Chapter 2100 Patentability

2105 Patentable Subject Matter—Microorganisms [R–3]

The decision of the Supreme Court in *Diamond* v. *Chakrabarty*, 206 U.S.P.Q. 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 is issuing 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 anything under the sun that is made by man.' S. Rep. No. 1979, 82d Cong. 2d Sess., 5 (1952)."

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

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

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

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

8. After reference to Funk Seed & 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 underlined portions):

- "The laws of nature, physical phenomena and abstract ideas" are not patentable subject matter
- "A nonnaturally 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 amendable 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 nonnaturally 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 § 101 determination. In addition, the requirements of 35 U.S.C. 112 must also be met. In this regard, see § 608.01 (p).

2110 Patentable Subject Matter—Mathematical Algorithms or Computer Programs [R–8]

The U.S. Supreme Court decision in *Diamond* v. *Diehr*, 450 U.S. 175, 209 USPQ 1 (1981) and *Diamond* v. *Bradley*, 450 U.S. 381, 209 USPQ 97 (1981) significantly affect an examiner's analysis under 35 U.S.C. 101 of patent applications involving mathematical equations, mathematical algorithms and computer programs.

In 35 U.S.C. 101, Congress has set forth the categories of inventions or discoveries which may be patentable as consisting of "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." Inventions involving mathematical equations, mathematical algorithms or computer programs, if statutory at all, would fall into the categories of statutory subject matter as processes, machines or manufactures. In constructing 35 U.S.C. 101, the Supreme Court in *Diamond* v. *Diehr*, 450 U.S. 175, 209 USPQ 1, 6 (1981) and *Diamond* v. *Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980), has applied a broad interpretation to statutory subject matter so as "to include anything under the sun that is made by man."

The Supreme Court also reiterated that certains categories of inventive activity should not be considered statutory subject matter. As set forth in *Diamond* v. *Diehr*, 209 USPQ 1, 7 (1981), "Excluded from such patent protection are laws of nature, physical phenomena, and abstract ideas." Citing *Parker* v. *Flook*, 437 U.S. 584, 198 USPQ 193 (1978); *Gottschalk* v. *Benson*, 409 U.S. 63, 175 USPQ 673 (1972). A "scientific truth, or the mathematical expression of it, is not a patentable invention," *Mackay Radio Corp. & Telegraph Co.* v. *Radio Corp. of America*, 306 U.S. 86, 94, 40 USPQ 199, 202 (1939). In *Gottschalk* v. *Benson*, supra, the Court concluded that an "algorithm, or mathematical formula, is like a law of nature, which cannot be the subject of a patent." Similarly, the Court in *Parker* v. *Flook*, supra, held that an improved "method for computing 'an alarm

limit'," where the application "did not purport to explain now the variables used in the formula were to be selected, nor did the application contain any disclosure relating to the chemical processes at work or the means of setting off an alarm or adjusting the alarm limit," is unpatentable subject matter under 35 U.S.C. 101. (See *Diamond* v. *Diehr*, 209 USPQ 1, 10 (1981)).

If the claims of an application are directed solely to one of the above judically excluded areas of inventive activity, it is clear that a patent shall not issue. However, a claim is not unpatentable under 35 U.S.C. 101 merely because it includes a step(s) or element(s) directed to a law of nature, mathematical algorithm, formula or computer program so long as the claim as a whole is drawn to subject matter otherwise statutory. In this regard, the following significant points of law may be gleaned from the *Diamond* v. *Diehr*, 209 USPQ 1, (1981) decision:

1. The "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." . . . "The 'novelty' of any element or steps in a process, or even of the process itself, is of *no relevance* in determining whether the subject matter of a claim falls within the 101 categories of possibly patentable subject matter" (emphasis added).

2. "When a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101."

3. "When a claim recites a mathematical formula (or scientific principle or phenomenon of nature), an inquiry must be made into whether the claim is seeking patent protection for that formula in the abstract." (If the claim does not seek protection for such a mathematical formula, it would be non-statutory under 35 U.S.C. 101).

4. "A mathematical formula as such is not accorded the protection of our patent laws, . . . and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment." . . . "Similarly, insignificant post solution activity will not transform an unpatentable principle into a patentable process."

5. When a claim as in *Parker* v. *Flook*, 198 USPQ 193 (1978), is drawn "to a method for computing an 'alarm limit' (which) is simply a number," the claim is non-statutory under 35 U.S.C. 101 because *Flook* "sought to protect a formula for computing this number."

6. "It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." Citing *Funk Bros. Seed Co.* v. *Kalo Co.*, 333 U.S. 127, 76 USPQ 280 (1948); *Eibel Process Co.* v. *Minnesota and Ontario Paper Co.*, 261 U.S. 45 (1923); *Cochrane* v. *Deener*, 94 U.S. 780 (1876); *O'Reilly* v. *Morse*, 15 How. 62 (1853); and *LeRoy* v. *Tatham*, 14 How. 156 (1852).

35 U.S.C. Claim Analysis

In determining eligibility for patent protection under 35 U.S.C. 101, the Supreme Court in *Diamond* v. *Diehr*, 209 USPQ 1 (1981), requires that the "claims must be considered as a whole." Consistent with this requirement, the Court concluded that "a claim drawn to subject matter otherwise statutory does not become non-statutory simply because it uses a mathematical formula, a computer program, or digital computer." Thus, the fact that a claim specifies that a computer performs certain calculation steps is irrelevant for the purpose of determining whether statutory subject matter has been recited. The fact that an application discloses that a mathematical formula is implemented solely by computer programming is likewise immaterial for this purpose.

The Court's requirement that the "claims must be considered as a whole" in effect leaves viable the CCPA's two-step procedure set forth in *In re Freeman*, 197 USPQ 464, (CCPA, 1978), as an appropriate test for determining if a claim involving mathematics and/or computer programming is in compliance with 35 U.S.C. 101. See also *In re Walter*, 205 USPQ 397 at 407 (CCPA, 1980) for clarification of the second *Freeman* step. In accordance with the first step of such analysis, each method or apparatus claim must be analyzed to determine whether a mathematical algorithm is either "directly" or "indirectly" recited. If the claim at issue fails to directly recite a mathematical algorithm, reference must be made to the specification in order to determine whether claim language indirectly recites mathematical calculations, formulas, or equations.

If a given claim directly or indirectly recites a mathematical algorithm, the second step of the analysis must be applied. Under this step, a determination must be made as to whether the claim as a *whole*, including all its steps or apparatus elements, merely recites a mathematical algorithm, or method of calculation. If so, the

claim does not recite statutory subject matter under 35 U.S.C. 101.

