Regards as Invention

Applicant's specification must conclude with claim(s) that set forth the subject matter which the applicant regards as the invention. The invention set forth in the claims is presumed to be that which applicant regards as the invention, unless applicant considers the invention to be something different from what has been claimed as shown by evidence, including admissions, outside the application as filed. An applicant may change what he or she regards as the invention during the prosecution of the application.

2. Claims Particularly Pointing Out and Distinctly Claiming the Invention

Office personnel shall determine whether the claims set out and circumscribe 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. However, the applicant need not explicitly recite in the claims every feature of the invention. For example, if an applicant indicates that the invention is a particular computer, the claims do not have to recite every element or feature of the computer. In fact, it is preferable for claims to be drafted in a form that emphasizes what the applicant has invented (i.e., what is new rather than old).

A means plus function limitation is distinctly claimed if the description makes it clear that the means corresponds to well-defined structure of a computer or computer component implemented in either hardware or software and its associated hardware platform. Such means may be defined as:

- a programmed computer with a particular functionality implemented in hardware or hardware and software;

– a logic circuit or other component of a programmed computer that performs a series of specifically identified operations dictated by a computer program; or

– a computer memory encoded with executable instructions representing a computer program that can cause a computer to function in a particular fashion.

The scope of a "means" limitation is defined as the corresponding structure or material (e.g., a specific logic circuit) set forth in the written description and equivalents. See MPEP § 2181 through § 2186. Thus, a claim using means plus function limitations without corresponding disclosure of specific structures or materials that are not well–known fails to particularly point out and distinctly claim the invention. For example, if the applicant discloses only the functions to be performed and provides no express, implied or inherent disclosure of hardware or a combination of hardware and software that performs the functions, the application has not disclosed any "structure" which corresponds to the claimed means. Office personnel should reject such claims under 35 U.S.C. 112, second paragraph. The rejection shifts the burden to the applicant to describe at least one specific structure or material that corresponds to the claimed means in question, and to identify the precise location or locations in the specification where a description of at least one embodiment of that claimed means can be found. In contrast, if the corresponding structure is disclosed to be a memory or logic circuit that has been configured in some manner to perform that function (e.g., using a defined computer program), the application has disclosed "structure" which corresponds to the claimed means.

When a claim or part of a claim is defined in computer program code, whether in source or object code format, a person of skill in the art must be able to ascertain the metes and bounds of the claimed invention. In certain circumstances, as where self–documenting programming code is employed, use of programming language in a claim would be permissible because such program source code presents "sufficiently high–level language and descriptive identifiers" to make it universally understood to others in the art without the programmer having to insert any comments. See Computer Dictionary 353 (Microsoft Press, 2ed. 1994) for a definition of "self–documenting code." Applicants should be encouraged to functionally define the steps the computer will perform rather than simply reciting source or object code instructions.

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

1. Adequate Written Description

The satisfaction of the enablement requirement does not satisfy the written description requirement. See *In re Barker*, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977), *cert. denied*, *Barker* v. *Parker*, 434 U.S. 1064 (1978) (a specification may be sufficient to enable one skilled in the art to make and use the invention, but still fail to comply with the written description requirement). See also *In re DiLeone*, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971). 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. The claimed invention subject matter need not be described literally, i.e., using the same terms, in order for the disclosure to satisfy the 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. For a computer–related invention, the disclosure must enable a skilled artisan to configure the computer to possess the requisite functionality, and, where applicable, interrelate the computer with other elements to yield the claimed invention, without the exercise of undue experimentation. The specification should disclose how to configure a computer to possess the requisite functionality or how to integrate the programmed computer with other elements of the invention, unless a skilled artisan would know how to do so without such disclosure. See, e.g., *Northern Telecom* v. *Datapoint Corp.*, 908 F.2d 931, 941–43, 15 USPQ2d 1321, 1328–30 (Fed. Cir.), *cert. denied*, *Datapoint Corp.* v. *Northern Telecom*, 498 U.S. 920 (1990) (judgment of invalidity reversed for clear error where expert testimony on both sides showed that a programmer of reasonable skill could write a satisfactory program with ordinary effort based on the disclosure); *DeGeorge* v. *Bernier*,

768 F.2d 1318, 1324, 226 USPQ 758, 762–63 (Fed. Cir. 1985) (superseded by statute with respect to issues not relevant here) (invention was adequately disclosed for purposes of enablement even though all of the circuitry of a word processor was not disclosed, since the undisclosed circuitry was deemed inconsequential because it did not pertain to the claimed circuit); *In re Phillips*, 608 F.2d 879, 882–83, 203 USPQ 971, 975 (CCPA 1979) (computerized method of generating printed architectural specifications dependent on use of glossary of predefined standard phrases and error–checking feature enabled by overall disclosure generally defining errors); *In re Donohue*, 550 F.2d 1269, 1271, 193 USPQ 136, 137 (CCPA 1977) ("Employment of block diagrams and descriptions of their functions is not fatal under 35 U.S.C. 112, first paragraph, providing the represented structure is conventional and can be determined without undue experimentation."); *In re Knowlton*, 481 F.2d 1357, 1366–68, 178 USPQ 486, 493–94 (CCPA 1973) (examiner's contention that a software invention needed a detailed description of all the circuitry in the complete hardware system reversed).

For many computer–related inventions, it is not unusual for the claimed invention to involve more than one field of technology. For such inventions, the disclosure must satisfy the enablement standard for each aspect of the invention. See *In re Naquin*, 398 F.2d 863, 866, 158 USPQ 317, 319 (CCPA 1968) ("When an invention, in its different aspects, involves distinct arts, that specification is adequate which enables the adepts of each art, those who have the best chance of being enabled, to carry out the aspect proper to their specialty."); *Ex parte Zechnall*, 194 USPQ 461, 461 (Bd. App. 1973) ("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"). As such, the disclosure must teach a person skilled in each art how to make and use the relevant aspect of the invention without undue experimentation. For example, to enable a claim to a programmed computer that determines and displays the three–dimensional structure of a chemical compound, the disclosure must

- enable a person skilled in the art of molecular modeling to understand and practice the underlying molecular modeling processes; and

- enable a person skilled in the art of computer programming to create a program that directs a computer to create and display the image representing the three–dimensional structure of the compound.

In other words, the disclosure corresponding to each aspect of the invention must be enabling to a person skilled in each respective art.

In many instances, an applicant will describe a programmed computer by outlining the significant elements of the programmed computer using a functional block diagram. Office personnel should review the specification to ensure that along with the functional block diagram the disclosure provides information that adequately describes each "element" in hardware or hardware and its associated software and how such elements are interrelated. See *In re Scarbrough*, 500 F.2d 560, 565, 182 USPQ 298, 301–02 (CCPA 1974) ("It is not enough that a person skilled in the art, by carrying on investigations along the line indicated in the instant application, and by a great amount of work eventually might find out how to make and use the instant invention. The statute requires the application itself to inform, not to direct others to find out for themselves (citation omitted)."); *Knowlton*, 481 F.2d at 1367, 178 USPQ at 493 (disclosure must constitute more than a "sketchy explanation of flow diagrams or a bare group of program listings together with a reference to a proprietary computer on which they might be run"). See also *In re Gunn*, 537 F.2d 1123, 1127–28, 190 USPQ 402, 405 (CCPA 1976); *In re Brandstadter*,
484 F.2d 1395, 1406–07, 17 USPQ 286, 294 (CCPA 1973); and *In re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727–28 (CCPA 1971).

VI. Determine Whether the Claimed Invention Complies with 35 U.S.C. 102 and 103

As is the case for inventions in any field of technology, assessment of a claimed computer–related 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. If no differences are found between the claimed invention and the prior art, the claimed invention lacks novelty and is to be rejected by Office personnel under 35 U.S.C. 102. Once distinctions are identified between the claimed invention and the prior art, those distinctions 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. Factors and considerations dictated by law governing 35 U.S.C. 103 apply without modification to computer-related inventions.

If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material, as described supra in Section IV. Functional descriptive material is a limitation in the claim and must be considered and addressed in assessing patentability under 35 U.S.C. 103. Thus, a rejection of the claim as a whole under 35 U.S.C. 103 is inappropriate unless the functional descriptive material would have been suggested by the prior art. Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. Cf. *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

Common situations involving nonfunctional descriptive material are:

- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,

- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or

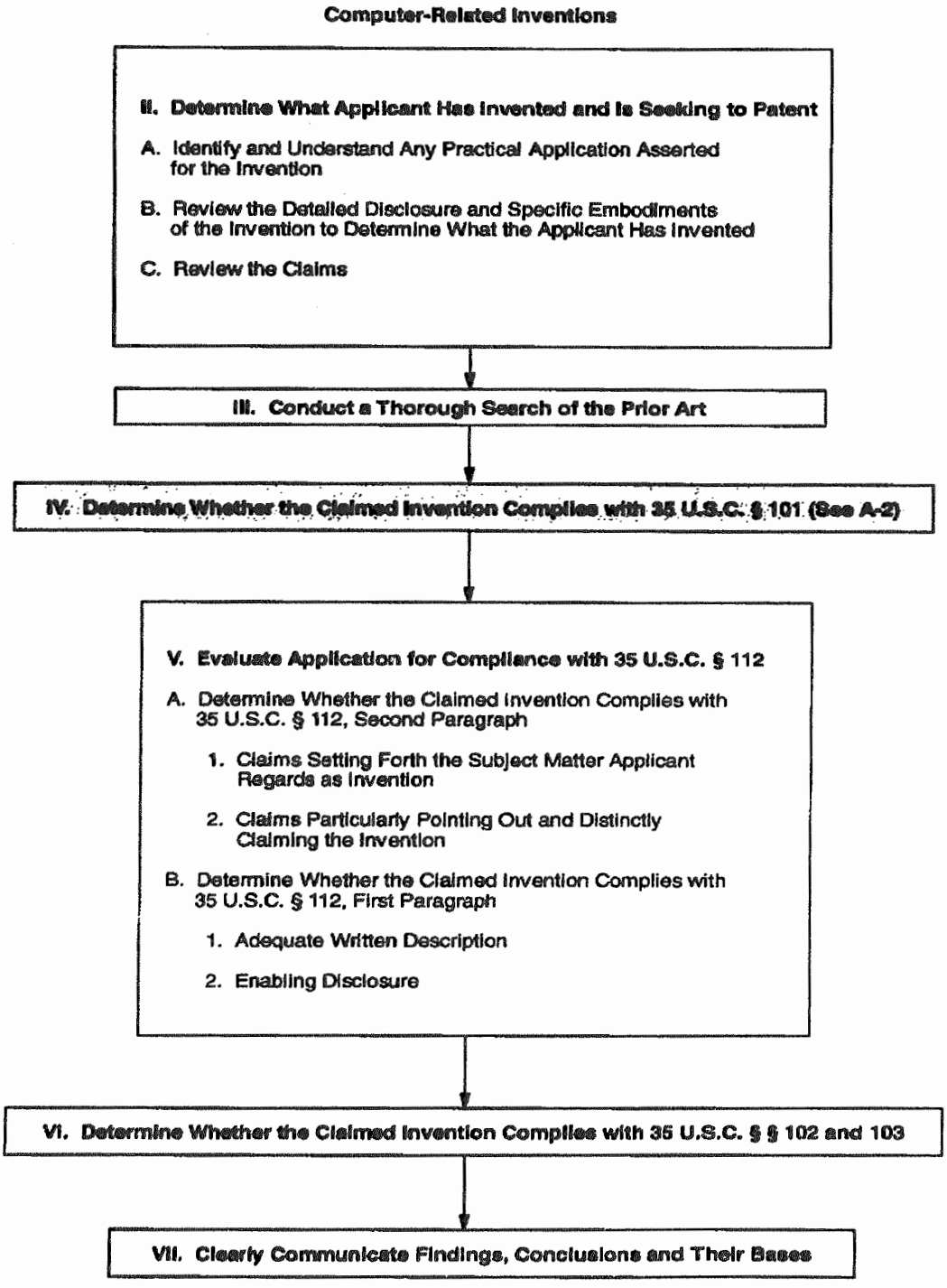
- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

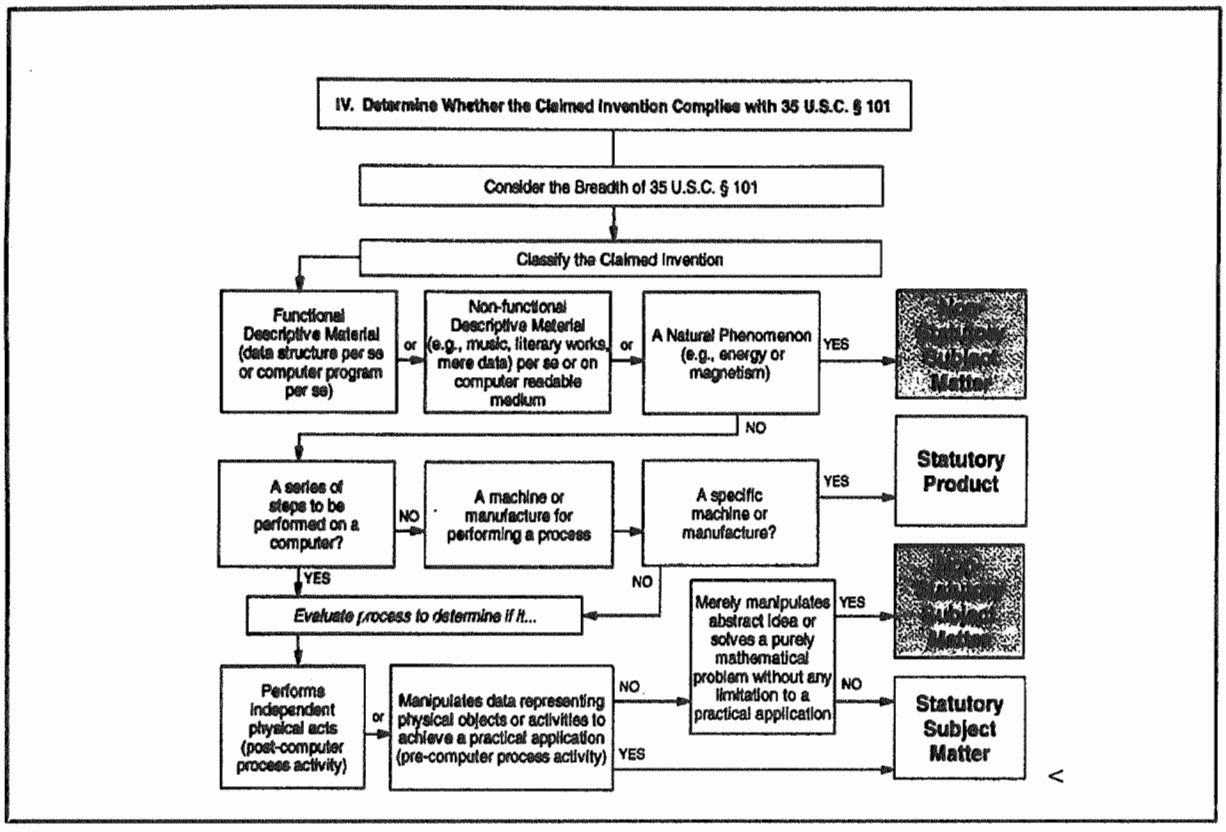
Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the claimed invention is simply a rearrangement of nonfunctional descriptive material.

VII. Clearly Communicate Findings, Conclusions and Their Bases

Once Office 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 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.

Appendix to Examination Guidelines for Computer-Related Inventions





2106.01 Computer Programming and 35 U.S.C. 112, First Paragraph [R–3]

The requirements for sufficient disclosure of inventions involving computer programming is the same as for all inventions sought to be patented. Namely, there must be an adequate written description, the original disclosure should be sufficiently enabling to allow one to make and use the invention as claimed, and there must be presentation of a best mode for carrying out the invention.

The following guidelines, while applicable to a wide range of arts, are intended to provide a guide for analyzing 35 U.S.C. 112, first paragraph, issues in applications involving computer programs, software, firmware, or block diagram cases wherein one or more of the "block diagram" elements are at least partially comprised of a computer software component. It should be recognized that sufficiency of disclosure issues in computer cases necessarily 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.

Written Description

The function of the 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*, 200 USPQ 711, 717 (CCPA 1979) and further reiterated in *In re Kaslow*, 217 USPQ 1089 (Fed. Cir. 1983). See also, MPEP § 2163 – § 2163.04.

Best Mode

While 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*, 135 USPQ 311, 315 (CCPA 1962); "**only evidence of concealment (accidental or intentional) is to be considered >[in judging the adequacy of a best mode disclosure]< . 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 dislosure is so poor as to effectively result in concealment." *In re Sherwood*, 204 USPQ 537, 544 (CCPA 1980). Also, see *White Consolidated Industries* v. *Vega Servo-Control*, 214 USPQ 796, 824 (S.D. Michigan, S. Div. 1982), aff'd on other grounds, 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, there must be an objective determination as to whether the best mode was disclosed in sufficient detail to allow one skilled in the art to practice it. *Fonar Corp.* v. *General Electric Co.*, ___F.3d ___, 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.*, ___ F.3d at ___, 41 USPQ2d at 1805 (citations omitted).<

Enablement

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, the examiner must establish on the record that he has 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*, 177 USPQ 691 (CCPA 1973); *In re Ghiron*, 169 USPQ 723 (CCPA 1971). Once the examiner has 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*, 179 USPQ at 232 (CCPA 1973); *In re Scarbrough*, 182 USPQ 298, 302 (CCPA 1974); *In re Ghiron, supra*. See also, MPEP § 2106, V.B.2 and § 2164 – § 2164.08(c).

2106.02 Disclosure in Computer Programming Cases [R-1]

>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 cases, it is not unusual for the claimed invention to involve two areas of prior art or more than one technology, (*White Consolidated, supra*, 214 USPQ at 821); e.g., an appropriately programmed computer and an area of application of said computer. 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*, 158 USPQ 317, (CCPA1968); *In re Brown*, 177 USPQ 691 (CCPA 1973); and *White Consolidated, supra* at B22.

In a typical computer case, system components are often represented in a "block diagram" format, i.e., a group of hollow rectangles representing the elements of the system, functionally labelled, and interconnected by lines. Such block diagram computer cases may be categorized into (1) systems which include but are more comprehensive than a computer and (2) systems wherein the block elements are totally within the confines of a computer.

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 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, supra, 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, supra,* at 301 and *In re Forman,* 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 has solved. See *In re Scarbrough, supra* 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, supra* 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 Consolidated, supra*, 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, supra*, at 279 et seq.). On the other hand, another court found that, where the required period of experimentation for skilled programmers to develop a particular program would run to 1½ to 2 man years, this would be "a clearly unreasonable requirement" (*White Consolidated, supra* at 963).

