Chapter 2100 Patentability

2105 Patentable Subject Matter — Living Subject Matter [R-1]

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

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

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

> 1. "Guided by these canons of construction, this Court has read the term 'manufacture' in § 101 in accordance with its dictionary definition to mean 'the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery.'"
>
> 2. "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."
>
> 3. "The Act embodied Jefferson's philosophy that 'ingenuity should receive a liberal encouragement.' 5 Writings of Thomas Jefferson, at 75-76. See *Graham* v. *John Deere Co.*, 383 U.S. 1, 7-10 (1966). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word 'art' with 'process,' but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 act inform us that Congress intended statutory subject matter to 'include any thing under the sun that is made by man.' S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952)."
>
> 4. "This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature,

physical phenomena, and abstract ideas have been held not patentable."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In analyzing the history of the Plant Patent Act of 1930, the Court stated: "In enacting the Plant Patent Act, Congress addressed both of these concerns [the concern that plants, even those artificially bred, were products of nature for purposes of the patent law and the concern that plants were thought not amenable to the written description]. It explained at length its belief that the work of the plant breeder 'in aid of nature' was patentable invention. S. Rep. No. 315, 71st Cong., 2d Sess., 6-8 (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess., 7-9 (1930)."

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 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).

**>In another case addressing< the scope of 35 U.S.C. 101, the **>Supreme Court< held that patentable subject matter under 35 U.S.C. 101 includes **>newly developed plant breeds<, even though plant protection is also available under the Plant Patent Act (35 U.S.C. 161 - 164) and the Plant Variety Protection Act (7 U.S.C. 2321 *et. seq.*). **> *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int' l, Inc.*, 534 U.S. 124, 143-46, 122 S.Ct. 593, 605-06, 60 USPQ2d 1865, 1874 (2001) (The scope of coverage of 35 U.S.C.101 is not limited by the Plant Patent Act or the Plant Variety Protection Act; each statute can be regarded as effective because of its different requirements and protections).< See also *Ex parte Hibberd*, 227 USPQ 443 (Bd. Pat. App. & Inter. 1985), wherein the Board held that plant subject matter may be the proper subject of

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

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-3]

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.

Office personnel should no longer rely on the Freeman-Walter-Abele test to determine whether a claimed invention is directed to statutory subject matter. *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F. 3d 1368, 1374, 47 USPQ2d 1596, 1601-02 (Fed. Cir. 1998) ("After *Diehr* and *Chakrabarty*, the Freeman-Walter-Abele test has little, if any, applicability to determining the presence of statutory subject matter.").

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., *State Street*, 149 F.3d at 1374-75, 47 USPQ2d at 1602 (Fed. Cir. 1998); *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?'" *In re Abele*, 684 F.2d 902, 907, 214 USPQ 682, 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, substantial, and credible utilities that have been asserted for the invention.

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

The claimed invention as a whole must accomplish a practical application. That is, it must produce a "useful, concrete and tangible result." *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601-02. 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); *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.

Apart from the utility requirement of 35 U.S.C. 101, usefulness under the patent eligibility standard requires significant functionality to be present to satisfy the useful result aspect of the practical application requirement. See *Arrhythmia*, 958 F.2d at 1057, 22 USPQ2d at 1036. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make the invention eligible for patenting. For example, a claim directed to a word processing file stored on a disk may satisfy the utility requirement of 35 U.S.C. 101 since the information stored may have some "real world" value. However, the mere fact that the claim may satisfy the utility requirement of 35 U.S.C. 101 does not mean that a useful result is achieved under the practical application requirement. The claimed invention as a whole must produce a "useful, concrete and tangible" result to have a practical application.

Although the courts have yet to define the terms useful, concrete, and tangible in the context of the practical application requirement for purposes of these guidelines, the following examples illustrate claimed inventions that have a practical application because they produce useful, concrete, and tangible result:

- Claims drawn to a long-distance telephone billing process containing mathematical algorithms were held to be directed to patentable subject matter because "the claimed process applies the Boolean principle to produce a useful, concrete, tangible result without pre-empting other uses of the mathematical principle." *AT&T Corp. v. Excel Communications, Inc*., 172 F.3d 1352, 1358, 50 USPQ2d 1447, 1452 (Fed. Cir. 1999);

- "[T]ransformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces 'a useful, concrete and tangible result' -- a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades." *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601; and

- Claims drawn to a rasterizer for converting discrete waveform data samples into anti-aliased pixel illumination intensity data to be displayed on a display means were held to be directed to patentable subject matter since the claims defined "a specific machine to produce a useful, concrete, and tangible result." *In re Alappat*, 33 F.3d 1526, 1544, 31 USPQ2d 1545, 1557 (Fed. Cir. 1994).

A process that consists solely of the manipulation of an abstract idea is not concrete or tangible. See *In re Warmerdam*, 33 F.3d 1354, 1360, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994). 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 as a whole is directed to solely an abstract idea or to manipulation of abstract ideas or does not produce a useful result. 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. Compare *Musgrave*, 431 F.2d at 893, 167 USPQ at 289; *In re Foster*, 438 F.2d 1011, 1013, 169 USPQ 99, 101 (CCPA 1971). 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.

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 first determine the scope of a claim by thoroughly analyzing the language of the claim before

determining if the claim complies with each statutory requirement for patentability. See *In re Hiniker Co.*, 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998) ("[T]he name of the game is the claim.").

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 or materials. Product claims are claims that are directed to either machines, manufactures or compositions of matter. The discrete physical structures or materials 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. >See also MPEP § 2111.04.<

Office personnel must rely on the applicant's disclosure to properly determine the meaning of the claims. *Markman v. Westview Instruments*, 52 F.3d 967, 980, 34 USPQ2d 1321, 1330 (Fed. Cir.) (*en banc*), *aff'd*, U.S., 116 S. Ct. 1384 (1996). Claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art. *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298, 67 USPQ2d 1132, 1136 (Fed. Cir. 2003)("In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art.") However, an applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning. *See In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) >and *Vitronics Corp. v. Conceptronic Inc.*, 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1576 (Fed. Cir. 1996)<. Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999) (meaning of words used in a claim is not construed in a "lexicographic vacuum, but in the context of the specification and drawings."). Any special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998). See also MPEP § 2111.01.

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. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim are not read into the claim. *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily). *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also *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 *en 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 1526, 1540, 31 USPQ2d 1545, 1554 (Fed. Cir. 1994) (in banc), 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 original 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 including the manner in which the claimed functions are performed. See *Kemco Sales, Inc. v. Control Papers Company, Inc.*, 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000). Further guidance in interpreting the scope of equivalents is provided in MPEP § 2181 through § 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 *Chakrabarty*, 447 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, ch. 11, § 1, 1 Stat. 318. 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 (148 USPQ 459, 462-464) (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). [Footnote omitted]

This perspective has been embraced by the Federal Circuit:

> The plain and unambiguous meaning of section 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 sections 102, 103, and 112. The use of the expansive term "any" in section 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 section 101 and the other parts of Title 35.... Thus, it is improper to read into section 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; *Warmerdam*, 33 F.3d at 1358, 31 USPQ2d at 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.

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. (20 Wall.) 498, 507 (1874) ("idea of itself is not patentable, but a new device by which it may be made practically useful is"); *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86, 94, 40 USPQ 199, 202 (1939) ("While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be."); *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." Abstract ideas, *Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759, or the mere manipulation of abstract ideas, *Schrader*, 22 F.3d at 292-93, 30 USPQ2d at 1457-58, are not patentable. 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 employed as a computer component. (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*. *Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759. 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 since use of technology permits the function of the descriptive material to be realized. Compare *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and *Warmerdam*, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in 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 statutory since no requisite functionality is present to satisfy the practical application requirement. 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 is not a computer component and it 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.

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. *Schrader*, 22 F.3d at 294-95, 30 USPQ2d at 1458-59. 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.

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.

(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 not capable of causing functional change in the computer. 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 computer software and hardware components 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." They are neither computer components nor 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 elements of a computer which permit the computer program's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer 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 paragraph IV.B.2(b), below. 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 paragraph IV.B.2(a), below.

(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 multi-media 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 phenomena. *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112-14 (1853). However, a signal claim directed to a practical application of electromagnetic energy is statutory regardless of its transitory nature. See *O'Reilly*, 56 U.S. at 114-19; *In re Breslow*, 616 F.2d 516, 519-21, 205 USPQ 221, 225-26 (CCPA 1980).

2. Statutory Subject Matter

For the purposes of a 35 U.S.C. 101 analysis, it is of little relevance whether the claim is directed to a machine or a process. The legal principles are the same. *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352, 1357, 50 USPQ2d 1447, 1451 (Fed. Cir. 1999).

(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." *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, or whether . . . [it] be [a] gas[], fluid[], powder[], or solid[]." *Id*. 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.

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.

A claim limited to a 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. See *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557 ("the claimed invention as a whole is directed to a combination of interrelated elements which combine to form a machine for converting discrete waveform data samples into anti-aliased pixel illumination intensity data to be displayed on a display means. This is not a disembodied mathematical concept which may be characterized as an 'abstract idea,' but rather a specific machine to produce a useful, concrete, and tangible result."); and *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601 ("the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces 'a useful, concrete and tangible result' – a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades."). Also see *AT&T*, 172 F.3d at 1358, 50 USPQ2d at 1452 (Claims drawn to a long-distance telephone billing process containing mathematical algorithms were held patentable subject matter because the process used the algorithm to produce a useful, concrete, tangible result without preempting other uses of the mathematical principle.).

(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. *Schrader*, 22 F.3d at 296, 30 USPQ2d at 1460. To be statutory, a claimed computer-related process must either: (A) 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 (B) be limited 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 applications") (citing *O'Reilly v. Morse*, 56 U.S. (15 How.) at 114-19). If a physical transformation occurs outside the computer, 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 for the claimed invention taken as a whole to produce a practical application if there is only a transformation of signals or data inside a computer or if a 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), 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.

Examples of claimed processes that do not achieve a practical application 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 "equating" the process outputs to the values of the last set of process inputs found to constitute storing the result of calculations (*In re Gelnovatch*, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979); 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.")); and

-step of displaying a calculation as a gray code scale (*In re Abele*, 684 F.2d 902, 908, 214 USPQ 682, 687 (CCPA 1982)).

- Manipulation of Data Representing Physical Objects or Activities (Pre-Computer 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)*; Arrhythmia*, 958 F.2d at 1056, 22 USPQ2d at 1036), 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 representation 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.

Examples of claimed processes that independently limit the claimed invention to safe harbor 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 claimed processes that do not limit the claimed invention to pre-computing safe harbor 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).

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 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* 33 F.3d 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). A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible and useful. See *AT&T*, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601) and/or when a specific machine is being claimed (as in *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557 (*>*en*< *banc*). 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.

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: (A) that the claim(s) set forth the subject matter applicants regard as the invention, and (B) that the claim(s) particularly point out and distinctly claim the invention. An application will be deficient under 35 U.S.C. 112, second paragraph when (A) 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 (B) 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:

(A) adequate written description,

(B) enablement, and

(C) 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. *Fonar Corp. v. General Electric Co.*, 107 F.3d 1543, 1548-49, 41 USPQ2d 1801, 1804 (Fed. Cir. 1997).

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). *In re Dossel*, 115 F.3d 942, 946, 42 USPQ2d 1881, 1884 (Fed. Cir. 1997).

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. *Atmel Corp. v. Information Storage Devices Inc., 198 F.3d 1374, 1380, 53 USPQ2d 1225, 1229 (Fed. Cir. 1999); B. Braun Medical, Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424, 43 USPQ2d 1896, 1899 (Fed. Cir. 1997). 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. *Dossel*, 115 F.3d at 946-47, 42 USPQ2d at 1884-85. 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. *B. Braun Medical*, 124 F.3d at 1424, 43 USPQ2d at 1899. 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) (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. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997); *Hyatt v. Boone*, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998). 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. Software aspects of inventions may be described functionally. See *Robotic Vision Sys. v. View Eng'g, Inc.*, 112 F.3d 1163, 1166, 42 USPQ2d 1619, 1622-23 (Fed. Cir. 1997); *Fonar Corp. v. General Electric Co.*, 107 F.3d 1543, 1549, 41 USPQ2d 1801, 1805 (Fed. Cir. 1997); *In re Hayes Microcomputer Prods., Inc.*, 982 F.2d 1527, 1537-38, 25 USPQ2d 1241, 1248-49 (Fed. Cir. 1992). See MPEP § 2163 for further guidance with respect to the evaluation of a patent application for compliance with the written description requirement.

2. Enabling Disclosure

An applicant's specification must enable a person skilled in the art to make and use the claimed invention without undue experimentation. The fact that experimentation is complex, however, will not make it undue if a person of skill in the art typically engages in such complex experimentation. 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., *Dossel*, 115 F.3d at 946-47, 42 USPQ2d at 1884-85; *Northern Telecom v. Datapoint Corp.*, 908 F.2d 931, 941-43, 15 USPQ2d 1321, 1328-30 (Fed. Cir.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, 179 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. Moreover, merely using a computer to automate a known process does not by itself impart nonobviousness to the invention. See >*In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958). See also< *Dann v. Johnston*, 425 U.S. 219, 227-30, 189 USPQ 257, 261 (1976) **.

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 paragraphs IV.B.1(a) and IV. B.1(b). 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. *In re Dembiczak*, 175 F.3d 994, 1000, 50 USPQ2d 1614, 1618 (Fed. Cir. 1999). Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. *In re Ngai*, **>367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004) (combining printed instructions and an old product into a kit will not render the claimed invention nonobvious even if the instructions detail a new use for the product).< 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.

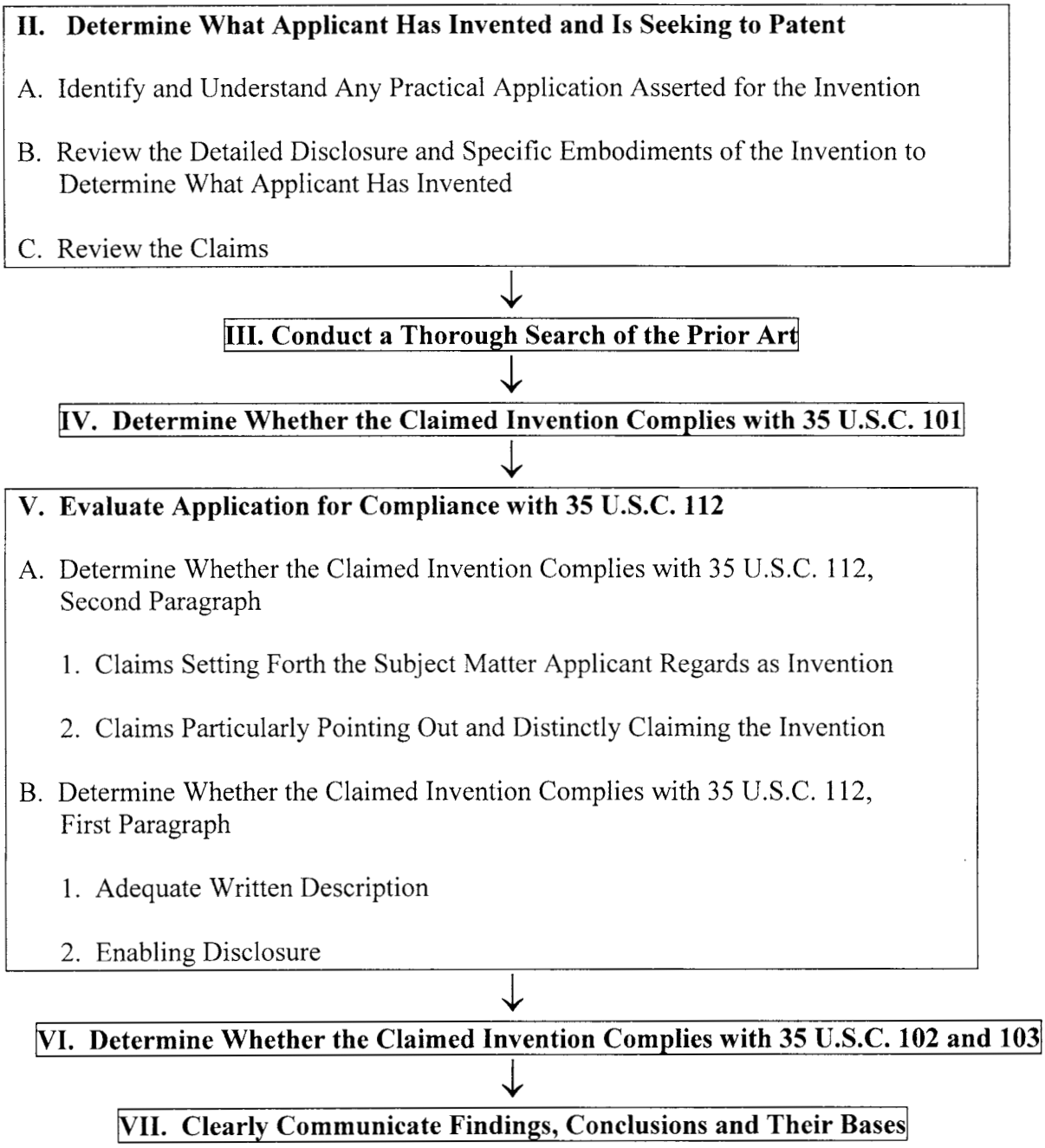
Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the claimed invention is simply a rearrangement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

Computer-Related Inventions



A-1

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

The requirements for sufficient disclosure of inventions involving computer programming *>are< 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.

>

I. < 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*, 591 F.2d 693, 700-01, 200 USPQ 711, 717 (CCPA 1979) and further reiterated in *In re Kaslow*, 707 F.2d 1366, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir. 1983). See also MPEP § 2163 - § 2163.04.