The Supreme Court in *Diamond* v. *Diehr*, 209 USPQ 1 (1981), provides some guidance in determinig whether the claim as a whole merely recites a mathematical algorithm or method of calculation. The Court suggests that if "a *claim* containing a mathematical formula implements or applies that formula in a structure or process which, when *considered as a whole*, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101." (emphasis added)

Focusing on the application or implementation of a mathematical algorithm, the Supreme Court in *Diehr*, 209 USPQ 1 at 89 (1981), citing *Mackay Radio Corp. and Telegraph Co.* v. *Radio Corp. of America*, 306 US 86, 94, 40 USPQ 199, 202 (1939), explained that "while a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of a scientific truth may be." In this regard, the CCPA noted in *In re Walter*, 205 USPQ 397 at 407, (CCPA, 1980), that "If it appears that the mathematical algorithm is implemented in a specific manner to define structural relationships between the physical elements of the claim (in apparatus claims) or to refine or limit claim steps (in process claim), the claim being otherwise statutory, the claim passes muster under § 101."

The Supreme Court in *Diehr* also indicated that "insignificant post-solution activity will not transform an unpatentable principle into a patentable process." The claims in *Parker* v. *Flook*, which were held to be non-statutory, recited a post-solution activity of updating a number (i.e., an alarm limit), a step relating more to a method of calculation than to the physical process alluded to in the claim preamble. In *Diehr*, the Supreme Court characterized the post calculation activity of the type claimed in *Parker* v. *Flook* as being "token post-solution activity." In contrast, the post-solution activity in the *Dehr* claims consisted of automatically opening a rubber molding press, a step clearly tied in with the physical process of rubber molding. As stated by the CCPA in *In re Walter*, 205 USPQ 397 at 407, (CCPA, 1980), "if the end-product of a claimed invention is a *pure number*, as in *Benson* and *Flook*, the invention is non-statutory regardless of any post-solution activity which makes it available for use by a person or machine for other purposes."

It must also be recognized that even though a claim contains an application limiting preamble, even though it does not cover every conceivable application of a formula, or even though it does not totally preempt the formula, such a claim would be non-statutory, if, when considered as a whole, it merely recites a mathematical algorithm or method of calculation. As stated by the Supreme Court in *Diehr*, 209 USPQ 1 at 10, (1981), "A mathematical formula does not suddenly become patentable subject matter simply by having the applicant acquiecs to limiting the reach of that formula to a particular technological use." Similarly, the CCPA pointed out in *Walter*, 205 USPQ 397 at 409 (1980) that "Although the class 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. The specific end use recited in the preamble does not save the claims from the holding in *Flook*, since they are drawn to methods of calculation, albeit improved. Examination of each claim demonstrates that each has no substance apart from the calculations involved."

Also, in *Walter*, a Jepson preamble was not regarded as limiting the "subject matter as a whole," so as to avoid the § 101 rejection. Similarly, preliminary data gathering steps may not affect the "subject matter as a whole" assessment. *In re Richman*, 195 USPQ 340, (CCPA 1977). Moreover, even the concluding step of building a bridge or dam may not suffice. *In re Sarker*, 200 USPQ 132 (CCPA, 1978). In other words, for purposes here, the "subject matter as a whole" must be viewed in context on a case by case basis.

In analyzing computer program related claims, it is essential to recognize that computer implemented "processes are encompassed within 35 U.S.C. 101 under the same principles as other machine implemented processes, subject to judicially determined exceptions, inter alia, mathematical formulas, methods of calculation, and mere ideas." *In re Johnson et al*, 200 USPQ 199 at 210, 211 (CCPA, 1978). In accordance with the two-step procedure outlined above, claims seeking coverage for a computer program would be non-statutory under 35 U.S.C. 101, only if, when considered as a whole, they merely recite a mathematical algorithm, or a method of calculation. Such an approach is the same as that contemplated for apparatus claims by the CCPA in *In re Bradley and Franklin*, 202 USPQ 480 (CCPA, 1979).

Certain computer program related claims may be non-statutory under 35 U.S.C. 101 as falling within judicially determined exceptions outside the mathematics area. For example, consider the following claims:

1) "A computer program comprising the steps of:

a) associating treatment rendered to a patient with a fee, and

b) billing said patient in accordance with the fee."

Here the computer program is claimed, not in terms of a specific instruction set, but alternatively as a series of steps broadly defining what the program is designed to accomplish. Such a claim should be viewed as non-statutory under 35 U.S.C. 101 as reciting a method of doing business.

2) "A computer program for comparing array A(N) with array B(M) to generate array C comprising the steps of:

Do 70 N=1, 10
Do 80 M=1, 20
If A(N)=B(N) then C(M)=B(M)
80 Continue
70 Continue * * *"

This bare set of instructions fails to recite subject matter that falls within any statutory category. In this regard, a bare set of computer instructions does not set forth a sequence of steps which could be viewed as a statutory process. Such a computer language listing of instructions, when not associated with a computing machine to accomplish a specific purpose, would not constitute a machine implemented process, but would constitute non-statutory subject matter as the mere idea or abstract intellectual concept of a programmer, or as a collection of printed matter.

Further guidance on handling 35 U.S.C. 101 issues may also be gleaned from the CCPA's detailed claim analysis in the following decisions: *In re Chatfield*, 191 USPQ 730 (CCPA, 1976); *In re Johnson, Parrack and Lundsford*, 200 USPQ 199 (CCPA, 1979); *In re Sarker*, 200 USPQ 132 (CCPA, 1978); *In re Gelovatch and Arell*, 201 USPQ 136 (CCPA, 1979); *In re Bradley and Franklin*, 202 USPQ 480 (CCPA, 1979); *In re Walter*, 205 USPQ 397 (CCPA, 1980).

In addition to handling 35 U.S.C. 101 issues in accordance with the above analytical approach, it should be emphasized that examiners must also carefully examine mathematical algorithm or computer programming related applications to insure that they comply with the disclosure requirements of Section 112 as well as the novelty and unobviousness requirements of Sections 102 and 103.

2120 The Statutory Bars of "Public Use" and "On Sale" (35 U.S.C. 102(b)) [R-3]

35 U.S.C. § 102(b). "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 * * *."

Introduction

The legal standards applied in judicial decisions treating public use and on sale issues lack uniformity. Whatever may be advanced as a reason for this lack of uniformity, the Patent and Trademark Office is still confronted with the pragmatics of 37 CFR 1.56 (Chapter 2000) and the increasingly active participation of "protestors" (Chapter 1900) in the patent examination process. One result has been the growing significance of public use and on sale issues to patent examiners.

The Office is mindful that public use and on sale questions

"encompass . . . an infinite variety of factual situations which, when viewed in terms of the policies underlying § 102(b), present an infinite variety of legal problems wholly unsuited to mechanically-applied, technical rules." *Philco Corp.* v. *Admiral Corp.*, 131 USPQ 413, 419 (D.Del. 1961)

However, notwithstanding an infinite variety of factual situations, there are still decisions to be made by examiners regarding the particular view to adopt or the particular legal decision or decisions to follow in any one of the many facets of § 102(b) activity.

Accordingly, guidance in this area is offered, short of "mechanically-applied, technical rules", so that patent applicants and examiners have a common reference point from which to foster uniformity and consistency of decision, at least within the framework of the patent examination process.