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*, 178 USPQ 486 (CCPA 1973), *In re Comstock and Gilmer*, 178 USPQ 616 (CCPA 1973). Most significantly, however, in both the Comstock and *Knowlton* cases, the decisions turned on the appellants disclosure of (1) a reference to and reliance on an identified prior art computer system and (2) 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 into 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 signifi-

cance 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, the examiner, when analyzing method claims, must recognize that the specification must be adequate to teach how to practice the claimed method. If such practice requires particular apparatus, it is axiomatic that the application must therefore provide a sufficient disclosure of that apparatus if such is not already available. See *In re Ghiron, supra* at 727 and *In re Gunn*, 190 USPQ 402, 406 (CCPA 1976). When the examiner questions the adequacy of computer system or computer programming disclosures, the examiner's 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 the examiner to reasonably challenge evidence submitted by the applicant. For example, in *In re Naquin, supra*, affiant's statement unchallenged by the examiner, that the average computer programmer was familiar with the subroutine necessary for performing the claimed process, was held to be a statement of fact which rendered the examiner's rejection baseless. In other words, unless the examiner presents 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 case will not be sustained on appeal. See *In re Naquin, supra, In re Morehouse and Bolton*, 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 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 an examiner has 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, arguments of counsel, or combinations of these approaches.

AFFIDAVIT PRACTICE (37 CFR 1.132)

In computer cases, affidavits must be critically analyzed. Affidavit practice usually initially involves analyzing the skill level and/or qualifications of the affiant, which should be of the routineer in the art. 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, Kienzle and Sykes*, 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 facie* case of nonenablement. See *Hirschfield v. Banner, Commissioner of Patents and Trademarks*, 200 USPQ 276, 281 (D.D.C. 1978). 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, supra* 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, supra* at, 406. In this 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.

REFERENCING PRIOR ART DOCUMENTS

Earlier, it had been discussed that citing in the specification 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 in an affidavit extracts from technical publications 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, supra* at 16. This analysis would appear to be less critical where the circuits comprising applicant's system are essentially standard components comprising 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*, 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 applicant's application 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, supra* at 301. 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 components 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 or complexity. See *In re Knowlton, supra* at 37 (CCPA 1974).

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. In these situations, an examiner may have failed to set forth any basis for questioning the adequacy of the disclosure or may not have considered the whole specification, including the drawings and the written description. 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, supra* at, 424; *In re Schulze*, 145 USPQ 716 (CCPA 1965); and *In re Cole*, 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, supra* at, 37 and *In re Wiseman*, 201 USPQ 658 (CCPA 1979).<

2107 General Principles Governing Utility Rejections [R-1]

>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 § 706.03(a)(1) 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 two purposes. First, 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). Second, 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 applicant believes the invention to be "useful." This can occur when an applicant fails to identify any specific 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 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 utility for the invention made by an applicant is not credible.

a. "Real world value" requirement

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 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 utility was inaccurate. For example, in *Nelson* v. *Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980), the CCPA reversed a finding by the Office that the applicant had not

set forth a "practical" utility under 35 U.S.C. 101 despite the fact that 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" or "specific utility" to refer to this aspect of the "useful invention" requirement of 35 U.S.C. 101. As the Court of Customs and Patent Appeals stated in *Nelson* v. *Bowler*:

> 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 specific assertions made by the applicant that an invention is "useful" for a particular reason. 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. 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).

Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific utility based on the setting in which the invention is to be used. One example are 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 specific invention is in fact "useful" in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified utility and inventions whose specific 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 utility for the invention.

Office personnel also 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 "specific" utility.

b. 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 ac-

complish 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 and did not work as the inventor claimed it did. Indeed, the use of many labels to describe a single problem (e.g., an assertion regarding utility that is false) 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 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)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 USPQ 221 (1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 USPQ 609 (CCPA 1969)). 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.

c. 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 CCPA 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 CCPA 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.

Recently, the Federal Circuit 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.

d. Relationship between 35 U.S.C. 112, first paragraph, and 35 U.S.C. 101

A deficiency under 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 compliance. 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 recently 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 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 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 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 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 Industries 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.<

2107.01 Procedural Considerations Related to Rejections for Lack of Utility [R-3]

a. 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 claim from which it depends has defined 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 a 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. A claim that raises this question is likely to be deficient under 35 U.S.C. 112, second paragraph, in terms of accurately defining the genus to encompass species that are sufficiently similar to constitute the genus.

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.

b. 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 utility for the invention.

i. An asserted utility must be specific, not general

A statement of specific 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 specific 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 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 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 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 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 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.

ii. 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 utility for the claimed invention. If no statements can be found asserting a specific utility for the claimed invention in the specification, Office personnel should determine if the claimed invention has a well–established utility. A well–established utility is one that would be immediately apparent to a person of ordinary skill based upon disclosed features or characteristics of the invention, or statements made by the applicant in the written description of the invention. 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 utility.

If a person of ordinary skill would not immediately recognize a specific 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 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

utility for the invention. The rejection should also specify that the applicant must respond by indicating why the invention is believed useful and where support for any subsequently asserted utility can be found in the specification as filed.

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.

c. Evaluating the credibility of an asserted utility

i. 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 (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 CCPA 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 CCPA 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 CCPA's 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 Marzocchi*, 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 US 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).

ii. 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 the proceed to base a rejection under 35 U.S.C. 101 on that presumption.

Rejections under 35 U.S.C. 101 have been rarely sustained by Federal courts. Generally speaking, in these rare cases, the 35 U.S.C. 101 rejection was sustained either because 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 therefore 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.

d. 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. The statement must articulate

sound reasons why a person of ordinary skill in the art would conclude that it is more likely than not that an asserted utility is not credible. The statement should specifically identify the scientific basis of any factual conclusions made in the *prima facie* showing. The statement must also explain why any evidence of record that supports the asserted utility would not be persuasive to one of ordinary skill.

In addition to the statement setting forth the *prima facie* showing, Office personnel must provide evidentiary support for the *prima facie* case. In most cases, documentary evidence (e.g., articles in scientific journals, or excerpts from patents or scientific treatises) can and should be cited to support any factual conclusions made in the prima facie showing. Only when documentary evidence is not readily available should the Examiner attempt to satisfy the Office's requirement for evidentiary support for the factual basis of the *prima facie* showing solely through an explanation of relevant scientific principles. It is imperative that Office personnel use specificity in setting forth an initial rejection under 35 U.S.C. 101 and support any factual conclusions made in the *prima facie* showing. For example, Office personnel should explain why any *in vitro* or *in vivo* data supplied by the applicant would not be reasonably predictive of an asserted therapeutic utility from the perspective of a person of ordinary skill in the art. 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.

e. 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 for 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).

f. Consideration of a response 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).

Once a response has been provided, Office personnel must review the complete record, including the claims, to determine if it is appropriate to maintain the rejections under 35 U.S.C. 101 and 35 U.S.C. 112. 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).

g. 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 *Ray Bellet* v. *Englehard*, 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.

2107.02 Special Considerations for Asserted Therapeutic or Pharmacological Utilities [R–1]

>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.

a. 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).

b. 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 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.

c. 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.").

d. 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.

e. 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).

f. 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, in the 1960'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-1]

>CLAIMS MUST BE GIVEN THEIR BROADEST REASONABLE INTERPRETATION

During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification." Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 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 section 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, e.g., the impermissible importation of subject matter from the specification into the claim.).<

2111.01 Plain Meaning [R-1]

>THE WORDS OF A CLAIM MUST BE GIVEN THEIR "PLAIN MEANING" UNLESS THEY ARE DEFINED IN THE SPECIFICATION

While the meaning of 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. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. *In re Zletz*, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)(discussed below). One must bear in mind that, especially in nonchemical cases, the words in a claim are generally not limited in their meaning by what is shown or disclosed in the specification. It is only when the specification provides definitions for terms appearing in the claims that the specification can be used in interpreting claim language. *In re Vogel*, 164 USPQ 619, 622 (CCPA 1970). There is one exception and that is 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). In that case, the specification must be consulted to determine the structure, material, or acts corresponding to the function recited in the claim. *In re Donaldson*, 29 USPQ2d 1845 (Fed. Cir. 1994)(see MPEP § 2181- § 2186).

In *In re Zletz*, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989), 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*, 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.' " 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*, 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. It should be noted that the limitation was part of a means plus function element.)

"PLAIN MEANING" REFERS TO THE MEANING GIVEN TO THE TERM BY THOSE OF ORDINARY SKILL IN THE ART

When not defined by applicant in the specification, the words of a claim must be given their plain meaning. In other words, they must be read as they would be interpreted by those of ordinary skill in the art. *In re Sneed*, 218 USPQ 385 (Fed. Cir. 1983) (The applicants had argued in an amendment after final rejection that the term "flexible plastic pipe," as used in the claims, pertained only to pipes of 2-inch diameter and 3-inch diameter and not to a pipe of 1.5 inch diameter. This definition of "flexible" was also advanced in an affidavit. The prior

art, however, described 1.5 inch pipe as flexible. The court held that the specification and the evidence (the prior art) failed to support the gloss appellants sought to put on the term "flexible." Note that applicant had not defined "flexible plastic pipe" in the specification.); *In re Barr,* 170 USPQ 330, 339 (CCPA 1971) ("The specification in this case attempts no definition of the claim language 'a phenyl radical.' Accordingly we must presume that the phrase was used in its commonly accepted technical sense. ...[Applicants] have not referred us to any standard work on chemistry which indicates that the commonly accepted technical meaning of the words 'a phenyl radical', without more, would encompass the hydroxyphenyl radical. On the contrary, Hackh's [Chemical Dictionary] quite plainly defines 'phenyl' as 'the monovalent radical ... derived from benzene ... or phenol.' ").

APPLICANT MAY BE OWN LEXICOGRAPHER

Applicant may be his or her own lexicographer as long as the meaning assigned to the term is not repugnant to the term's well known usage. *In re Hill,* 73 USPQ 482 (CCPA 1947).<

2111.02 Weight of Preamble [R-1]

>PREAMBLE IS NONLIMITING UNLESS IT BREATHES LIFE AND MEANING INTO THE CLAIM

The preamble is not given the effect of a limitation unless it breathes life and meaning into the claim. In order to limit the claim, the preamble must be "essential to point out the invention defined by the claim." *Kropa* v. *Robie,* 88 USPQ 478, 481 (CCPA 1951) (discussed below). In claims directed to articles and apparatus, any phrasecology in the preamble that limits the structure of that article or apparatus must be given weight. *In re Stencel,* 4 USPQ2d 1071 (Fed. Cir. 1987) (discussed below). On the other hand, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. *In re Hirao,* 535 F.2d 67, 190 USPQ 15 (CCPA 1976) (process claims, discussed below); *Kropa* v. *Robie,* 88 USPQ 478, 481 (CCPA 1951)(claims directed to apparatus, products, chemical structure, etc., as discussed below).

In *In re Hirao,* 535 F.2d 67, 190 USPQ 15 (CCPA 1976), the claim preamble set forth "A process for preparing foods and drinks sweetened mildly, and protected against discoloration, Streckler's reaction, and moisture absorption." The body of the claim recited two steps directed to the formation of high purity maltose and a third step of adding the maltose to foods and drinks as a sweetener. The court held that the preamble was only directed to the purpose of the process, the steps could stand alone and did not depend on the preamble for completeness.

In *Kropa* v. *Robie,* 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 said that "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.' " *Id.* at 481. Therefore, the preamble served to further define the structure of the article produced.

In *In re Stencel,* 4 USPQ2d 1071 (Fed. Cir. 1987), the claim was directed to a driver for setting a joint of a threaded collar. The claim did not directly include the structure of the collar as part of the claimed article. The preamble did set forth the structure of the collar but the examiner had not given this recitation any weight. 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. The court stated that "the 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.

COMPOSITION CLAIMS — THE PREAMBLE IS GENERALLY NONLIMITING IF THE PREAMBLE MERELY RECITES AN INHERENT PROPERTY

When the claim is directed to a product, the preamble is generally nonlimiting if the body of the claim is directed to an old composition and the preamble merely recites a property inherent in the old composition. *Kropa* v. *Robie,* 88 USPQ 478, 480-81 (CCPA 1951) (discussed above).

THE INTENDED USE MAY FURTHER LIMIT THE CLAIM IF IT DOES MORE THAN MERELY STATE PURPOSE OR INTENDED USE

Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 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.)<

2111.03 Transitional Phrases [R-3]

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 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. *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").

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 225 (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."). Transitional phrases such as "composed of," "having," or "being" must be interpreted in light of the specification to determine whether open or closed claim language is intended. 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).

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.). See also *Atlas Powder Co.* 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.* v. *Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). When 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.").

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).<

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

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). 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.

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, F2d 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, 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

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).<

"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.).

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* **, 205 USPQ 594 (CCPA 1980), 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. 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. Applicant 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.

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–1]

>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,* 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,* 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,* 195 USPQ 430, 433 (CCPA 1977).

See also *Titanium Metals Corp.* v. *Banner,* 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.);

In re Ludtke, 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.).

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*, 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.").<

2112.02 Process Claims [R–1]

>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*, 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. 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*, 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 Huck*, 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,* 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 old composition." 363 F.2d at 934, 150 USPQ at 628 (emphasis in original).).<

2113 Product by Process Claims [R–1]

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

"Even 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,* 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.).

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,* 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,* 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 (–NGF) isolated from human placental tissue. The claim was directed to –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*, 173 USPQ 685, 688 (CCPA 1972).<

2114 Apparatus and Article Claims – Functional Language [R-1]

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

APPARATUS CLAIMS MUST BE STRUCTURALLY DISTINGUISHABLE FROM THE PRIOR ART

Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danley*, 120 USPQ 528, 531 (CCPA 1959). "Apparatus claims cover what a device is, not what a device does."(emphasis in original) *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

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.).

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*, 146 USPQ 211 (CCPA 1965) as implicitly modified by *In re Donaldson*, 29 USPQ2d 1845 (Fed. Cir. 1994).<

2115 Material or Article Worked Upon by Apparatus [R-1]

>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, "Inclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." *In re Young*, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In *In re Young*, 25 USPQ 69 (CCPA 1935), 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*, 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 [R-1]

>MATERIAL RECITED IN PROCESS CLAIM MUST BE CONSIDERED IN PATENTABILITY DETERMINATION

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-2]

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> 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. To support a rejection under 35 U.S.C. 103, the collective teachings of the prior art must have suggested to one of ordinary skill in the art that, at the time the invention was made, applicant's claimed invention would have been obvious. In applying this test to the claims on appeal in *Ochiai* and *Brouwer*, the court held that there simply was no suggestion or motivation in the prior art to make or use novel, nonobvious products in the claimed processes. Consequently, the court overturned the rejections based upon 35 U.S.C. 103.

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. Motivation to make or use the nonobvious product must be present in the prior art for a 35 U.S.C. 103 rejection to be sustained. 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*, 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." 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.). <

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2121 Prior Art; General Level of Operability Required to Make a *Prima Facie* Case [R–1]

>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*, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07.

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*, 129 USPQ 227 (CCPA 1961).<

2121.01 Use of Prior Art in Rejections Where Operability Is in Question [R–1]

>A REJECTION IS APPROPRIATE IF ONE OF ORDINARY SKILL COULD PRACTICE THE CLAIMED INVENTION GIVEN THE TEACHINGS OF THE REFERENCE COMBINED WITH KNOWLEDGE IN THE ART

"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*, 158 USPQ 596 (CCPA 1968). 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*, 226 USPQ 619 (Fed. Cir. 1985).

(a) 35 U.S.C. 102 Rejections and addition of evidence showing reference is operable

SECONDARY EVIDENCE SHOWING REFERENCE CONTAINS AN "ENABLING DISCLOSURE" CAN BE COMBINED WITH THE REFERENCE TO MAKE OUT A 35 U.S.C. 102 REJECTION

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*, 226 USPQ 619, 621 (Fed. Cir. 1985). 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."

(b) 35 U.S.C. 103 rejections – Use of inoperative prior art

AN INOPERATIVE REFERENCE CAN BE USED IN A 35 U.S.C. 103 REJECTION FOR WHAT IT DOES TEACH

"Even if a reference discloses an inoperative device, it is prior art for all that it teaches." *Beckman Instruments v. LKB Produkter AB*, 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 Technologies Inc. v. Opticon Inc.*, 19 USPQ2d 1241, 1247 (Fed. Cir. 1991).<

2121.02 Compounds and Compositions – What Constitutes Enabling Prior Art [R-1]

>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*, 158 USPQ 596 (CCPA 1968). Note, however, that a reference is presumed operable until applicant provides facts rebutting the presumption of operatibility. *In re Sasse*, 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.

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*, 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*, 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-1]

>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*, 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 Thompson*, 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 LeGrice by finding that the catalogue picture of the rose of 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.).<

2121.04 Apparatus and Articles – What Constitutes Enabling Prior Art [R–1]

>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–1]

>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*, 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." 22 USPQ2d at 1673. It is enough that the claimed compound is taught by the reference.).<

2123 Rejection Over Prior Art's Broad Disclosure Instead of Preferred Embodiments [R–1]

>THE BROAD DISCLOSURE OF A REFERENCE IS RELEVANT PRIOR ART FOR ALL IT WOULD HAVE SUGGESTED TO THOSE OF ORDINARY SKILL

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*, 10 USPQ2d 1843 (Fed. Cir. 1989).

NONPREFERRED EMBODIMENT CONSTITUTE PRIOR ART

Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 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*, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to a 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, while the reference did teach away from using epoxy, the "teaching away" was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." *Id.* at 1132.)

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*, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)).<

2124 Exception to the Rule That the Critical Reference Date Must Precede the Filing Date [R-1]

>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*, 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*, 204 USPQ 702, 706 n.5 (CCPA 1980) (quoting *In re Hogan*, 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*, 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).<

2125 Drawings as Prior Art [R-1]

>DRAWINGS CAN BE USED AS PRIOR ART

Drawings and pictures can anticipate claims if they clearly show the structure which is claimed. *In re Marz*, 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*, 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. 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*, 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." *Id.* at 335-36.)<

2126 Availability of a Document as a "Patent" for Purposes of Rejection Under 3 U.S.C. 102(a), (b), and (d) [R-1]

>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* 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*, 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. 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*, 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*, 28 USPQ2d 1789 (Fed. Cir. 1993). See MPEP § 2135 – § 2135.01 for more information on 35 U.S.C. 102(d).

In re Carlson, 25 USPQ2d 1207, 1211 (Fed. Cir. 1992) ("We recognize that *Geschmacksmustern* 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.")<

2126.01 Date of Availability of a Patent As a Reference [R-2]

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*, 118 USPQ 349 (CCPA 1958).

Note that MPEP § 901.05 section F 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 CPK1-520.

2126.02 Scope of Reference's Disclosure Which Can Be Used to Reject Claims When the Reference Is a "Patent" but Not a "Publication" [R-1]

>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*, 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." *Id.* 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." *Id.* at 1789.)

In re Fuge, 124 USPQ 105 (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]." *Id.* at 107. (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-3]

(a) Abandoned applications, including provisional applications

37 CFR 1.108. Abandoned applications not cited

Abandoned applications as such will not be cited as references except those which have been opened to inspection by the public following a defensive publication.