>

II. < BEST MODE

The purpose of the best mode requirement is to "restrain inventors from applying for patents while at the same time concealing from the public the preferred embodiments of their inventions which they have in fact conceived," *In re Gay*, 309 F.2d 769, 772, 135 USPQ 311, 315 (CCPA 1962); "only evidence of concealment + (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 disclosure is so poor as to effectively result in concealment." *In re Sherwood*, 613 F.2d 809, 816-817, 204 USPQ 537, 544 (CCPA 1980). Also, see *White Consol. Indus. v. Vega Servo-Control Inc.*, 214 USPQ 796, 824 (S.D. Mich. 1982), *aff'd on related grounds*, 713 F.2d 788, 218 USPQ 961 (Fed. Cir. 1983). See also MPEP § 2165 - § 2165.04.

There are two factual inquiries to be made in determining whether a specification satisfies the best mode requirement. First, there must be a subjective determination as to whether at the time the application was filed, the inventor knew of a best mode of practicing the invention. Second, if the inventor had a best mode of practicing the invention, 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.*, 107 F.3d 1543, 41 USPQ2d 1801, 1804 (Fed. Cir. 1997); *Chemcast Corp. v. Arco Industries*, 913 F.2d 923, 927-28, 16 USPQ2d 1033, 1036 (Fed. Cir. 1990). "As a general rule, where software constitutes part of a best mode of carrying out an invention, description of such a best mode is satisfied by a disclosure of the functions of the software. This is because, normally, writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed. . . . [F]low charts or source code listings are not a requirement for adequately disclosing the functions of software." *Fonar Corp.*, 107 F.3d at 1549, 41 USPQ2d at 1805 (citations omitted).

>

III. < 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 or she 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*, 477 F.2d 946, 177 USPQ 691 (CCPA 1973); *In re Ghiron*, 442 F.2d 985, 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*, 482 F.2d 1385, 1392, 179 USPQ 227, 232 (CCPA 1973); *In re Scarbrough*, 500 F.2d 560, 566, 182 USPQ 298, 302 (CCPA 1974); *In re Ghiron, supra*. See also MPEP § 2106, paragraph V.B.2 and § 2164 - § 2164.08(c).

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 applications, it is not unusual for the claimed invention to involve two areas of prior art or more than one technology, e.g., an appropriately programmed computer and an area of application of said computer. *White Consol. Indus.*, 214 USPQ at 821. In regard to the "skilled in the art" standard, in cases involving both the art of computer programming, and another technology, the examiner must recognize that the knowledge of persons skilled in both technologies is the appropriate criteria for determining sufficiency. See *In re Naquin*, 398 F.2d 863, 158 USPQ 317 (CCPA 1968); *In re Brown*, 477 F.2d 946, 177 USPQ 691 (CCPA 1973); and *White Consol. Indus. v. Vega Servo-Control, Inc.*, 214 USPQ 796, 822 (S.D.Mich. 1982), *aff'd on related grounds*, 713 F.2d 788, 218 USPQ 961 (Fed. Cir. 1983).

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

BLOCK ELEMENTS MORE COMPREHENSIVE THAN A COMPUTER

The first category of such block diagram cases involves systems which include a computer as well as other system hardware and/or software components. In order to meet his or her burden of establishing a reasonable basis for questioning the adequacy of such disclosure, the examiner should initiate a factual analysis of the system by focusing on each of the individual block element components. More specifically, such an inquiry should focus on the diverse functions attributed to each block element as well as the teachings in the specification as to how such a component could be implemented. If based on such an analysis, the examiner can reasonably contend that more than routine experimentation would be required by one of ordinary skill in the art to implement such a component or components, that component or components should specifically be challenged by the examiner as part of a 35 U.S.C. 112, first paragraph rejection. Additionally, the examiner should determine whether certain of the hardware or software components depicted as block elements are themselves complex assemblages which have widely differing characteristics and which must be precisely coordinated with other complex assemblages. Under such circumstances, a reasonable basis may exist for challenging such a functional block diagram form of disclosure. See *In re Ghiron*, 442 F.2d 985, 169 USPQ 723 (CCPA 1971) and *In re Brown, supra*. Moreover, even if the applicant has cited prior art patents or publications to demonstrate that particular block diagram hardware or software components are old, it should not always be considered as self-evident how such components are to be interconnected to function in a disclosed complex manner. See *In re Scarbrough*, 500 F.2d 560, 566, 182 USPQ 298, 301 (CCPA 1974) and *In re Forman*, 463 F.2d 1125, 1129, 175 USPQ 12, 16 (CCPA 1972). Furthermore, in complex systems including a digital computer, a microprocessor, or a complex control unit as one of many block diagram elements, timing between various system elements may be of the essence and without a timing chart relating the timed sequences for each element, an unreasonable amount of work may be required to come up with the detailed relationships an applicant alleges that he or she has solved. See *In re Scarbrough*, 500 F.2d at 566, 182 USPQ at 302.

For example, in a block diagram disclosure of a complex claimed system which includes a microprocessor and other system components controlled by the microprocessor, a mere reference to a prior art,

commercially available microprocessor, without any description of the precise operations to be performed by the microprocessor, fails to disclose how such a microprocessor would be properly programmed to either perform any required calculations or to coordinate the other system components in the proper timed sequence to perform the functions disclosed and claimed. If, in such a system, a particular program is disclosed, such a program should be carefully reviewed to ensure that its scope is commensurate with the scope of the functions attributed to such a program in the claims. See *In re Brown,* 477 F.2d at 951, 177 USPQ at 695. If the disclosure fails to disclose any program and if more than routine experimentation would be required of one skilled in the art to generate such a program, the examiner clearly would have a reasonable basis for challenging the sufficiency of such a disclosure. The amount of experimentation that is considered routine will vary depending on the facts and circumstances of individual cases. No exact numerical standard has been fixed by the courts, but the "amount of required experimentation must, however, be reasonable." *White Consol. Indus.*, 713 F.2d at 791, 218 USPQ at 963. One court apparently found that the amount of experimentation involved was reasonable where a skilled programmer was able to write a general computer program, implementing an embodiment form, within 4 hours. *Hirschfield v. Banner*, 462 F. Supp. 135, 142, 200 USPQ 276, 279 (D.D.C. 1978), *aff'd*, 615 F.2d 1368 (D.C. Cir. 1986), *cert. denied*, 450 U.S. 994 (1981). 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 1 to 2 man years, this would be "a clearly unreasonable requirement" (*White Consol. Indus.*, 713 F.2d at 791, 218 USPQ 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*, 481 F.2d 1357, 178 USPQ 486 (CCPA 1973), *In re Comstock*, 481 F.2d 905, 178 USPQ 616 (CCPA 1973). Most significantly, however, in both the *Comstock* and *Knowlton* cases, the decisions turned on the appellants' disclosure of (A) a reference to and reliance on an identified prior art computer system and (B) an operative computer program for the referenced prior art computer system. Moreover, in *Knowlton* the disclosure was presented in such a detailed fashion that the individual program's steps were specifically interrelated with the operative structural elements in the referenced prior art computer system. The court in *Knowlton* indicated that the disclosure did not merely consist of a sketchy explanation of flow diagrams or a bare group of program listings together with a reference to a proprietary computer in which they might be run. The disclosure was characterized as going into considerable detail in explaining the interrelationships between the disclosed hardware and software elements. Under such circumstances, the Court considered the disclosure to be concise as well as full, clear, and exact to a sufficient degree to satisfy the literal language of 35 U.S.C. 112, first paragraph. It must be emphasized that because of the significance of the program listing and the reference to and reliance on an identified prior art computer system, absent either of these items, a block element disclosure within the confines of a computer should be scrutinized in precisely the same manner as the first category of block diagram cases discussed above.

Regardless of whether a disclosure involves block elements more comprehensive than a computer or block elements totally within the confines of a computer, 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 a 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*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971) and *In re Gunn*, 537 F.2d 1123, 1128, 190 USPQ 402, 406 (CCPA 1976). When 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 chal-

lenge 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 application will not be sustained on appeal. See *In re Naquin, supra,* and *In re Morehouse,* 545 F.2d 162, 165-66, 192 USPQ 29, 32 (CCPA 1976).

While no specific universally applicable rule exists for recognizing an insufficiently disclosed application involving computer programs, an examining guideline to generally follow is to challenge the sufficiency of such disclosures which fail to include either the computer program itself or a reasonably detailed flowchart which delineates the sequence of operations the program must perform. In programming applications 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,* 484 F.2d 1395, 179 USPQ 286 (CCPA 1973), illustrates the extent of the inquiry into the factual basis underlying an affiant's conclusions or opinions. In *Brandstadter*, the invention concerned a stored program controller (computer) programmed to control the storing, retrieving, and forwarding of messages in a communications system. The disclosure consisted of broadly defined block diagrams of the structure of the invention and no flowcharts or program listings of the programs of the controller. The Court quoted extensively from the Examiner's Office Actions and Examiner's Answer in its opinion where it was apparent that the Examiner consistently argued that the disclosure was merely a broad system diagram in the form of labelled block diagrams along with statements of a myriad of desired results. Various affidavits were presented in which the affiants stated that all or some of the system circuit elements in the block diagrams were either well-known in the art or "could be constructed" by the skilled design engineer, that the controller was "capable of being programmed" to perform the stated functions or results desired, and that the routineer in the art "could design or construct or was able to program" the system. The Court did consider the affiants' statements as being some evidence on the ultimate legal question of enablement but concluded that the

statements failed in their purpose since they recited conclusions or opinions with few facts to support or buttress these conclusions. With reference to the lack of a disclosed computer program or even a flowchart of the program to control the message switching system, the record contained no evidence as to the number of programmers needed, the number of man-hours and the level of skill of the programmers to produce the program required to practice the invention.

It should be noted also that it is not opinion evidence directed to the ultimate legal question of enablement, but rather factual evidence directed to the amount of time and effort and level of knowledge required for the practice of the invention from the disclosure alone which can be expected to rebut a *prima faci*e case of nonenablement. See *Hirschfield*, 462 F. Supp. at 143, 200 USPQ at 281. It has also been held that where an inventor described the problem to be solved to an affiant, thus enabling the affiant to generate a computer program to solve the problem, such an affidavit failed to demonstrate that the application alone would have taught a person of ordinary skill in the art how to make and use the claimed invention. See *In re Brown*, 477 F.2d at 951, 177 USPQ at 695. The Court indicated that it was not factually established that the applicant did not convey to the affiant vital and additional information in their several meetings in addition to that set out in the application. Also of significance for an affidavit to be relevant to the determination of enablement is that it must be probative of the level of skill of the routineer in the art as of the time the applicant filed his application. See *In re Gunn*, 537 F.2d at 1128, 190 USPQ 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*, 463 F.2d at 1129, 175 USPQ 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*, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976). An analogous point was made in *In re Gunn, supra*, where the court indicated that patents issued after the filing date of the 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*, 560 F.2d at 565, 182 USPQ 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 patents provide better detail of disclosure as to such components than an applicant's own disclosure. Also any patent or publication cited to provide evidence that a particular programming technique is well-known in the programming art does not demonstrate that one of ordinary skill in the art could make and use correspondingly disclosed programming techniques unless both programming techniques are of approximately the same degree of complexity. See *In re*

Knowlton, 500 F.2d 566, 572, 183 USPQ 33, 37 (CCPA 1974).

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*, 537 F.2d at 538, 190 USPQ at 424; *In re Schulze*, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); *In re Cole*, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See *In re Knowlton*, 500 F.2d at 572, 183 USPQ at 37; *In re Wiseman*, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979).

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

I. INTRODUCTION

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

II. EXAMINATION GUIDELINES FOR THE UTILITY REQUIREMENT

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

(A) Read the claims and the supporting written description.

(1) Determine what the applicant has claimed, noting any specific embodiments of the invention.

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

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

(B) Review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible:

(1) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.

(i) A claimed invention must have a specific and substantial utility. This requirement excludes "throw-away," "insubstantial," or "nonspecific" utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. 101.

(ii) Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of

the applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.

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

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

(i) Explicitly identify a specific and substantial utility for the claimed invention; and

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

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

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

(i) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;

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

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

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

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

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

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

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

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

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

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

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

2107.01 General Principles Governing Utility Rejections [R-3]

35 U.S.C. 101. Inventions patentable

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

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

The Office must examine each application to ensure compliance with the "useful invention" or utility requirement of 35 U.S.C. 101. In discharging this obligation, however, Office personnel must keep in mind several general principles that control application of the utility requirement. As interpreted by the Federal courts, 35 U.S.C. 101 has 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 invention is "useful." This can occur when an applicant fails to identify any specific and substantial utility for the invention or fails to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966); *In re Ziegler*, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993). The second type of deficiency arises in the rare instance where an assertion of specific and substantial utility for the invention made by an applicant is not credible.

I. SPECIFIC AND SUBSTANTIAL REQUIREMENTS

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

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

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

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

>

A. < Specific Utility

A "specific utility" is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. Similarly, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. Assertions that fall in the former category are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear that a "useful" invention may arise from what has been disclosed by the applicant. *Knapp v. Anderson*, 477 F.2d 588, 177 USPQ 688 (CCPA 1973).

>

B. < Substantial Utility

A "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

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

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

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

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

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

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

C. < Research Tools

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

II. WHOLLY INOPERATIVE INVENTIONS; "INCREDIBLE" UTILITY

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

Situations where an invention is found to be "inoperative" and therefore lacking in utility are rare, and rejections maintained solely on this ground by a Federal court even rarer. In many of these cases, the utility asserted by the applicant was thought to be "incredible in the light of the knowledge of the art, or factually misleading" when initially considered by the Office. *In re Citron*, 325 F.2d 248, 253, 139 USPQ 516, 520 (CCPA 1963). Other cases suggest that on initial evaluation, the Office considered the asserted

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

III. THERAPEUTIC OR PHARMACOLOGICAL UTILITY

Inventions asserted to have utility in the treatment of human or animal disorders are subject to the same legal requirements for utility as inventions in any other field of technology. *In re Chilowsky*, 229 F.2d 457, 461-2, 108 USPQ 321, 325 (CCPA 1956) ("There appears to be no basis in the statutes or decisions for requiring any more conclusive evidence of operativeness in one type of case than another. The character and amount of evidence needed may vary, depending on whether the alleged operation described in the application appears to accord with or to contravene established scientific principles or to depend upon principles alleged but not generally recognized, but the degree of certainty as to the ultimate fact of operativeness or inoperativeness should be the same in all cases"); *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967) ("Thus, in the usual case where the mode of operation alleged can be readily understood and conforms to the known laws of physics and chemistry, operativeness is not questioned, and no further evidence is required."). As such, pharmacological or therapeutic inventions that provide any "immediate benefit to the public" satisfy 35 U.S.C. 101. The utility being asserted in *Nelson* related to a compound with pharmacological utility. *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980). Office personnel should rely on *Nelson* and other cases as providing general guidance when evaluating the utility of an invention that is based on any therapeutic, prophylactic, or pharmacological activities of that invention.

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

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

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

In *Nelson v. Bowler*, the court addressed the practical utility requirement in the context of an interference proceeding. Bowler challenged the patentability of the invention claimed by Nelson on the basis that Nelson had failed to sufficiently and persuasively disclose in his application a practical utility for the invention. Nelson had developed and claimed a class of synthetic prostaglandins modeled on naturally

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

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

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

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

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

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

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

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

162 USPQ 594 (CCPA 1969); *In re Watson*, 517 F.2d 465, 186 USPQ 11 (CCPA 1975).

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

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

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

A deficiency under 35 U.S.C. 101 also creates a deficiency under 35 U.S.C. 112, first paragraph. See *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995); *In re Jolles*, 628 F.2d 1322, 1326 n.10, 206 USPQ 885, 889 n.11 (CCPA 1980); *In re Fouche*, 439 F.2d 1237, 1243, 169 USPQ 429, 434 (CCPA 1971) ("If such compositions are in fact useless, appellant's specification cannot have taught how to use them."). Courts have also cast the 35 U.S.C. 101/35 U.S.C. 112 relationship such that 35 U.S.C. 112 presupposes compliance with 35 U.S.C. 101. See *In re Ziegler*, 992 F.2d 1197, 1200-1201, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993) ("The how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. 101 that the specification disclose as a matter of fact a practical utility for the invention. ... If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112."); *In re Kirk*, 376 F.2d 936, 942, 153 USPQ 48, 53 (CCPA 1967) ("Necessarily, compliance with § 112 requires a description of how to use presently useful inventions, otherwise an applicant would anomalously be required to teach how to use a useless invention."). For example, the Federal Circuit noted, "[o]bviously, if a claimed invention does not have utility, the specification cannot enable one to use it." *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). As such, a rejection properly imposed under 35 U.S.C. 101 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 Indus. Corp.*, 913 F.2d 923, 927-928, 16 USPQ2d 1033, 1036-1037 (Fed. Cir. 1990)). See also *Transco Products Inc. v. Performance Contracting Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994); *Glaxo Inc. v. Novopharm Ltd.* 52 F.3d 1043, 34 USPQ2d 1565 (Fed. Cir. 1995). The fact that an applicant has disclosed a specific utility for an invention and provided a credible basis supporting that specific utility does not provide a basis for concluding that the claims comply with all the requirements of

35 U.S.C. 112, first paragraph. For example, if an applicant has claimed a process of treating a certain disease condition with a certain compound and provided a credible basis for asserting that the compound is useful in that regard, but to actually practice the invention as claimed a person skilled in the relevant art would have to engage in an undue amount of experimentation, the claim may be defective under 35 U.S.C. 112, but not 35 U.S.C. 101. To avoid confusion during examination, any rejection under 35 U.S.C. 112, first paragraph, based on grounds other than "lack of utility" should be imposed separately from any rejection imposed due to "lack of utility" under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph.