2121 General Overview [R-3]

The Differences Between Public Use And On Sale Activity

"Public use" and "on sale" activities are often referred to interchangeably. Although these

activities have much in common, each has certain attributes which stand alone and relate to differing policy considerations. *Dart Industries* v. *E.I. duPont de Nemours & Co.*, 179 USPQ 392, 396 (7th Cir. 1973)

For example, there may be a public use of an invention absent *any* sales activity. Likewise, there may be a non-public, 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" § 102(b) activity may not be viewed the same as similar "commercial" activity. Likewise, "public use" activity by an applicant may not be considered in the same light as similar "public use" activity by one other than an applicant. Additionally, the concepts of "completion" and "experimental use" have differing significance in "commercial" and "non-commercial" environments.

THE POLICY CONSIDERATIONS

A basic policy consideration underlying § 102 (b) permits an inventor a one year grace period to finish his inventive work in order to avoid the filing of a patent application before his invention is complete or perfected. *Gen'l Elec. Co.* v. *United States*, 206 USPQ 260, 272 (Ct. Cl. 1979) There is an additional policy against premature "commercial exploitation":

> "[I]t is a condition upon an inventor's right to a patent that he shall not *exploit* his discovery *competitively* after it is ready for patenting; he must content himself with either secrecy, or legal monopoly . . . [I]f he goes beyond [the one year grace] period . . . he forfeits his right [to a patent] regardless of how little the public may have learned about the invention . . . ." *Metallizing Eng'g. Co.* v. *Kenyon Bearing & Auto Parts Co.*, 68 USPQ 54, 58 (2d Cir. 1946) (emphasis supplied).

ACTIVITY BY ONE OTHER THAN AN APPLICANT

Public use *or* on sale activity of an invention, *by anyone*, with or without the consent or knowledge of a patent applicant claiming that invention, may constitute a statutory bar to that applicant under § 102(b). *Electric Storage Battery Co.* v. *Shimadzu*, 307 U.S. 5, 19–20 (1939); *Andrews* v. *Hovey*, 123 U.S. 267, 275 (1887) *Lorenz* v. *Colgate-Palmolive Peet Co.*, 77 USPQ 138, 144 (3d Cir. 1948). Thus, a publicly used or sold invention of one other than an applicant may be "prior art" to that applicant *Gen'l Elec. Co.* v. *United States*, 206 USPQ 260, 272 (Ct. Cl. 1979), assuming the other requisites of § 102(b) are present. See generally § 2124.

However, in the case of *public use* activity by a party other than an applicant, and, absent evidence of a fiduciary or contractual relationship between the applicant and the "other party" (*see Smith and Griggs Mfg. Co.* v. *Sprague*, 123 U.S. 249, 257 (1887), the relevant inquiry is the extent that the public becomes "informed" of an invention from such public use activity. *Metallizing Eng'g. Co.* v. *Kenyon Bearing & Auto Parts Co.*, 68 USPQ 54, 58 (2d Cir. 1946) This inquiry into the extent that the public becomes informed is not of initial concern to the examiner, since a *prima facie* case of public use (§ 2124) may be established regardless of the "source" of § 102(b) activity. *Electric Storage Battery Co., supra.* The burden to overcome the *prima facie* case in this regard rests with an applicant. § 2124.

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. By way of *example only*, in an allegedly "secret" use by a party other than an applicant, if a large number of the 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 others 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 §§ 102(f) and 102(g). See *Dunlop Holdings* v. *Ram Golf Corp.*, 188 USPQ 481 (7th Cir. 1975)

2122 Preliminary Handling [R–3]

HOW THE QUESTIONS MAY ARISE

Questions involving § 102(b) activity may arise during the patent examination process in a number of ways. An applicant or his appointed representative may raise the questions in compliance with the "duty of disclosure" responsibilities of 37 CFR § 1.56 (Chapter 2000). One other than an applicant may present the questions by filing a protest under 37 CFR §§ 1.291(a), 1.291(b) (Chapter 1900), or by petitioning for institution of public use proceedings under 37 CFR § 1.292 (§ 720). Additionally, the questions may become manifest from a Recommendation of the Board of Patent Interferences (37 CFR § 1.259) or from an interference record itself, e.g., a specific finding that an actual reduction to practice occurred more than one year prior to the filing date of an ap-

plication, coupled with evidence of related commercial exploitation. Regardless of how the questions arise, the examiner must review thoroughly all the evidence of record before formulating a possible rejection of claimed subject matter under § 102(b).

When questions of public use or on sale activity occur in a reissue application, the facts presented may raise issues relative to compliance with the "duty of disclosure" (37 CFR § 1.56; Chapter 2000) during the pendency of the original patent. See *In re Stockebrand*, 197 USPQ 857 (Comm.Pat. 1978), *aff'd. sub. nom., Digital Equipment Corp.* v. *Parker*, —— USPQ —— (D.Mass. 1980); *In re Altenpohl*, 198 USPQ 289 (Comm.Pat. 1976), *aff'd., Altenpohl* v. *Diamond*, —— USPQ —— (D.D.C. 1980).

Affidavit Or Declaration Under 37 CFR § 1.131

Affidavits or declarations submitted under 37 CFR § 1.131 to swear behind a reference (§ 715.07) may constitute, among other things, an admission that an invention was "complete" (§ 2125.01) more than one year before the filing of an application. *In re Foster*, 145 USPQ 166, 173 (CCPA 1965); *Dart Industries* v. *E. I. duPont de Nemours & Co.*, 179 USPQ 392, 396 (7th Cir. 1973).

Requirement For Information

As an aid to the examiner in resolving public use or on sale issues, an applicant may be required, or any other party to the proceeding who has access to an application (§ 1901.01) may be requested, to answer specific questions posed by the examiner and to explain or supplement any evidence already of record. 35 USC § 132, 37 CFR § 1.104(b); regarding reissue applications, see § 1.175(b). Information sought should be restricted to that which is *reasonably necessary* for the examiner to render a decision on patentability.

A one or two month time period should be set by the examiner for any response to the requirement, unless the requirement is a part of an Office action having a shortened statutory period, in which case the period for response to the Office action will apply also to the requirement. If an *applicant* fails to respond in a timely fashion to a requirement for information, the application will be regarded as abandoned, 35 USC § 133.

2123 Forms of Evidence [R–3]

Evidence and/or information submitted to examiners with regard to § 102(b) activity may take the form of affidavits; declarations; depositions; answers to interrogatories; exhibits; transcripts of hearings or trials; stipulations; documents containing offers for sale, orders, invoices, receipts, delivery schedules; etc. Regardless of the form in which such evidence and/or information is submitted, examiners must resolve any related evidentiary issues of authenticity and probative value.