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 is reference[d] in the disclosure of another patent, in a publication, or by voluntary disclosure...." *Lee Pharmaceutical* v. *Kreps*, >577 F.2d 610, 613,< 198 USPQ 601, 605 (9th Cir. 1978). See also 37 CFR 1.14(*>a<). The abandoned patent application becomes available as prior art only as of the date the public gains access to it as, for instance, when a patent which incorporates it by reference is granted. Thus, the subject matter of an abandoned application, including both provisional and nonprovisional applications, referred to in a prior art U.S. patent cannot be relied on in a 35 U.S.C. 102(e) rejection based on that patent since the disclosure of the abandoned application is not public as of the filing date of the patent. *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 MPEP § 2136.02 and § 2136.03 for the 35 U.S.C. 102(c) date of a U.S. patent claiming priority under 35 U.S.C. 119 or 120.<

(b) Applications which have issued into U.S. patents

A 35 U.S.C 102(c) 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 wrapper 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(c) rejections see MPEP § 2136.02.

(c) 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 (MPEP § 901.05).

(d) Pending U.S. applications

As specified in 37 CFR 1.14(a), all pending U.S. applications are preserved in *>confidence< except for 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 two copending applications have a common assignee or inventor, 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 is obvious in view of the other, a provisional rejection over 35 U.S.C. 102(e) or 103 is made. See MPEP § 706.02(f) and 706.02(k) for procedure.

2128 "Printed Publications" as Prior Art [R-1]

>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*, 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*, 210 USPQ at 794.).

See also *Carella* v. *Starlight Archery*, 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).).

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*,

210 USPQ 790 (CCPA 1981); *In re Hall*, 228 USPQ 453 (Fed. Cir. 1986).<

2128.01 Level of Public Accessibility Required [R-1]

>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*, 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*, 196 USPQ 670 (CCPA 1978).

In *In re Hall*, 228 USPQ 453 (Fed. Cir. 1986), 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*, 13 USPQ2d 1070 (Fed. Cir.1989) (The 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*, 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.*, 163 USPQ 144 (7th Cir. 1969) (calling the holding of *Ex parte Hershberger* "extreme"). Compare *In re Bayer*, 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.).

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.).

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. *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. *U.S.*, 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.*, 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.").<

2128.02 Date Publication Is Available as a Reference [R–1]

>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., 7 USPQ2d 1057 (Fed. Cir. 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,* 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–3]

ADMISSIONS BY APPLICANT CONSTITUTE PRIOR ART

When applicant states that something is prior art, it is taken as being available as prior art against the claims. Admitted prior art can be used in obviousness rejections. *In re Nomiya*, 184 USPQ 607, 610 (CCPA 1975) (Figures in the application labeled "prior art" held to be an admission that what was pictured was prior art relative to applicant's invention.).

A JEPSON CLAIM RESULTS IN AN IMPLIED ADMISSION THAT PREAMBLE IS PRIOR ART

The preamble elements in a Jepson–type claim (i.e., a claim of the type discussed in 37 CFR 1.75(e); see MPEP § 608.01(m)) >"<are impliedly admitted to be old in the art, >...< but it is only an implied admission." *In re Ehrreich,* >590 F.2d 902, 909–910< 200 USPQ 504, 510 (CCPA 1979) (emphasis in original) (citations omitted). >See also *Sjolund* v. *Musland*, 847 F.2d 1573, 1577, 6 USPQ2d 2020, 2023 (Fed. Cir. 1988); *Pentec, Inc.* v. *Graphic Controls Corp.*, 776 F.2d 309, 315, 227 USPQ 766, 770 (Fed. Cir. 1985); and *Reading & Bates Construction Co.* v. *Baker Energy Resources Corp.*, 748 F.2d 645, 650, 223 USPQ 1168, 1172 (Fed. Cir. 1984).< Claims must be read in light of the specification. Where the specification confirms that the subject matter of the preamble was invented by another before applicant's invention, the preamble is treated as prior art. However, certain art may be prior art to one inventive entity, but not to the public in general. *In re Fout,* >675 F.2d 297, 300–301,<213 USPQ 532, 535–36 (CCPA 1982). This is the case when applicant has made an improvement on his or her own prior invention. An applicant's own foundational work should not, unless there is a statutory bar, be treated as prior art solely because knowledge of this

work is admitted. Therefore, when applicant explains that the *Jepson* format is being used to avoid a double patenting rejection over their own copending application, the implication that the pre- amble is admitted prior art is overcome. *Reading & Bates Construction Co.* v. *Baker Energy* >*Resources Corp.*, 748 F.2d 645, 650<, 223 USPQ 1168>, 1172< (Fed. Cir. 1984). >Compare< *In re Fout*, >675 F.2d 297, 300–01,< 213 USPQ 532, 535–36 (CCPA 1982) (The court held that the preamble was admitted prior art because the specification explained that Paglaro, a different inventor, had invented the subject matter described in the preamble.).

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

(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, or

(f) he did not himself invent the subject matter sought to be patented, or (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention 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*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson* v. *Suzuki Motor Co.*, 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*, 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 [R–1]

>(a) General rule

IN SOME CIRCUMSTANCES MORE THAN ONE REFERENCE CAN BE USED IN A 102 REJECTION

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 (1) prove the primary reference contains an "enabled disclosure"; (2) explain the meaning of a term used in the primary reference; or (3) show that a characteristic not disclosed in the reference is inherent. See paragraphs b–d below for more explanation of each circumstance.

(b) 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*, 197 USPQ 1 (CCPA 1978) and *In re Donohue*, 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.).

(c) 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,* 21 USPQ2d 1281 (Fed. Cir. 1991) (Baxter Travenol's 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'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.)

(d) 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.,* 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." *Id.* at 1749–50.) Note that, in other cases, the courts have held that there is no requirement that those of ordinary skill in the art know of the inherent property. See MPEP § 2112 – § 2113 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–1]

>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,* 125 USPQ 345, 347 (CCPA 1960); *In re Gosteli,* 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; *In re Sivaramakrishnan*, 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*, 133 USPQ 275 (CCPA 1962).

In *In re Petering*, 133 USPQ 275 (CCPA 1962), 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]-iso-alloxazine 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, 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*, 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*, 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−1]

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

"When, 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,* 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.).

PRIOR ART WHICH TEACHES A RANGE WITHIN, 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, overlaps or is within 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, the reference teaches a broad range, and there is evidence of unexpected results within the claimed narrow 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. The unexpected results 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 motivational 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.<

2131.04 Secondary Considerations [R−1]

>EVIDENCE OF SECONDARY CONSIDERATIONS CANNOT OVERCOME A 35 U.S.C. 102 REJECTION

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,* 179 USPQ 421, 425 (CCPA 1973).<

2131.05 Nonanalogous Art [R−1]

>ART CANNOT BE "NONANALOGOUS ART" WHEN IT ANTICIPATES THE CLAIM

"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. *U. S.,* 231 USPQ 417, 424 (Cl. Ct. 1986) (quoting *In re Self,* 213 USPQ 1, 7 (CCPA 1982)).<

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

*****

(a) "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,* 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.,* 220 USPQ 303 (Fed. Cir. 1983).

See MPEP § 2128 − § 2128.02for 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. *W.L. Gore & Assoc.* v. *Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983).

(b) "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*, 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.

(c) "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*, 215 USPQ 14 (CCPA 1982).

(d) "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 [R–1]

>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*, 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*, 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*, 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,* 164 USPQ 623 (CCPA 1970).

In *In re Katz,* 215 USPQ 14 (CCPA 1982), *Katz* stated in a co-authoreclaration 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 RULE 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,* 145 USPQ (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) [R-1]

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

A person shall be entitled to a patent unless --

****

(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.

*****

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).

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,* 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,* 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 [R-1]

>UNSUPPORTED CLAIMS IN A CONTINUATION-IN-PART CAN BE REJECTED UNDER 35 U.S.C. 103 OR 35 U.S.C. 102(b) BY ANY REFERENCE AVAILABLE AS PRIOR ART MORE THAN 1 YEAR BEFORE THE CIP FILING DATE

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*, 231 USPQ 649, 653 (Fed. Cir. 1986).<

2133.02 Rejections Based on Publications and Patents [R-1]

>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. *U.S.*, 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, 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*, 145 USPQ 166, 170 (CCPA 1965).<

2133.03 Rejections Based on "Public Use" or "On Sale" [R-1]

>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 Industries* v. *E.I. du Pont de Nemours & Co.*, 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*, 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 1 other than an applicant. See MPEP § 2133.03(a) and § 2133.03(e) (7). Additionally, the concepts of "completion" and "experimental use" have differing significance in "commercial" and "non-commercial" environments. See MPEP § 2133.03(c) and § 2133.03(e) – § 2133.03(c)(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. *I.T.C.*, 22 USPQ2d 1025, 1028 (Fed. Cir. 1992).

POLICY CONSIDERATIONS

(1) "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.*, 12 USPQ2d 1449, 1454 (Fed. Cir. 1989).

(2) The public use and on-sale bars are meant 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.*, 12 USPQ2d 1449, 1454 (Fed. Cir. 1989). See MPEP § 2133.03(e)(1).

(3) 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.*, 16 USPQ2d 1587, 1591 (Fed. Cir. 1990).<

2133.03(a) "Public Use" [R-3]

ONE USE IN THE PUBLIC DOMAIN BY ONE PERSON MAY BAR A PATENT

"[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).

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. *T.P. Lab.* v. *Professional Positions, Inc.*, 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 for information on 35 U.S.C. 102(a).

i. Commercial versus noncommercial use and the impact of secrecy

"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 Lab.* v. *Professional Positioners, Inc.*, 220 USPQ 577, 583 (Fed. Cir. 1983) (citations omitted).

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*, 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.).

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.*, 229 USPQ 803, 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.").

ii. 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*, 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.*, 229 USPQ 803, 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.).

iii. 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 Provisions Co.* v. *Owens Country Sausage*, 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*, 46 USPQ 430 (2d Cir. 1940); *Dunlop Holdings* v. *Ram Golf Corp.*, 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.*, 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.*, 16 USPQ2d 1587, 1591 (Fed. Cir. 1990) (quoting *King Instrument Corp.* v. *Otari Corp.*, 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.*, 159 USPQ 139, 154 (D.Md. 1968), aff'd., 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* v. *Ram Golf Corp.*, 188 USPQ 481 (7th Cir. 1975). See MPEP § 2137 and § 2138 for more information on cases construing 35 U.S.C. 102(f) and 102(g).

2133.03(b) "On Sale" [R-3]

THE BASIC TEST

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.*, 33 USPQ2d 1512, 1514 (Fed. Cir. 1995).

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*, 226 USPQ 1, 4 (Fed. Cir. 1985).

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.*, 168 USPQ 8, 12 (5th Cir. 1970).

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*, 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.").

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.*, 23 USPQ2d 1481, 1483 (Fed. Cir. 1992).

A SALE OF RIGHTS IS NOT A SALE OF THE INVENTION AND WILL NOT IN ITSELF BAR A PATENT

"An assignment or sale of the rights, such as patent rights, in the invention is not a sale of 'the invention' within the meaning of section 102(b)." The sale must involve the delivery of the physical invention itself. *Moleculon Research Corp.* v. *CBS, Inc.*, 229 USPQ 805, 809 (Fed. Cir. 1986).

BUYER MUST BE UNCONTROLLED BY THE SELLER OR OFFERER

A sale or offer for sale must take place between separate entities. *In re Caveney*, 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.*, 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

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*, 204 USPQ 188, 192 (CCPA 1979). Even a rejected offer may create an on sale bar. *UMC Elecs.* v. *United States*, 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).

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.*, 7 USPQ2d 1325, 1327-28 (Fed. Cir. 1988) (citations omitted).

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.*, 229 USPQ 435, 438 (Fed. Cir. 1986). However, the invention must be more than a mere conception and at least close to completeness (see MPEP § 2133.03(c)) before the critical date. *UMC Elecs.* v. *United States*, 2 USPQ2d 1465 (Fed. Cir. 1987). 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.*, 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 Maschineenfabrik AG* v. *Murata Mach., Ltd.*, 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).).

iii. Sale by inventor, assignee or others associated with the inventor in the course of business

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*, 171 USPQ 713, 720 (5th Cir. 1971).

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*, 113 USPQ 289, 292 (CCPA 1957); *C.T.S. Corp.* v. *Electro Mat'ls.*, 202 USPQ 22, 38 (S.D.N.Y. 1979).

OBJECTIVE EVIDENCE OF INTENT TO SELL IS NEEDED

In determining if a sale or offer to sell has occurred a key question to ask is whether, under the totality of the circumstances, the inventor placed his or her invention on sale, objectively manifested by a sale or offer for sale of 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.*, 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 more than 1 year prior to filing of patent application for the inventive design did specify use of inventive design.). The purchaser need not have actual knowledge of the invention for it to be on sale. "For example, merely offering to sell a product by way of an advertisement or invoice may be evidence of a definite offer for sale or a sale of a claimed invention even though no details are disclosed. That 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.*, 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.*, 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

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*, 226 USPQ 1, 3–4 (Fed. Cir. 1985).

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*, 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–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 –

* * * * *

(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

* * * * *

(i) Level of completeness required

The level of completion required likely will differ in cases of "public use" which are not intertwined with a sale. *UMC Elecs. Co.* v. *United States*, 2 USPQ2d 1465, 1468 n.6 (Fed. Cir. 1987)). The court decisions do not address the level required in pure "public use" cases but it is unlikely that the invention can be publicly used without a working embodiment. The case law presented below is directed to "on sale" situations.

THE INVENTION NEED NOT BE "COMPLETE" OR "REDUCED TO PRACTICE" AT THE TIME OF THE SALE

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. *In re Hamilton*, 11 USPQ2d 1890, 1893 (Fed. Cir. 1989). Actual reduction to practice in this context 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*, 86 USPQ 373, 379 (CCPA 1950); *Steinberg* v. *Seitz*, 186 USPQ 209, 212 (CCPA 1975).

A reduction to practice of the claimed invention is not an absolute requirement of the on sale bar. *KeyStone Retaining Wall Sys. Inc.* v. *Westrock Inc.*, 27 USPQ2d 1297, 1303 (Fed. Cir. 1993). Sometimes "something less than a complete embodiment of the invention will suffice." However, the offering for sale of a mere conception of the invention before the critical date is not enough. One must look at the totality of the circumstances and what they show as to whether the inventor was attempting to commercialize the invention and thereby impermissibly extend the patent term or otherwise contravene any other of the policies furthered by the "on sale" bar. *UMC Elecs. Co.* v. *United States*, 2 USPQ2d 1465, 1471–72 (Fed. Cir. 1987). In *UMC Elecs. Co.*, the court held that the invention, while uncompleted before the critical date, was on sale within the meaning of 35 U.S.C. 102(b) and enunciated several factors leading to its decision. The development of the subject invention was far beyond a mere conception. Much of the invention was embodied in tangible form. The prior art devices embodied each element of the claimed invention, save one, and that portion was and had been sufficiently tested to demonstrate to the satisfaction of the inventor that the invention as ultimately claimed would work for its intended purpose.

DEPENDS ON HOW CERTAIN THE INVENTOR IS OF THE NATURE AND USEFULNESS OF THE DEVICE

Even if the inventor has not translated his or her invention into a working device, the invention may be sufficiently complete to create an "on sale" bar. *Philco Corp.* v. *Admiral Corp.*, 131 USPQ 413, 430 (D. Del. 1961).

"What is required is that the inventor have some certainty as to the nature and usefulness of the finished product." In other words, "the invention must have been 'sufficiently tested to demonstrate that it will work for its intended purpose.' " *Shatterproof Glass Corp.* v. *Libbey-Owens Ford Co.*, 225 USPQ 634, 640 (Fed. Cir. 1985). >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.").<

Circumstances Showing Certainty

If, at the time the device is offered for sale, the inventor is close to production of the device embodied in the claims and both the seller and offerer know what is to be sold, the invention is sufficiently complete to give rise to an on-sale bar. *Philco Corp.* v. *Admiral Corp.*, 131 USPQ 413, 430 (D. Del. 1961).

Where the evidence establishes that an inventor's confidence in an invention is shared by a party to whom the inventor has shown specific drawings, which in turn precipitated initial commercial activity relative to the invention by the other party, the invention is sufficiently "complete" to invoke an "on sale" bar. *Langsett* v. *Marmet Corp.*, 141 USPQ 903, 910-11 (W.D. Wisc. 1964). However, where parties enter into a contract to construct a device to meet certain performance factors, a sufficient level of "completeness" may not be present until there is reasonable agreement that the performance factors have in fact been met.

Even if an invention has been reduced "to a reality," the invention is not necessarily "complete" enough to create an "on sale" bar unless one would know how the invention would work upon installation, *In re Dybel*, 187 USPQ 593, 598 (CCPA 1975). However, such knowledge is not synonymous with a lack of any expectation of "problems" upon installation. As long as the "problems" are not due to "fundamental defects" in the invention, there will be sufficient "completion." *In re Theis*, 204 USPQ 188, 195 n. 11 (CCPA 1979); *National Biscuit Co.* v. *Crown Baking Co.*, 42 USPQ 214, 215 (1st Cir. 1939).

The invention need not be ready for satisfactory commercial marketing for sale to bar a patent. *Atlantic Thermoplastics Co.* v. *Faytex Corp.*, 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 (MPEP § 715.10) may constitute, among other things, an admission that an invention was "complete" more than 1 year before the filing of an application. *In re Foster*, 145 USPQ 166, 173 (CCPA 1965); *Dart Indus.* v. *E.I. duPont de Nemours & Co.*, 179 USPQ 392, 396 (7th Cir. 1973).

2133.03(d) "In This Country" [R-1]

>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* v. *Lawrence Mfg. Co.*, 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. *C.T.S. Corp.* v. *Piher Int'l Corp.*, 201 USPQ 649 (7th Cir. 1979).<

2133.03(e) Permitted Activity; Experimental Use [R-1]

>The basic test is that 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. *I.T.C.*, 22 USPQ2d 1025, 1028 (Fed. Cir. 1992) (quoting *Pennwalt Corp.* v. *Akzona Inc.*, 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*, 218 USPQ 976, 983 (Fed. Cir. 1983).<

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

>THERE MUST BE NO ATTEMPT AT MARKET PENETRATION BEFORE THE CRITICAL DATE

A strong 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, at any level, 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*, 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*, 204 USPQ 188, 194 (CCPA 1979); *Robbins Co. v. Lawrence Mfg. Co.*, 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*, 140 USPQ 341 (Ct.Cl. 1964); *Cloud v. Standard Packaging Corp.*, 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 nearly completed 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:

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

(2) preparation of price lists (*Akron Brass v. Elkhart Brass Mfg.*, 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));

(3) display of samples to prospective customers (*Cataphote Corp. v. DeSoto Chemical Coatings*, 148 USPQ 527, 529 (9th Cir. 1966); *Chicopee Mfg. Corp. v. Columbus Fiber Mills Co.*, 118 USPQ 53, 65-67 (M.D.Ga. 1958));

(4) 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.*, 188 USPQ 241, 244-45 (7th Cir. 1975); *Philco Corp. v. Admiral Corp.*, 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.*,62 USPQ 409, 412 (9th Cir. 1944));

(5) use of an invention where an admission fee is charged (*In re Josserand*, 89 USPQ 371, 376 (CCPA 1951); *Greenewalt v. Stanley*, 12 USPQ 122 (3d Cir. 1931)); and

(6) advertising in publicity releases, brochures, and various periodicals (*In re Theis*, 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 v. Elkhart Brass Mfg.*,147 USPQ 301, 305 (7th Cir.1965); *Tucker Aluminum Prods v. Grossman*, 136 USPQ 244, 245 (9th Cir. 1963)).