2107.02 Procedural Considerations Related to Rejections for Lack of Utility [R-1]

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

The claimed invention is the focus of the assessment of whether an applicant has satisfied the utility requirement. Each claim (i.e., each "invention"), therefore, must be evaluated on its own merits for compliance with all statutory requirements. Generally speaking, however, a dependent claim will define an invention that has utility if the 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 an identified genus of compounds, and presents a generic claim covering the genus, as a general matter, that claim should be treated as being sufficient under 35 U.S.C. 101. Only where it can be established that other species clearly encompassed by the claim do not have utility should a rejection be imposed on the generic claim. In such cases, the applicant should be encouraged to amend the generic claim so as to exclude the species that lack utility.

It is common and sensible for an applicant to identify several specific utilities for an invention, particularly where the invention is a product (e.g., a machine, an article of manufacture or a composition of matter). However, regardless of the category of invention that is claimed (e.g., product or process), an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112; additional statements of utility, even if not "credible," do not render the claimed invention lacking in utility. See, e.g., *Raytheon v. Roper*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. 101 is clearly shown."); *In re Gottlieb*, 328 F.2d 1016, 1019, 140 USPQ 665, 668 (CCPA 1964) ("Having found that the antibiotic is useful for some purpose, it becomes unnecessary to decide whether it is in fact useful for the other purposes 'indicated' in the specification as possibly useful."); *In re Malachowski*, 530 F.2d 1402, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988). Thus, if applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established.

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

and raise issues not relevant to examination of that claim.

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

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

A. An Asserted Utility Must Be Specific and Substantial

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

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

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

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

Occasionally, an applicant will not explicitly state in the specification or otherwise assert a specific and substantial utility for the claimed invention. If no statements can be found asserting a specific and substantial utility for the claimed invention in the specification, Office personnel should determine if the claimed invention has a well-established utility. An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible. If an invention has a well-established utility, rejections under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph, based on lack of utility should not be imposed. *In re Folkers*, 344 F.2d 970, 145 USPQ 390 (CCPA 1965). For example, if an application teaches the cloning and characterization of the nucleotide sequence of a well-known protein such as insulin, and those skilled in the art at the time of filing knew that insulin had a well-established use, it would be improper to reject the claimed invention as

lacking utility solely because of the omitted statement of specific and substantial utility.

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

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

III. EVALUATING THE CREDIBILITY OF AN ASSERTED UTILITY

A. An Asserted Utility Creates a Presumption of Utility

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

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

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

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

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

Compliance with 35 U.S.C. 101 is a question of fact. *Raytheon v. Roper*, 724 F.2d 951, 956, 220 USPQ 592, 596 (Fed. Cir. 1983) *cert. denied*, 469 U.S. 835 (1984). Thus, to overcome the presumption of truth that an assertion of utility by the applicant

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

B. When Is an Asserted Utility Not Credible?

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

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

Rejections under 35 U.S.C. 101 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.

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

To properly reject a claimed invention under 35 U.S.C. 101, the Office must (A) make a *prima*

facie showing that the claimed invention lacks utility, and (B) provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing. *In re Gaubert*, 524 F.2d 1222, 1224, 187 USPQ 664, 666 (CCPA 1975) ("Accordingly, the PTO must do more than merely question operability - it must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability."). If the Office cannot develop a proper *prima facie* case and provide evidentiary support for a rejection under 35 U.S.C. 101, a rejection on this ground should not be imposed. See, e.g., *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) ("[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.... If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent."). See also *Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 USPQ 848 (Fed. Cir. 1985) (applying *prima facie* case law to 35 U.S.C. 101); *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984).

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

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

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

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

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

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

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

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

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

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

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

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

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

In appropriate situations the Office may require an applicant to substantiate an asserted utility for a claimed invention. See *In re Pottier*, 376 F.2d 328, 330, 153 USPQ 407, 408 (CCPA 1967) ("When the operativeness of any process would be deemed unlikely by one of ordinary skill in the art, it is not

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

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

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

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

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

VII. EVALUATION OF EVIDENCE RELATED TO UTILITY

There is no predetermined amount or character of evidence that must be provided by an applicant to support an asserted utility, therapeutic or otherwise. Rather, the character and amount of evidence needed to support an asserted utility will vary depending on what is claimed (*Ex parte Ferguson*, 117 USPQ 229 (Bd. App. 1957)), and whether the asserted utility appears to contravene established scientific principles and beliefs. *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967); *In re Chilowsky*, 229 F.2d 457, 462, 108 USPQ 321, 325 (CCPA 1956). Furthermore, the applicant does not have to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt." *In re Irons*, 340 F.2d 974, 978, 144 USPQ 351, 354 (CCPA 1965). Nor must an applicant provide evidence such that it establishes an asserted utility as a matter of statistical certainty. *Nelson v. Bowler*, 626 F.2d 853, 856-57, 206 USPQ 881, 883-84 (CCPA 1980) (reversing the Board and rejecting Bowler's arguments that the evidence of utility was statistically insignificant. The court pointed out that a rigorous correlation is not necessary when the test is reasonably predictive of the response). See also *Rey-Bellet v. Englehardt*, 493 F.2d 1380, 181 USPQ 453 (CCPA 1974) (data from animal testing is relevant to asserted human therapeutic utility if there is a "satisfactory correlation between the effect on the animal and that ultimately observed in human beings"). Instead, evidence will be sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true.

2107.03 Special Considerations for Asserted Therapeutic or Pharmacological Utilities

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

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

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

II. STRUCTURAL SIMILARITY TO COMPOUNDS WITH ESTABLISHED UTILITY

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

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

If reasonably correlated to the particular therapeutic or pharmacological utility, data generated using *in vitro* assays, or from testing in an animal model or a combination thereof almost invariably will be sufficient to establish therapeutic or pharmacological utility for a compound, composition or process. A cursory review of cases involving therapeutic inventions where 35 U.S.C. 101 was the dispositive issue illustrates the fact that the Federal courts are not particularly receptive to rejections under 35 U.S.C. 101 based on inoperability. Most striking is the fact that in those cases where an applicant supplied a reasonable evidentiary showing supporting an asserted therapeutic utility, almost uniformly the 35 U.S.C. 101-based rejection was reversed. See, e.g., *In re Brana*, 51 F.3d 1560, 34 USPQ 1436 (Fed. Cir. 1995); *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980); *In re Malachowski*, 530 F.2d 1402, 189 USPQ 432 (CCPA 1976); *In re Gaubert*, 530 F.2d 1402, 189 USPQ 432 (CCPA 1975); *In re Gazave*, 379 F.2d 973, 154 USPQ 92 (CCPA 1967); *In re Hartop*, 311 F.2d 249, 135 USPQ 419 (CCPA 1962); *In re Krimmel*, 292 F.2d 948, 130 USPQ 215 (CCPA 1961). Only in those cases where the applicant was unable to come forward with any relevant evidence to rebut a finding by the Office that the claimed invention was inoperative was a 35 U.S.C. 101 rejection affirmed by the court. *In re Citron*, 325 F.2d 248, 253, 139 USPQ 516, 520 (CCPA 1963) (therapeutic utility for an uncharacterized biological extract not supported or scientifically credible); *In re Buting*, 418 F.2d 540, 543, 163 USPQ 689, 690 (CCPA 1969) (record did not establish a credible basis for the assertion that the single class of compounds in question would be useful in treating disparate types of cancers); *In re Novak*, 306 F.2d 924, 134 USPQ 335 (CCPA 1962) (claimed compounds did not have capacity to effect physiological activity upon which utility claim based). Contrast, however, *In re Buting* to *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973), *reh'g denied*, 480 F.2d 879 (CCPA 1973), in which the court held that utility for a genus was found to be supported through a showing of utility for one species. In no case has a Federal court required an applicant to support an asserted utility with data from human clinical trials.

If an applicant provides data, whether from *in vitro* assays or animal tests or both, to support an asserted utility, and an explanation of why that data supports the asserted utility, the Office will determine if the data and the explanation would be viewed by one skilled in the art as being reasonably predictive of the asserted utility. See, e.g., *Ex parte Maas*, 9 USPQ2d 1746 (Bd. Pat. App. & Inter. 1987); *Ex parte Balzarini*, 21 USPQ2d 1892 (Bd. Pat. App. & Inter. 1991). Office personnel must be careful to evaluate all factors that might influence the conclusions of a person of ordinary skill in the art as to this question, including the test parameters, choice of animal, relationship of the activity to the particular disorder to be treated, characteristics of the compound or composition, relative significance of the data provided and, most importantly, the explanation offered by the applicant as to why the information provided is believed to support the asserted utility. If the data

supplied is consistent with the asserted utility, the Office cannot maintain a rejection under 35 U.S.C. 101.

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

IV. HUMAN CLINICAL DATA

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

V. SAFETY AND EFFICACY CONSIDERATIONS

The Office must confine its review of patent applications to the statutory requirements of the patent law. Other agencies of the government have been assigned the responsibility of ensuring conformance to standards established by statute for the advertisement, use, sale or distribution of drugs. The FDA pursues a two-prong test to provide approval for testing. Under that test, a sponsor must show that the investigation does not pose an unreasonable and significant risk of illness or injury and that there is an acceptable rationale for the study. As a review matter, there must be a rationale for believing that the compound could be effective. If the use reviewed by the FDA is not set forth in the specification, FDA review may not satisfy 35 U.S.C. 101. However, if the reviewed use is one set forth in the specification, Office personnel must be extremely hesitant to challenge utility. In such a

situation, experts at the FDA have assessed the rationale for the drug or research study upon which an asserted utility is based and found it satisfactory. Thus, in challenging utility, Office personnel must be able to carry their burden that there is no sound rationale for the asserted utility even though experts designated by Congress to decide the issue have come to an opposite conclusion. "FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws." *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) (citing *Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir. 1994)).

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

VI. TREATMENT OF SPECIFIC DISEASE CONDITIONS

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

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

2111 Claim Interpretation; Broadest Reasonable Interpretation [R-1]

CLAIMS MUST BE GIVEN THEIR BROADEST REASONABLE INTERPRETATION

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

The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999) (The Board's construction of the claim limitation "restore hair growth" as requiring the hair to be returned to its original state was held to be an ** >incorrect< interpretation of the limitation. The court held that, consistent with applicant's disclosure and the disclosure of three patents from analogous arts using the same phrase to require only some increase in hair growth, one of ordinary skill would construe "restore hair growth" to mean that the claimed method increases the amount of hair grown on the scalp, but does not necessarily produce a full head of hair.).

2111.01 Plain Meaning [R-3]

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

While the claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. *In re American Academy of Science Tech Center*, **>367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004)< (The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). 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*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (discussed below); *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004) (Ordinary, simple English words whose meaning is clear and unquestionable, absent any indication that their use in a particular context changes their meaning, are construed to mean exactly what they say. Thus, "heating the resulting batter-coated dough to a temperature in the range of about 400^{o}F to 850^{o}F" required heating the dough, rather than the air inside an oven, to the specified temperature.). 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. See, e.g., *Liebel-Flarsheim Co. v. Medrad Inc.*, 358 F.3d 898, 906, 69 USPQ2d 1801, 1807 (Fed. Cir. 2004)(discussing recent cases wherein the court expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment). 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*, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970). See also *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004) ("Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment."); *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) ("Interpretation of descriptive statements in a patent's written description is a difficult task, as an inherent tension exists as to whether a statement is a clear lexicographic definition or a description of a preferred embodiment. The problem is to interpret claims 'in view of the specification' without unnecessarily importing limitations from the specification into the claims."); *Altiris Inc. v. Symantec Corp.*, 318 F.3d 1363, 1371, 65 USPQ2d 1865, 1869-70 (Fed. Cir. 2003) (Although the specification discussed only a single embodiment, the court held that it was improper to read a specific order of steps into method claims where, as a matter of logic or grammar, the language of the method claims did not impose a specific order on the performance of the method steps, and the specification did not directly or implicitly require a particular order). See also paragraph III., below. 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*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994) (see MPEP § 2181- § 2186).

In *In re Zletz*, *supra*, the examiner and the Board had interpreted claims reading "normally solid polypropylene" and "normally solid polypropylene having a crystalline polypropylene content" as being limited to "normally solid linear high homopolymers of propylene which have a crystalline polypropylene content." The court ruled that limitations, not present in the claims, were improperly imported from the specification. See also *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) ("Claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation'." 710 F.2d at 802, 218 USPQ at 292 (quoting *In re Okuzawa*, 537 F.2d 545, 548, 190 USPQ 464, 466 (CCPA 1976)) (emphasis in original). The court looked to the specification to construe "essentially free of alkali metal" as including unavoidable levels of impurities but no more.). Compare *In re Weiss*, 989 F.2d 1202, 26 USPQ2d 1885 (Fed. Cir. 1993) (unpublished decision - cannot be cited as precedent) (The claim related to an athletic shoe with cleats that "break away at a preselected level of force" and thus prevent injury to the wearer. The examiner rejected the claims over prior art teaching athletic shoes with cleats not intended to break off and rationalized that the cleats would break away given a high enough force. The court reversed the rejection stating that when interpreting a claim term which is ambiguous, such as "a preselected level of force", we must look to the specification for the meaning ascribed to that term by the inventor." The specification had defined "preselected level of force" as that level of force at which the breaking away will prevent injury to the wearer during athletic exertion. It should be noted that the limitation was part of a means plus function element.)

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

**>"[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, __F.3d__, 75 USPQ2d 1321 (Fed. Cir. 2005) (*en banc*).< *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003)("In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art."). It is the use of the words in the context of the written description and customarily by

those skilled in the relevant art that accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims. *Ferguson Beauregard/Logic Controls v. Mega Systems*, 350 F.3d 1327, 1338, 69 USPQ2d 1001, 1009 (Fed. Cir. 2003) (Dictionary definitions were used to determine the ordinary and customary meaning of the words "normal" and "predetermine" to those skilled in the art. In construing claim terms, the general meanings gleaned from reference sources, such as dictionaries, must always be compared against the use of the terms in context, and the intrinsic record must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor.); *ACTV, Inc. v. The Walt Disney Company*, 346 F.3d 1082, 1092, 68 USPQ2d 1516, 1524 (Fed. Cir. 2003) (Since there was no definition given for the term "URL" in the specification, the term should be given its broadest reasonable interpretation and take on the ordinary and customary meaning attributed to it by those of ordinary skill in the art; thus, the term "URL" was held to encompass both relative and absolute URLs.); and *E-Pass Technologies, Inc. v. 3Com Corporation*, 343 F.3d 1364, 1368, 67 USPQ2d 1947, 1949 (Fed. Cir. 2003) (Where no explicit definition for the term "electronic multi-function card" was given in the specification, this term should be given its ordinary meaning and broadest reasonable interpretation; the term should not be limited to the industry standard definition of credit card where there is no suggestion that this definition applies to the electronic multi-function card as claimed, and should not be limited to preferred embodiments in the specification.).

The ordinary and customary meaning of a term may be evidenced by a variety of sources, **>*Phillips v. AWH Corp.*, __F.3d__, 75 USPQ2d 1321 (Fed. Cir. 2005) (*en banc*),< including: the claims themselves, *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999); dictionaries and treatises, *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202, 64 USPQ2d 1812, 1818 (Fed. Cir. 2002); and the written description, the drawings, and the prosecution history, see, e.g., *DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1324, 57 USPQ2d 1889, 1894 (Fed. Cir. 2001). If extrinsic reference sources, such as dictionaries, evidence more than one definition for the term, the intrinsic record must be consulted to identify which of the different possible definitions is most consistent with applicant's use of the terms. *Brookhill-Wilk 1*, 334 F. 3d at 1300, 67 USPQ2d at 1137; see also *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998) ("Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings.") >and *Vitronics Corp. v. Conceptronic Inc.*, 90 F.3d 1576, 1583, 39 USPQ2d 1573, 1577 (Fed. Cir. 1996) (construing the term "solder reflow temperature" to mean "peak reflow temperature" of solder rather than the "liquidus temperature" of solder in order to remain consistent with the specification.)<. If more than one extrinsic definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all consistent meanings. *Tex. Digital*, 308 F.3d at 1203, 64 USPQ2d at 1819. See also *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001)(explaining the court's analytical process for determining the meaning of disputed claim terms); *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)("[W]ords in patent claims are given their ordinary meaning in the usage of the field of the invention, unless the text of the patent makes clear that a word was used with a special meaning."). Compare *MSM Investments Co. v. Carolwood Corp.*, 259 F.3d 1335, 1339-40, 59 USPQ2d 1856, 1859-60 (Fed. Cir. 2001) (Claims directed to a method of feeding an animal a beneficial amount of methylsulfonylmethane (MSM) to enhance the animal's diet were held anticipated by prior oral administration of MSM to human patients to relieve pain. Although the ordinary meaning of "feeding" is limited to provision of food or nourishment, the broad definition of "food" in the written description warranted finding that the claimed method encompasses the use of MSM for both nutritional and pharmacological purposes.); and *Rapoport v. Dement*, 254 F.3d 1053, 1059-60, 59 USPQ2d 1215, 1219-20 (Fed. Cir. 2001) (Both intrinsic evidence and the plain meaning of the term "method for treatment of sleep apneas" supported construction of the term as being limited to treatment of the underlying sleep apnea disorder itself, and not encompassing

treatment of anxiety and other secondary symptoms related to sleep apnea.).