Authenticity And Probative Value

Each item of § 102(b) evidence must be evaluated by examiners with respect to *both* authenticity and the weight it should be accorded, i.e., probative value. Evidence in this regard submitted by an applicant which is adverse to his interests, i.e., not favorable to patentability, constitutes an implicit admission that such evidence is authentic, unless stated affirmatively to the contrary by the applicant. On the other hand, each item of submitted evidence favorable to patentability must be reviewed critically by the examiner for authenticity and probative value, bearing in mind the "uncompromising duty of candor and good faith" owed by an applicant to the Office with respect to such a submission and any representations made relative thereto. 37 CFR § 1.56; Chapter 2000. Of course, affidavits or declarations identifying the source of each item of evidence and explaining its relevance and meaning would be helpful. However, despite such identifying affidavits or declarations, the examiner should note that even an applicant's good faith *adverse* testimony in this regard may be of little weight against substantial evidence to the contrary. *In re Theis*, 204 USPQ 188, 193 (CCPA 1979); *Robbins Co.* v. *Lawrence Mfg. Co.*, 178 USPQ 577, 581 (9th Cir. 1973).

If the authenticity of documentary evidence is contested by an applicant, of if alleged public use or on sale activity is by one other than an applicant or his assignee, the appropriate vehicle for determining § 102(b) questions may be a public use proceeding under 37 CFR § 1.292. (§ 720)

Requirement For Information

As an aid to resolving issues of authenticity, as well as to other related matters of § 102(b) activity, an applicant may be required, or any other party to the proceeding who has access to an application (§ 1901.01) may be requested, to answer specific questions posed by the examiner and to explain or supplement any evidence already of record. 35 USC § 132, 37 CFR § 1.104(b); regarding reissue applications, see § 1.175(b). Information sought should be restricted to that which is *reasonably necessary* for the examiner to render a decision on patentability.

A one or two month time period should be set by the examiner for any response to the requirement, unless the requirement is a part of an Office action having a shortened statutory

period, in which case the period for response to the Office action will apply also to the requirement. If an *applicant* fails to respond in a timely fashion to a requirement for information, the application will be regarded as abandoned, 35 USC § 133.

2124 Determination of the Prima Facie Case [R-5]

PREPONDERANCE v. CLEAR AND CONVINCING

Upon resolution of any evidentiary issues of authenticity and/or probative value (§ 2123), the examiner must first determine whether there is a "*prima facie* case" under 35 USC § 102(b). *In re Dybel*, 187 USPQ 593, 598 (CCPA 1975); *In re Blaisdell*, 113 USPQ 289, 293 (CCPA 1957). In order to make this determination, the examiner must ascertain if the § 102(b) evidence appears to be sufficient in the absence of rebuttal evidence. *In re Lintner*, 173 USPQ 560, 562 (CCPA 1972); *In re Freeman*, 177 USPQ 139, 142 (CCPA 1973).

Many judicial decisions have articulated varying statements *in litigation* regarding the standard of proof necessary to overcome the statutory presumption of validity (35 USC § 282) after a patent issues. See *Hobbs* v. *United States*, 171 USPQ 713, 717–18 (5th Cir. 1971). However, *in the examination* of an application before a patent issues, the standard by which the examiner should be guided is the "preponderance of the evidence test", that is, it is more likely than not from the evidence of record that § 102(b) activity was present. See *Dickstein* v. *Seventy Corp.*, 187 USPQ 138, 139–40 (6th Cir. 1975), *cert. denied*, 423 U.S. 1055 (1976); *Bergstrom* v. *Sears, Roebuck & Co.*, 199 USPQ 269, 276 (D. Minn. 1978). This test is essentially synonymous with the standards enunciated in *Lintner* and *Freeman*, *supra*. In this regard, the examiner is reminded that an application of doubtful patentability should not be allowed unless and until issues pertinent to such doubt have been raised and overcome in the course of examination and prosecution, § 706.

Thus, if the examiner determines that a *prima facie* case exists, a rejection under § 102 (b) should be made. In response to this rejection, it is incumbent upon an applicant to come forward with "objective evidence" (*In re Rinehart*, 189 USPQ 143, 147 (CCPA 1976); *In re Fielder et al.*, 176 USPQ 300, 302 (CCPA 1973)) to (1) rebut/overcome, or (2) excuse, the *prima facie* case. Rebuttal evidence is submitted to contradict or disprove the *prima facie* case. For example, an applicant may seek to show that alleged § 102(b) activity (1) took place within the one year grace period (§ 2126), or (2) was not "public", in the case of "public use" activity (§ 2125.02). Contrasted to this is evidence alleging "excused conduct", meaning "experimental use" (§ 2128.01), where the existence of the *prima facie* case is not necessarily denied but it is advanced by an applicant that circumstances attending § 102(b) activity were such as to constitute a legally-recognized "excuse".

In determining whether the *prima facie* case exists, the examiner should *not* be concerned initially with any evidence of excused conduct. Evidence of excused conduct becomes relevant only *after* the establishment of the *prima facie* case, when the burden shifts to an applicant to show the excused conduct by clear and convincing evidence. *In re Dybel*, 187 USPQ 593, 598 (CCPA 1975); *Strong* v. *Gen'l Electric Co.*, 168 USPQ 8, 9 (5th Cir. 1970). § 2128. This does not mean, of course, that excused conduct should be overlooked entirely in evaluating evidence of § 102(b) activity. However, *before* such conduct is scrutinized by the examiner, the *initial* step of determining the existence of the *prima facie* case must be taken. In this regard, the different standards of proof (1) to establish/overcome the *prima facie* case (i.e., preponderance of the evidence), and (2) to excuse the *prima facie* case (i.e., clear and convincing evidence), must be recognized and appreciated. As discussed in *Hobbs* v. *United States*, *supra*, the "clear and convincing evidence" standard is greater than the standard for "preponderance of the evidence".

Determination by the examiner of the existence of a *prima facie* case must also be made in light of the different aspects of "public use", "on sale", and activity by one other than an applicant; as well as the import of evidence of "commercial exploitation", § 2121.

Documentary evidence is normally presented with respect to the *prima facie* case. However, testimony alone, if convincing and corroborated, may be sufficient. *Anderson Co.* v. *Trico Products Corp.*, 122 USPQ 52 (2d Cir. 1959). In the context of the patent examination process, testimony may take the form of depositions, interrogatories, court transcripts or other similar evidence. See § 2123 for a discussion of the related problems of authenticity and probative value. Although testimony of an applicant's subjective intent may be probative if adequately corroborated, it is of little weight against substantial evidence to the contrary. *In re Theis*, 204 USPQ 188, 193 (CCPA 1979); *Robbins Co.* v. *Lawrence Mfg. Co.*, 178 USPQ 577, 581 (9th Cir. 1973).

ESTABLISHING A PRIMA FACIE CASE

The principal inquiry with respect to the *prima facie* case (§§ 2125–2127) will cause the

examiner to determine from the evidence: (1) exactly *what* was in public use or on sale in the United States; (2) when public use or on sale activity took place; and (3) whether any pending *claims* are anticipated by what was found to be in public use or on sale.