The above activities may be determinative of "commercial exploitation" even though (1) prices are esti-

mated rather than established, (2) no commercial production runs have been made, and (3) the invention is never actually sold, *Chromalloy Am. Corp.* v. *Alloy Surfaces Co.*, 173 USPQ 295, 301–02 (D.Del. 1972).<

2133.03(e)(2) Intent [R–1]

>"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.* v. *I.T.C.*, 22 USPQ2d 1025, 1029 (Fed. Cir. 1992) (quoting *Harrington Mfg.* v. *Co.* v. *Powell Mfg. Co.*, 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–1]

>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.*, 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 362, 366 (S.D.N.Y. 1979); *Skill Corp.* v. *Lucerne Prods*, 178 USPQ 562, 565 (N.D.Ill. 1973), aff'd., 183 USPQ 396, 399 (7th Cir. 1974), *cert. denied*, 183 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*, 204 USPQ 188, 194 (CCPA 1979).

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*, 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*, 113 USPQ 289 (CCPA 1957); *contra, Watson* v. *Allen*, 117 USPQ 68 (D.C.Cir. 1957).<

2133.03(e)(4) Factors Indicative of an Experimental Purpose [R–1]

>The Court in *City of Elizabeth* v. *American Nicholson Pavement Co.*, 97 U.S. 126 (1878) found several factors persuasive of experimental activity:

(a) the nature of the invention was such that any testing had to be to some extent public;

(b) testing had to be for a substantial period of time;

(c)testing was conducted under the supervision and control of the inventor; and

(d) the inventor regularly inspected the invention during the period of experimentation.

Supreme Court decisions subsequent to *City of Elizabeth* identify other significant factors which may be determinative of experimental purpose:

(e) extent of any obligations or limitation placed on a user during a period of experimental activity, as well as the extent of an testing actually performed during such period (*Egbert* v. *Lippmann*, 104 U.S. 333 (1881));

(f) conditional nature of any sale associated with experimental activity (*Hall* v. *Macneale*, 107 U.S. 90 (1882)); and

(g) length of time and number of cases in which experimental activity took place, viewed in light of what was reasonably necessary for an alleged experimental purpose (*International Tooth Crown Co.* v. *Gaylord*, 140 U.S. 55 (1891)).

Other judicial opinions have supplemented these factors by looking to the extent of any:

(h) explicit or implicit obligations placed upon a user to supply an inventor with the results of any testing conducted during an experimental period and the extent of inquiry made by the inventor regarding the testing (*Robbins Co.* v. *Lawrence Mfg. Co.*, 178 USPQ 577, 583 (9th Cir. 1973));

(i) disclosure by an inventor to a user regarding what the inventor considers as unsatisfactory operation of the invention (*In re Dybel*, 187 USPQ 593, 599 (CCPA 1975));

(j) effort on the part of an inventor to retrieve any experimental samples at the end of an experimental period (*Omark Indus.* v. *Carlton Co.*, 201 USPQ 825, 830 (D.Ore. 1978)); and

(k) a doctor–patient relationship where the inventor/doctor conducted the experimentation (*TP Lab.* v. *Professional Positioners, Inc.*, 220 USPQ 577, 582 (Fed. Cir. 1984).

Summarizing the above, 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 (a) through (k) is necessarily determinative of this purpose.<

2133.03(e)(5) Experimentation and Degree of Supervision and Control [R–1]

>THE INVENTOR MUST MAINTAIN SUFFICIENT CONTROL OVER THE INVENTION DURING TESTING BY THIRD PARTIES

As discussed with reference to *City of Elizabeth* v. *American Nicholson Pavement Co.*, 97 U.S. 126 (1878), a significant determinative factor in questions of experimental purpose is the extent of supervision and control maintained by an inventor over an invention during an alleged period of experimentation. 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*, 113 USPQ 289, 293 (CCPA 1957).<

2133.03(e)(6) Permitted Experimental Activity and Testing [R–1]

>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.*, 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.

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*, 204 USPQ 188, 193–94 (CCPA 1979).

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, 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 [R-1]

>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.*, 168 USPQ 392, 394 (7th Cir. 1971), *Bourne* v. *Jones*, 98 USPQ 206, 210 (S.D. Fla. 1951). aff'd., 98 USPQ 205 (5th Cir. 1953), *cert. denied*, 99 USPQ 490 (1953); contra, *Watson* v. *Allen*, 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.

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. *U.S.*, 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.*, 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.*, 227 USPQ 337, 350 (Fed. Cir. 1985). Abandonment, suppression and concealment are treated by the courts under 35 U.S.S. 102(g). See MPEP § 2138.03 for more information on this issue.<

2135 35 U.S.C. 102(d) [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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(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:

(1) 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);

(2) 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.

(3) 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.

(4) 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 case law which further clarifies each of the four requirements of 35 U.S.C. 102(d).<

2135.01 The Four Requirements of 35 U.S.C. 102(d) [R-1]

>(a) Foreign application must be filed more than 12 months before the effective U.S. filing date.

AN ANNIVERSARY DATE ENDING ON A WEEK-END 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).

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 Langenhoven*, 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 non-obvious 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).

(b) 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.

(c) The foreign patent or inventor's certificate was actually granted before the U.S. filing date.

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.*, 149 USPQ 722 (8th Cir.), *cert. denied*, 385 US 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.).

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 court explained that the provisional rights are minimal and do not come into force if the application is withdrawn or refused.).

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).).

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.).

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*, 28 USPQ2d 1789 (Fed. Cir. 1993) (An invention is "patented" for purposes of 35 U.S.C. 102(d) when the patentees 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 Fed. 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.).

(d) 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*, 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" *Id.* 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*, 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-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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(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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ONLY U.S. PATENTS AND SIRS ARE ELIGIBLE AS PRIOR ART UNDER 35 U.S.C. 102(e)

The reference must be a U.S. patent to be eligible for use in a 35 U.S.C. 102(e) rejection. *Ex parte Smolka*, 207 USPQ 232 (Bd. App. 1980) (A foreign patent document with priority back to an abandoned U.S. application cannot be the basis for a 35 U.S.C. 102(e) rejection. The foreign document cannot be prior art until it is patented or published.). Statutory Invention Registrations can also be used in 35 U.S.C. 102(e) rejections as of their filing dates.

DEFENSIVE PUBLICATIONS ARE NOT PRIOR ART AS OF THEIR FILING DATE

A defensive publication is not a patent, it is a publication. Therefore, it is prior art only as of its publication date. *Ex parte Osmond*, 191 USPQ 334 (Bd. App. 1973) (Examiner rejected the claims over Defensive Publication T-858,018 issued by the PTO to Jacobson. The examiner made a 35 U.S.C. 102(a) rejection contending that a defensive publication can be used as a reference under 35 U.S.C. 102(a) as of its filing date. This position was authorized at that time by the MPEP and a Commissioner's Notice establishing the Defensive Publication Program. The Board found that in order for a 35 U.S.C. 102(a) rejection to apply, the reference must be of public knowledge and a Defensive publication is not public knowledge at the time of its filing. Thus, the Board reversed the rejection. The Board also found that 35 U.S.C. 102(e) could not be used as a basis for rejection because the use of Defensive Publications as of their filing dates was not supported by section 102(e).) See MPEP § 711.06(a) for more information on Defensive Publications as references.<

2136.01 Status of U.S. Patent as a Reference Before and After Issuance [R-1]

>WHEN THERE IS NO COMMON ASSIGNEE OR INVENTOR, AN APPLICATION MUST ISSUE AS A PATENT BEFORE IT IS AVAILABLE AS PRIOR ART UNDER 35 U.S.C. 102(e)

Generally, a U.S. patent must issue before it can be used as a reference in a 35 U.S.C. 102(e) rejection. *Ex parte Smolka*, 207 USPQ 232 (Bd. App. 1980) (An application to Smolka and Schwuger was rejected over 35 U.S.C. 102(e) based on a pending U.S. application to Corkill whose filing date antedated the Smolka et al. application. A German application corresponding to the Corkill application had been published, but did not antedate the effective filing date of the Smolka et al. application. The Board reversed the rejection holding that a U.S. patent had to be issued to Corkill before it could become available as prior art under 102(e). There was no common assignee nor any common inventor between the two applications.).

WHEN THERE IS A COMMON ASSIGNEE OR INVENTOR, A PROVISIONAL 35 U.S.C. 102(e) REJECTION OVER AN EARLIER FILED APPLICATION CAN BE MADE

Based on the assumption that an application will ripen into a U.S. patent, it is permissible to provisionally reject a later application over an earlier application under 35 U.S.C. 102(e). *In re Irish*, 167 USPQ 764 (CCPA 1970). 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 In re Bartfeld*, 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 must remain confidential. MPEP § 706.02(f) and § 706.02(k) discuss the procedures to be used in provisional rejections over 35 U.S.C. 102(e) and 103.<

2136.02 Content of the Prior Art Available Against the Claims [R-3]

A 35 U.S.C. 102(e) REJECTION MAY RELY ON ANY PART OF THE PATENT DISCLOSURE

Under 35 U.S.C. 102(e), the entire disclosure of a U.S. patent having an earlier filing date can be relied on to reject the claims. *Sun Studs, Inc.* v. *ATA Equipment Leasing*, 10 USPQ2d 1338, 1342 (Fed. Cir. 1989).

U.S. PATENT REFERENCE MUST ITSELF CONTAIN THE SUBJECT MATTER RELIED ON IN THE REJECTION

When a U.S. patent 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. It is the filing date of the U.S. patent being relied on as the critical reference date and subject matter not included in the patent 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 and thus cannot be relied on in a 35 U.S.C. 102(e) rejection over the issued patent. **>*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 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.)

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).

2136.03 Critical Reference Date [R-3]

(a) Foreign priority date

REFERENCE'S FOREIGN PRIORITY DATE UNDER 35 U.S.C. 119(a)-(d) CANNOT BE USED AS THE 35 U.S.C. 102(e) REFERENCE DATE

A U.S. patent reference is effective prior art as of its U.S. filing date. 35 U.S.C. 119(a)-(d) does not modify section 102(e) which is explicitly limited to patent references "filed in the United States before the invention thereof by the applicant" (emphasis added). Therefore, the foreign priority date of the reference under 35 U.S.C. 119(a)-(d) 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.

(b) International (PCT) filing date

REFERENCE'S INTERNATIONAL FILING DATE CAN BE USED AS THE 35 U.S.C. 102(e) REFERENCE DATE

When the U.S. patent reference is entitled to the benefit of an international application (PCT) under 35 U.S.C. 120, the 35 U.S.C. 102(e) critical date of the reference is the international filing date as defined by 35 U.S.C. 363. Therefore, the international filing date of a U.S. patent reference can be used to antedate the application being examined. **>However, when a U.S. national stage application filed under 35 U.S.C. 371 becomes a U.S. patent, the 35 U.S.C. 102(e) date of the U.S. Patent as a prior art reference is the date applicant fulfilled the requirements of 35 U.S.C. 371(c)(1), (c)(2), and (c)(4).< See * MPEP § 715 and § 1896.

(c) 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 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, except in the case of a U.S. patent granted on an international (PCT) application in which the requirements of paragraphs (1), (2) and (4) of 35 U.S.C. 371 have been fulfilled. By the terms of 35 U.S.C. 102(e), the critical reference date of a U.S. patent granted on such a 35 U.S.C. 371 application is the date on which paragraphs (1), (2) and (4) have been fulfilled, not the filing date of the provisional application.

(d) 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 CLAIMS OF THE ISSUED CHILD

In order to carry back the 35 U.S.C. 102(e) critical date of the U.S. patent reference to the filing date of a parent application, the parent application must (1) have a right of priority to the earlier date under 35 U.S.C. 120 and (2) support the invention claimed as required by 35 U.S.C. 112, first paragraph. "For if a patent could not theoretically have issued the day the application was filed, it is not entitled to be used against another as 'secret prior art' " under 35 U.S.C. 102(e). *In re Wertheim*, >646 F.2d 527, 537,< 209 USPQ 554, 564 (CCPA 1981) (The examiner made a 35 U.S.C. 103 rejection over a U.S. patent to Pfluger. The Pfluger patent (Pfluger IV) was the child of a string of abandoned parent applications (Pfluger I, the first application, Pfluger II and III, both CIPs). Pfluger IV was a continuation of Pfluger III. The court characterized the contents of the applications as follows: Pfluger I - subject matter A, II-AB, III-ABC, IV-ABC. ABC anticipated the claims of the examined application, but the filing date of III was later than the application filing date. So the examiner reached back to "A" in Pfluger I and combined this disclosure with another reference to establish obviousness. The court held that the examiner impermissibly carried over "A" and should have instead determined which of the parent

applications contained the subject matter which made Pfluger patentable. Only if B and C were not claimed, or at least not critical to the patentability of Pfluger IV, could the filing date of Pfluger I be used. The court reversed the rejection based on a determination that Pfluger IV was only entitled to the Pfluger III filing date. The added new matter (C) was critical to the claims of the issued patent.). Note that *In re Wertheim* modified the holding of *In re Lund*, >376 F.2d 982,< 153 USPQ 625 (CCPA 1967) as to "carrying back" the subject matter to the parent applications.

See also *Ex parte Gilderdale*, 1990 Pat. App. LEXIS 25 (Bd. Pat. App. & Inter. Appeal no. 89–0352) (The examiner made a 35 U.S.C. 102(e) rejection over a U.S. patent to *Hernandez et al. Hernandez et al.* was a continuation of a continuation–in–part. Both the parent and grandparent had been abandoned. The parent listed a different inventive entity but supported the subject matter of the child's claims. The parent was filed on the same day as the examined application and thus no 35 U.S.C. 102(e) rejection could be made based on the parent's filing date. The Board reversed the rejection, explaining that the Hernandez patent was entitled to the filing date of its parent, as the parent supported the patent claims and 35 U.S.C. 120 was satisfied. Under 35 U.S.C. 120, an application can claim the benefit of an earlier filing date even if not all inventors are the same. However, Hernandez was not entitled to the grandparent filing date because the parent and child applications contained new matter as compared to the grandparent.).

Compare *Ex parte Ebata*, 19 USPQ2d 1952 (Bd. Pat. App. & Inter. 1991) (The claims were directed to a method of administering a salt of lysocellin to animals. A 35 U.S.C. 102(c) rejection was made over Martin. Martin was a continuation of an application which was in turn a continuation–in–part of an abandoned application. The grandparent application disclosed administering a manganese complex of lysocellin to animals. The Board found that "the new matter relates to additional forms of lysocellin which are useful in Martin's process, i.e., species or embodiments other than the manganese complex. This is far different from adding limitations which are required or necessary for patentability." Unlike the situation in *In re Wertheim*, Martin's invention was patentable as presented in the grandparent application.).

(e) Date of conception or reduction to practice

35 U.S.C. 102(e) REFERENCE DATE IS THE FILING DATE NOT DATE OF PATENTEE'S CONCEPTION OR REDUCTION TO PRACTICE

If the U.S. patent applied as a 35 U.S.C. 102(e) reference discloses, but does not claim the subject matter of the claims being examined or an obvious variant, the patent is not prior art under 35 U.S.C. 102(g). When the cases are not in interference, the effective date of the reference U.S. patent as prior art is its filing date in the United States, as stated in 35 U.S.C. 102(e). The date that the prior art U.S. patent 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 Equipment Leasing*, >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(c) 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 PATENT REFERENCE IS "BY ANOTHER"

"Another" means other than applicants, *In re Land*, 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 patent 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 U.S. PATENT IS "BY ANOTHER"

As stated by the House and Senate reports on the bills enacting section 35 U.S.C. 102(e), 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 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 section 102(e). *In re Mathews*, 161 USPQ 276 (CCPA 1969); *In re Facius*, 161 USPQ 294 (CCPA 1969); *Ex parte DesOrmeaux*, 25 USPQ2d 2040 (Bd. Pat. App. & Inter. 1992). See MPEP § 2136.05 for discussion of methods of overcoming 102(e) rejections.<

2136.05 Overcoming a Rejection Under 35 U.S.C. 102(e) [R-2]

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 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 a U.S. patent) of the U.S. patent 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*, 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*, 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*, 219 USPQ 389 (Fed. Cir. 1983). A terminal disclaimer also does not overcome a 35 U.S.C. 102(e) rejection. *In re Bartfeld*, 17 USPQ2d 1885 (Fed. Cir. 1991) (The examiner made a provisional 35 U.S.C. 102(e)/103 rejection over a commonly owned copending application with a different inventive entity. The rejected application was a continuation-in-part (CIP) of the reference application. Applicants argued that the terminal disclaimer they had submitted should be effective to overcome the 35 U.S.C. 102(e)/103 rejection ** because Congress enacted ** 35 U.S.C. 103>(c)< to foster free exchange of ideas and concepts at universities and corporate research centers by prohibiting the use of "secret prior art" in making obvious determinations when the subject matter originates in the same organization. The court responded by explaining that the plain language of 35 U.S.C. 103>(c)<** says that "subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 does not preclude patentability" (emphasis added). Therefore, rejections under 35 U.S.C. 102(e) are not covered by 35 U.S.C. 103>(c)<** and a terminal disclaimer will not remove the 35 U.S.C. 102(e)/103 rejection.).

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 102(e) REJECTION CAN BE OVERCOME BY SHOWING THE PATENT 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.*, 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*, 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*, 214 USPQ 933 (CCPA 1982) (citing *In re Katz*, 215 USPQ 14 (CCPA 1982)). Therefore, when the unclaimed subject matter of a patent is applicant's own invention, applicant may overcome a *prima facie* case based on the patent by showing that the patent disclosure is a description of applicant's own previous work. Such a showing can be made by proving that the patentee was associated with applicant (e.g. worked for the same company) and learned of applicant's invention from applicant. *In re Mathews*, 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 and then the joint application was filed. *In re Land*, 151 USPQ 621 (CCPA 1966).

In *In re Land*, 151 USPQ 621 (CCPA 1966), 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*, 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 applicant (Carreira et al.) 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.