Furthermore, the specification must be reviewed to determine "whether the presumption of ordinary and customary meaning is rebutted." *Tex. Digital*, 308 F.3d at 1204. "The presumption will be overcome where the patentee, acting as his own lexicographer, has set forth a definition for the term different from its ordinary and customary meaning or where the patentee has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *International Rectifier Corp. v. IXYS Corp*., 361 F.3d 1363, 1368, 70 USPQ2d 1209, 1214 (Fed. Cir. 2004). >In *Astrazeneca AB v. Mutual Pharm. Co.*, 384 F.3d 1333, 1339-40, 72 USPQ2d 1726, 1730-31 (Fed. Cir. 2004), the court found deliberate lexicography in the specification limiting the scope of the claim term "solubilizer" to surfactants because there was a clear disavowal of nonsurfactant solubilizers in the specification. In contrast, the court held in *W.E. Hall Co. v. Atlanta Corrugating LLC*, 370 F.3d 1343, 1350-53, 71 USPQ2d 1135, 1140-42 (Fed. Cir. 2004), that the claim terms "open channels" and "single piece construction" were properly assigned their ordinary and customary meanings because patentee did not act as his own lexicographer and the prosecution history and written description were ambiguous as to whether the terms were used in a manner inconsistent with their ordinary and customary meanings. In *Innova/ Pure Water Inc. v. Safari Water Filtration Sys. Inc.*, 381 F.3d 1111, 1117-20, 72 USPQ2d 1001, 1006-08 (Fed. Cir. 2004), the court noted that the disputed claim term "operatively connected" is "a general descriptive claim term frequently used in patent drafting to reflect a functional relationship between claimed components," and that the intrinsic record showed that the patentee did not act as his own lexicographer to redefine "operatively connected" to be limited to only embodiments in which a filter tube and cap were tenaciously physically engaged. In the patent claim at issue, "subject to any clear and unmistakable disavowal of claim scope, the term 'operatively connected' takes the full breath of its ordinary meaning, i.e., 'said tube [is] operatively connected to said cap' when the tube and cap are arranged in a manner capable of performing the function of filtering." *Id.*< See also paragraph III., below.

III. APPLICANT MAY BE OWN LEXICOGRAPHER

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

terms to justify the counterintuitive definition of "about." ("When a patentee acts as his own lexicographer in redefining the meaning of particular claim terms away from their ordinary meaning, he must clearly express that intent in the written description.").

See also MPEP § 2173.05(a).<

2111.02 Effect of Preamble [R-3]

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

"[A] claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003)(In considering the effect of the preamble in a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the claims' recitation of a patient or a human "in need" gives life and meaning to the preamble's statement of purpose.). *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) (A preamble reciting "An abrasive article" was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder and the process of making it. The court stated "it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable *inter alia* of use as abrasive grains and a binder is not an 'abrasive article.'" Therefore, the preamble served to further define the structure of the article produced.).
>

I. < PREAMBLE STATEMENTS LIMITING STRUCTURE

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

II. < PREAMBLE STATEMENTS RECITING PURPOSE OR INTENDED USE

The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and

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

During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of no significance to the structure and process of making.); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim did not distinguish over the prior art apparatus). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (anticipation rejection affirmed based on Board's factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant's claim 1 (a dispensing top for dispensing popcorn in a specified manner)) and cases cited therein. See also MPEP § 2112 - § 2112.02.

>However, a "preamble may provide context for claim construction, particularly, where … that preamble's statement of intended use forms the basis for distinguishing the prior art in the patent's prosecution history." *Metabolite Labs., Inc. v. Corp. of Am. Holdings*, 370 F.3d 1354, 1358-62, 71 USPQ2d 1081, 1084-87 (Fed. Cir. 2004). The patent claim at issue was directed to a two-step method for detecting a deficiency of vitamin B_{12} or folic acid, involving (i) assaying a body fluid for an "elevated level" of homocysteine, and (ii) "correlating" an "elevated" level with a vitamin deficiency. 370 F.3d at 1358-59, 71 USPQ2d at 1084. The court stated that the disputed claim term "correlating" can include comparing with either an unelevated level or elevated level, as opposed to only an elevated level because adding the "correlating" step in the claim during prosecution to overcome prior art tied the preamble directly to the

"correlating" step. 370 F.3d at 1362, 71 USPQ2d at 1087. The recitation of the intended use of "detecting" a vitamin deficiency in the preamble rendered the claimed invention a method for "detecting," and, thus, was not limited to detecting "elevated" levels. *Id.*

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

2111.03 Transitional Phrases [R-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. See, e.g., >*Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term 'comprising,' the terms 'containing' and 'mixture' are open-ended.").< *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). >In *Gillette Co. v. Energizer Holdings Inc.*, 405 F.3d 1367, 1371-73, 74 USPQ2d 1586, 1589-91 (Fed. Cir. 2005), the court held that a claim to "a safety razor blade unit comprising a guard, a cap, and a group of first, second, and third blades" encompasses razors with more than three blades because the transitional phrase "comprising" in the preamble and the phrase "group of" are presumptively open-ended. "The word 'comprising' transitioning from the preamble to the body signals that the entire claim is presumptively open-ended." *Id.* In contrast, the court noted the phrase "group consisting of" is a closed term, which is often used in claim drafting to signal a "Markush group" that is by its nature closed. *Id.* The court also emphasized that reference to "first," "second," and "third" blades in the claim was not used to show a serial or numerical limitation but instead was used to distinguish or identify the various members of the group. *Id.*<

The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("consisting of" defined as "closing the claim to the inclusion of materials other than those recited

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

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

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

OTHER TRANSITIONAL PHRASES

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

2111.04 "Adapted to," "Adapted for," "Wherein," and "Whereby" Clauses [R-3]

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

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

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

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

The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact,

arises both in the context of anticipation and obviousness." *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on '*prima facie* obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

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

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

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

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

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

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the

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

See also *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971) (Claim 1 was directed to a parachute canopy having concentric circumferential panels radially separated from each other by radially extending tie lines. The panels were separated "such that the critical velocity of each successively larger panel will be less than the critical velocity of the previous panel, whereby said parachute will sequentially open and thus gradually decelerate." The court found that the claim was anticipated by Menget. Menget taught a parachute having three circumferential panels separated by tie lines. The court upheld the rejection finding that applicant had failed to show that Menget did not possess the functional characteristics of the claims.); *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) (A patent to a pencil for cleaning fingernails was held invalid because a pencil of the same structure for writing was found in the prior art.).

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

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

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

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

2112.02 Process Claims

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

Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device

will inherently perform the claimed process. *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986) (The claims were directed to a method of enhancing color effects produced by ambient light through a process of absorption and reflection of the light off a coated substrate. A prior art reference to *Donley* disclosed a glass substrate coated with silver and metal oxide 200-800 angstroms thick. While Donley disclosed using the coated substrate to produce architectural colors, the absorption and reflection mechanisms of the claimed process were not disclosed. However, King's specification disclosed using a coated substrate of Donley's structure for use in his process. The Federal Circuit upheld the Board's finding that "Donley inherently performs the function disclosed in the method claims on appeal when that device is used in 'normal and usual operation' " and found that a *prima facie* case of anticipation was made out. *Id.* at 138, 801 F.2d at 1326. It was up to applicant to prove that Donley's structure would not perform the claimed method when placed in ambient light.). See also *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) (Applicant claimed a process for preparing a hydrolytically-stable zeolitic aluminosilicate which included a step of "cooling the steam zeolite ... at a rate sufficiently rapid that the cooled zeolite exhibits a X-ray diffraction pattern ...." All the process limitations were expressly disclosed by a U.S. patent to Hansford except the cooling step. The court stated that any sample of Hansford's zeolite would necessarily be cooled to facilitate subsequent handling. Therefore, a *prima facie* case under 35 U.S.C. 102/103 was made. Applicant had failed to introduce any evidence comparing X-ray diffraction patterns showing a difference in cooling rate between the claimed process and that of Hansford or any data showing that the process of Hansford would result in a product with a different X-ray diffraction. Either type of evidence would have rebutted the *prima facie* case under 35 U.S.C. 102. A further analysis would be necessary to determine if the process was unobvious under 35 U.S.C. 103.); *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia.* A U.S. patent to *Dart* disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating.).

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

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

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

>The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.)<

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

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

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

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

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

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

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

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*, 347 F.2d 843, 146 USPQ 211 (CCPA 1965) as implicitly modified by *In re Donaldson*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994). See also *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.).

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

MATERIAL OR ARTICLE WORKED UPON DOES NOT LIMIT APPARATUS CLAIMS

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

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

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

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

2116 Material Manipulated in Process

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

2116.01 Novel, Unobvious Starting Material or End Product [R-2]

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

In re Ochiai, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996) addressed the issue of whether an otherwise conventional process could be patented if it were limited to making or using a nonobvious product. In both cases, the Federal Circuit held that the use of *per se* rules is improper in applying the test for obviousness under 35 U.S.C. 103. Rather, 35 U.S.C. 103 requires a highly fact-dependent analysis involving taking the claimed subject matter as a whole and comparing it to the prior art. >"A process yielding a novel and nonobvious product may nonetheless be obvious; conversely, a process yielding a well-known product may yet be nonobvious." *TorPharm, Inc. v. Ranbaxy Pharmaceuticals, Inc.*, 336 F.3d 1322, 1327, 67 USPQ2d 1511, 1514 (Fed. Cir. 2003).< 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*, 910 F.2d 823, 15 USPQ2d 1738 (Fed. Cir. 1990) (Methods of bonding polymer and filler using a novel silane coupling agent held patentable even though methods of bonding using other silane coupling agents were well known because the process could not be conducted without the new agent); *In re Kuehl*, 475 F.2d 658, 177 USPQ 250 (CCPA 1973) (Process of cracking hydrocarbons using novel zeolite catalyst found to be patentable even though catalytic cracking process was old. "The test under 103 is whether in view of the prior art the invention as a whole would have been obvious at the time it was made, and the prior art here does not include the zeolite, ZK-22. The obviousness of the process of cracking hydrocarbons with ZK-22 as a catalyst must be determined without reference to knowledge of ZK-22 and its properties." 475 F.2d at 664-665, 177 USPQ at 255.); and *In re Mancy*, 499 F.2d 1289, 182 USPQ 303 (CCPA 1974) (Claim to a process for the production of a known antibiotic by cultivating a novel, unobvious microorganism was found to be patentable.).

2121 Prior Art; General Level of Operability Required to Make a *Prima Facie* Case

PRIOR ART IS PRESUMED TO BE OPERABLE/ ENABLING

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

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

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

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

"In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'... ." *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v.*

**>*Mayo Found. For Med. Educ. & Research*<, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003) (At issue was whether a prior art reference enabled one of ordinary skill in the art to produce Elan's claimed transgenic mouse without undue experimentation. Without a disclosure enabling one skilled in the art to produce a transgenic mouse without undue experimentation, the reference would not be applicable as prior art.). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985).

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

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

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

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

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

>

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

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

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

When a prior art reference merely discloses the structure of the claimed compound, evidence showing that attempts to prepare that compound were unsuccessful before the date of invention will be adequate to show inoperability. *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1971). However, the fact that an author of a publication did not attempt to make the compound disclosed, without more, will not overcome a rejection based on that publication. *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985) (In this case, the examiner had made a rejection under 35 U.S.C. 102(b) over a publication, which disclosed the claimed compound, in combination with two patents teaching a general process of making the particular class of compounds. The applicant submitted an affidavit stating that the authors of the publication had not actually synthesized the compound. The court held that the fact that the publication's author

did not synthesize the disclosed compound was immaterial to the question of reference operability. The patents were evidence that synthesis methods were well known. The court distinguished *Wiggins*, in which a very similar rejection was reversed. In *Wiggins*, attempts to make the compounds using the prior art methods were all unsuccessful.). Compare *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968) (A claim to a compound was rejected over a patent to *De Boer* which disclosed compounds similar in structure to those claimed (obvious homologs) and a process of making these compounds. Applicant responded with an affidavit by an expert named Wiley which stated that there was no indication in the *De Boer* patent that the process disclosed in *De Boer* could be used to produce the claimed compound and that he did not believe that the process disclosed in *De Boe*r could be adapted to the production of the claimed compound. The court held that the facts stated in this affidavit were legally sufficient to overcome the rejection and that applicant need not show that all known processes are incapable of producing the claimed compound for this showing would be practically impossible.).

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

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

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

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

2121.04 Apparatus and Articles — What Constitutes Enabling Prior Art

PICTURES MAY CONSTITUTE AN "ENABLING DISCLOSURE"

Pictures and drawings may be sufficiently enabling to put the public in the possession of the article pictured. Therefore, such an enabling picture may be used to reject claims to the article. However, the picture must show all the claimed structural features

and how they are put together. *Jockmus v. Leviton*, 28 F.2d 812 (2d Cir. 1928). See also MPEP § 2125 for a discussion of drawings as prior art.

2122 Discussion of Utility in the Prior Art

UTILITY NEED NOT BE DISCLOSED IN REFERENCE

In order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. *In re Schoenwald*, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992) (The application claimed compounds used in ophthalmic compositions to treat dry eye syndrome. The examiner found a printed publication which disclosed the claimed compound but did not disclose a use for the compound. The court found that the claim was anticipated since the compound and a process of making it was taught by the reference. The court explained that "no utility need be disclosed for a reference to be anticipatory of a claim to an old compound." 964 F.2d at 1124, 22 USPQ2d at 1673. It is enough that the claimed compound is taught by the reference.).

2123 Rejection Over Prior Art's Broad Disclosure Instead of Preferred Embodiments [R-3]

>

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

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

A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.").

>

II. < NONPREFERRED >AND ALTERNATIVE< EMBODIMENTS CONSTITUTE PRIOR ART

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

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

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

In certain circumstances, references cited to show a universal fact need not be available as prior art before applicant's filing date. *In re Wilson*, 311 F.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism. Some specific examples in which later publications showing factual evidence can be cited include situations where the facts shown in the reference are evidence "that, as of an application's filing date, undue experimentation would have been required, *In re Corneil*, 347 F.2d 563, 568, 145 USPQ 702, 705 (CCPA 1965), or that a parameter absent from the claims was or was not critical, *In re Rainer*, 305 F.2d 505, 507 n.3, 134 USPQ 343, 345 n.3 (CCPA 1962), or that a statement in the specification was inaccurate, *In re Marzocchi*, 439 F.2d 220, 223 n.4, 169 USPQ 367, 370 n.4 (CCPA 1971), or that the invention was inoperative or lacked utility, *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974), or that a claim was indefinite, *In re Glass*, 492 F.2d 1228,1232 n.6, 181 USPQ 31, 34 n.6 (CCPA 1974), or that characteristics of prior art products were known, *In re Wilson*, 311 F.2d 266, 135 USPQ 442 (CCPA 1962)." *In re Koller*, 613 F.2d 819, 823 n.5, 204 USPQ 702, 706 n.5 (CCPA 1980) (quoting *In re Hogan*, 559 F.2d 595, 605 n.17, 194 USPQ 527, 537 n.17 (CCPA 1977) (emphasis in original)). However, it is impermissible to use a later factual reference to determine whether the application is enabled or described as required under 35 U.S.C. 112, first paragraph. *In re Koller*, 613 F.2d 819, 823 n. 5, 204 USPQ 702, 706 n.5 (CCPA 1980). References which do not qualify as prior art because they postdate the claimed invention may be relied upon to show the level of ordinary skill in the art at or around the time the invention was made. *Ex parte Erlich*, 22 USPQ 1463 (Bd. Pat. App. & Inter. 1992).

2125 Drawings as Prior Art

DRAWINGS CAN BE USED AS PRIOR ART

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

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

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

by the distance the liquor needs to 'traverse the pores of the wood' (albeit in reference to the thickness of the barrelhead)" would have suggested the desirability of an increased chime length to one of ordinary skill in the art bent on further reducing whiskey losses." 569 F.2d at 1127, 193 USPQ at 335-36.)

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

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

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

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

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

Even if a patent grants an exclusionary right (is enforceable), it is not available as prior art under 35 U.S.C. 102(a) or (b) if it is secret or private. *In re Carlson*, 983 F.2d 1032, 1037, 25 USPQ2d 1207, 1211 (Fed. Cir. 1992). The document must be at least minimally available to the public to constitute prior art. The patent is sufficiently available to the public for the purposes of 35 U.S.C. 102(a) or (b) if it is laid open for public inspection or disseminated in printed form. See, e.g., *In re Carlson,* 938 F.2d at 1037, 25 USPQ2d at 1211 ("We recognize that *Geschmacksmuster* on display for public view in remote cities in a far-away land may create a burden of discovery for one without the time, desire, or resources to journey there in person or by agent to observe that which was registered under German law. Such a burden, however, is by law imposed upon the hypothetical person of ordinary skill in the art who is charged with knowledge of all contents of the relevant prior art."). The date that the patent is made available to the public is the date it is available as a 35 U.S.C. 102(a) or (b) reference. *In re Ekenstam*, 256 F.2d 321, 118 USPQ 349 (CCPA 1958). But a period of secrecy after granting the patent has been held to have no effect in connection with 35 U.S.C. 102(d). These patents are usable in rejections under 35 U.S.C. 102(d) as of the date patent rights are granted. *In re Kathawala,* 9 F.3d 942, 28 USPQ2d 1789 (Fed. Cir. 1993). See MPEP § 2135 - § 2135.01 for more information on 35 U.S.C. 102(d).