With regard to (3) directly above, even if some or all of the claims of an application are not deemed by the examiner to be anticipated by an invention found to have been in public use or on sale, a claimed invention should also be considered with respect to obviousness. *In re Foster*, 145 USPQ 166, 174 (CCPA 1965); In re Corcoran, 208 USPQ 867, 870 (CCPA 1981). A rejection may be based upon the obviousness of claimed subject matter in view of a § 102(b) invention, since such an invention becomes part of the prior art for purposes of § 103. *Timely Products Corp.* v. *Arron*, 187 USPQ 257, 267 (2d Cir. 1975) Furthermore, evidence of public use activity by one other than an applicant may also constitute sufficient grounds to support a rejection of claimed subject matter under §§ 102 (a), 102(f), or 102(g). See *Dunlop Holdings* v. *Ram Gulf Corp.*, 188 USPQ 481 (7th Cir. 1975).

2125 Determination of What Was In Public Use or On Sale in The United States [R–3]

In order to determine what was in public use or on sale the examiner must look to the primary components of the *prima facie* case, i.e., "the invention [which] was . . . in public use or on sale in this country . . .". 35 USC § 102(b).

2125.01 "The Invention" [R–3]

35 U.S.C. § 102(b). "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 * * *."

"The Invention" Generally

As a general proposition, an invention cannot be considered in public use or on sale until it has been reduced "to a reality", i.e., until a working model or prototype has been made. *In re Theis*, 204 USPQ 188, 193 (CCPA 1979); *Hobbs* v. *United States*, 171 USPQ 713, 720 (5th Cir. 1971). Many courts equate reduction "to a reality" with an "actual" reduction to practice, as that test is normally used in interference proceedings, 35 USC § 102(g). 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).

Although the test of an "actual" reduction to practice may be applicable to § 102(b) activity, as where the nature of a particular invention requires development over a considerable period of time (*In re Josserand*, 89 USPQ 371 (CCPA 1951)), the better test is whether or not an invention is "complete". See also *Gen'l Elec. Co.* v. *United States* 206 USPQ 260, 271 (Ct. Cl. 1979).

The test for "completeness" of an invention is basically a matter of evaluating the subjective intent of an inventor, as manifested by the objective factual circumstances surrounding the development of the invention, § 2125.01. However, an inventor's testimony alone with regard to such intent may be of little weight against substantial evidence to the contrary. *In re Theis*, 204 USPQ 188, 193 (CCPA 1979); *Robbins Co.* v. *Lawrence Mfg. Co.*, 178 USPQ 577, 581 (9th Cir. 1973). Since the test for "completeness" is often so intimately related to the "experimental use exception" and its component parts, the examiner should also refer to § 2128.01 in this regard.

The "Complete" Invention

The nature of many inventions is such that an "actual" reduction to practice prior to the filing of a patent application never takes place. For inventions of this nature, the filing of the application serves as a "constructive" reduction to practice of the invention, § 715.07. Although there may be no reduction "to a reality" in this situation, objective factors are identifiable to indicate the degree of confidence and certainty which an inventor has in the nature, usefulness, and operability of his invention, i.e., whether or not the invention is "complete". *Philco Corp.* v. *Admiral Corp.*, 131 USPQ 413, 430 (D.Del. 1961). For example, 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, "completeness" is present. *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, "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" unless one would know how the invention would work upon installation, *In re Dybel*, 187 USPQ 593, 598 (CCPA 1975). Such knowledge is not synonymous with a lack of *any* expecta-

tion of "problems" upon installation, as long as the "problems" are not due to "fundamental defects" in the invention. *In re Theis*, 204 USPQ 188, 195 n. 11 (CCPA 1979); *Nat'l. Biscuit Co.* v. *Crown Baking Co.*, 42 USPQ 214, 215 (1st Cir. 1939).

The entire question of "completeness" may be mooted, however, where an affidavit or declaration is submitted by an applicant under 37 CFR § 1.131 to swear behind a reference, § 715. Such an affidavit or declaration may constitute, among other things, an admission that an invention was "complete" more than one year before the filing of an application. *In re Foster*, 145 USPQ 166, 173 (CCPA 1965); *Dart Industries* v. *E. I. duPont de Nemours & Co.*, 179 USPQ 392, 396 (7th Cir. 1973).

2125.02 "In Public Use" [R–3]

35 U.S.C. § 102(b). "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 * * *."

The phrase "in public use" is often referred to in its entirety, without careful delineation between its component parts—"public" and "use".

The "public" aspect of "public use" would seem to connote some impartation of knowledge to the public regarding the workings of an invention. Accordingly, there is a "public use" of an invention when it is used by the public (*Pennock* v. *Dialogue*, 27 U.S. 1 (1829)) or by an inventor himself in public (*City of Elizabeth* v. *American Nicholson Pavement Co.*, 97 U.S. 126 (1877)). A single "public use" of an invention is within the meaning of the statutory terms. *Egbert* v. *Lippmann*, 104 U.S. 333, 336 (1881).

However, an invention does not have to be "knowingly" exposed to the public in order to constitute a public use. There is a "public use" within the meaning of § 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 public in its natural and intended way. *Hall* v. *Macneale*, 107 U.S. 90, 96–97 (1882); *In re Blaisdell*, 113 USPQ 289, 292 (CCPA 1957).

"Public" is not necessarily synonymous with "non-secret". Accordingly, a "secret" *or* a "non-secret" use of an invention by an inventor or his assignee in the ordinary course of a business for trade or profit is a "public use" of the invention (*Manning* v. *Cape Ann Isinglass & Glue Co.*, 108 U.S. 462, 465 (1883)), whether or not the invention could have been ascertained by a member of the public as a result of that use (*Metallizing Eng'g. Co.* v. *Kenyon Bearing & Auto-Parts Co.*, 68 USPQ 54, 58 (2d Cir. 1946)). In similar fashion, any "nonsecret" use of an invention by one other than an inventor 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 one other than an 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). However, a purely private use of an invention by an inventor and his immediate family for their own enjoyment and pleasure is not necessarily "public". *Bergstrom* v. *Sears, Roebuck & Co.*, 199 USPQ 269 (D. Minn. 1978).

2125.03 "On Sale" [R–3]

35 U.S.C. § 102(b). "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 * * *."

Unlike questions of public use, there is no requirement that "on sale" activity be "public", *Hobbs* v. *United States*, 171 USPQ 713, 720 (5th Cir. 1971). "Secret" on sale activity is still within the statutory terms.

Introduction

An invention is "on sale" if it is sold, whether the patent owner has knowledge that the sale actually includes the invention (*C.T.S. Corp.* v. *Electro Mat'ls.*, 202 USPQ 22, 38 (S.D.N.Y. 1979)), or whether the sale is for profit (*Strong* v. *Gen'l. Electric Co.*, 168 USPQ 8, 12 (5th Cir. 1970)) or conditional (*Henry* v. *Francestown Soap-Stone Co.*, 2 F. 78 (C.C.N.H. 1880)). Furthermore, the sale of even a single device may constitute a statutory bar. *Consolidated Fruit-Jar Co.* v. *Wright*, 94 U.S. 92, 94 (1876); *In re Theis*, 204 USPQ 188, 192 (CCPA 1979).