APPLICANT NEED NOT SHOW DILIGENCE OR REDUCTION TO PRACTICE WHEN THE SUBJECT MATTER DISCLOSED IN THE REFERENCE IS APPLICANT'S OWN WORK

When the U.S. patent 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 patent 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*, 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 PATENT DOES NOT ITSELF ESTABLISH THAT THE PATENTEE INVENTED THOSE ELEMENTS

The existence of combination claims in a U.S. patent 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*, 214 USPQ 933 (CCPA 1982) (citing *In re Facius*, 161 USPQ 294, 301 (CCPA 1969)).

See also *In re Mathews*, 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) [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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(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, MPEP § 2325, 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*, 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*, 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 response 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*, 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.*, 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*, 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-2]

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 petition 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 petition 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.

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*, 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." 214 USPQ at 936 (quoting *In re Facius*, 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).

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*, 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 (Dep. Asst. Comm'r Pat. 1984). See also *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.

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., Inc.* v. *A.W. Chesterton Co.*, 23 USPQ2d 1622, 1626 (Fed. Cir. 1992) (Adoption of the ideas and materials from another can become a derivation.).

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*, 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*, 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*, 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).

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 Distributing*, 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").

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:

(1) 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.*, 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

(2) 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. In this situation, a rejection under 35 U.S.C. 102(f)/103 or 102(g)/103 is precluded by ** 35 U.S.C. 103>(c)<.

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–2]

The last sentence of 35 U.S.C. 103 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 subsection (f), and the claimed invention of an application under examination were owned by the same person or subject to an obligation of assignment to the same person at the time the invention was made. See MPEP § 706.02(l) and § 2146.

2138 35 U.S.C. 102(g) [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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(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention 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. *New Idea Farm Equipment Corp.* v. *Sperry Corp.*, 916 F.2d 1561, 16 USPQ2d 1424, 1428 (Fed. Cir. 1990). For example, 35 U.S.C. 102(g) and 35 U.S.C. 103 have been combined in the context of an ex parte rejection entirely divorced from the award of priority in an interference. *In re Bass*, 474 F.2d 1276, 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). See also *Du Pont de Nemours* v. *Phillips Petroleum Co.*, 849 F.2d 1430, 7 USPQ2d 1129, 1132 (Fed. Cir.), *cert. denied*, 488 U.S. 986 (1988) (determining whether patent claims were novel under 35 U.S.C. 102(g) in an infringement proceeding); *In re Costello*, et al., 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); *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-1]

>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. *Bigham* v. *Godtfredsen*, 857 F.2d 1415, 8 USPQ2d 1266, 1267 (Fed. Cir. 1988), 35 U.S.C. 135, 37 CFR 1.601+ 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 (37 CFR 1.601(i)). 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, 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 Corporation of America* v. *Radio Engineering Laboratories, Inc.*, 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*, 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*, 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.).

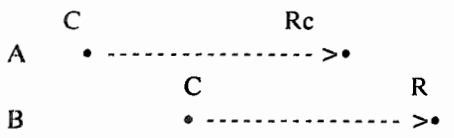
PRIORITY TIME CHARTS

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*, 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.

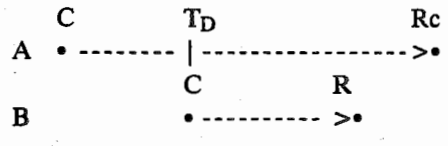
I.



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 in-

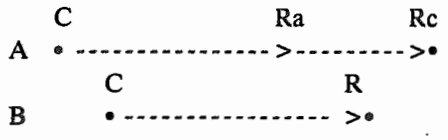
vention to practice before B reduced the invention to practice. The same result would be reached if the conception date was the same for both inventors A and B.

II.



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.

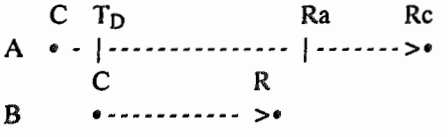
III.



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.

IV.



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.

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.

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" [R-1]

>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 subsection (g) is limited to an invention that is made. *In re Katz*, 687 F.2d 450, 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 subsection (g) has ever been made).

Subject matter under subsection (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").

Note, however, that 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" [R-1]

>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)). See also MPEP § 2332. *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*, 217 USPQ 753, 756 (Fed. Cir. 1983) quoting *International Glass Co.* v. *United States*, 408 F.2d 395, 159 USPQ 434, 441 (Ct. Cl. 1969) (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*, 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*, 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*, 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*, 180 USPQ 388, n.3 and 391 (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*, 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* 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*, 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*, 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*, 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*, 217 USPQ 753, 755 (Fed. Cir. 1983) (an invention cannot be abandoned until it is first reduced to practice).<

2138.04 "Conception" [R-1]

>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*, 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*, 197 USPQ 482 (CCPA 1978). See also *Coleman* v. *Dines*, 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.").

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*, 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.).

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").

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*, 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"); *Langer* v. *Kaufman*, 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.*, 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.).

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*, 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*, 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 (formerly Sugano)*, 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*, 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*, 167 USPQ 550, 552–553 (CCPA 1970). See also *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.*, 32 USPQ2d 1915, 1920 (Fed. Cir. 1994).

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*, 219 USPQ 389, 392 (Fed. Cir. 1983).<

2138.05 "Reduction to Practice" [R-1]

>Reduction to practice may be an actual reduction or a constructive reduction to practice, i.e., filing of a patent application. *Dunn* v. *Ragin*, 50 USPQ 472, 474 (Bd. Pat. Inter. 1941) (asexually reproduced plants require an actual reduction to practice). 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*, 219 USPQ 389, 392 (Fed. Cir. 1983).

CONSTRUCTIVE REDUCTION TO PRACTICE REQUIRES COMPLIANCE WITH 35 U.S.C. 112, FIRST PARAGRAPH

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*, 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.). See also *Bigham* v. *Godtfredsen*, 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).

The first conceiver may rely on earlier filed applications under 35 U.S.C. 120 (*Ginos* v. *Nedelec*, 220 USPQ 831, 833 (Bd. Pat. Inter. 1983)) provided the earlier application satisfies 35 U.S.C. 112, first paragraph (*Suh* v. *Hoefle*, 23 USPQ2d 1321, 1325 (Bd. Pat. App. & Inter. 1992)).

REQUIREMENTS TO ESTABLISH ACTUAL REDUCTION TO PRACTICE

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*, 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. 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.*, 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*, 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."); *Corona* v. *Dovan*, 273 U.S. 692, 1928 CD 252 (1928) ("A process is reduced to practice when it is successfully performed. A machine is reduced to practice when it is assembled, adjusted and used. A manufacture [i.e., article of manufacture] is reduced to practice when it is completely manufactured. A composition of matter is reduced to practice when it is completely composed." 1928 C.D. at 262-263 (emphasis added).); *Fitzgerald* v. *Arbib*, 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").

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*, 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).

REDUCTION TO PRACTICE REQUIRES RECOGNITION AND APPRECIATION OF THE INVENTION

The invention must be recognized and appreciated for a reduction to practice to occur. *Alsenz* v. *Hargraves*, 13 USPQ2d 1371, 1374 (Bd. Pat. App. & Int. 1989) (a reduction to practice cannot be established *nunc pro tunc*); *Meitzner* v. *Corte*, 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); *Parker* v. *Frilette*, 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").

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*, 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).

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*, 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*, 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*, 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*, 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.).

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 inter-

mediate. 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*, 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*, 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*, 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*, 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*, 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*, 219 USPQ 189, 193 (Fed. Cir. 1983) (37 CFR 1.131 issue); *Fitzgerald* v. *Arbib*, 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*, 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*, 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*, 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*, 190 USPQ 113 (CCPA 1976) (budgetary limits and availability of animals for testing not sufficiently described); *Morway* v. *Bondi*, 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*, 196 USPQ 294,296 (CCPA 1977), *cert. denied*, 439 U.S. 826 (1978). "[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*, 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*, 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*, 213 USPQ 192, 195 (CCPA 1982). *Bey* v. *Kollonitsch*, 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, 340–1 (Bd. Pat. Inter. 1971).<

2141 35 U.S.C. 103; The Graham Factual Inquiries [R-2]

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)< Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (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 invention was made, owned by the same person or subject to an obligation of assignment to the same person.

STANDARD OF PATENTABILITY TO BE APPLIED IN OBVIOUSNESS REJECTIONS

Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. The Supreme Court in *Graham* v. *John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated that,

> "Under § 103, the scope and content of the prior art to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquires may have relevancy. . .
>
> "This in not to say, however, that there will not be difficulties in applying the nonobviousness test. What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context. The difficulties, however, are comparable to those encountered daily by the courts in such frames of reference as negligence and scienter, and should be amenable to a case-by-case development. We believe that strict observance of the requirements laid down here will result in that uniformity and definitiveness which Congress called for in the 1952 Act.

Office policy has consistently been to follow *Graham* v. *John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. 103. As quoted above, the four factual inquires enunciated therein as a background for determining obviousness are briefly as follows:

(1) Determining of the scope and contents of the prior art;

(2) Ascertaining the differences between the prior art and the claims in issue;

(3) Resolving the level of ordinary skill in the pertinent art; and

(4) Evaluating evidence of secondary considerations.

The Supreme Court reaffirmed and relied upon the *Graham* three pronged test in its consideration and determination of obviousness in the fact situations presented in both the *Sakraida* v. *Ag Pro, Inc.*, 425 U.S. 273, 189 USPQ 449, reh'g denied, 426 U.S. 955 (1976) and *Anderson's-Black Rock, Inc.* v. *Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969) decisions. In each case, the Court went on to discuss whether the claimed combinations produced a "new or different function" and a "synergistic result," but clearly decided whether the claimed inventions were unobvious on the basis of the three-way test in *Graham*. Nowhere in its decisions in those cases does the Court state that the "new or different function" and "synergistic result" tests supersede a finding of unobviousness or obviousness under the *Graham* test.

Accordingly, examiners should apply the test for patentability under 35 U.S.C. 103 set forth in *Graham*. See below for a detailed discussion of each of the *Graham* factual inquiries. It should be noted that the Supreme Court's application of the *Graham* test to the fact circumstances in *Ag Pro* was somewhat stringent, as it was in *Black Rock*. Note *Republic Industries, Inc.* v. *Schlage Lock Co.*, 592 F.2d 963, 200 USPQ 769 (7th Cir. 1979). The Court of Appeals for the Federal Circuit stated in *Stratoflex, Inc.* v. *Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871, 880 (Fed. Cir. 1983) that

> A requirement for synergism or a synergistic effect is nowhere found in the statute, 35 U.S.C. When present, for example in a chemical case, synergism may point toward nonobviousness, but its absence has no place in evaluating the evidence on obviousness. The more objective findings suggested in *Graham*, *supra*, are drawn from the language of the statute and are fully adequate guides for evaluating the evidence relating to compliance with 35 U.S.C. 103. *Bowser Inc.* v. *United States*, 388 F. 2d 346, 156 USPQ 406 (Ct. Cl. 1967).

BASIC CONSIDERATIONS WHICH APPLY TO OBVIOUSNESS REJECTIONS

When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

(1) the claimed invention must be considered as a whole;

(2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

(3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention and

(4) reasonable expectation of success is the standard with which obviousness is determined. *Hodosh* v. *Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187, n.5 (Fed. Cir. 1986).

OBJECTIVE EVIDENCE MUST BE CONSIDERED

Objective evidence or secondary considerations such as unexpected results, commercial success, long-felt need, failure of others, copying by others, licensing, and skepticism of experts are relevant to the issue of obviousness and must be considered in every case in which they are present. When evidence of any of these secondary considerations is submitted, the examiner must evaluate the evidence. The weight to be accorded to the evidence depends on the individual factual circumstances of each case. *Stratoflex, Inc.* v. *Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Hybritech, Inc.* v. *Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). The ultimate determination on patentability is made on the entire record. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

See MPEP § 716 – § 716.06 for a discussion of objective evidence and its role in the final legal determination of whether a claimed invention would have been obvious under 35 U.S.C. 103.

2141.01 Scope and Content of the Prior Art [R-2]

(a) 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 Manufacturing Co.*, 810 F.2d 1561, 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.").

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 is said to be a statutory bar just as if it anticipated the claims under 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.

(b) 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.).

(c) Content of the prior art is determined at the time the invention was made to avoid hindsight

Requirement for "at the time the invention was made" is to avoid impermissible hindsight. See MPEP § 2145, paragraph (j) 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 who is presented only with the references, and who is normally guided by the then-accepted wisdom 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).

*(d) 35 U.S.C. 103>(c)<** — evidence required to show conditions of 35 U.S.C. 103 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 qualifies as prior art under subsection (f) or (g) of section 102 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). Note that **>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. *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (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." 17 USPQ2d at 1888.).

See MPEP § 706.02(l) for the requirements which must be met to establish common ownership.

2141.01(a) Analogous and Nonanalogous Art [R-1]

>TO RELY ON A REFERENCE UNDER 35 U.S.C. 103, IT MUST BE ANALOGOUS PRIOR ART

The examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also *In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); *In re Clay*, 966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem."); and *Wang Laboratories Inc.* v. *Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993).

PTO CLASSIFICATION IS SOME EVIDENCE OF ANALOGY, BUT SIMILARITIES AND DIFFERENCES IN STRUCTURE AND FUNCTION CARRY MORE WEIGHT

While Patent Office classification of references and the cross-references in the official search notes 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, 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).); *In re Clay*, 966 F.2d 656, 23 USPQ2d 1058 (Fed. Cir. 1992) (Claims were directed to a process for storing a refined liquid hydrocarbon product in a storage tank having a dead volume between the tank bottom and its outlet port wherein a gelled solution filled the tank's dead volume to prevent loss of stored product while preventing contamination. One of the references relied upon disclosed a process for

reducing the permeability of natural underground hydrocarbon bearing formations using a gel similar to that of applicant to improve oil production. The court disagreed with the PTO's argument that the reference and claimed inventions were part of the same endeavor, "maximizing withdrawal of petroleum stored in petroleum reserves," and found that the inventions involved different fields of endeavor since the reference taught the use of the gel in a different structure for a different purpose under different temperature and pressure conditions, and since the application related to storage of liquid hydrocarbons rather than extraction of crude petroleum. The court also found the reference was not reasonably pertinent to the problem with which the inventor was concerned because a person having ordinary skill in the art would not reasonably have expected to solve the problem of dead volume in tanks for refined petroleum by considering a reference dealing with plugging underground formation anomalies.).

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 vermiculite 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.).

ANALOGY IN THE MECHANICAL ARTS

See, for example, *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992) (Applicant claimed an improvement in a hose clamp which differed from the prior art in the presence of a preassembly "hook" which maintained the preassembly condition of the clamp and disengaged automatically when the clamp was tightened. The Board relied upon a reference which disclosed a hook and eye fastener for use in garments, reasoning that all hooking problems are analogous. The court held the reference was not within the field of applicant's endeavor, and was not reasonably pertinent to the particular problem with which the inventor was concerned because it had not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments. The Commissioner further argued in the brief on appeal that a disengageable catch is a common everyday mechanical concept, however the court held that the Commissioner did not explain why a "catch" of unstated structure is such a concept, and why it would have made the claimed invention obvious.). Compare *Stevenson* v. *International Trade Commission*, 612 F.2d 546, 204 USPQ 276 (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." 204 USPQ at 280.);

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 di-

rected 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.);

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.).

ANALOGY IN THE ELECTRICAL ARTS

See, for example, *Wang Laboratories Inc.* v. *Toshiba Corp.*, 993 F.2d 858, 26 USPQ2d 1767 (Fed. Cir. 1993) (Patent claims were directed to single in-line memory modules (SIMMs) for installation on a printed circuit motherboard for use in personal computers. Reference to a SIMM for an industrial controller was not necessarily in the same field of endeavor as the claimed subject matter merely because it related to memories. Reference was found to be in a different field of endeavor because it involved memory circuits in which modules of varying sizes may be added or replaced, whereas the claimed invention involved compact modular memories. Furthermore, since memory modules of the claims at issue were intended for personal computers and used dynamic random-access-memories, whereas reference SIMM was developed for use in large industrial machine controllers and only taught the use of static random-access-memories or read-only-memories, the finding that the reference was nonanalogous was supported by substantial evidence.);

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.).

EXAMPLES OF ANALOGY IN THE DESIGN ARTS

See MPEP § 1504.03(a)(1) 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, 28 USPQ2d 1399 (Fed. Cir. 1993) (unpublished – not citable as precedent) (The claimed invention, a spherical design for a combined insect repellant 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 repellant and air freshener would therefore not have reason to know of or look to a design for a metal ball anode." 28 USPQ at 1400.).<

2141.02 Differences Between Prior Art and Claimed Invention [R-2]

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.

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." 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." 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.).

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, 230 USPQ 416, 419, 420 (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, 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 Manufacturing 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).

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, 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*, 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.

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.).

DISCLOSED INHERENT PROPERTIES ARE PART OF "AS A WHOLE" INQUIRY

"In determining whether the invention as a whole would have been obvious under section 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 those properties of the subject matter that 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 section 103." *In re Antonie*, 559 F.2d 618, 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, 137 USPQ 42, 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.

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 100% 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.).

2141.03 Level of Ordinary Skill in the Art [R-1]

>FACTORS TO CONSIDER IN DETERMINING LEVEL OF ORDINARY SKILL

"Factors that may be considered in determining level of ordinary skill in the art include (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Environmental Designs, Ltd.* v. *Union Oil Co.*, 713 F.2d 693, 218 USPQ 865, 868 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984).

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).

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).

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 Manufacturing Co.* v. *Nu-Star Inc.*, 950 F.2d 714, 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-1]

>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 80 (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 suggest 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

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some 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. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 – § 2143.03 for decisions pertinent to each of these criteria.

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). See MPEP § 2144 – § 2144.09 for examples of reasoning supporting obviousness rejections.

When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper. *Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986). A statement of a rejection that includes a large number of rejections must explain with reasonable specificity at least one rejection, otherwise the examiner procedurally fails to establish a *prima facie* case of obviousness. *Ex parte Blanc*, 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989) (Rejection based on nine references which included at least 40 prior art rejections without explaining any one rejection with reasonable specificity was reversed as procedurally failing to establish a *prima facie* case of obviousness.).

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 response 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 Basic Requirements of a *Prima Facie* Case of Obviousness [R-1]

>To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some 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. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).<

2143.01 Suggestion or Motivation to Modify the References [R-1]

>THE PRIOR ART MUST SUGGEST THE DESIRABILITY OF THE CLAIMED INVENTION

"In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 173 USPQ 560, 562 (CCPA 1972).

Obviousness can only 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 found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *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).

In *In re Fine*, the claims were directed to a system for detecting and measuring minute quantities on nitrogen compounds comprising a gas chromatograph, a converter which converts nitrogen compounds into nitric oxide by combustion, and a nitric oxide detector. The primary reference disclosed a system for monitoring sulfur compounds comprising a chromatograph, combustion means, and a detector, and the secondary reference taught nitric oxide detectors. The examiner and Board asserted that it would have been within the skill of the art to substitute one type of detector for another in the system of the primary reference, however the court found there was no support or explanation of this conclusion and reversed.