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

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

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

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

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

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

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

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

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

2127 Domestic and Foreign Patent Applications as Prior Art [R-2]

I. ABANDONED APPLICATIONS, INCLUDING PROVISIONAL APPLICATIONS

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

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

II. APPLICATIONS WHICH HAVE ISSUED INTO U.S. PATENTS

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

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

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

Laid Open Applications May Constitute "Published" Documents

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

Older cases have held that laid open patent applications are not "published" and cannot constitute prior art. *Ex parte Haller*, 103 USPQ 332 (Bd. App. 1953). However, whether or not a document is "published" for the purposes of 35 U.S.C. 102 and 103 depends on how accessible the document is to the public. As technology has made reproduction of documents easier, the accessibility of the laid open applications has increased. Items provided in easily reproducible form have thus become "printed publications" as the phrase is used in 35 U.S.C. 102. *In re Wyer*, 655 F.2d 221, 226, 210 USPQ 790, 794 (CCPA 1981) (Laid open Australian patent application held to be a "printed publication" even though only the abstract was published because it was laid open for public inspection, microfilmed, "diazo copies" were distributed to five suboffices having suitable reproduction equipment and the diazo copies were available for sale.). The contents of a foreign patent application should not be relied upon as prior art until the date of publication (i.e., the insertion into the laid open application) can be confirmed by an examiner's review of a copy of the document. See MPEP § 901.05.

IV. PENDING U.S. APPLICATIONS

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

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

2128 "Printed Publications" as Prior Art

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

A reference is proven to be a "printed publication" "upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it." *In re Wyer,* 655 F.2d 221, 210 USPQ 790 (CCPA 1981) (quoting *I.C.E. Corp. v. Armco Steel Corp.*, 250 F. Supp. 738, 743, 148 USPQ 537, 540 (SDNY 1966)) ("We agree that 'printed publication' should be approached as a unitary concept. The traditional dichotomy between 'printed' and 'publication' is no longer valid. Given the state of technology in document duplication, data storage, and data retrieval systems, the 'probability of dissemination' of an item very often has little to do with

whether or not it is 'printed' in the sense of that word when it was introduced into the patent statutes in 1836. In any event, interpretation of the words 'printed' and 'publication' to mean 'probability of dissemination' and 'public accessibility' respectively, now seems to render their use in the phrase 'printed publication' somewhat redundant.") *In re Wyer*, 655 F.2d at 226, 210 USPQ at 794.

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

ELECTRONIC PUBLICATIONS AS PRIOR ART

Status as a "Printed Publication"

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

The Office policy requiring recordation of the field of search and search results (see MPEP § 719.05) weighs in favor of finding that Internet and on-line database references cited by the examiner are "accessible to persons concerned with the art to which the document relates and thus most likely to avail themselves of its contents." *Wyer*, 655 F.2d at 221, 210 USPQ at 790. Office copies of an electronic document must be retained if the same document may not be available for retrieval in the future. This is especially important for sources such as the Internet and online databases.

Date of Availability

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

Extent of Teachings Relied Upon

An electronic publication, like any publication, may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art. See MPEP § 2121.01 and § 2123. Note, however, that if an electronic document which is the abstract of a patent or printed publication is relied upon in a rejection under 35 U.S.C. 102 or 103, only the text of the abstract (and not the underlying document) may be relied upon to support the rejection. In situations where the electronic version and the published paper version of the same or a corresponding patent or printed publication differ appreciably, each may need to be cited and relied upon as independent references based on what they disclose.

Internet Usage Policy

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

EXAMINER NEED NOT PROVE ANYONE ACTUALLY LOOKED AT THE DOCUMENT

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

2128.01 Level of Public Accessibility Required [R-3]

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

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

In *In re Hall*, general library cataloging and shelving practices showed that a doctoral thesis deposited in university library would have been indexed, cataloged and shelved and thus available to the public before the critical date. Compare *In re Cronyn*, 890 F.2d 1158, 13 USPQ2d 1070 (Fed. Cir. 1989) wherein doctoral theses were shelved and indexed by index cards filed alphabetically by student name and kept in a shoe box in the chemistry library. The index cards only listed the student name and title of the thesis. Two of three judges held that the students' theses were not accessible to the public. The court reasoned that the theses had not been either cataloged or indexed in a meaningful way since thesis could only be found if the researcher's name was known, but the name bears no relationship to the subject of the thesis. One judge, however, held that the fact that the theses were shelved in the library was enough to make them sufficiently accessible to the public. The nature of the index was not determinative. This judge relied on prior Board decisions (*Gulliksen v. Halberg*, 75 USPQ 252, 257 (Bd. App. 1937) and *Ex parte Hershberger*, 96 USPQ 54, 56 (Bd. App. 1952)), which held that shelving a single copy in a public library makes the work a "printed publication." It should be noted that these Board decisions have not been expressly overruled but have been criticized in other decisions. See *In re Tenney*, 254 F.2d 619, 117 USPQ 348 (CCPA 1958) (concurring opinion by *J.Rich*) (A document, of which there is but one copy, whether it be handwritten, typewritten or on microfilm, may be technically accessible to anyone who can find it. Such a document is not "printed" in the sense that a printing press has been used to reproduce the document. If only technical accessibility were required "logic would require the inclusion within the term [printed] of all unprinted public documents for they are all 'accessible.' While some tribunals have gone quite far in that direction, as in the 'college thesis cases' I feel they have done so unjustifiably and on the wrong theory. Knowledge is not in the possession *of the public* where there has been no dissemination, as distinguished from technical accessibility..." The real significance of the word "printed" is grounded in the "*probability* of wide circulation."). See also *Deep Welding, Inc. v. Sciaky Bros.*, 417 F.2d 1227, 163 USPQ 144 (7th Cir. 1969) (calling the holding of *Ex parte Hershberger* "extreme"). Compare *In re Bayer*, 568 F.2d 1357, 196 USPQ 670 (CCPA 1978) (A reference will constitute a "printed publication" as long as a presumption is raised that the portion of the public concerned with the art would know of the invention even if accessibility is restricted to only this part of the public. But accessibility to applicant's thesis was restricted to only three members of a graduate committee. There can be no presumption that those concerned with the art would have known of the invention in this case.).

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

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

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

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

>

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

A publicly displayed document where persons of ordinary skill in the art could see it and are not precluded from copying it can constitute a "printed publication," even if it is not disseminated by the distribution of reproductions or copies and/or indexed in a library or database. As stated in *In re Klopfenstein*, 380 F.3d 1345, 1348, 72 USPQ2d 1117, 1119 (Fed. Cir. 2004), "the key inquiry is whether or not a reference has been made 'publicly accessible.'" Prior to the critical date, a fourteen-slide presentation disclosing the invention was printed and pasted onto poster boards. The printed slide presentation was displayed with no confidentiality restrictions for approximately three cumulative days at two different industry events. 380 F.3d at 1347, 72 USPQ2d at 1118. The court noted that "an entirely oral presentation that includes neither slides nor copies of the presentation is without question not a 'printed publication' for the purposes of 35 U.S.C. § 102(b). Furthermore, a presentation that includes a transient display of slides is likewise not necessarily a 'printed publication.'" 380 F.3d at 1349 n.4, 72 USPQ2d at 1122 n.4. In resolving whether or not a temporarily displayed reference that was neither distributed nor indexed was nonetheless made sufficiently publicly accessible to count as a "printed publication" under 35 U.S.C. 102(b), the court considered the following factors: "the length of time the display was exhibited, the expertise of the target audience, the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and the simplicity or ease with which the material displayed could have been copied." 380 F.3d at 1350, 72 USPQ2d at 1120. Upon reviewing the above factors, the court concluded that the display "was sufficiently publicly accessible to count as a 'printed publication.'" 380 F.3d at 1352, 72 USPQ2d at 1121.<

2128.02 Date Publication Is Available as a Reference

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

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

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

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

2129 Admissions as Prior Art [R-3]

I. ADMISSIONS BY APPLICANT CONSTITUTE PRIOR ART

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

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

II. DISCUSSION OF PRIOR ART IN SPECIFICATION

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

III. *JEPSON* CLAIMS

Drafting a claim in *Jepson* format (i.e., the format described in 37 CFR 1.75(e); see MPEP § 608.01(m)) is taken as an implied admission that the subject mater of the preamble is the prior art work of another. *In re Fout,* 675 F.2d 297, 301, 213 USPQ 532, 534 (CCPA 1982) (holding preamble of *Jepson*-type claim to be admitted prior art where applicant's specification credited another as the inventor of the subject matter of the preamble). However, this implication may be overcome where applicant gives another credible reason for drafting the claim in *Jepson* format. *In re Ehrreich*, 590 F.2d 902, 909-910, 200 USPQ 504, 510 (CCPA 1979) (holding preamble not to be admitted prior art where applicant explained that the *Jepson*

format was used to avoid a double patenting rejection in a co-pending application and the examiner cited no art showing the subject matter of the preamble). Moreover, where the preamble of a *Jepson* claim describes applicant's own work, such may not be used against the claims. *Reading & Bates Construction Co. v. Baker Energy Resources Corp.*, 748 F.2d 645, 650, 223 USPQ 1168, 1172 (Fed. Cir. 1984); *Ehrreich*, 590 F.2d at 909-910, 200 USPQ at 510.

IV. INFORMATION DISCLOSURE *>STATEMENT< (IDS)

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

2131 Anticipation — Application of 35U.S.C. 102(a), (b), and (e) [R-1] [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 — (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or<

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

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

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

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

use multiple references in a 35 U.S.C. 102 rejection. See MPEP § 2131.01.

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

Normally, only one reference should be used in making a rejection under 35 U.S.C. 102. However, a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:

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

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

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

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

I. TO PROVE REFERENCE CONTAINS AN "ENABLED DISCLOSURE"

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

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

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

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

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

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

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

"To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.,* 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (The court went on to explain that "this modest flexibility in the rule that 'anticipation'

requires that every element of the claims appear in a single reference accommodates situations in which the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." 948 F.2d at 1268, 20 USPQ at 1749-50.). Note that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (Two prior art references disclosed blasting compositions containing water-in-oil emulsions with identical ingredients to those claimed, in overlapping ranges with the claimed composition. The only element of the claims arguably not present in the prior art compositions was "sufficient aeration . . . entrapped to enhance sensitivity to a substantial degree." The Federal Circuit found that the emulsions described in both references would inevitably and inherently have "sufficient aeration" to sensitize the compound in the claimed ranges based on the evidence of record (including test data and expert testimony). This finding of inherency was not defeated by the fact that one of the references taught away from air entrapment or purposeful aeration.). See also *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985). See MPEP § 2112 - § 2112.02 for case law on inherency. Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP § 2124.

2131.02 Genus-Species Situations

A SPECIES WILL ANTICIPATE A CLAIM TO A GENUS

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

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

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

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

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

In *In re Petering*, the prior art disclosed a generic chemical formula "wherein X, Y, Z, P, and R'- represent either hydrogen or alkyl radicals, R a side chain containing an OH group." The court held that this formula, without more, could not anticipate a claim to 7-methyl-9-[d, l'-ribityl]-isoalloxazine because the generic formula encompassed a vast number and perhaps even an infinite number of compounds. However, the reference also disclosed preferred substituents for X, Y, Z, R, and R' as follows: where X, P, and R' are hydrogen, where Y and Z may be hydrogen or methyl, and where R is one of eight specific isoalloxazines. The court determined that this more limited generic class consisted of about 20 compounds. The limited number of compounds covered by the preferred formula in combination with the fact that the number of substituents was low at each site, the ring positions were limited, and there was a large unchanging structural nucleus, resulted in a finding that the reference sufficiently described "each of the various permutations here involved as fully as if he had drawn each structural formula or had written each name." The claimed compound was 1 of these 20 compounds. Therefore, the reference "described" the claimed compound and the reference anticipated the claims.

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

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

2131.03 Anticipation of Ranges [R-2]

>

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

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

containing 0.25% Mo and 0.75% Ni and this composition was within the claimed range of compositions.).
>

II. < PRIOR ART WHICH TEACHES A RANGE 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.
>

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

"[A]nticipation under § 102 can be found only when the reference discloses exactly what is claimed and that where there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account." *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims to titanium (Ti) alloy with 0.8% nickel (Ni) and 0.3% molybdenum (Mo) were not anticipated by, although they were held obvious over, a graph in a Russian article on Ti-Mo-Ni alloys in which the graph contained an actual data point corresponding to a Ti alloy containing 0.25% Mo and 0.75% Ni.).<

2131.04 Secondary Considerations

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

2131.05 Nonanalogous Art [R-2]

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

A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. The question whether a reference "teaches away" from the invention is inapplicable to an anticipation analysis. *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The prior art was held to anticipate the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). See also

Atlas Powder Co. v. IRECO, Inc., 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (Claimed composition was anticipated by prior art reference that inherently met claim limitation of "sufficient aeration" even though reference taught away from air entrapment or purposeful aeration.).

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

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

A person shall be entitled to a patent unless -

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

*****

I. "KNOWN OR USED"

"Known or Used" Means Publicly Known or Used

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

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

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

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

II. "IN THIS COUNTRY"

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

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

III. "BY OTHERS"

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

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

IV. "PATENTED IN THIS OR A FOREIGN COUNTRY"

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

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

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

A *prima facie* case is made out under 35 U.S.C. 102(a) if, within 1 year of the filing date, the invention, or an obvious variant thereof, is described in a "printed publication" whose authorship differs in any way from the inventive entity unless it is stated within

the publication itself that the publication is describing the applicant's work. *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). See MPEP § 2128 for case law on what constitutes a "printed publication." Note that when the reference is a U.S. patent published within the year prior to the application filing date, a 35 U.S.C. 102(e) rejection should be made. See MPEP § 2136 - § 2136.05 for case law dealing with 102(e).

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

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

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

In *Ex parte Kroger*, 219 USPQ 370 (Bd. Pat. App. & Inter. 1982), Kroger, Knaster and others were listed as authors on an article on photovoltaic power generation. The article was used to reject the claims of an application listing Kroger and Rod as inventors. Kroger and Rod submitted affidavits declaring themselves to be the inventors. The affidavits also stated that Knaster merely carried out assignments and worked under the supervision and direction of Kroger. The Board stated that if this were the only evidence in the case, it would be established, under *In re Katz*, that Kroger and Rod were the only inventors. However, in this case, there was evidence that Knaster had refused to sign an affidavit disclaiming inventorship and Knaster had introduced evidence into the case in the form of a letter to the PTO in which he alleged that he was a co-inventor. The Board held that the evidence had not been fully developed enough to overcome the rejection. Note that the rejection had been made under 35 U.S.C. 102(f) but the Board treated the issue the same as if it had arisen under 35 U.S.C. 102(a). See also case law dealing with overcoming 102(e) rejections as presented in MPEP § 2136.05. Many of the issues are the same.

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

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

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

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

A person shall be entitled to a patent unless -

*****

(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 WEEK-END

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

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

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

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

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

2133.02 Rejections Based on Publications and Patents

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

"Any invention described in a printed publication more than one year prior to the date of a patent application is prior art under Section 102(b), even if the printed publication was authored by the patent applicant." *De Graffenried v. United States*, 16 USPQ2d 1321, 1330 n.7 (Cl. Ct. 1990). "Once an inventor has decided to lift the veil of secrecy from his [or her] work, he [or she] must choose between the protection of a federal patent, or the dedication of his [or her] idea to the public at large." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148, 9 USPQ2d 1847, 1851 (1989).

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

A rejection under 35 U.S.C. 102(b) cannot be overcome by affidavits and declarations under 37 CFR

novel antibiotics so produced. *In re Argoudelis*, 434 F.2d 1390, 168 USPQ 99 (CCPA 1970). As stated by the court, "a unique aspect of using microorganisms as starting materials is that a sufficient description of how to obtain the microorganism from nature cannot be given." 434 F.2d at 1392, 168 USPQ at 102. It was determined by the court that availability of the biological product via a public depository provided an acceptable means of meeting the written description and the enablement requirements of 35 U.S.C. 112, first paragraph.

To satisfy the enablement requirement a deposit must be made "prior to issue" but need not be made prior to filing the application. *In re Lundak*, 773 F.2d 1216, 1223, 227 USPQ 90, 95 (Fed. Cir. 1985).

The availability requirement of enablement must also be considered in light of the scope or breadth of the claim limitations. The Board of Appeals considered this issue in an application which claimed a fermentative method using microorganisms belonging to a species. Applicants had identified three novel individual strains of microorganisms that were related in such a way as to establish a new species of microorganism, a species being a broader classification than a strain. The three specific strains had been appropriately deposited. The issue focused on whether the specification enabled one skilled in the art to make any member of the species other than the three strains which had been deposited. The Board concluded that the verbal description of the species was inadequate to allow a skilled artisan to make any and all members of the claimed species. *Ex parte Jackson*, 217 USPQ 804, 806 (Bd. App. 1982).

See MPEP § 2402 - § 2411.03 for a detailed discussion of the deposit rules. See MPEP § 2411.01 for rejections under 35 U.S.C. 112 based on deposit issues.

III. DRUG CASES

See MPEP § 2107 - § 2107.03 for a discussion of the utility requirement under 35 U.S.C. 112, first paragraph, in drug cases.

2164.06(b) Examples of Enablement Issues — Chemical Cases

The following summaries should not be relied on to support a case of lack of enablement without carefully reading the case.

SEVERAL DECISIONS RULING THAT THE DISCLOSURE WAS NONENABLING

(A) In *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999), the court held that claims in two patents directed to genetic antisense technology (which aims to control gene expression in a particular organism), were invalid because the breadth of enablement was not commensurate in scope with the claims. Both specifications disclosed applying antisense technology in regulating three genes in *E. coli*. Despite the limited disclosures, the specifications asserted that the "[t]he practices of this invention are generally applicable with respect to any organism containing genetic material which is capable of being expressed … such as bacteria, yeast, and other cellular organisms." The claims of the patents encompassed application of antisense methodology in a broad range of organisms. Ultimately, the court relied on the fact that (1) the amount of direction presented and the number of working examples provided in the specification were very narrow compared to the wide breadth of the claims at issue, (2) antisense gene technology was highly unpredictable, and (3) the amount of experimentation required to adapt the practice of creating antisense DNA from *E. coli* to other types of cells was quite high, especially in light of the record, which included notable examples of the inventor's own failures to control the expression of other genes in *E. coli* and other types of cells. Thus, the teachings set forth in the specification provided no more than a "plan" or "invitation" for those of skill in the art to experiment using the technology in other types of cells.