An outright sale of an invention is not the only act within the ambit of § 102(b). Since the statute creates a bar when an invention is placed "on sale", a mere offer to sell is sufficient commercial activity (*In re Theis*, 204 USPQ 188, 192 (CCPA 1979); *Akron Brass Co.* v. *Elkhart Brass Mfg. Co.*, 147 USPQ 301, 305 (7th Cir. 1965); *Gen'l Elec. Co.* v. *United States* 206, US PQ 260, 271 (Ct. Cl. 1979)), even though the offer is never actually received by a prospective purchaser (*Wende* v. *Horine*, 225 F. 501 (7th Cir. 1915). While some cases follow what has been termed the "on-hand doctrine" (*see, e.g., McCreery Eng'g. Co.* v. *Mass. Fan Co.*, 195 F.

498 (1st Cir. 1912)), this doctrine is not followed by the Office. Thus, actual delivery or present ability to deliver commercial quantities of an invention is not a prerequisite to a *prima facie* case under § 102(b), *Johns-Manville Corp.* v. *Certain-Teed Corp.* 146 USPQ 152, 157 (C.D. Cal. 1977).

SIGNIFICANT FACTORS INDICATIVE OF "COMMERCIAL EXPLOITATION"

As discussed in § 2121, a policy consideration in questions of § 102(b) activity is premature "commercial exploitation" of a "completed" invention (§ 2125.01). The extent of commercial activity which constitutes § 102(b) "on sale" status is dependent upon the circumstances of the activity—the basic indicator being the subjective intent of the inventor. However, because an inventor's intent may be manifested in a multitude of ways, no one or particular combination of which is necessarily determinative of "commercial exploitation", 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. (§ 2123);

(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. *Gen'l. 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 (*Gen'l. 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 Corp.*, 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 Products* v. *Grossman*, 136 USPQ 244, 245 (9th Cir. 1963)).

The above activities may be determinative of "commercial exploitation" even though (1) prices are estimated rather than established, (2) no commercial production runs have been made, and (3) the invention is never actually sold, *Chromalloy American Corp.* v. *Alloy Surfaces Co.*, 173 USPQ 295, 301–02 (D.Del. 1972).

2125.04 "In This Country" [R–3]

35 U.S.C. § 102(b). "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 * * *."

For purposes of judging the applicability of the § 102(b) bars, public use or on sale activity must take place in the United States. While 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)), "on sale" status can be found if "substantial activity prefatory to a sale" occurs in the United States. *Robbins Co.* 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" (§ 2126.01) *C.T.S. Corp.* v. *Piher Int'l. Corp.*, 201 USPQ 649 (7th Cir. 1979).

2126 Determination of When Public Use or On Sale Activity Took Place [R–3]

In determining when public use or on sale activity took place, the time period which must be considered is one year before the filing date of an application.

2126.01 "More Than One Year Prior to the Date of the Application for Patent in the United States" [R–3]

35 U.S.C. § 102(b). "A person shall be entitled to a patent unless— * * * (b) the invention was . . . in public use or on sale in this conutry, *more than one year prior to the date of the application for patent in the United States* * * *."

The "critical date" for purposes of activity under 35 USC § 102(b) is one year prior to the

effective filing date in the United States of an application for patent. In computing the one year period, the general rule of excluding the day on which the event occurs applies. Regarding the termination point, 35 USC § 21 is dispositive. See § 201.13; *Ex parte Olah*, 131 USPQ 41 (Bd.App. 1960).

Of course, an application for patent may be entitled to the benefit of an earlier foreign filing date pursuant to the provisions of 35 USC § 119, § 201.13. However, for purposes of § 102(b), the "critical date" of an application claiming the benefit of foreign priority is one year before the *actual filing date* of the application in the United States, and *not* the foreign priority date to which the application may be entitled. 35 USC §§ 104; 119, first paragraph.

The determination of the "critical date" of an application for purposes of § 102(b) is not always a matter of merely looking to the application filing date. Continuing applications filed under § 120, especially continuation-in-part applications, require extra care in determining the earliest effective filing date to which *particular claimed subject matter* is entitled. See generally § 201.07.

LATE-CLAIMING

Under certain circumstances, the filing date of an amendment which includes subject matter found to have been in public use or on sale can affect the determination of the "critical date". This is the result of *Muncie Gear Works* v. *Outboard Motor Co.*, 315 U.S. 759, 53 USPQ 1, 5 (1942), where the Court invalidated claims because

"there was public use, or sale, of devices embodying the asserted invention, . . . before it was *first presented* to the Patent Office." (Emphasis added.)

In invalidating the claims in question, the Court noted that

"the amendments of December 8, 1928, like the original application, *wholly failed to disclose* the invention now asserted." (Emphasis supplied.)

The above quotations from *Muncie Gear* should be, and most often have been, read as merely involving an issue of "new matter", prohibited by what is now 35 USC § 132. See *Cardinal of Adrian* v. *Peerless Wood Products*, 185 USPQ 712, 715–16 (6th Cir. 1975); *Faulkner* v. *Baldwin Piano & Organ Co.*, 195 USPQ 410, 413–15 (7th Cir. 1977); *Chicopee Mfg. Corp.* v. *Kendall Co.*, 129 USPQ 90, 93 (4th Cir. 1961); *Azoplate Corp.* v. *Silverlith*, 180 USPQ 616, 631 (D. Del. 1973).

The examiner should be guided by the "new matter" reading. *In re Goldman*, 205 USPQ 1086, 1089 (Comm. Pat. 1980). Accordingly,

"'where the invention has been continuously disclosed in the application, an intervening public use or sale prior to the claiming of the invention will not constitute a bar.'"

Thus, in determining the "critical date" for all circumstances of § 102(b) activity, the examiner should ascertain the effective U.S. filing date to which specific claimed subject matter is entitled in view of the original disclosure, §§ 201.07, 608.04. The date which particular subject matter was "first claimed" in a given application is not determinative.

2127 Determination of Whether Any Pending Claims Are Anticipated by an Invention Found To Be In Public Use or On Sale [R–3]

All pending *claims* of an application must be compared by the examiner with the invention found to have been in public use or on sale. If any one claim of the application is anticipated by this invention, there is a *prima facie* case with respect to that particular claim.