In *In re Jones*, the claimed invention was the 2-(2'-aminoethoxy)ethanol salt of dicamba, a compound with herbicidal activity. The primary reference disclosed *inter alia* the substituted ammonium salts of dicamba as herbicides, however the reference did not specifically teach the claimed salt. Secondary references teaching the amine portion of the salt were directed to shampoo additives and a byproduct of the production of morpholine. The court found there was no suggestion to combine these references to arrive at the claimed invention.

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*, 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.).

FACT THAT REFERENCES CAN BE COMBINED OR MODIFIED IS NOT 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 prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (Claims were directed to an apparatus for producing an aerated cementitious composition by drawing air into the cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not require that the output pump be run at the claimed speed so that air is drawn into the mixing chamber and is entrained in the ingredients during operation. Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 16 USPQ2d at 1432.). See also *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992) (flexible landscape edging device which is conformable to a ground surface of varying slope not suggested by combination of prior art references).

FACT 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).

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.).

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." 123 USPQ at 352.).<

2143.02 Reasonable Expectation of Success Is Required [R-1]

>OBVIOUSNESS REQUIRES ONLY A REASONABLE EXPECTATION OF SUCCESS

The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is 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.).

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, 18 USPQ2d 1016 (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. 18 USPQ2d at 1022, 1023.); *In re O'Farrell*, 853 F.2d 894, 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.).

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 Taught or Suggested [R-1]

>To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "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, 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).

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*, 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).

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 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103 [R-1]

>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 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, 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).

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, 217 USPQ 1, 5–6 (Fed. Cir. 1983).

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 case law as the rationale 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).

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. *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). Although *Ex parte Levengood*, 28 USPQ2d 1300, 1302 (Bd. Pat. App. & Inter. 1993) states that obviousness cannot be established by combining references "without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done" (emphasis added), reading the quotation in context it is clear that while there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.

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'." 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." 16 USPQ2d at 1901 (emphasis in original).

See MPEP § 2145, paragraph (b) for case law pertaining to the presence of additional advantages or latent properties not recognized in the prior art.<

2144.01 Implicit Disclosure [R-1]

>"[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, 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, 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-1]

>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.). Although the theoretical mechanism of an invention may be explained by logic and sound scientific reasoning, this fact does not support an obviousness determination unless logic and scientific reasoning would have led one of ordinary skill in the art to make the claimed invention. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993).<

2144.03 Reliance on Common Knowledge in the Art or "Well Known" Prior Art [R-1]

>The rationale supporting an obviousness rejection may be based on common knowledge in the art or "well-known" prior art. The examiner may take official notice of facts outside of the record which are capable of instant and unquestionable demonstration as being "well-known" in the art. *In re Ahlert*, 424 F.2d 1088, 165 USPQ 418, 420 (CCPA 1970) (Board properly took judicial notice that "it is common practice to postheat a weld after the welding operation is completed" and that "it is old to adjust the intensity of a flame in accordance with the heat requirements."). See also *In re Seifreid*, 407 F.2d 897, 160 USPQ 804 (CCPA 1969) (Examiner's statement that polyethylene terephthalate films are commonly known to be shrinkable is a statement of common knowledge in the art, supported by the references of record.).

If justified, the examiner should not be obliged to spend time to produce documentary proof. If the knowledge is of such notorious character that judicial notice can be taken, it is sufficient so to state. *In re Malcolm*, 129 F.2d 529, 54 USPQ 235 (CCPA 1942). If the applicant traverses such an assertion the examiner should cite a reference in support of his or her position.

When a rejection is based on facts within the personal knowledge of the examiner, the data should be stated as specifically as possible, and the facts must be supported, when called for by the applicant, by an affidavit from the examiner. Such an affidavit is subject to contradiction or explanation by the affidavits of the applicant and other persons. See 37 CFR 1.107.

Applicant must also seasonably challenge well known statements and statements based on personal knowledge when they are made by the Board of Patent Appeals and Interferences. *In re Selmi*, 156 F.2d 96, 70 USPQ 197 (CCPA 1946); *In re Fischer*, 125 F.2d 725, 52 USPQ 473 (CCPA 1942). See also *In re Boon*, 439 F.2d

724, 169 USPQ 231 (CCPA 1971) (a challenge to the taking of judicial notice must contain adequate information or argument to create on its face a reasonable doubt regarding the circumstances justifying the judicial notice).

For further views on official notice, see *In re Ahlert*, 424 F.2d 1088, 165 USPQ 418, 420–421 (CCPA 1970) ("[A]ssertions of technical facts in areas of esoteric technology must always be supported by citation of some reference work" and "allegations concerning specific 'knowledge' of the prior art, which might be peculiar to a particular art should also be supported." Furthermore the applicant must be given the opportunity to challenge the correctness of such assertions and allegations. "The facts so noticed serve to 'fill the gaps' which might exist in the evidentiary showing" and should not comprise the principle evidence upon which a rejection is based.). See also *In re Barr*, 444 F.2d 588, 170 USPQ 330 (CCPA 1971) (scientific journal references were not used as a basis for taking judicial notice that controverted phrases were art–recognized because the court was not sure that the meaning of the term at issue was indisputable among reasonable men); and *In re Eynde*, 480 F.2d 470, 178 USPQ 470,474 (CCPA 1973) ("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 [judicial] notice.").<

If applicant does not seasonably traverse the well known statement during examination, then the object of the well known statement is taken to be admitted prior art. *In re Chevenard*, 139 F.2d 71, 60 USPQ 239 (CCPA 1943). A seasonable challenge constitutes a demand for evidence made as soon as practicable during prosecution. Thus, applicant is charged with rebutting the well known statement in the next response after the Office Action in which the well known statement was made. This is necessary because the examiner must be given the opportunity to provide evidence in the next Office Action or explain why no evidence is required. If the examiner adds a reference to the rejection in the next action after applicant's rebuttal, the newly cited reference, if it is added merely as evidence of the prior well known statement, does not result in a new issue and thus the action can potentially 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.

2144.04 Legal Precedent as Source of Supporting Rationale [R–1]

>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.

(a) 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).).

(b) Elimination of a step or an element and its function

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 poly-

basic 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).

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.).

(c) Automating a manual activity

In re Venner, 262 F.2d 91, 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.).

(d) Changes in size, shape, or sequence of adding ingredients

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." 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.

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.).

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*, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.).

(e) Making portable, integral, separable, adjustable, or continuous

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.).

MAKING INTEGRAL

In re Larson, 340 F.2d 965, 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.).

MAKING SEPARABLE

In re Dulberg, 289 F.2d 522, 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.").

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.).

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.).

(f) Reversal, duplication, or rearrangement of parts

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.).

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 perpendicular to the workface and in the joint, and a plurality of "ribs" which are parallel to the workface, forming the following shape(‡). 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).

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 Manufacturing Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984).

(g) Purifying an old product

Pure materials are novel vis-a-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 β-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 β-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-1]

>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.

(a) 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). 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 Corporation 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.).

(b) Optimization of ranges

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, 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 *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), and *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990).

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).

(c) Obviousness rebuttable with secondary evidence

Applicants can rebut a *prima facie* case of obviousness based on overlapping ranges by showing unexpected results or 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.<

2144.06 Art Recognized Equivalence for the Same Purpose [R-1]

>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, 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). But see *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987) ("Based upon the prior art and the fact that each of the three components of the composition used in the claimed method is conventionally employed in the art for treating cooling water systems, the board held that it would have been *prima facie* obvious, within the meaning of 35 U.S.C. 103, to employ these components in combination for their known functions and to optimize the amount of each additive.... Appellant argues ... hindsight reconstruction or at best, ... 'obvious to try'.... We agree with appellant.").

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 express recognition of an art-recognized or obvious equivalent may be used to refute an argument that such equivalency does not exist.); *In re Scott*, 323 F.2d 1016, 139 USPQ 297 (CCPA 1963) (Claims were drawn to a hollow fiberglass shaft for archery and a process for the production thereof where the shaft differed from the prior art in the use of a paper tube as the core of the shaft as compared with the light wood or hardened foamed resin core of the prior art. The Board found the claimed invention would have been obvious, reasoning that the prior art foam core is the functional and mechanical equivalent of the claimed paper core. The court reversed, holding that components which are functionally or mechanically equivalent are not necessarily obvious in view of one another, and in this case, the use of a light wood or hardened foam resin core does not fairly suggest the use of a paper core.); *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-1]

>"The motivation to combine [prior art references] can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose." *In re Floyd*, Appeal No. 94-1071, slip op. at page 4 (Fed. Cir. July 20, 1994) (unpublished—not citable as precedent). The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co., Inc.* 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." 65 USPQ at 301.).

See also *In re Leshin*, 227 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-3]

**>I. Interim Guidelines for the Examination of Claims Directed to Species of Chemical Compositions Based Upon a Single Prior Art Reference

These "Genus-Species Guidelines" are to assist Office personnel in the examination of applications which contain claims to species or a subgenus of chemical compositions for compliance with 35 U.S.C. 103 based upon 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 follow these guidelines to determine whether a single reference 35 U.S.C. 103 rejection would be appropriate. The 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.

The analysis of the guidelines begins at the point during examination after a single prior art reference is found disclosing a genus encompassing the claimed species or subgenus. Before reaching this point, Office personnel should follow normal examination procedures. Accordingly, Office personnel should first analyze the claims as a whole in light of and consistent with the written description, considering all claim limitations. When evaluating the scope of a claim, every limitation in the claim must be considered. See, e.g., *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). However, the claimed invention may not be dissected into discrete elements to be analyzed in isolation, but must be considered as a whole. See, e.g., *W.L. Gore & Assoc., Inc.* v. *Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); *Jones* v. *Hardy*, 727 F.2d 1524, 1530, 220 USPQ 1021, 1026 (Fed. Cir. 1983) ("treating the advantage as the invention disregards the statutory requirement that the invention be viewed 'as a whole' "). Next, Office personnel should conduct a thorough search of the prior art and identify all relevant references. Both claimed and unclaimed aspects of the invention should be searched if there is a reasonable expectation that the unclaimed aspects may be later claimed. If the most relevant prior art consists of a single prior art reference disclosing a genus encompassing the claimed species or subgenus, Office personnel should follow the guidelines set forth herein.

These guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. Rather, they are to assist Office personnel in analyzing claimed subject matter for compliance with substantive law. Thus, rejections must be based upon the substantive law, and it is these rejections which are appealable, not any failure by Office personnel to follow these guidelines.

Office personnel are to rely on these guidelines in the event of any inconsistent treatment of issues between these guidelines and any earlier provided guidance from the Office.

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*), *cert. denied*, 500 U.S. 904 (1991). 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).

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: (1) determine the scope and contents of the prior art; (2) ascertain the differences between the prior art and the claims in issue; (3) determine the level of skill in the pertinent art; and (4) 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.*

A. Establishing a *Prima Facie* Case of Obviousness

To establish a *prima facie* case of obviousness in a genus–species chemical composition situation, as in any other 35 U.S.C. § 103 case, it is essential that Office personnel find some motivation or suggestion to make the claimed invention in light of the prior art teachings. See, e.g., *In re Brouwer*, 77 F.3d 422, 425, 37 USPQ2d 1663, 1666 (Fed. Cir. 1996) ("[T]he mere possibility that one of the esters or the active methylene group–containing compounds . . . could be modified or replaced such that its use would lead to the specific sulfoalkylated resin recited in claim 8 does not make the process recited in claim 8 obvious "unless the prior art suggested the desirability of [such a] modification' or replacement.") (quoting *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984); *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991) ("[A] proper analysis under § 103 requires, *inter alia*, consideration of . . . whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process."). In order to find such motivation or suggestion there should be a reasonable likelihood that the claimed invention would have the properties disclosed by the prior art teachings. The prior art disclosure may be express, implicit, or inherent. Regardless of the type of disclosure, the prior art must provide some motivation to one of ordinary skill in the art to make the claimed invention in order to support a conclusion of obviousness. See, e.g., *Vaeck*, 947 F.2d at 493, 20 USPQ2d at 1442 (A proper obviousness analysis requires consideration of "whether the prior art would also have revealed that in so making or carrying out [the claimed invention], those of ordinary skill would have a reasonable expectation of success."); *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988) ("The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art."); *Hodosh* v. *Block Drug Co.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir.), *cert. denied*, 479 U.S. 827 (1986). These disclosed findings should be made with a complete understanding of the first three "Graham factors." When evidence of secondary considerations such as unexpected results is initially before the Office, for example in the specification, that evidence should be considered in deciding whether there is a *prima facie* case of obviousness. The determination as to whether a *prima facie* case exists should be made on the full record before the Office at the time of the determination. Thus, Office personnel should (1) determine the "scope and content of the prior art"; (2) ascertain the "differences between the prior art and the claims at issue"; and (3) determine "the level of ordinary skill in the pertinent art." *Graham* v. *John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). *Accord*, e.g., *In re Paulsen*, 30 F.3d 1475, 1482, 31 USPQ2d 1671, 1676 (Fed. Cir. 1994).

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.) ("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."), *cert. denied*, 481 U.S. 1052 (1987)), and should be in the field of applicant's endeavor, or be reasonably pertinent to the particular problem with which the inventor was concerned. *In re Oetiker*, 977 F.2d 1443, 1447, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). *Accord;* e.g., *In re Clay*, 966 F.2d 656, 658–59, 23 USPQ2d 1058, 1060 (Fed. Cir. 1992).

In the case of a prior art reference disclosing a genus, Office personnel should make findings as to (1) the structure of the disclosed prior art genus and that of any expressly described species or subgenus within the genus; (2) 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; (3) the predictability of the technology; and (4) the number of species encompassed by the genus taking into consideration all of the variables possible.

2. Ascertain The Differences Between the Prior Art Genus and the Claimed Species or Subgenus

Once a relevant prior art genus is 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 prior art reference 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 Manufacturing 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.), *cert. denied*, 488 U.S. 825 (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 one of ordinary skill in the relevant art would have been motivated to make the claimed invention as a whole, *i.e.*, to select the claimed species or subgenus from the disclosed prior art genus. See, e.g., *Ochiai*, 71 F.3d at 1569–70, 37 USPQ2d at 1131; *Deuel*, 51 F.3d at 1557, 34 USPQ2d at 1214 ("[A] *prima facie* case of unpatentability requires that the teachings of the prior art suggest *the claimed compounds* to a person of ordinary skill in the art." (emphasis in original)); *Jones*, 958 F.2d at 351, 21 USPQ2d at 1943–44 (Fed. Cir. 1992); *Dillon*, 919 F.2d at 692, 16 USPQ2d at 1901; *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984) ("The prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound."). See also *In re Kemps*, 97 F.3d 1427, 1430, 40 USPQ2d 1309, 1311 (Fed. Cir. 1996) (discussing motivation to combine). 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. Some motivation to select the claimed species or subgenus must be taught by the prior art. See, e.g., *Deuel*, 51 F.3d at 1558–59, 34 USPQ2d at 1215 ("No particular one of these DNAs can be obvious unless there is something in the prior art to lead to the particular DNA and indicate that it should be prepared."); *Baird*, 16 F.3d at 382–83, 29 USPQ2d at 1552; *Bell*, 991 F.2d at 784, 26 USPQ2d at 1531 ("Absent anything in the cited prior art suggesting which of the 10^{36} possible sequences suggested by Rinderknecht corresponds to the IGF gene, the PTO has not met its burden of establishing that the prior art would have suggested the claimed sequences."). However, a genus may be so small that it would anticipate the claimed species or subgenus. For example, it has been held that a prior art genus containing only 20 compounds 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). *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 which would have motivated 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.), *cert. denied*, 493 U.S. 975 (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 there is sufficient motivation 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 motivate 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."). The utility of such properties will normally provide some motivation to make the claimed species or subgenus. See *Id.*

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). *C.f. 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). Similarly, a claimed protein compound having an amino acid sequence including Met–Phe–Pro–Leu–$(Asp)_4$–Lys–Y was held to be obvious in light of structural similarities to the prior art. One reference provided motivation to create fusion proteins in the forms X–$(Asp)_4$–Lys–Y. Other references taught positioning Met at the start of the amino acid sequence and that the sequences Phe–Pro–Ile or Leu–Pro–Leu could serve as X in the basic formula. The known structural similarity of Ile and Leu meant that appellants merely substituted one element known in the art for a known equivalent. Thus, the substitution was held to be obvious. *In re Mayne*, 104 F.3d 1339, 1342–43, 41 USPQ2d 1451, 1454–55 (Fed. Cir. 1997). Other structural similarities have been found to support a *prima facie* case of obviousness; 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 a 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. *Id.* 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 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.), *cert. denied*, 481 U.S. 1052 (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.

B. Determining Whether Rebuttal Evidence Is Sufficient To Overcome the *Prima Facie* Case of Obviousness

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., *Dillon*, 919 F.2d at 692, 16 USPQ2d at 1901. 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., *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995) (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 (Fed. Cir. 1997) (conclusory statements that claimed compound posesses 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), *cert. denied*, 480 U.S. 947 (1987). 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.).

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 ex parte 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 also, 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. 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.