(B) In *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993), the 1983 application disclosed a vaccine against the RNA tumor virus known as Prague Avian Sarcoma Virus, a member of the Rous Associated Virus family. Using functional language, Wright claimed a vaccine "comprising an immunologically effective amount" of a viral expression product. *Id.*, at 1559, 27 USPQ2d at 1511. Rejected claims covered all RNA viruses as well as avian RNA viruses. The examiner provided a teaching that in 1988, a vaccine for another retrovirus (i.e., AIDS) remained an intractable problem. This evidence, along with evidence that the RNA viruses were a diverse and complicated genus, convinced the Federal Circuit

that the invention was not enabled for either all retroviruses or even for avian retroviruses.

(C) In *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993), a 1985 application functionally claimed a method of producing protein in plant cells by expressing a foreign gene. The court stated: "[n]aturally, the specification must teach those of skill in the art 'how to make and use the invention as broadly as it is claimed.'" *Id.* at 1050, 29 USPQ2d at 2013. Although protein expression in dicotyledonous plant cells was enabled, the claims covered any plant cell. The examiner provided evidence that even as late as 1987, use of the claimed method in monocot plant cells was not enabled. *Id.* at 1051, 29 USPQ2d at 2014.

(D) In *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991), the court found that several claims were not supported by an enabling disclosure "[t]aking into account the relatively incomplete understanding of the biology of cyanobacteria as of appellants' filing date, as well as the limited disclosure by appellants of the particular cyanobacterial genera operative in the claimed invention...." The claims at issue were not limited to any particular genus or species of cyanobacteria and the specification mentioned nine genera and the working examples employed one species of cyanobacteria.

(E) In *In re Colianni*, 561 F.2d 220, 222-23, 195 USPQ 150, 152 (CCPA 1977), the court affirmed a rejection under 35 U.S.C. 112, first paragraph, because the specification, which was directed to a method of mending a fractured bone by applying "sufficient" ultrasonic energy to the bone, did not define a "sufficient" dosage or teach one of ordinary skill how to select the appropriate intensity, frequency, or duration of the ultrasonic energy.

SEVERAL DECISIONS RULING THAT THE DISCLOSURE WAS ENABLING

(A) In *PPG Ind. v. Guardian Ind.*, 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996), the court ruled that even though there was a software error in calculating the ultraviolet transmittance data for examples in the specification making it appear that the production of a cerium oxide-free glass that satisfied the transmittance limitation would be difficult, the specification indicated that such glass could be made. The specification was found to indicate how to minimize the cerium content while maintaining low ultraviolet transmittance.

(B) In *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the court reversed the rejection for lack of enablement under 35 U.S.C. 112, first paragraph, concluding that undue experimentation would not be required to practice the invention. The nature of monoclonal antibody technology is such that experiments first involve the entire attempt to make monoclonal hybridomas to determine which ones secrete antibody with the desired characteristics. The court found that the specification provided considerable direction and guidance on how to practice the claimed invention and presented working examples, that all of the methods needed to practice the invention were well known, and that there was a high level of skill in the art at the time the application was filed. Furthermore, the applicant carried out the entire procedure for making a monoclonal antibody against HBsAg three times and each time was successful in producing at least one antibody which fell within the scope of the claims.

(C) In *In re Bundy*, 642 F.2d 430, 434, 209 USPQ 48, 51-52 (CCPA 1981), the court ruled that appellant's disclosure was sufficient to enable one skilled in the art to use the claimed analogs of naturally occurring prostaglandins even though the specification lacked any examples of specific dosages, because the specification taught that the novel prostaglandins had certain pharmacological properties and possessed activity similar to known E-type prostaglandins.

2164.07 Relationship of Enablement Requirement to Utility Requirement of 35 U.S.C. 101

The requirement of 35 U.S.C. 112, first paragraph as to how to use the invention is different from the utility requirement of 35 U.S.C. 101. The requirement of 35 U.S.C. 101 is that some specific, substantial, and credible use be set forth for the invention. On the other hand, 35 U.S.C. 112, first paragraph requires an indication of how the use (required by 35 U.S.C. 101) can be carried out, i.e., how the invention can be used.

If an applicant has disclosed a specific and substantial utility for an invention and provided a credible basis supporting that utility, that fact alone does not provide a basis for concluding that the claims comply with all the requirements of 35 U.S.C. 112, first para-

graph. For example, if an applicant has claimed a process of treating a certain disease condition with a certain compound and provided a credible basis for asserting that the compound is useful in that regard, but to actually practice the invention as claimed a person skilled in the relevant art would have to engage in an undue amount of experimentation, the claim may be defective under 35 U.S.C. 112, but not 35 U.S.C. 101. To avoid confusion during examination, any rejection under 35 U.S.C. 112, first paragraph, based on grounds other than "lack of utility" should be imposed separately from any rejection imposed due to "lack of utility" under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph.

I. WHEN UTILITY REQUIREMENT IS NOT SATISFIED

A. Not Useful or Operative

If a claim fails to meet the utility requirement of 35 U.S.C. 101 because it is shown to be nonuseful or inoperative, then it necessarily fails to meet the how-to-use aspect of the enablement requirement of 35 U.S.C. 112, first paragraph. As noted in *In re Fouche*, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971), if "compositions are in fact useless, appellant's specification cannot have taught how to use them." 439 F.2d at 1243, 169 USPQ at 434. The examiner should make both rejections (i.e., a rejection under 35 U.S.C. 112, first paragraph and a rejection under 35 U.S.C. 101) where the subject matter of a claim has been shown to be nonuseful or inoperative.

The 35 U.S.C. 112, first paragraph, rejection should indicate that because the invention as claimed does not have utility, a person skilled in the art would not be able to use the invention as claimed, and as such, the claim is defective under 35 U.S.C. 112, first paragraph. A 35 U.S.C. 112, first paragraph, rejection should not be imposed or maintained unless an appropriate basis exists for imposing a rejection under 35 U.S.C. 101. In other words, Office personnel should not impose a 35 U.S.C. 112, first paragraph, rejection grounded on a "lack of utility" basis unless a 35 U.S.C. 101 rejection is proper. In particular, the factual showing needed to impose a rejection under 35 U.S.C. 101 must be provided if a 35 U.S.C. 112, first paragraph, rejection is to be imposed on "lack of utility" grounds. See MPEP § 2107 - § 2107.03 for a more detailed discussion of the utility requirements of 35 U.S.C. 101 and 112, first paragraph.

B. Burden on the Examiner

When the examiner concludes that an application is describing an invention that is nonuseful, inoperative, or contradicts known scientific principles, the burden is on the examiner to provide a reasonable basis to support this conclusion. Rejections based on 35 U.S.C. 112, first paragraph and 35 U.S.C. 101 should be made.

Examiner Has Initial Burden To Show That One of Ordinary Skill in the Art Would Reasonably Doubt the Asserted Utility

The examiner has the initial burden of challenging an asserted utility. Only after the examiner has provided evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince one of ordinary skill in the art of the invention's asserted utility. *In re Swartz*, 232 F.3d 862, 863, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000); *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (citing *In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981)).

C. Rebuttal by Applicant

If a rejection under 35 U.S.C. 101 has been properly imposed, along with a corresponding rejection under 35 U.S.C. 112, first paragraph, the burden shifts to the applicant to rebut the *prima facie* showing. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). There is no predetermined amount or character of evidence that must be provided by an applicant to support an asserted utility. Rather, the character and amount of evidence needed to support an asserted utility will vary depending on what is claimed (*Ex parte Ferguson*, 117 USPQ 229, 231 (Bd. App. 1957)), and whether the asserted utility appears to contravene established scientific principles and beliefs. *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967*); In re Chilowsky*, 229 F.2d 457, 462, 108 USPQ 321, 325 (CCPA 1956). Furthermore, the applicant does not have to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt." *In re Irons*, 340 F.2d

974, 978, 144 USPQ 351, 354 (CCPA 1965). Instead, evidence will be sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true. See MPEP § 2107.02 for a more detailed discussion of consideration of a reply to a *prima facie* rejection for lack of utility and evaluation of evidence related to utility.

II. WHEN UTILITY REQUIREMENT IS SATISFIED

In some instances, the use will be provided, but the skilled artisan will not know how to effect that use. In such a case, no rejection will be made under 35 U.S.C. 101, but a rejection will be made under 35 U.S.C. 112, first paragraph. As pointed out in *Mowry v. Whitney*, 81 U.S. (14 Wall.) 620 (1871), an invention may in fact have great utility, i.e., may be "a highly useful invention," but the specification may still fail to "enable any person skilled in the art or science" to use the invention. 81 U.S. (14 Wall.) at 644.

2164.08 Enablement Commensurate in Scope With the Claims [R-2]

All questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim is enabled. Accordingly, the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims. >See, e.g., *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003)(When a range is claimed, there must be reasonable enablement of the scope of the range. Here, the claims at issue encompassed amounts of silicon as high as 10% by weight, however the specification included statements clearly and strongly warning that a silicon content above 0.5% by weight in an aluminum coating causes coating problems. Such statements indicate that higher amounts will not work in the claimed invention.).< The examiner should determine what each claim recites and what the subject matter is when the claim is considered as a whole, not when its parts are analyzed individually. No claim should be overlooked. With respect to dependent claims, 35 U.S.C. 112, fourth paragraph, should be followed. This paragraph states that "a claim in a dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers" and requires the dependent claim to further limit the subject matter claimed.

The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. >*AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003);< *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003) (alleged "pioneer status" of invention irrelevant to enablement determination).

The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of the enablement involves two stages of inquiry. The first is to determine how broad the claim is with respect to the disclosure. The entire claim must be considered. The second inquiry is to determine if one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation.

How a teaching is set forth, by specific example or broad terminology, is not important. *In re Marzocchi*, 439 F.2d 220, 223-24 169 USPQ 367, 370 (CCPA 1971). A rejection of a claim under 35 U.S.C. 112 as broader than the enabling disclosure is a first paragraph enablement rejection and not a second paragraph definiteness rejection. Claims are not rejected as broader than the enabling disclosure under 35 U.S.C. 112 for noninclusion of limitations dealing

with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. *In re Skrivan*, 427 F.2d 801, 806, 166 USPQ 85, 88 (CCPA 1970). One does not look to the claims but to the specification to find out how to practice the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1558, 220 USPQ 303, 316-17 (Fed. Cir. 1983); *In re Johnson*, 558 F.2d 1008, 1017, 194 USPQ 187, 195 (CCPA 1977). In *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976), the court stated:

> [T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

When analyzing the enabled scope of a claim, the teachings of the specification must not be ignored because claims are to be given their broadest reasonable interpretation that is consistent with the specification. "That claims are interpreted in light of the specification does not mean that everything in the specification must be read into the claims." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957, 220 USPQ 592, 597 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984).

The record must be clear so that the public will have notice as to the patentee's scope of protection when the patent issues. If a reasonable interpretation of the claim is broader than the description in the specification, it is necessary for the examiner to make sure the full scope of the claim is enabled. Limitations and examples in the specification do not generally limit what is covered by the claims.

The breadth of the claims was a factor considered in *Amgen v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991). In the *Amgen* case, the patent claims were directed to a purified DNA sequence encoding polypeptides which are analogs of erythropoietin (EPO). The Court stated that:

> Amgen has not enabled preparation of DNA sequences sufficient to support its all-encompassing claims. . . . [D]espite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. . . . This disclosure might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen's desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them.

927 F.2d at 1213-14, 18 USPQ2d at 1027. However, when claims are directed to any purified and isolated DNA sequence encoding a specifically named protein where the protein has a specifically identified sequence, a rejection of the claims as broader than the enabling disclosure is generally not appropriate because one skilled in the art could readily determine any one of the claimed embodiments.

See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (The evidence did not show that a skilled artisan would have been able to carry out the steps required to practice the full scope of claims which encompass "any and all live, non-pathogenic vaccines, and processes for making such vaccines, which elicit immunoprotective activity in any animal toward any RNA virus." (original emphasis)); *In re Goodman*, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993) (The specification did not enable the broad scope of the claims for producing mammalian peptides in plant cells because the specification contained only an example of producing gamma-interferon in a dicot species, and there was evidence that extensive experimentation would have been required for encoding mammalian peptide into a monocot plant at the time of filing); *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (Where applicant claimed a composition suitable for the treatment of arthritis having a potency of "at least" a particular value, the court held that the claim was not commensurate in scope with the enabling disclosure because the disclosure was not enabling for compositions having a slightly higher potency. Simply because applicant was the first to achieve a composition beyond a particular threshold potency did not justify or support a claim that would dominate every composition that exceeded that threshold value.); *In re Vaeck*, 947 F.2d 488, 495,

20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (Given the relatively incomplete understanding in the biotechnological field involved, and the lack of a reasonable correlation between the narrow disclosure in the specification and the broad scope of protection sought in the claims, a rejection under 35 U.S.C. 112, first paragraph for lack of enablement was appropriate.).

If a rejection is made based on the view that the enablement is not commensurate in scope with the claim, the examiner should identify the subject matter that is considered to be enabled.

2164.08(a) Single Means Claim

A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. *In re Hyatt*, 708 F.2d 712, 714-715, 218 USPQ 195, 197 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to *Hyatt* is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor.

2164.08(b) Inoperative Subject Matter

The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984) (prophetic examples do not make the disclosure nonenabling).

Although, typically, inoperative embodiments are excluded by language in a claim (e.g., preamble), the scope of the claim may still not be enabled where undue experimentation is involved in determining those embodiments that are operable. A disclosure of a large number of operable embodiments and the identification of a single inoperative embodiment did not render a claim broader than the enabled scope because undue experimentation was not involved in determining those embodiments that were operable. *In re Angstadt*, 537 F.2d 498, 502-503, 190 USPQ 214, 218 (CCPA 1976). However, claims reading on significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative. *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984); *In re Cook*, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

2164.08(c) Critical Feature Not Claimed

A feature which is taught as critical in a specification and is not recited in the claims should result in a rejection of such claim under the enablement provision section of 35 U.S.C. 112. See *In re Mayhew*, 527 F.2d 1229, 1233, 188 USPQ 356, 358 (CCPA 1976). In determining whether an unclaimed feature is critical, the entire disclosure must be considered. Features which are merely preferred are not to be considered critical. *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976).

Limiting an applicant to the preferred materials in the absence of limiting prior art would not serve the constitutional purpose of promoting the progress in the useful arts. Therefore, an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality.

2165 The Best Mode Requirement

A third requirement of the first paragraph of 35 U.S.C. 112 is that:

> The specification. . . shall set forth the best mode contemplated by the inventor of carrying out his invention.

"The best mode requirement creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for

practicing the claimed invention." *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 963, 58 USPQ2d 1865, 1874 (Fed. Cir. 2001).

The best mode requirement is a safeguard against the desire on the part of some people to obtain patent protection without making a full disclosure as required by the statute. The requirement does not permit inventors to disclose only what they know to be their second-best embodiment, while retaining the best for themselves. *In re Nelson*, 280 F.2d 172, 126 USPQ 242 (CCPA 1960).

Determining compliance with the best mode requirement requires a two-prong inquiry. First, it must be determined whether, at the time the application was filed, the inventor possessed a best mode for practicing the invention. This is a subjective inquiry which focuses on the inventor's state of mind at the time of filing. Second, if the inventor did possess a best mode, it must be determined whether the written description disclosed the best mode such that a person skilled in the art could practice it. This is an objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art. *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 963, 58 USPQ2d 1865, 1874 (Fed. Cir. 2001).

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 Labs. 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-2]

I. DETERMINE WHAT IS THE INVENTION

Determine what the invention is — the invention is defined in the claims. The specification need not set forth details not relating to the essence of the invention. *In re Bosy*, 360 F.2d 972, 149 USPQ 789 (CCPA 1966). See also *Northern Telecom Ltd. v. Samsung Electronics Co.*, 215 F.3d 1281, 55 USPQ2d 1065 (Fed. Cir. 2000) (Unclaimed matter that is unrelated to the operation of the claimed invention does not trigger the best mode requirement); *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 966, 58 USPQ2d 1865, 1877 (Fed. Cir. 2001) ("[P]atentee's failure to disclose an unclaimed preferred mode for accomplishing a routine detail does not violate the best mode requirement because one skilled in the art is aware of alternative means for accomplishing the routine detail that would still produce the best mode of the claimed invention.").

II. SPECIFIC EXAMPLE IS NOT REQUIRED

There is no statutory requirement for the disclosure of a specific example — a patent specification is not intended nor required to be a production specification. *In re Gay*, 309 F.2d 768, 135 USPQ 311 (CCPA 1962).

The absence of a specific working example is not necessarily evidence that the best mode has not been disclosed, nor is the presence of one evidence that it has. Best mode may be represented by a preferred range of conditions or group of reactants. *In re Honn*, 364 F.2d 454, 150 USPQ 652 (CCPA 1966).

III. DESIGNATION AS BEST MODE IS NOT REQUIRED

There is no requirement in the statute that applicants point out which of their embodiments they consider to be their best; that the disclosure includes the best mode contemplated by applicants is enough to satisfy the statute. *Ernsthausen v. Nakayama*, 1 USPQ2d 1539 (Bd. Pat. App. & Inter. 1985).

IV. UPDATING BEST MODE IS NOT REQUIRED

There is no requirement to update in the context of a foreign priority application under 35 U.S.C. 119, *Standard Oil Co. v. Montedison, S.p.A.*, 494 F.Supp. 370, 206 USPQ 676 (D.Del. 1980) (better catalyst developed between Italian priority and U.S. filing dates), 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 >former< 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 CIP). 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 CIP that were not present in the parent application. In *Carter-Wallace, Inc. v. Riverton Labs., 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 CIP application.