Evidence of public use activity by one other than an applicant may also constitute sufficient grounds to support a rejection of claimed subject matter under §§ 102(a), 102(f), or 102(g). See *Dunlop Holdings* v. *Ram Golf Corp.*, 188 USPQ 481 (7th Cir. 1975). Furthermore, even if some or all of the claims of an application are not deemed by the examiner to be anticipated by an invention found to have been in public use or on sale, a claimed invention should also be considered with respect to obviousness, *In re Foster*, 145 USPQ 166, 174 (CCPA 1965). A rejection may be based upon the obviousness of claimed subject matter in view of a § 102(b) invention, since such an invention becomes part of the prior art for purposes of § 103. *Timely Products Corp.* v. *Arron*, 187 USPQ 257, 267 (2d Cir. 1975)

2128 Excused Activity [R–3]

Once the examiner determines that a *prima facie* case exists, a rejection under § 102(b) should be made. As discussed in § 2124, it is incumbent upon an applicant, in response to this rejection, to come forward with "objective evidence" (*In re Rinehart*, 189 USPQ 143, 147 (CCPA 1976); *In re Fielder et al.*, 176 USPQ 300, 302 (CCPA 1973)) to (1) rebut/overcome, or (2) excuse, the *prima facie* case. Thus, evidence of excused activity becomes relevant only after the establishment of the *prima facie* case, when the burden shifts to an applicant to show such activity by clear and convincing evidence. *In re Dybel*, 187 USPQ 593, 598 (CCPA 1975);

Strong v. *Gen'l. Electric Co.*, 168 USPQ 8, 9 (5th Cir. 1970). The "clear and convincing evidence" standard is greater than the "preponderance of the evidence" standard used in connection with the *prima facie* case, § 2124.

The basis for excused activity under § 102(b) is that a public use or sale was for "experimental" purposes.

2128.01 The Experimental Use Exception [R–3]

Introduction

As a general rule, a *prima facie* case under 35 USC § 102(b) cannot be found by the examiner unless an invention is "complete", § 2125.01. Experimental activity is quite often conducted by an inventor to determine "completeness", that is, operability and/or usefulness, as well as to ascertain if further modifications or refinements to an invention may be necessary. However, the extent of experimental activity permissible under § 102(b) depends upon the nature of an invention and the scope and circumstances of the particular activity conducted, viewed in light of the subjective intent of an inventor, and *not* the intent or motives of a prospective customer or present user. *In re Theis*, 204 USPQ 188, 193 (CCPA 1979); *Tool Rsch. & Eng'g. Co.* v. *Honcor Corp.*, 145 USPQ 249, 252 (S.D.Cal. 1964), *aff'd.*, 151 USPQ 236 (9th Cir. 1966), *cert. denied*, 387 U.S. 919 (1967).

Significant Factors Indicative Of An Experimental Purpose

Various judicial decisions have enunciated "tests" which are considered indicative of experimental purpose. These "tests" look to whether alleged excused activity was "solely" experimental (*Dart Industries* v. *E.I. duPont de Nemours & Co.*, 179 USPQ 392, 397 n. 13 (7th Cir. 1973)), "primarily" experimental (*Robbins Co.* v. *Lawrence Mfg. Co.*, 178 USPQ 577, 582 (9th Cir. 1973)), or experimental from a "weighing of the motives" of an inventor (*In re Yarn Processing Patent Validity Litigation*, 183 USPQ 65 (5th Cir. 1974)). Since these decisions all emanate from the same source—*City of Elizabeth* v. *American Nicholson Pavement Co.*, 97 U.S. 126 (1878)—careful analysis of that source is instructive.

The Court in *City of Elizabeth* found several factors persuasive of excused 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.

Some lower court decisions have highlighted the lack of any apparent "profit motive" in *City of Elizabeth* for the proposition that true experimental activity cannot reveal *any* evidence of profit. However, *bona fide* experimental activity may involve some incidental income. *In re Dybel*, 187 USPQ 593, 597 n. 5 (CCPA 1975). Of course, the extent and circumstances precipitating the incidental income may be indicative of the *bona fide* nature of the experimental activity.

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 limitations* placed on a user during a period of experimental activity, as well as the extent of any 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 (*Int'l 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)); and

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

Summarizing the above, once alleged experimental activity is advanced by an applicant to excuse a *prima facie* case under § 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 or particular combination of

"factors" (a) through (j) are necessarily determinative of this purpose.

In the case of "public use" activity, if the examiner finds clear and convincing evidence of reasonableness, then any profit or commercial advantage achieved as a result of experimental activity may be viewed as merely incidental to the primary purpose of experimentation. *Smith & Griggs Mfg. Co.* v. *Sprague*, 123 U.S. 249, 256 (1887); *In re Theis*, 204 USPQ 188, 194 (CCPA 1979). On the other hand, in the case of "on sale" activity, or of public use activity with commercial overtones, if the examiner finds that the circumstances of any alleged experimental activity went beyond what was reasonable, then the exception would not apply. In these latter situations, the examiner should be guided by the "primarily for experimental purpose" test of *Robbins Co.* v. *Lawrence Mfg. Co.*, 178 USPQ 577, 582 (9th Cir. 1973); *In re Theis*, 204 USPQ 188, 194 (CCPA 1979). Accordingly, alleged experimental activity in these latter situations

". . . must be so limited as not to interfere with the effectuation of the policy underlying the general rule of early disclosure. An inventor may not be permitted to use a period of experimentation as a competitive tool." *Koehring Co.* v. *Nat'l. Automatic Tool Co.*, 149 USPQ 887, 890 (7th Cir. 1966)

Experimental Activity Subsequent To "Completion" Of An Invention

Whether experimental activity can continue after an invention is "complete" (§ 2125.01) is a matter of scrutiny of the subjective intent of an inventor, viewed in light of the objective factual circumstances surrounding the particular activity.

Once an invention passes out of the experimental stage and becomes a "reality" for purposes of § 102(b), later refinements or improvements will not ordinarily excuse the *prima facie* case. *In re Theis*, 204 USPQ 188, 193–94 (CCPA 1979); *Gould* v. *United States*, 198 USPQ 156 (Ct.Cl. 1978). However, if an invention requires testing over a considerable period of time and the evidence shows no attempt by an inventor to use the invention for commercial purposes during this period, the testing may be excused. *In re Josserand*, 89 USPQ 371 (CCPA 1951)

Regardless of intent, any "continued" experimental activity must relate to the *same* invention which was found to have been "complete". *In re Blaisdell*, 113 USPQ 289, 293 (CCPA 1957) The examiner is cautioned that an inventor's testimony in this regard may have little probative value against substantial evidence to the contrary. *In re Theis*, 204 USPQ 188, 193 (CCPA 1979); *Robbins Co.* v. *Lawrence Mfg. Co.*, 178 USPQ 577, 581 (9th Cir. 1973).

Experimental Activity in an Atmosphere of "Commercial Exploitation"

If an applicant's purpose with regard to alleged experimental activity has commercial overtones, the policy against "commercial exploitation" is paramount, § 2121. Thus, even if there is *bona fide* experimental activity, an inventor may not commercially exploit an invention more than one year prior to the filing date of an application. *In re Theis*, 204 USPQ 188, 194 (CCPA 1979)

As the degree of commercial exploitation surrounding § 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 excuse 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).