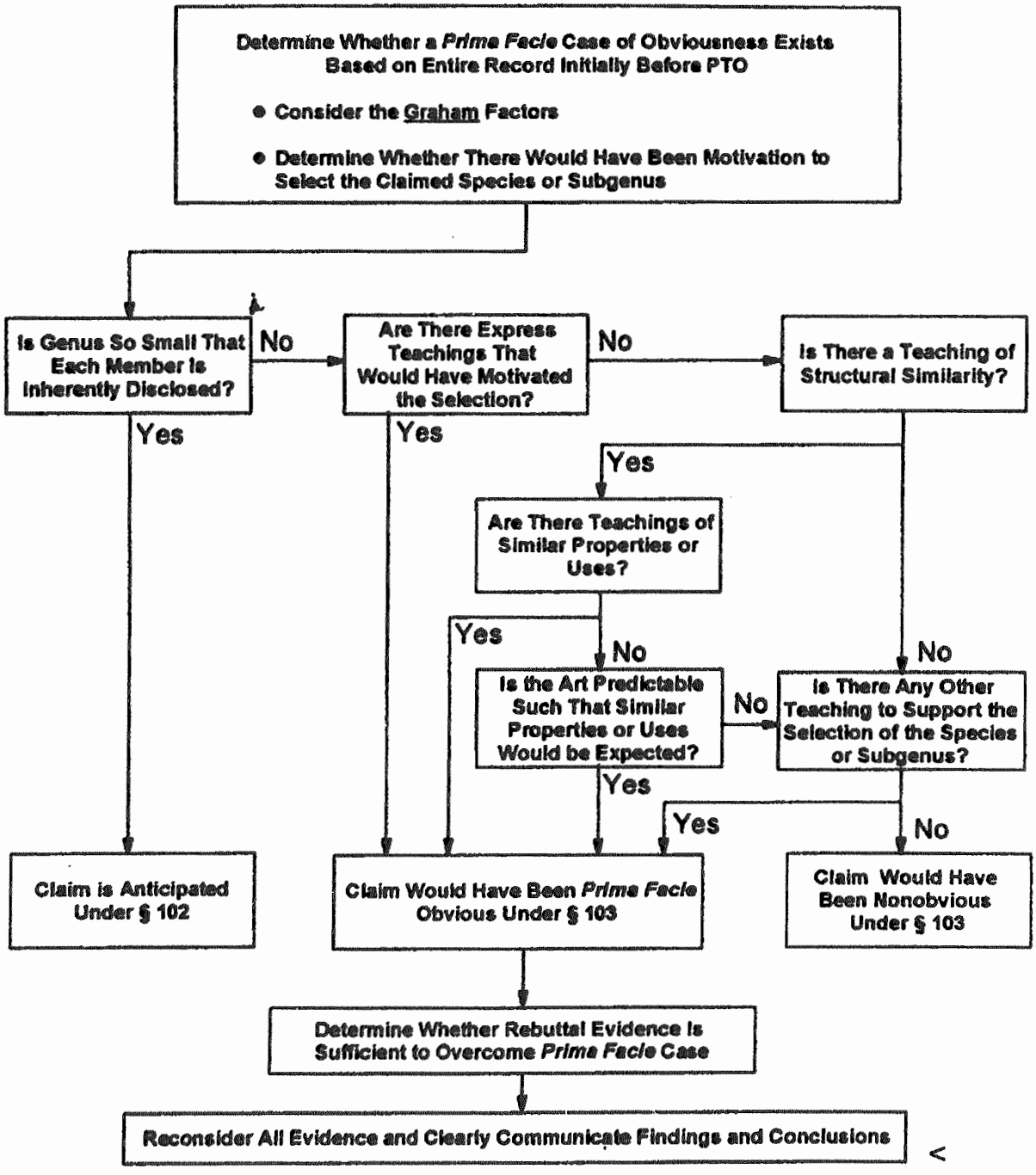
Office personnel should not evaluate rebuttal evidence for its "knockdown" value against the *prima facie* case, *Piasecki*, 745 F.2d at 1473, 223 USPQ at 788, or summarily dismiss it as not compelling or insufficient. If the evidence is deemed insufficient to rebut the *prima facie* case of obviousness, Office personnel should specifically set forth the facts and reasoning that justify this conclusion.

III. Reconsider All Evidence and Clearly Communicate Findings and Conclusions

A determination under 35 U.S.C. 103 should rest on all the evidence and should not be influenced by any earlier conclusion. See, e.g., *Piasecki*, 745 F.2d at 1472–73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should reconsider any initial obviousness determination in view of the entire record. See, e.g., *Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743. All the proposed rejections and their bases should be reviewed to confirm their correctness. Only then should any rejection be imposed in an Office action. The Office action should clearly communicate the Office's findings and conclusions, articulating how the conclusions are supported by the findings.

Where applicable, the findings should clearly articulate which portions of the reference support any rejection. Explicit findings on motivation or suggestion to select the claimed invention should also be articulated in order to support a 35 U.S.C. 103 ground of rejection. *Dillon*, 919 F.2d at 693, 16 USPQ2d at 1901; *In re Mills*, 916 F.2d 680, 683, 16 USPQ2d 1430, 1433 (Fed. Cir. 1990). Conclusory statements of similarity or motivation, without any articulated rationale or evidentiary support, do not constitute sufficient factual findings.

If the closest prior art is a single reference disclosing a genus, 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 by performing the following analysis...



2144.09 Close Structural Similarity Between Chemical Compounds (Homologs, Analogues, Isomers) [R-3]

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, 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).<

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.).

PRESENCE OF A TRUE HOMOLOGOUS ORISOMERIC 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 Leu);< *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 I.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.).

>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, 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. >In the biotechnology arts, 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. *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995) ("[T]he existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs."); *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993). However, 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).<

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.).

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 not sufficient to render structurally similar claims *prima facie* obvious because there is no motivation for one of ordinary skill in the art to make the reference compounds, much less any structurally related compounds. *In re Stemniski*, 444 F.2d 581, 170 USPQ 343 (CCPA 1971).

Where structurally similar "prior art compounds 'cannot be regarded as useful' for the sole use disclosed [by the reference], . . . a person having ordinary skill in the art would lack the 'necessary impetus' to make the claimed compounds." *In re Albrecht*, 514 F.2d 1389, 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." 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 have been motivated to 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).

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–3]

(a) 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). 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.

(b) 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." 201 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*, 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.

(c) 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, 208 USPQ 871, 881 (CCPA 1981). See also *In re Sneed*, 710 F.2d 1544, 218 USPQ 385, 389 (Fed. Cir. 1983) ("it 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.

(d) 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).

(e) 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.).

(f) 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, 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.

(g) 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.).

(h) 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, 193 USPQ 332, 335 (CCPA 1977) (One hundred 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).

(i) Arguing that prior art is nonanalogous

A prior art reference is analogous if the reference is in the field of applicant's endeavor or, if not, the reference is reasonably pertinent to the particular problem with which the inventor was concerned. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

See MPEP § 2141.01(a) for case law pertaining to analogous art.

(j) Arguing improper rationales for combining references

(1) 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, 170 USPQ 209, 212 (CCPA 1971).

(2) Obvious to try rationale

An applicant may argue the examiner is applying an improper "obvious to try" rationale in support of an obviousness rejection.

"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, 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.). See the cases cited in *O'Farrell* for examples of decisions where the court discussed an improper "obvious to try" approach. See also *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) and *In re Ball Corp.*, 18 USPQ2d 1491 (Fed. Cir. 1991) (unpublished) for examples of cases where appellants argued that an improper "obvious to try" standard was applied, but the court found that there was proper motivation to modify the references.

(3) Lack of suggestion to combine references

As discussed in MPEP § 2143.01, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine reference teachings. The Federal Circuit has produced a number of decisions overturning obviousness rejections due to a lack of suggestion in the prior art of the desirability of combining references, as discussed in the aforementioned section.

(4) 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).

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, 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.).

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, 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.).

>Form Paragraphs: See MPEP § 707.07 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–2]

35 U.S.C. 103 Conditions of patentability; non–obvious subject matter

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>(c)<Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (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 invention was made, owned by the same person or subject to an obligation of assignment to the same person.

** 35 U.S.C. 103>(c)< provides that subject matter developed by another which qualifies as "prior art" only under 35 U.S.C. 102(f) or (g) is not to be considered

when determining whether an invention sought to be patented is obvious under 35 U.S.C. 103, provided the subject matter and the claimed invention were commonly owned at the time the invention was made. 35 U.S.C.>103(c)<** applies only to subject matter which qualifies as prior art under 35 U.S.C. 103; it does not affect subject matter which qualifies as prior art under 35 U.S.C. 102, i.e., anticipatory prior art. See MPEP § 706.02(l) regarding Office practice with respect to ** 35 U.S.C. 103>(c)<.

2161 Three Separate Requirements for Specification Under 35 U.S.C. 112, First Paragraph [R-1]

>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:

(1) a written description of the invention;

(2) the manner and process of making and using the invention (the enablement requirement); and

(3) 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, 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).<

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 127°C 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, 148 USPQ 479, 484 (1966).

2162 Policy Underlying 35 U.S.C. 112, First Paragraph [R-1]

>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 will be 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 and 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 The Written Description Requirement [R-1]

>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), *cert. denied*, 434 U.S. 1064 (1978). Another objective is to put the public in possession of what the applicant claims as the invention so that the public may ascertain if the patent applicant claims anything that is in common use, or already known. *Evans* v. *Eaton*, 20 U.S. (7 Wheat.) 356 (1822).

An applicant's specification 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, i.e., whatever is now claimed. *Vas-Cath Inc.* v. *Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). The written description requirement prevents an applicant from claiming subject matter that was not described in the application as filed, and 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 to the informational content of a patent application after it is filed.<

2163.01 Support for the Claimed Subject Matter in Disclosure [R-1]

>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 [R-1]

>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, 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 a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed. 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.<

2163.03 Typical Circumstances Where Adequate Written Description Issue Arises [R-1]

>A description requirement issue can arise in a number of different circumstances where it must be determined whether the subject matter of a new or amended claim is supported in an application as filed. The following circumstances are typical:

(a) 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). Original claims constitute their own description. *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980). 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.

(b) 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. *In re Scheiber*, 587 F.2d 59, 199 USPQ 782 (CCPA 1978).

(c) 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).

(d) Support for a claim corresponding to a count in an interference

A broad generic disclosure to a class of compounds was not a sufficient written description of a specific compound within the class. *Fields* v. *Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1970).<

2163.04 Burden on the Examiner With Regard to the Written Description Requirement [R-1]

>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). The examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 265, 191 USPQ 90, 98 (CCPA 1976); *Ex parte Sorenson*, 3 USPQ2d 1462, 1463 (Bd. Pat. App. & Inter. 1987).

(a) Statement of rejection requirements

Any time an examiner bases a rejection of a claim or the denial of the effect of a filing date of a previously filed application on the lack of a written description, the examiner should:

(1) identify the claim limitation not described; and

(2) provide reasons why persons skilled in the art at the time the application was filed would not have recognized the description of this limitation in the disclosure of the application as filed. A typical reason points out the differences between what is disclosed and what is claimed. A simple statement that "There does not

appear to be a written description of the claim limitation '_____' in the application as filed." may be sufficient where the support is not apparent and the applicant has not pointed out where the limitation is supported.

(b) Response to amendments

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. Accordingly, the examiner should identify what portion(s) of the amendment lack support in the originally filed disclosure, and should fully explain the basis for the examiner's finding. The examiner also should comment on the substance of applicant's remarks. Any affidavits attesting to what one of ordinary skill in the art would consider disclosed by the application as originally filed must be thoroughly analyzed and discussed in the Office action.<

2163.05 Changes to the Scope of Claims [R-1]

>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.

(a) Broadening claim

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. *In re Peters*, 723 F.2d 891, 221 USPQ 952 (Fed. Cir. 1983).

However, in *In re Wilder*, 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984), the Federal Circuit affirmed that part of a Board of Appeals decision rejecting reissue claims for a recording apparatus which omitted a limitation that required indexing means to scan an array of light emitting diodes "in synchronism" with the scanning of the record medium by scanning means. The court held that the generic invention represented by the reissue claims (i.e., covering scanning means and indexing means not in synchronism) 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.

The benefit of foreign priority was denied in *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989), because claims in the U.S. application were not supported in the foreign priority application. In the claims of the U.S. application, chemical compounds representing antibiotics were generically claimed via reference to a structure with varying moieties and were also claimed subgenerically in a Markush format. The foreign application disclosed only 2 of the species presented in the broad generic claim and in the 21 compounds listed in the Markush claims. The court concluded that the additional subject matter in the U.S. application was not adequately described in the foreign document.

(b) 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. 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 this 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).

(c) 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.<

2163.06 Relationship of Written Description Requirement to New Matter [R–3]

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.

(a) Treatment of new matter

The regulations provide for the treatment of new matter as follows:

37 CFR 1.118 Amendment of disclosure.

(a) No amendment shall introduce new matter into the disclosure of an application after the filing date of the application, see 37 CFR 1.53(b). All amendments to the specification, including the claims and the drawings filed after the filing date of the application must conform to at least one of them as it was at the time of the filing of the application. Matter not found in either, involving a departure from or an addition to the original disclosure, cannot be added to the application after its filing date even though supported by an oath or declaration in accordance with 37 CFR 1.63 or 37 CFR 1.67 filed after the filing date of the application.

(b) If it is determined that an amendment filed after the filing date of the application introduces new matter, claims containing new matter will be rejected and deletion of the new matter in the specification and drawings will be required even if the amendment is accompanied by an oath or declaration in accordance with 37 CFR 1.63 or 37 CFR 1.67.

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.

Whenever an objection or rejection is made based on 35 U.S.C. 112, first paragraph, the examiner should in the interest of expeditious prosecution call attention to 37 CFR 1.118.

When an amendment is filed in response 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.

(b) 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.

(c) 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.

2163.07 Amendments to Application Which Are Supported in the Original Description [R-1]

>Amendments to an application which are supported in the original description are NOT new matter.

(a) 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.

(b) 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 Oda*, 443 F.2d 1200, 170 USPQ 260 (CCPA 1971).

Where a non-English foreign priority document under 35 U.S.C. 119 is of record in the application file, applicant may not rely on the disclosure of that document to support correction of an error in the pending application. *Ex parte Bondiou*, 132 USPQ 356 (Bd. App. 1961). This prohibition would apply 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 in a situation where the original application is in a non-English language (37 CFR 1.52(d)), or where the original application explicitly incorporates a non-English language document by reference.<

2163.07(a) Inherent Function, Theory, or Advantage [R-1]

>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).<

2163.07(b) Incorporation by Reference [R-1]

>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 MPEP § 608.01(p) for Office policy regarding incorporation by reference.<

2164 The Enablement Requirement [R-3]

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. 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-3]

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).< 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. duPont 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.*,< M.I.T. 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).

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>2164.01(a) Undue Experimentation Factors [R-3]

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:

(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. *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 [R-3]

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 CCPA 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 [R-3]

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. The applicant need not demonstrate that the invention is completely safe. See also MPEP § 2107.

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 [R-3]

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):

> based 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-3]

> 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.

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, 368–70 (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–3]

>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,(a) (2), 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 [R-3]

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) ("[t]esting 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-3]

>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. 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 [R-3]

>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 USPQ 2d 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 [R-3]

>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, 218 (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–3]<

It is common that the 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.

(a) 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.

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.

(b) 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.<

(c) Drug Cases

See MPEP § 2107 – § 2107.02 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 [R–3]

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 Non-enabling

(1) 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.

(2) 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.

(3) 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 appellant's filing date, as well as the limited disclosure by appellants of the particular cyanbacterial 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.

(4) 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

(1) 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.

(2) 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.

(3) 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.<

2164.07 Relationship of Enablement Requirement to Utility Requirement of 35 U.S.C. 101 [R–3]

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 use be set forth for the invention, and that the use be provable and not against public policy. On the other hand, 35 U.S.C. 112, first paragraph requires an indication of how the use (required by section 101) can be carried out, i.e., how the invention can be used.

>If an applicant has disclosed a specific utility for an invention and provided a credible basis supporting that specific 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.<

(a) When utility requirement is not satisfied

(1) 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 § 706.03(a) (1) and § 2107 – § 2107.02 for a more detailed discussion of the utility requirements of 35 U.S.C. 101 and 112, first paragraph.

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*(2) ** >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 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)).

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(3) 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 § 2107.01 for a more detailed discussion of consideration of a response to a *prima facie* rejection for lack of utility and evaluation of evidence related to utility. <

(b) 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–3]

>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. 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. *In re Moore*, 439 F.2d 1232, >1236,< 169 USPQ 236>, 239< (CCPA 1971).

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:

> to 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 Pharm. 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, 27 USPQ2d 1510 (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." 999 F.2d at 1562, 27 USPQ2d at 1513 (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 [R-3]

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.

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2164.08(b) Inoperative Subject Matter [R-3]

> 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. duPont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984) (prophetic examples do not make the disclosure non-enabling).<

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 [R-3]

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-3]

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 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).

The failure to disclose a better method will not invalidate a patent if the inventor, at the time of filing the application, did not know of the better method OR did not appreciate that it was the best method. 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 Laboratories Ltd.* v. *R.K. Laros Co.*, 209 F. Supp. 639, 135 USPQ 11 (E.D. Pa. *>1962<).

ACTIVE CONCEALMENT OR GROSSLY INEQUITABLE CONDUCT IS NOT REQUIRED TO ESTABLISH FAILURE TO DISCLOSE THE BEST MODE

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 or invalidate a patent. 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).

If the failure to set forth the best mode in a patent disclosure is the result of inequitable conduct (e.g., where the patent specification omitted crucial ingredients and disclosed a fictitious and inoperable slurry as Example 1), not only is that patent in danger of being held unenforceable, but other patents dealing with the same technology that are sought to be enforced in the same cause of action are subject to being held unenforceable. *Consolidated Aluminum Corp.* v. *Foseco Inc.*, 910 F.2d 804, 15 USPQ2d 1481 (Fed. Cir. 1990).

2165.01 Considerations Relevant to Best Mode [R-1]

>(a) 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).

(b) 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).

(c) 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 USPQ 2d 1539 (Bd. Pat. App. & Inter. 1985).

(d) 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), and continuing applications claiming the benefit of an earlier filing date under 35 U.S.C. 120, *Transco Products, Inc.* v. *Performance Contracting Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994) (continuation under 37 CFR 1.60); *Sylgab Steel and Wire Corp.* v. *Imoco–Gateway Corp.*, 357 F.Supp. 657, 178 USPQ 22 (N.D. Ill. 1973) (continuation); *Johns–Manville Corp.* v. *Guardian Industries Corp.*, 586 F.Supp. 1034, 221 USPQ 319 (E.D. Mich. 1983) (continuation and C–I–P). In the last cited case, the court stated that applicant would have been obliged to disclose an updated refinement if it were essential to the successful practice of the invention and it related to amendments to the C–I–P that were not present in the parent application. In *Carter–Wallace, Inc.* v. *Riverton Laboratories, Inc.*, 433 F.2d 1034, 167 USPQ 656 (2d Cir. 1970), the court assumed, but did not decide, that an applicant must update the best mode when filing a C–I–P application.

(e) 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 [R–1]

>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* v. *Coherent*, 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 USPQ 2d 1033 (Fed. Cir. 1990), a proper best mode analysis has two components:

(1) 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

(a) at the time the application was filed
(b) 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:

(2) Compare what was known in (1) 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–1]

>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.

(a) 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 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. Ltd.*, 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).

(b) 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 USPQ 2d 1692 (Fed. Cir. 1988).<

2171 Two Separate Requirements for Claims Under 35 U.S.C. 112, Second Paragraph [R-1]

>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:

(1) the claims must set forth the subject matter that applicants regard as their invention; and

(2) 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 [R-1]

>(a) 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).

(b) 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, *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.

(c) 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-3]

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); 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).<

2173 Claims Must Particularly Point Out and Distinctly Claim the Invention [R-1]

>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.<

2173.01 Claim Terminology [R-1]

>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 the terms are not used in ways that are contrary to accepted meanings in the art. 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.<

2173.02 Clarity and Precision [R-1]

>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 (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) 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. If the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, a rejection of the claims under 35 U.S.C. 112, second paragraph is appropriate. *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1973).<

2173.03 Inconsistency Between Claim and Specification Disclosure or Prior Art [R-1]

>Although the terms of a claim may appear to be definite, inconsistency with the specification disclosure or prior art teachings may make an otherwise definite claim take on an unreasonable degree of uncertainty. *In re Cohn*, 438 F.2d 989, 169 USPQ 95 (CCPA 1971); *In re Hammack*, 427 F.2d 1378, 166 USPQ 204 (CCPA 1970). In *Cohn*, the claim was directed to a process of treating a surface with a corroding solution until the metallic appearance is supplanted by an "opaque" appearance. 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 description, definitions and examples set forth in the specification relating to the appearance of the surface after treatment were inherently inconsistent and rendered the claim indefinite.<

2173.04 Breadth Is Not Indefiniteness [R-1]

>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.