V. DEFECT IN BEST MODE CANNOT BE CURED BY NEW MATTER

If the best mode contemplated by the inventor at the time of filing the application is not disclosed, such a defect cannot be cured by submitting an amendment seeking to put into the specification something required to be there when the patent application was originally filed. *In re Hay*, 534 F.2d 917, 189 USPQ 790 (CCPA 1976).

Any proposed amendment of this type (adding a specific mode of practicing the invention not described in the application as filed) should be treated as new matter. New matter under 35 U.S.C. 132 and 251 should be objected to and coupled with a requirement to cancel the new matter.

2165.02 Best Mode Requirement Compared to Enablement Requirement

The best mode requirement is a separate and distinct requirement from the enablement requirement of the first paragraph of 35 U.S.C. 112. *In re Newton*, 414 F.2d 1400, 163 USPQ 34 (CCPA 1969).

The best mode provision of 35 U.S.C. 112 is not directed to a situation where the application fails to set forth any mode — such failure is equivalent to nonenablement. *In re Glass*, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974).

The enablement requirement looks to placing the subject matter of the claims generally in the possession of the public. If, however, the applicant develops specific instrumentalities or techniques which are recognized by the applicant at the time of filing as the best way of carrying out the invention, then the best mode requirement imposes an obligation to disclose that information to the public as well. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 3 USPQ 2d 1737 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987).

2165.03 Requirements for Rejection for Lack of Best Mode [R-1]

ASSUME BEST MODE IS DISCLOSED UNLESS THERE IS EVIDENCE TO THE CONTRARY

The examiner should assume that the best mode is disclosed in the application, unless evidence is presented that is inconsistent with that assumption. It is extremely rare that a best mode rejection properly would be made in *ex parte* prosecution. The information that is necessary to form the basis for a rejection based on the failure to set forth the best mode is rarely accessible to the examiner, but is generally uncovered during discovery procedures in interference, litigation, or other *inter partes* proceedings.

EXAMINER MUST DETERMINE WHETHER THE INVENTOR KNEW THAT ONE MODE WAS BETTER THAN ANOTHER, AND IF SO, WHETHER THE DISCLOSURE IS ADEQUATE TO ENABLE ONE OF ORDINARY SKILL IN THE ART TO PRACTICE THE BEST MODE

According to the approach used by the court in *Chemcast Corp. v. Arco Industries*, 913 F.2d 923, 16 USPQ2d 1033 (Fed. Cir. 1990), a proper best mode analysis has two components:

(A) >Determine whether, at the time the application was filed, the inventor knew of a mode of practicing the claimed invention that the inventor considered to be better than any other.<

The first component is a subjective inquiry because it focuses on the inventor's state of mind at the time the application was filed. Unless the examiner has evidence that the inventors had information in their possession

(1) at the time the application was filed

(2) that a mode was considered to be better than any others by the inventors,

there is no reason to address the second component and there is no proper basis for a best mode rejection. If the facts satisfy the first component, then, and only then, is the following second component analyzed:

(B) Compare what was known in (A) with what was disclosed - is the disclosure adequate to enable one skilled in the art to practice the best mode?

Assessing the adequacy of the disclosure in this regard is largely an objective inquiry that depends on the level of skill in the art. Is the information contained in the specification disclosure sufficient to enable a person skilled in the relevant art to make and use the best mode?

A best mode rejection is proper only when the first inquiry can be answered in the affirmative, and the second inquiry answered in the negative with reasons to support the conclusion that the specification is nonenabling with respect to the best mode.

2165.04 Examples of Evidence of Concealment [R-3]

In determining the adequacy of a best mode disclosure, only evidence of concealment (accidental or intentional) is to be considered. That evidence must tend to show that the quality of an applicant's best mode disclosure is so poor as to effectively result in concealment.

I. EXAMPLES — BEST MODE REQUIREMENT SATISFIED

In one case, even though the inventor had more information in his possession concerning the contemplated best mode than was disclosed (a known computer program) the specification was held to delineate the best mode in a manner sufficient to require only the application of routine skill to produce a workable digital computer program. *In re Sherwood*, 613 F.2d 809, 204 USPQ 537 (CCPA 1980).

In another case, the claimed subject matter was a time controlled thermostat, but the application did not disclose the specific Quartzmatic motor which was used in a commercial embodiment. The Court concluded that failure to disclose the commercial motor did not amount to concealment since similar clock motors were widely available and widely advertised. There was no evidence that the specific Quartzmatic motor was superior except possibly in price. *Honeywell v. Diamond*, 208 USPQ 452 (D.D.C. 1980).

There was held to be no violation of the best mode requirement even though the inventor did not disclose the only mode of calculating the stretch rate for plastic rods that he used because that mode would have been employed by those of ordinary skill in the art at the time the application was filed. *W.L. Gore & Assoc., Inc. v. Garlock Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983).

>There was no best mode violation where the patentee failed to disclose in the specification "[k]nown ways to perform a known operation" to practice the claimed invention. "Known ways of performing a known operation cannot be deemed intentionally concealed absent evidence of intent to deliberately withhold that information." *High Concrete Structures Inc. v. New Enter. Stone & Lime Co.*, 377 F.3d 1379, 1384, 71 USPQ2d 1948, 1951 (Fed. Cir. 2004). The unintentional failure to disclose in the specification the use of a crane to support the patented frame in order to carry out the method of loading and tilting the frame was held not to defeat the best mode requirement because one of ordinary skill in the art would understand and use a crane to move heavy loads. *Id.* "The

best mode requirement of [35 U.S.C.] §112 is not violated by unintentional omission of information that would be readily known to persons in the field of the invention." *Id.*<

There was no best mode violation where there was no evidence that the monoclonal antibodies used by the inventors differed from those obtainable according to the processes described in the specification. It was not disputed that the inventors obtained the antibodies used in the invention by following the procedures in the specification, that these were the inventors' preferred procedures, and that the data reported in the specification was for the antibody that the inventors had actually used. *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ 2d 1001 (Fed. Cir. 1991).

Where an organism was created by the insertion of genetic material into a cell obtained from generally available sources, all that was required to satisfy the best mode requirement was an adequate description of the means for carrying out the invention, not deposit of the cells. As to the observation that no scientist could ever duplicate exactly the cell used by applicants, the court observed that the issue is whether the disclosure is adequate, not that an exact duplication is necessary. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ 2d 1016 (Fed. Cir. 1991).

There was held to be no violation of the best mode requirement where the Solicitor argued that concealment could be inferred from the disclosure in a specification that each analog is "surprisingly and unexpectedly more useful than one of the corresponding prostaglandins . . . for at least one of the pharmacological purposes." It was argued that appellant must have had test results to substantiate this statement and this data should have been disclosed. The court concluded that no withholding could be inferred from general statements of increased selectivity and narrower spectrum of potency for these novel analogs, conclusions which could be drawn from the elementary pharmacological testing of the analogs. *In re Bundy*, 642 F.2d 430, 435, 209 USPQ 48, 52 (CCPA 1981).

II. EXAMPLES — BEST MODE REQUIREMENT NOT SATISFIED

The best mode requirement was held to be violated where inventors of a laser failed to disclose details of their preferred TiCuSil brazing method which were not contained in the prior art and were contrary to criteria for the use of TiCuSil as contained in the literature. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 3 USPQ 2d 1737 (Fed. Cir. 1987).

The best mode requirement was violated because an inventor failed to disclose whether to use a specific surface treatment that he knew was necessary to the satisfactory performance of his invention, even though how to perform the treatment itself was known in the art. The argument that the best mode requirement may be met solely by reference to what was known in the prior art was rejected as incorrect. *Dana Corp. v. IPC Ltd. Partnership*, 860 F.2d 415, 8 USPQ2d 1692 (Fed. Cir. 1988).

2171 Two Separate Requirements for Claims Under 35 U.S.C. 112, Second Paragraph

The second paragraph of 35 U.S.C. 112 is directed to requirements for the claims:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

There are two separate requirements set forth in this paragraph:

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

(B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

The first requirement is a subjective one because it is dependent on what the applicants for a patent regard as their invention. The second requirement is an objective one because it is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite — i.e., whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art.

Although an essential purpose of the examination process is to determine whether or not the claims define an invention that is both novel and nonobvious over the prior art, another essential purpose of patent examination is to determine whether or not the claims are precise, clear, correct, and unambiguous. The

uncertainties of claim scope should be removed, as much as possible, during the examination process.

The inquiry during examination is patentability of the invention as applicant regards it. If the claims do not particularly point out and distinctly claim that which applicants regard as their invention, the appropriate action by the examiner is to reject the claims under 35 U.S.C. 112, second paragraph. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). If a rejection is based on 35 U.S.C. 112, second paragraph, the examiner should further explain whether the rejection is based on indefiniteness or on the failure to claim what applicants regard as their invention. *Ex parte Ionescu*, 222 USPQ 537, 539 (Bd. App. 1984).

2172 Subject Matter Which Applicants Regard as Their Invention

I. FOCUS FOR EXAMINATION

A rejection based on the failure to satisfy this requirement is appropriate only where applicant has stated, somewhere other than in the application as filed, that the invention is something different from what is defined by the claims. In other words, the invention set forth in the claims must be presumed, in the absence of evidence to the contrary, to be that which applicants regard as their invention. *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971).

II. EVIDENCE TO THE CONTRARY

Evidence that shows that a claim does not correspond in scope with that which applicant regards as applicant's invention may be found, for example, in contentions or admissions contained in briefs or remarks filed by applicant, *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 55 USPQ2d 1279 (Fed. Cir. 2000); *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969), or in affidavits filed under 37 CFR 1.132, *In re Cormany*, 476 F.2d 998, 177 USPQ 450 (CCPA 1973). The content of applicant's specification is not used as evidence that the scope of the claims is inconsistent with the subject matter which applicants regard as their invention. As noted in *In re Ehrreich*, 590 F.2d 902, 200 USPQ 504 (CCPA 1979), agreement, or lack thereof, between the claims and the specification is properly considered only with respect to 35 U.S.C. 112, first paragraph; it is irrelevant to compliance with the second paragraph of that section.

III. SHIFT IN CLAIMS PERMITTED

The second paragraph of 35 U.S.C. 112 does not prohibit applicants from changing what they regard as their invention during the pendency of the application. *In re Saunders*, 444 F.2d 599, 170 USPQ 213 (CCPA 1971) (Applicant was permitted to claim and submit comparative evidence with respect to claimed subject matter which originally was only the preferred embodiment within much broader claims (directed to a method).). The fact that claims in a continuation application were directed to originally disclosed subject matter which applicants had not regarded as part of their invention when the parent application was filed was held not to prevent the continuation application from receiving benefits of the filing date of the parent application under 35 U.S.C. 120. *In re Brower*, 433 F.2d 813, 167 USPQ 684 (CCPA 1970).

2172.01 Unclaimed Essential Matter [R-1]

A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 U.S.C. 112, first paragraph, as not enabling. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). See also MPEP § 2164.08(c). Such essential matter may include missing elements, steps or necessary structural cooperative relationships of elements described by the applicant(s) as necessary to practice the invention.

In addition, a claim which fails to interrelate essential elements of the invention as defined by applicant(s) in the specification may be rejected under 35 U.S.C. 112, second paragraph, for failure to point out and distinctly claim the invention. See *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976); *In re Collier*, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968). >But see *Ex parte Nolden*, 149 USPQ 378, 380 (Bd. Pat. App. 1965) ("[I]t is not essential to a patentable combination that there be interdependency between the elements of the claimed device or that all the elements operate concurrently toward the desired result"); *Ex parte Huber*, 148 USPQ 447, 448-49 (Bd. Pat. App. 1965) (A claim does not necessarily fail to comply with 35 U.S.C. 112, second paragraph where

the various elements do not function simultaneously, are not directly functionally related, do not directly intercooperate, and/or serve independent purposes.).<

2173 Claims Must Particularly Point Out and Distinctly Claim the Invention

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-2]

A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as **>any special meaning assigned to a term is clearly set forth in the specification. See MPEP § 2111.01.< Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in *In re Swinehart*, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought.

2173.02 Clarity and Precision [R-3]

The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. See, e.g., *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). See also *In re Larsen*, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished) (The preamble of the *Larsen* claim recited only a hanger and a loop but the body of the claim positively recited a linear member. The court observed that the totality of all the limitations of the claim and their interaction with each other must be considered to ascertain the inventor's contribution to the art. Upon review of the claim in its entirety, the court concluded that the claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112 paragraph 2.). >See also *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004) ("The requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles….Only when a claim remains

insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite.").

Accordingly, a claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible. *Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004) (holding that the disputed claim term "surrender value protected investment credits" which was not defined or used in the specification was discernible and hence not indefinite because "the components of the term have well recognized meanings, which allow the reader to infer the meaning of the entire phrase with reasonable confidence").<

If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph, would be appropriate. See *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993). However, if the language used by applicant satisfies the statutory requirements of 35 U.S.C. 112, second paragraph, but the examiner merely wants the applicant to improve the clarity or precision of the language used, the claim must not be rejected under 35 U.S.C. 112, second paragraph, rather, the examiner should suggest improved language to the applicant.

For example, a claim recites "a suitable liquid such as the filtrate of the contaminated liquid to be filtered and solids of a filtering agent such as perlite, cellulose powder, etc." The mere use of the phrase "such as" in the claim does not by itself render the claim indefinite. Office policy is not to employ *per se* rules to make technical rejections. Examples of claim language which have been held to be indefinite set forth in MPEP § 2173.05(d) are fact specific and should not be applied as *per se* rules. The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). If one skilled in the art is able to ascertain in the example above, the meaning of the terms "suitable liquid" and "solids of a filtering agent" in light of the specification, 35 U.S.C. 112, second paragraph, is satisfied. If upon review of the claim as a whole in light of the specification, the examiner determines that a rejection under 35 U.S.C. 112, second paragraph, is not appropriate in the above-noted example, but is of the opinion that the clarity and the precision of the language can be improved by the deletion of the phrase "such as" in the claim, the examiner may make such a suggestion to the applicant. If applicant does not accept the examiner's suggestion, the examiner should not pursue the issue.

If upon review of a claim in its entirety, the examiner concludes that a rejection under 35 U.S.C. 112, second paragraph, is appropriate, such a rejection should be made and an analysis as to why the phrase(s) used in the claim is "vague and indefinite" should be included in the Office action. If applicants traverse the rejection, with or without the submission of an amendment, and the examiner considers applicant's arguments to be persuasive, the examiner should indicate in the next Office communication that the previous rejection under 35 U.S.C. 112, second paragraph, has been withdrawn and provide an explanation as to what prompted the change in the examiner's position (e.g., examiners may make specific reference to portions of applicant's remarks that were considered to be the basis as to why the previous rejection was withdrawn).

By providing an explanation as to the action taken, the examiner will enhance the clarity of the prosecution history record. As noted by the Supreme Court in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S.Ct. 1831, 1838, 62 USPQ2d 1705, 1710 (2002), a clear and complete prosecution file record is important in that "[p]rosecution history estoppel requires that the claims of a patent be interpreted in light of the proceedings in the PTO during the application process." In *Festo*, the court held that "a narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel." With respect to amendments made to comply with the requirements of 35 U.S.C. 112, the court stated that "[i]f a § 112 amendment is truly cosmetic, then it would not narrow the patent's scope or raise an estoppel. On the other hand, if a § 112 amendment is necessary and narrows the patent's scope—even if only for the purpose of better description—estoppel may apply." *Id.*, at 1840, 62 USPQ2d at 1712. The court

further stated that "when the court is unable to determine the purpose underlying a narrowing amendment—and hence a rationale for limiting the estoppel to the surrender of particular equivalents—the court should presume that the patentee surrendered all subject matter between the broader and the narrower language…the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question." *Id*., at 1842, 62 USPQ2d at 1713. Thus, whenever possible, the examiner should make the record clear by providing explicit reasoning for making or withdrawing any rejection related to 35 U.S.C. 112, second paragraph.

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

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.

>See MPEP § 2181 for guidance in determining whether an applicant has complied with the requirements of 35 U.S.C. 112, second paragraph, when 35 U.S.C. 112, sixth paragraph, is invoked.<

2173.05(a) New Terminology [R-3]

I. THE MEANING OF EVERY TERM SHOULD BE APPARENT

The meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. Applicants need not confine themselves to the terminology used in the prior art, but are required to make clear and precise the terms that are used to define the invention whereby the metes and bounds of the claimed invention can be ascertained. During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); *In re Prater*,

415 F.2d 1393, 162 USPQ 541 (CCPA 1969). See also MPEP § 2111 - § 2111.01. When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

II. THE REQUIREMENT FOR CLARITY AND PRECISION MUST BE BALANCED WITH THE LIMITATIONS OF THE LANGUAGE

Courts have recognized that it is not only permissible, but often desirable, to use new terms that are frequently more precise in describing and defining the new invention. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Although it is difficult to compare the claimed invention with the prior art when new terms are used that do not appear in the prior art, this does not make the new terms indefinite.

New terms are often used when a new technology is in its infancy or is rapidly evolving. The requirements for clarity and precision must be balanced with the limitations of the language and the science. If the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the statute (35 U.S.C. 112, second paragraph) demands no more. *Shatterproof Glass Corp. v. Libbey Owens Ford Co.*, 758 F.2d 613, 225 USPQ 634 (Fed. Cir. 1985) (interpretation of "freely supporting" in method claims directed to treatment of a glass sheet); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986) (interpretation of a limitation specifying a numerical value for antibody affinity where the method of calculation was known in the art at the time of filing to be imprecise). This does not mean that the examiner must accept the best effort of applicant. If the proposed language is not considered as precise as the subject matter permits, the examiner should provide reasons to support the conclusion of indefiniteness and is encouraged to suggest alternatives that are free from objection.