2128.02 The Experimental Exception and the Development of Prototypes [R–3]

The construction of a prototype, or model, of an invention is not necessarily determinative of "completion". As discussed at § 2125.01, the nature of many inventions is such that an "actual" reduction to practice prior to the filing of a patent application never takes place. Thus, where a prototype has not been made or tested, commercial activity regarding such an invention may well constitute permissible solicitation of suggestions regarding modifications or refinements not significant under § 102(b). § 2128.05

However, where an inventor has confidence in the utility and operability of an invention, which confidence is shared by a potential purchaser who begins commercialization based upon information or drawings supplied by the inventor, prohibitive § 102(b) activity is present.

Langsett v. *Marmet Corp.*, 141 USPQ 903, 910–11 (W.D.Wisc. 1964); § 2125.01.

Where a prototype of an invention *has* been constructed, inquiry by the examiner should be upon the general requisites of "completion" (§ 2125.01), which do *not* require that the invention be at a stage of development for full scale commercial production. *Johns-Manville Corp.* v. *Certain-Teed Corp.*, 196 USPQ 152, 157 (C.D.Cal. 1977). In similar fashion, 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); *Skil Corp.* v. *Lucerne Products*, 178 USPQ 562, 565 (N.D.Ill. 1973), *aff'd.*, 183 USPQ 396, 399 (7th Cir. 1974), *cert. denied*, 183 USPQ 65 (1975).

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 § 102(b). *In re Blaisdell*, 113 USPQ 289 (CCPA 1957); *contra*, *Watson* v. *Allen*, 117 USPQ 68 (D.C.Cir. 1957).

2128.03 The Experimental Exception and the Degree of Supervision and Control Maintained by an Inventor over an Invention [R–3]

As discussed with reference to *City of Elizabeth* v. *American Nicholson Pavement Co.*, 97 U.S. 126 (1878) (§ 2128.01), 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. See also *Root* v. *Third Avenue R.R. Co.*, 146 U.S. 210 (1892). When an inventor relinquishes supervision and control, subsequent activity with an invention must be scrutinized carefully by the examiner to determine whether there is clear and convincing evidence that such activity is reasonably consistent with the experimental purpose advanced by the inventor. *Magnetics* v. *Arnold Eng'g. Co.*, 168 USPQ 392, 394 (7th Cir. 1971). However, 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 § 102(b) bar. *In re Blaisdell*, 113 USPQ 289, 293 (CCPA 1957).

2128.04 The Experimental Exception and the Testing of an Invention [R–3]

Testing of an invention in the normal context of its technological development is generally within the experimental exception. Likewise, experimentation to determine "utility", as that term is applied in 35 USC § 101, may also constitute permissible activity. See *Gen'l. 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 (§§ 101; 112, first paragraph), continued testing to find utility would likely be permissible under § 102 (b), absent a sale of the composition or other evidence of commercial exploitation.

On the other hand, 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 experimental use exception. *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 (*In re Theis*, 204 USPQ 188, 193 (CCPA 1979); *Cataphote Corp.* v. *DeSota Chem. Coatings*, 143 USPQ 229, 231–32 (N.D.Cal. 1964), *aff'd.*, 148 USPQ 229 (9th Cir.), *mod. on other grounds*, 149 USPQ 159 (9th Cir.), *cert. denied*, 385 U.S. 832 (1966)) or to conduct "minor 'tune up' procedures not requiring an inventor's skills, but rather the skills of a competent technician . . ." (*In re Theis*, *supra*, at 194 n. 8), are also not within the exception.

2128.05 The Experimental Exception Vis-a-Vis Modifications and Refinements to an Invention [R–3]

The fact that alleged experimental activity does not lead to specific modifications or refinements to an invention is evidence, although not conclusive evidence, that such activity is not within the "experimental exception". This is especially the case where the evidence of record clearly demonstrates to the examiner that an invention was considered "complete" by an in-

ventor at the time of the activity. See § 2125.01. 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); *Minn. Mining & Mfg. Co.* v. *Kent Industries*, 161 USPQ 321, 322–23 (6th Cir. 1969)

2128.06 Activity of an Independent Third Party Inventor [R–3]

The statutory bars of § 102(b) are applicable even though public use or on sale activity is by a party other than an applicant, § 2121. Where an applicant presents evidence of experimental activity by such *other party*, the evidence will not excuse the *prima facie* case under § 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). Accordingly, the "experimental use exception" is personal to an applicant.

2128.07 Evidence in Support of Excused Activity [R–3]

The examiner must always look to the objective factual circumstances surrounding alleged excused activity. In this regard, caution should be exercised when experimental intent is manifested by an affidavit or declaration filed by an applicant. While such evidence may be probative if adequately corroborated, it is of little weight against substantial evidence to the contrary. *In re Theis*, 204 USPQ 188, 193 (CCPA 1979); *Robbins Co.* v. *Lawrence Mfg. Co.*, 178 USPQ 577, 581 (9th Cir. 1973).

2129 The Written Action by the Examiner [R–5]

After consideration of all the evidence of record, the legal authorities cited by an applicant and any other party to the proceeding (§ 1901.01), and the guidelines set forth in this chapter of the Manual, the examiner must determine whether or not there is a *prima facie* case under § 102(b), § 2124. If the *prima facie* case exists, the examiner must *then* consider whatever evidence has been submitted to (1) overcome, or (2) excuse, the *prima facie* case, §§ 2124 and 2128.

If an applicant fails to meet his burden with regard to (1) rebutting/overcoming (i.e., preponderance of the evidence), or (2) excusing (i.e., clear and convincing evidence), the *prima facie* case; or, in the absence of *any* rebuttal evidence to the *prima facie* case, all the claims so affected should be rejected under 35 USC § 102(b), § 2127. Even if some or all of the claims are not deemed by the examiner to be anticipated by an invention found to have been in public use or on sale, a claimed invention should also be considered with respect to obviousness. *In re Foster*, 145 USPQ 166, 174 (CCPA 1965); In re Corcoran, 208 USPQ 867, 870 (CCPA 1981). A rejection may be based upon the obviousness of claimed subject matter in view of § 102(b) invention, since such an invention becomes part of the prior art for purposes of § 103. *Timely Products Corp.* v. *Arron*, 187 USPQ 257, 267 (2d Cir. 1975).

In addition to citing the statutory bases, the written action by the examiner in cases involving a rejection founded upon § 102(b) activity must explain why the evidence is sufficient to support the *prima facie* case, and must particularly point out the deficiencies in the evidence presented to rebut or excuse the *prima facie* case. Even if a rejection is not made, the examiner's written action should reflect that the evidence of § 102(b) activity *has in fact been considered.* Likewise, if the examiner concludes that a *prima facie* case (1) has not been established, (2) has been established and rebutted (§ 2124), or (3) has been established and excused (§ 2124), then the examiner's written action should so indicate. Strict adherence to this format should cause the rationale employed by the examiner in the written action to be self evident. In this regard, the use of reasons for allowance pursuant to 37 CFR § 1.109 may also be appropriate, § 1302.14.