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.<

2173.05(a) New Terminology [R-1]

>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 Prater*, 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).

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.

A TERM MAY NOT BE GIVEN A MEANING REPUGNANT TO ITS USUAL MEANING

While a term used in the claims may be given a special meaning in the description of the invention, generally no term may be given a meaning repugnant to the usual meaning of the term. *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). However, it has been stated that consistent with the well-established axiom in patent law that a patentee is free to be his or her own lexicographer, a patentee may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings. *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. 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).<

2173.05(b) Relative Terminology [R-1]

>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.*, 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.

WHEN A TERM OF DEGREE IS PRESENT, DETERMINE WHETHER A STANDARD IS DISCLOSED OR WHETHER ONE OF ORDINARY SKILL IN THE ART WOULD BE APPRISED OF THE SCOPE OF THE CLAIM

When a term of degree is presented in a claim, first a determination is to be made as to whether the specification provides some standard for measuring that degree. If it does not, a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably apprised of the scope of the invention. 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.

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

The term "about" used to define the area of the lower end of a mold as between 25 to about 45% of the mold entrance was held to be clear, but flexible. *Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968). Similarly, 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* v. *Chugai Pharmaceutical Co. Ltd.*, 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 cut-off 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 641 (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 Comm'r Dec. 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."<

2173.05(c) Numerical Ranges and Amounts Limitations [R-1]

>Generally, the recitation of specific numerical ranges in a claim does not raise an issue of whether a claim is definite.

(a) 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 the claims. If stated in the claims, examples and preferences 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 are (1) "a temperature of between 45 and 78 degrees Celsius, preferably between 50 and 60 degrees Celsius"; and (2) "a predetermined quantity, for example, the maximum capacity."

(b) 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).

(c) "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 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:

(1) "R is halogen, for example, chlorine";

(2) "material such as rock wool or asbestos" *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1949);

(3) "lighter hydrocarbons, such, for example, as the vapors or gas produced" *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949); and

(4) "normal operating conditions such as while in the container of a proportioner" *Ex parte Steigerwald*, 131 USPQ 74 (Bd. App. 1961).<

2173.05(e) Lack of Antecedent Basis [R−1]

>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. *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.

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.<

2173.05(f) Reference to Limitations in Another Claim [R-1]

>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-1]

>A functional limitation is an attempt to define something 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, 169 USPQ 226 (CCPA 1971).

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. 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 33 (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).<

2173.05(h) Alternative Limitations [R-1]

>*(a) 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. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925).

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); and *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.

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

A situation may occur in which a patentee has presented a number of examples which, in the examiner's opinion, are sufficiently representative to support a generic claim and yet a court may subsequently hold the claim invalid on the ground of undue breadth. Where this happens the patentee is often limited to species claims which may not provide him with suitable protection.

The allowance of a Markush-type claim under a true genus claim would appear to be beneficial to the applicant without imposing any undue burden on the Patent and Trademark Office or in any way detracting from the rights of the public. Such a subgenus claim would enable the applicant to claim all the disclosed operative embodiments and afford applicant an intermediate level of protection in the event the true genus claims should be subsequently held invalid.

The examiners are therefore instructed not to reject a Markush-type claim merely because of the presence of a true genus claim embracive thereof.

See also MPEP § 608.01(p) and § 715.03.

See MPEP § 803 for restriction practice re Markush-type claims.

(b) "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."

(c) "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 [R-3]

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. See *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-1]

>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 CCPA pointed out in *In re Bernhardt*, 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 *Bernhardt* 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]

>Rejections on the ground of aggregation should be based upon a lack of cooperation between the elements of the claim.

Example of aggregation: A washing machine associated with a dial telephone.

A claim is not necessarily aggregative because the various elements do not function simultaneously, e.g., a typewriter. *In re Worrest*, 201 F.2d 930, 96 USPQ 381 (1953). Neither is a claim necessarily aggregative merely because elements which do cooperate are set forth in specific detail.

A rejection on aggregation should be made only after consideration of the court's comments in *In re Gustafson*, 331 F.2d 905, 141 USPQ 585 (1964), wherein the court indicated it is improper to reject claims as "aggregative" without specifying the statutory basis of the rejection, i.e., an applicant is entitled to know whether his claims are being rejected under 35 U.S.C. 101, 103, or 112. In *Gustafson*, the court found that the real objection to the claims was that they failed to comply with 35 U.S.C. 112, second paragraph.<

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2173.05(m) Prolix [R-1]

>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 or unimportant details which hide or obscure the invention. *Ex parte Iagan*, 1911 C.D. 10, 162 O.G. 538 (Comm'r Pat. 1910), expresses the thought that very long detailed claims setting forth so many elements that invention cannot possibly reside in the combination should be rejected as prolix. See also *In re Ludwick*, 4 F.2d 959, 1925 C.D. 306, 339 O.G. 393 (D.C. Cir. 1925).<

2173.05(n) Multiplicity [R-3]

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.

(c) One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. Any dependent claim which refers to more than one other claim ("multiple dependent claim") shall refer to such other claims in the alternative only. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. For fee calculation purposes under § 1.16, a multiple dependent claim will be considered to be that number of claims to which direct reference is made therein. For fee calculation purposes, also, any claim depending from a multiple dependent claim will be considered to be that number of claims to which direct reference is made in that multiple dependent claim. In addition to the other filing fees, any original application which is filed with, or is amended to include, multiple dependent claims must have paid the fee set forth in § 1.16(d). Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of each of the particular claims In relation to which it is being considered.

(d) (1) The claim or 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 may be ascertained by reference to the description (See § 1.58(a)).

(2) See §§ 1.141 to 1.146 as to claiming different inventions in one application.

(e) Where the nature of the case admits, as in the case of an improvement, any independent claim should contain in the following order, (1) a preamble comprising a general description of all elements or steps of the claimed combination which are conventional or known, (2) a phrase such as "wherein the improvement comprises," and (3) those elements, steps, and/or relationships which constitute that portion of the claimed combination which the applicant regards as the new or improved portion.

(f) If there are several claims, they shall be numbered consecutively in Arabic numerals.

>(g) The least restrictive claim should be presented as claim number 1, and all dependent claims should be grouped together with the claim or claims to which they refer to the extent practicable.

(h) The claim or claims must commence on a separate sheet.

(i) Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation.<

An unreasonable number of claims, that is, unreasonable in view of the nature and scope of applicant's invention and the state of the art, may afford a basis for a rejection on the ground of multiplicity. A rejection on this ground should include all the claims in the case inasmuch as it relates to confusion of the issue.

To avoid the possibility that an application which has been rejected on the ground of undue multiplicity of claims may be appealed to the Board of Patent Appeals and Interferences prior to an examination on the merits of at least some of the claims presented, the examiner should, at the time of making the rejection on the ground of multiplicity of claims, specify the number of claims which in his or her judgment is sufficient to properly define applicant's invention and require the applicant to select certain claims, not to exceed the number specified, for examination on the merits. The examiner should be reasonable in setting the number to afford the applicant some latitude in claiming the invention.

The earlier views of the Court of Customs and Patent Appeals on multiplicity were set forth in *In re*

Chandler, 45 CCPA 911, 117 USPQ 361 (1958) and *In re Chandler*, 50 CCPA 1422, 138 USPQ 138 (1963) (Applicants latitude in stating their claims in regard to number and phraseology employed "should not be extended to sanction that degree of repetition and multiplicity which beclouds definition in a maze of confusion." 138 USPQ at 148.). These views have been somewhat revised by its views in *In re Flint*, 411 F.2d 1353, 162 USPQ 228 (CCPA 1969) ("The [42] claims differed from one another and we have no difficulty in understanding the scope of protection. Nor is it clear, on this record, that the examiner or board was confused by the presentation of claims in this case or that the public will be." 162 USPQ at 231.) and *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970) ("Examination of forty claims in a single application may be tedious work, but this is no reason for saying that the invention is obscured by the large number of claims. We note that the claims were clear enough for the examiner to apply references against all of them in his first action." 164 USPQ at 639.).

If a rejection on multiplicity is in order the examiner should make a telephone call explaining that the claims are unduly multiplied and will be rejected on that ground. Note MPEP § 408. The examiner should request selection of a specified number of claims for purposes of examination.

If time for consideration is requested arrangements should be made for a second telephone call, preferably within three working days.

When claims are selected, a formal multiplicity rejection is made, including a complete record of the telephone interview, followed by an action on the selected claims.

When applicant refuses to comply with the telephone request, a formal multiplicity rejection is made. The applicant's response to a formal multiplicity rejection of the examiner, to be complete, must either:

(1) Reduce the number of claims presented to those selected previously by telephone, or if no previous selection has been made to a number not exceeding the number specified by the examiner in the Office action, thus overcoming the rejection based upon the ground of multiplicity, or

(2) In the event of a traverse of said rejection applicant, besides specifically pointing out the supposed errors of the multiplicity rejection, is required to confirm the selection previously made by telephone, or if no previous selection has been made, select certain claims for purpose of examination, the number of which is not greater than the number specified by the examiner.

If the rejection on multiplicity is adhered to, all claims retained will be included in such rejection and the selected claims only will be additionally examined on their merits. This procedure preserves applicant's right to have the rejection on 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. 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 [R-1]

>While the concept that double inclusion of an element in members of a Markush group recited in a claim is, per se, objectionable and renders a claim indefinite is supported by some of the older cases like *Ex parte White*, 759 O.G. 783 (Bd. App. 1958) and *Ex parte Clark*, 174 USPQ 40 (Bd. App. 1971), other decisions clearly hold that there is no per se rule of indefiniteness concerning overlapping members where alternatives are recited in a claim – e.g., members of a Markush group. *In re Kelly*, 305 F.2d 909, 134 USPQ 397 (CCPA 1962).

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-1]

>(a) Product-by-process

There are many situations where claims are permissively drafted to include a reference to more than one statutory class of invention. 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 Moeller*, 28 CCPA 932, 48 USPQ 542, 1941 C.D. 316; *In re Luck*, 177 USPQ 523 (CCPA 1973); *In re Steppan*, 156 USPQ 143 (CCPA 1967); and *In re Pilkington*, 162 USPQ 145 (CCPA 1969). 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.

The fact that it is necessary for an applicant to describe his product in product-by-process terms does not prevent him from presenting claims of varying scope, *Ex parte Pantzer and Feier*, 176 USPQ 141 (Bd. App. 1972).

(b) 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. In *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990), a claim directed to an automatic transmission workstand and the method steps of using it was held to be ambiguous and properly rejected under 35 U.S.C. 112, second paragraph.

Such claims should also be rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. *Id.* at 1551.<

2173.05(q) "Use" Claims [R-1]

>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 [R-2]

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 (reproduced in 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 [R-1]

>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 [R-1]

>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 et al.*, 134 USPQ 407 (Bd. App. 1961) and *Ex parte Sobin et al.*, 139 USPQ 528 (Bd. App. 1962) in this regard.

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 et al.*, 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 [R-2]

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 [R-1]

>In view of the decision of the Court of Customs and Patent Appeals in *In re Tarczy-Hornoch*, 397 F.2d 856, 158 USPQ 141 (CCPA 1968) process or method claims are not subject to rejection by 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. 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 Prior Art Rejection of Claim Rejected as Indefinite [R-1]

>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: (1) a rejection based on indefiniteness under 35 U.S.C. 112, second paragraph; and (2) a rejection over the prior art based on the interpretation of the claims which renders the prior art applicable. *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 [R-2]

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 re Panagrossi*, 277 F.2d 181, 125 USPQ 410 (CCPA 1960). 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.

2181 Identifying a 35 U.S.C. 112, Sixth Paragraph Limitation [R-3]

The purpose of this section is to set forth guidelines for the examination of 35 U.S.C. 112, sixth paragraph "means or step plus function" limitations in a claim. 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 that:

> 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. 29 USPQ2d at 1850.

Thus, examiners must interpret a 35 U.S.C. 112, sixth paragraph "means or step plus function" limitation in a claim as limited to the corresponding structure, materials or acts described in the specification and equivalents thereof in accordance with the following guidelines.

LANGUAGE FALLING WITHIN 35 U.S.C. 112, SIXTH PARAGRAPH

**>In determining whether to apply the statutory procedures of 35 U.S.C. 112, sixth paragraph, the examiner must determine whether the applicant intends to invoke the statutory mandates for means-plus function clauses. Although the use of the term "means," particularly "means for," generally invokes 35 U.S.C. 112, sixth paragraph, and the use of a different formulation generally does not, there is no particular language that must appear in a claim in order for it to fall within the scope of 35 U.S.C. 112, sixth paragraph. *Greenberg* v. *Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1584, 39 USPQ2d 1783, 1786-87 (Fed. Cir. 1996). However, it must be clear that the element in the claim 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. *York Products Inc.* v. *Central Tractor Farm & Family Center*, 99 F.3d 1568, 1574, 40 USPQ2d 1619, 1624 (Fed. Cir. 1996) ("Without an identified function, the term 'means' in this claim cannot invoke 35 U.S.C. § 112, paragraph 6."). See also *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."). 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*, 91 F.3d at 1583, 39 USPQ2d at 1786 ("detent mechanism" defined in functional terms was not intended to invoke 35 U.S.C. 112, sixth paragraph). Although use of the term "means" in a clause reciting predominantly structure does not evoke 35 U.S.C. 112, sixth paragraph, *York Products*, 99 F.3d at 1574, 40 USPQ2d at 1623, "[t]he recitation of some structure in a means plus function element does not preclude applicability of section 112(6)." *Laitram Corp.* v. *Rexnord, Inc.*, 939 F.2d 1533, 1536, 19 USPQ2d 1367, 1369 (Fed. Cir. 1991). It is necessary to decide on an element by element basis whether 35 U.S.C. 112, sixth paragraph applies. *Cole* v. *Kimberly-Clark Corp.*, 102 F.3d 524, 531, 41

USPQ2d 1001, 1006 (Fed. Cir. 1996) (term "perforation means . . . for tearing" did not invoke 35 U.S.C. 112, sixth paragraph because it recited a definite structure which performed the described tearing function, as well as the location and extent of the structure).< Limitations that fall within the scope of 35 U.S.C. 112, sixth paragraph include:

(1) a jet driving device so constructed and located on the rotor as to drive the rotor . . . ["means" unnecessary]. The term "device" coupled with a function is a proper definition of structure in accordance with the last paragraph of 35 U.S.C. 112. The addition of the words "jet driving" to the term "device" merely renders the latter more definite and specific. *Ex parte Stanley*, 121 USPQ 621 (Bd. App. 1958);

(2) "printing means" and "means for printing" which would have the same connotations. *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967). However, the terms "plate" and "wing," as modifiers for the structureless term "means," specify no function to be performed, and do not fall under the last paragraph of 35 U.S.C. 112;

(3) force generating means adapted to provide . . . . *De Graffenreid* v. *U.S.*, 20 Ct. Cl. 458, 16 USPQ2d 1321 (Ct. Cl. 1990);

(4) call cost register means, including a digital display for providing a substantially instantaneous display for . . . . *Intellicall Inc.* v. *Phonometrics, Inc.*, 952 F.2d 1384, 21 USPQ2d 1383 (Fed. Cir. 1992);

(5) reducing the coefficient of friction of the resulting film [step plus function; "step" unnecessary], *In re Roberts*, 470 F.2d 1399, 176 USPQ 313 (CCPA 1973); and

(6) raising the pH of the resultant pulp to about 5.0 to precipitate . . . . *Ex parte Zimmerley*, 153 USPQ 367 (Bd. App. 1966).

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.

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.

2182 Scope of the Search and Identification of the Prior Art [R-1]

>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. 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. 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.<

2183 Making a *Prima Facie* Case of Equivalence [R-1]

>If the examiner finds that a prior art element performs the function specified in the claim, and is not excluded by any explicit definition provided in the specification for an equivalent, the examiner should infer from that finding that the prior art element is an equivalent, and should then conclude that the claimed limitation is anticipated by the prior art element. 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 (C.C.P.A. 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 (C.C.P.A. 1971) (a case in which the CCPA 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 for the factors to be considered 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-3]

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:

(1) teachings in the specification that particular prior art is not equivalent,

(2) teachings in the prior art reference itself that may tend to show nonequivalence, or

(3) Rule 132 affidavit evidence of facts tending to show nonequivalence.

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. 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.

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 (1) the claimed invention is a combination of elements, one or more of which are selected from elements that are old, per se, or (2) apparatus claims are treated as indistinguishable from method claims. See, for example, *In re Meyer*, 688 F.2d 789, 215 USPQ 193 (1982); *In re Abele*, 684 F.2d 902, 909, 214 USPQ 682, 688 (C.C.P.A. 1982); *In re Walter*, 618 F.2d 758, 767, 205 USPQ 397, 406–07 (C.C.P.A. 1980); *In re Maucorps*, 609 F.2d 481, 203 USPQ 812 (C.C.P.A. 1979); *In re Johnson*, 589 F.2d 1070, 200 USPQ 199 (C.C.P.A. 1978); and *In re Freeman*, 573 F.2d 1237, 1246, 197 USPQ 464, 471 (C.C.P.A. 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.

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. Among the indicia that will support a conclusion that one element is or is not an equivalent of another are:

(1) Whether the prior art element performs the function specified in the claim in substantially the same way, and produces substantially the same results as the corresponding element disclosed in the specification. *Lockheed Aircraft Corporation* 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).

(2) Whether 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. *Lockheed Aircraft Corporation* 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).

(3) Whether the prior art element is a structural equivalent of the corresponding element disclosed in the specification being examined. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). That is, the prior art element performs the function specified in the claim in substantially the same manner as the function is performed by the corresponding element described in the specification.

(4) Whether >there are insubstantial differences between the prior art element and< the structure, material or acts disclosed in the specification **>*Warner–Jenkinson Co.* v. *Hilton Davis Chemical Co.*,** U.S. **, 65 U.S.L.W. 4162, –, 41 USPQ2d 1865, 1875 (1997);< . *Valmont Industries. Inc.* v. *Reinke Manufacturing Co. Inc.*, 983 F.2d 1039, 25 USPQ2d 1451 (Fed. Cir. 1993).

These examples are not intended to be an exhaustive list of the indicia that would support a finding that one element is or is not an equivalent of another element for the purposes of 35 U.S.C. 112, sixth paragraph. A finding according to any of the above examples would represent a sufficient, but not the only possible, basis to support a conclusion that an element is or is not an equivalent. There could be other indicia that also would support the conclusion.

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.

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–1]

>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 1st 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:

(1) 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);

(2) under 35 U.S.C. 112, second paragraph, as being indefinite because the element or step is not defined in the specification by corresponding structure, material or acts; and

(3) 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 [R-3]

**>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.*, ** U.S. **, 65 U.S.L.W. 4162, ___, 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.