III. TERMS USED CONTRARY TO THEIR ORDINARY MEANING MUST BE CLEARLY REDEFINED IN THE WRITTEN DESCRIPTION

Consistent with the well-established axiom in patent law that a patentee or applicant is free to be his or her own lexicographer, a patentee or applicant may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings if the written description clearly redefines the terms. See, e.g., *Process Control Corp. v. HydReclaim Corp*., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999) ("While we have held many times that a patentee can act as his own lexicographer to specifically define terms of a claim contrary to their ordinary meaning," in such a situation the written description must clearly redefine a claim term "so as to put a reasonable competitor or one reasonably skilled in the art on notice that the patentee intended to so redefine that claim term."); *Hormone Research Foundation Inc. v. Genentech Inc.*, 904 F.2d 1558, 15 USPQ2d 1039 (Fed. Cir. 1990). Accordingly, when there is more than one definition for a term, it is incumbent upon applicant to make clear which definition is being relied upon to claim the invention. Until the meaning of a term or phrase used in a claim is clear, a rejection under 35 U.S.C. 112, second paragraph is appropriate. In applying the prior art, the claims should be construed to encompass all definitions that are consistent with applicant's use of the term. See *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202, 64 USPQ2d 1812, 1818 (Fed. Cir. 2002). It is appropriate to compare the meaning of terms given in technical dictionaries in order to ascertain the accepted meaning of a term in the art. *In re Barr*, 444 F.2d 588, 170 USPQ 330 (CCPA 1971). >See also MPEP § 2111.01.<

2173.05(b) Relative Terminology

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, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

B. "Essentially"

The phrase "a silicon dioxide source that is essentially free of alkali metal" was held to be definite because the specification contained guidelines and examples that were considered sufficient to enable a person of ordinary skill in the art to draw a line between unavoidable impurities in starting materials and essential ingredients. *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (CCPA 1983). The court further observed that it would be impractical to require applicants to specify a particular number as a cutoff between their invention and the prior art.

C. "Similar"

The term "similar" in the preamble of a claim that was directed to a nozzle "for high-pressure cleaning units or similar apparatus" was held to be indefinite since it was not clear what applicant intended to cover by the recitation "similar" apparatus. *Ex parte Kristensen*, 10 USPQ2d 1701 (Bd. Pat. App. & Inter. 1989).

A claim in a design patent application which read: "The ornamental design for a feed bunk or similar structure as shown and described." was held to be indefinite because it was unclear from the specification what applicant intended to cover by the recitation of "similar structure." *Ex parte Pappas*, 23 USPQ2d 1636 (Bd. Pat. App. & Inter. 1992).

D. "Substantially"

The term "substantially" is often used in conjunction with another term to describe a particular characteristic of the claimed invention. It is a broad term. *In re Nehrenberg*, 280 F.2d 161, 126 USPQ 383 (CCPA 1960). The court held that the limitation "to substantially increase the efficiency of the compound as a copper extractant" was definite in view of the general guidelines contained in the specification. *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). The court held that the limitation "which produces substantially equal E and H plane illumination patterns" was definite because one of ordinary skill in the art would know what was meant by "substantially equal." *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988).

E. "Type"

The addition of the word "type" to an otherwise definite expression (e.g., Friedel-Crafts catalyst) extends the scope of the expression so as to render it indefinite. *Ex parte Copenhaver*, 109 USPQ 118 (Bd. App. 1955). Likewise, the phrase "ZSM-5-type aluminosilicate zeolites" was held to be indefinite because it was unclear what "type" was intended to convey. The interpretation was made more difficult by the fact that the zeolites defined in the dependent claims were not within the genus of the type of zeolites defined in the independent claim. *Ex parte Attig*, 7 USPQ2d 1092 (Bd. Pat. App. & Inter. 1986).

F. Other Terms

The phrases "relatively shallow," "of the order of," "the order of about 5mm," and "substantial portion" were held to be indefinite because the specification lacked some standard for measuring the degree intended and, therefore, properly rejected as indefinite under 35 U.S.C. 112, second paragraph. *Ex parte Oetiker*, 23 USPQ2d 1641 (Bd. Pat. App. & Inter. 1992).

The term "or like material" in the context of the limitation "coke, brick, or like material" was held to render the claim indefinite since it was not clear how the materials other than coke or brick had to resemble the two specified materials to satisfy the limitations of the claim. *Ex parte Caldwell*, 1906 C.D. 58 (Comm'r Pat. 1906).

The terms "comparable" and "superior" were held to be indefinite in the context of a limitation relating the characteristics of the claimed material to other materials - "properties that are superior to those obtained with comparable" prior art materials. *Ex parte Anderson*, 21 USPQ2d 1241 (Bd. Pat. App. & Inter. 1991). It was not clear from the specification which properties had to be compared and how comparable the properties would have to be to determine infringement issues. Further, there was no guidance as to the meaning of the term "superior."

2173.05(c) Numerical Ranges and Amounts Limitations

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

I. NARROW AND BROADER RANGES IN THE SAME CLAIM

Use of a narrow numerical range that falls within a broader range in the same claim may render the claim indefinite when the boundaries of the claim are not discernible. Description of examples and preferences is properly set forth in the specification rather than in a single claim. A narrower range or preferred embodiment may also be set forth in another independent claim or in a dependent claim. If stated in a single claim, examples and preferences lead to confusion over the intended scope of the claim. In those instances where it is not clear whether the claimed narrower range is a limitation, a rejection under 35 U.S.C. 112, second paragraph should be made. The Examiner should analyze whether the metes and bounds of the claim are clearly set forth. Examples of claim language which have been held to be indefinite are (A) "a temperature of between 45 and 78 degrees Celsius, preferably between 50 and 60 degrees Celsius"; and (B) "a predetermined quantity, for example, the maximum capacity."

While a single claim that includes both a broad and a narrower range may be indefinite, it is not improper under 35 U.S.C. 112, second paragraph, to present a dependent claim that sets forth a narrower range for an element than the range set forth in the claim from which it depends. For example, if claim 1 reads "A circuit … wherein the resistance is 70-150 ohms." and claim 2 reads "The circuit of claim 1 wherein the resistance is 70-100 ohms.", then claim 2 should not be rejected as indefinite.

II. OPEN-ENDED NUMERICAL RANGES

Open-ended numerical ranges should be carefully analyzed for definiteness. For example, when an independent claim recites a composition comprising "at least 20% sodium" and a dependent claim sets forth specific amounts of nonsodium ingredients which add up to 100%, apparently to the exclusion of sodium, an ambiguity is created with regard to the "at least" limitation (unless the percentages of the nonsodium ingredients are based on the weight of the nonsodium ingredients). On the other hand, the court held that a composition claimed to have a theoretical content greater than 100% (i.e., 20-80% of A, 20-80% of B and 1-25% of C) was not indefinite simply because the claims may be read in theory to include compositions that are impossible in fact to formulate. It was observed that subject matter which cannot exist in fact can neither anticipate nor infringe a claim. *In re Kroekel*, 504 F.2d 1143, 183 USPQ 610 (CCPA 1974).

In a claim directed to a chemical reaction process, a limitation required that the amount of one ingredient in the reaction mixture should "be maintained at less than 7 mole percent" based on the amount of another ingredient. The examiner argued that the claim was indefinite because the limitation sets only a maximum amount and is inclusive of substantially no ingredient resulting in termination of any reaction. The court did not agree because the claim was clearly directed to a reaction process which did not warrant distorting the overall meaning of the claim to preclude performing the claimed process. *In re Kirsch*, 498 F.2d 1389, 182 USPQ 286 (CCPA 1974).

Some terms have been determined to have the following meanings in the factual situations of the reported cases: the term "up to" includes zero as a lower limit, *In re Mochel*, 470 F.2d 638, 176 USPQ 194 (CCPA 1974); and "a moisture content of not more than 70% by weight" reads on dry material, *Ex parte Khusid*, 174 USPQ 59 (Bd. App. 1971).

III. "EFFECTIVE AMOUNT"

The common phrase "an effective amount" may or may not be indefinite. The proper test is whether or not one skilled in the art could determine specific values for the amount based on the disclosure. See *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). The phrase "an effective amount . . . for growth stimulation" was held to be definite where the amount was not critical and those skilled in the art would be able to determine from the written disclosure, including the examples, what an effective amount is. *In re Halleck*, 422 F.2d 911, 164 USPQ 647 (CCPA 1970). The phrase "an effective amount" has been held to be indefinite when the claim fails to state the function which is to be achieved and more than one effect can be implied from the specification or the relevant art. *In re Fredericksen* 213 F.2d 547, 102 USPQ 35 (CCPA 1954). The more recent cases have tended to accept a limitation such as "an effective amount" as being definite when read in light of the supporting disclosure and in the absence of any prior art which would give rise to uncertainty about the scope of the claim. In *Ex parte Skuballa*, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989), the Board held that a pharmaceutical composition claim which recited an "effective amount of a compound of claim 1" without stating the function to be achieved was definite, particularly when read in light of the supporting disclosure which provided guidelines as to the intended utilities and how the uses could be effected.

2173.05(d) Exemplary Claim Language ("for example," "such as") [R-1]

Description of examples or preferences is properly set forth in the specification rather than the claims. If stated in the claims, examples and preferences >may< lead to confusion over the intended scope of a claim. In those instances where it is not clear whether the claimed narrower range is a limitation, a rejection under 35 U.S.C. 112, second paragraph should be made. The examiner should analyze whether the metes and bounds of the claim are clearly set forth. Examples of claim language which have been held to be indefinite because the intended scope of the claim was unclear are:

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

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

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

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

>The above examples of claim language which have been held to be indefinite are fact specific and should not be applied as *per se* rules. See MPEP § 2173.02 for guidance regarding when it is appropriate to make a rejection under 35 U.S.C. 112, second paragraph.<

2173.05(e) Lack of Antecedent Basis [R-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. >See *Bose Corp. v. JBL, Inc*., 274 F.3d 1354, 1359, 61 USPQ2d 1216, 1218-19 (Fed. Cir 2001) (holding that recitation of "an ellipse" provided antecedent basis for "an ellipse having a major diameter" because "[t]here can be no dispute that mathematically an inherent characteristic of an ellipse is a major diameter").<

EXAMINER SHOULD SUGGEST CORRECTIONS TO ANTECEDENT PROBLEMS

Antecedent problems in the claims are typically drafting oversights that are easily corrected once they are brought to the attention of applicant. The examiner's task of making sure the claim language complies with the requirements of the statute should be carried out in a positive and constructive way, so that minor problems can be identified and easily corrected, and so that the major effort is expended on more substantive issues. However, even though indefiniteness in claim language is of semantic origin, it is not rendered unobjectionable simply because it could have been corrected. *In re Hammack*, 427 F.2d 1384 n.5, 166 USPQ 209 n.5 (CCPA 1970).

A CLAIM TERM WHICH HAS NO ANTECEDENT BASIS IN THE DISCLOSURE IS NOT NECESSARILY INDEFINITE

The mere fact that a term or phrase used in the claim has no antecedent basis in the specification disclosure does not mean, necessarily, that the term or phrase is indefinite. There is no requirement that the words in the claim must match those used in the specification disclosure. Applicants are given a great deal of latitude in how they choose to define their invention so long as the terms and phrases used define the invention with a reasonable degree of clarity and precision.

A CLAIM IS NOT *PER SE* INDEFINITE IF THE BODY OF THE CLAIM RECITES ADDITIONAL ELEMENTS WHICH DO NOT APPEAR IN THE PREAMBLE

The mere fact that the body of a claim recites additional elements which do not appear in the claim's preamble does not render the claim indefinite under 35 U.S.C. 112, second paragraph. See *In re Larsen*, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished) (The preamble of the *Larsen* claim recited only a hanger and a loop but the body of the claim positively recited a linear member. The examiner rejected the claim under 35 U.S.C. 112, second paragraph, because the omission from the claim's preamble of a critical element (i.e., a linear member) renders that

claim indefinite. The court reversed the examiner's rejection and stated that the totality of all the limitations of the claim and their interaction with each other must be considered to ascertain the inventor's contribution to the art. Upon review of the claim in its entirety, the court concluded that the claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, paragraph 2.).

2173.05(f) Reference to Limitations in Another Claim

A claim which makes reference to a preceding claim to define a limitation is an acceptable claim construction which should not necessarily be rejected as improper or confusing under 35 U.S.C. 112, second paragraph. For example, claims which read: "The product produced by the method of claim 1." or "A method of producing ethanol comprising contacting amylose with the culture of claim 1 under the following conditions ....." are not indefinite under 35 U.S.C. 112, second paragraph, merely because of the reference to another claim. See also *Ex parte Porter*, 25 USPQ2d 1144 (Bd. Pat. App. & Inter. 1992) where reference to "the nozzle of claim 7" in a method claim was held to comply with 35 U.S.C. 112, second paragraph. However, where the format of making reference to limitations recited in another claim results in confusion, then a rejection would be proper under 35 U.S.C. 112, second paragraph.

2173.05(g) Functional Limitations [R-3]

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. >In *Innova/Pure Water Inc. v. Safari Water Filtration Sys. Inc.*, 381 F.3d 1111, 1117-20, 72 USPQ2d 1001, 1006-08 (Fed. Cir. 2004), the court noted that the claim term "operatively connected" is "a general descriptive claim term frequently used in patent drafting to reflect a functional relationship between claimed components," that is, the term "means the claimed components must be connected in a way to perform a designated function." "In the absence of modifiers, general descriptive terms are typically construed as having their full meaning." *Id*. at 1118, 72 USPQ2d at 1006. In the patent claim at issue, "subject to any clear and unmistakable disavowal of claim scope, the term 'operatively connected' takes the full breath of its ordinary meaning, i.e., 'said tube [is] operatively connected to said cap' when the tube and cap are arranged in a manner capable of performing the function of filtering." *Id.* at 1120, 72 USPQ2d at 1008.<

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

I. MARKUSH GROUPS

Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. 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

Genus, subgenus, and Markush-type claims, if properly supported by the disclosure, are all acceptable ways for applicants to claim their inventions. They provide different ways to present claims of different scope. Examiners should therefore not reject Markush-type claims merely because there are genus claims that encompass the Markush-type claims.

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

See MPEP § 803.02 for restriction practice re Markush-type claims.

II. "OR" TERMINOLOGY

Alternative expressions using "or" are acceptable, such as "wherein R is A, B, C, or D." The following phrases were each held to be acceptable and not in violation of 35 U.S.C. 112, second paragraph in *In re Gaubert*, 524 F.2d 1222, 187 USPQ 664 (CCPA 1975): "made entirely or in part of"; "at least one piece"; and "iron, steel or any other magnetic material."

III. "OPTIONALLY"

An alternative format which requires some analysis before concluding whether or not the language is indefinite involves the use of the term "optionally." In *Ex parte Cordova*, 10 USPQ2d 1949 (Bd. Pat. App. & Inter. 1989) the language "containing A, B, and optionally C" was considered acceptable alternative

language because there was no ambiguity as to which alternatives are covered by the claim. A similar holding was reached with regard to the term "optionally" in *Ex parte Wu*, 10 USPQ2d 2031 (Bd. Pat. App. & Inter. 1989). In the instance where the list of potential alternatives can vary and ambiguity arises, then it is proper to make a rejection under 35 U.S.C. 112, second paragraph, and explain why there is confusion.

2173.05(i) Negative Limitations

The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation. So long as the boundaries of the patent protection sought are set forth definitely, albeit negatively, the claim complies with the requirements of 35 U.S.C. 112, second paragraph. Some older cases were critical of negative limitations because they tended to define the invention in terms of what it was not, rather than pointing out the invention. Thus, the court observed that the limitation "R is an alkenyl radical other than 2-butenyl and 2,4-pentadienyl" was a negative limitation that rendered the claim indefinite because it was an attempt to claim the invention by excluding what the inventors did not invent rather than distinctly and particularly pointing out what they did invent. *In re Schechter*, 205 F.2d 185, 98 USPQ 144 (CCPA 1953).

A claim which recited the limitation "said homopolymer being free from the proteins, soaps, resins, and sugars present in natural Hevea rubber" in order to exclude the characteristics of the prior art product, was considered definite because each recited limitation was definite. *In re Wakefield*, 422 F.2d 897, 899, 904, 164 USPQ 636, 638, 641 (CCPA 1970). In addition, the court found that the negative limitation "incapable of forming a dye with said oxidized developing agent" was definite because the boundaries of the patent protection sought were clear. *In re Barr*, 444 F.2d 588, 170 USPQ 330 (CCPA 1971).

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support. *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993). See MPEP § 2163 - § 2163.07(b) for a discussion of the written description requirement of 35 U.S.C. 112, first paragraph.

2173.05(j) Old Combination

A CLAIM SHOULD NOT BE REJECTED ON THE GROUND OF OLD COMBINATION

With the passage of the 1952 Patent Act, the courts and the Board have taken the view that a rejection based on the principle of old combination is NO LONGER VALID. Claims should be considered proper so long as they comply with the provisions of 35 U.S.C. 112, second paragraph.

A rejection on the basis of old combination was based on the principle applied in *Lincoln Engineering Co. v. Stewart-Warner Corp.*, 303 U.S. 545, 37 USPQ 1 (1938). The principle was that an inventor who made an improvement or contribution to but one element of a generally old combination, should not be able to obtain a patent on the entire combination including the new and improved element. A rejection required the citation of a single reference which broadly disclosed a combination of the claimed elements functionally cooperating in substantially the same manner to produce substantially the same results as that of the claimed combination. The case of *In re Hall*, 208 F.2d 370, 100 USPQ 46 (CCPA 1953) illustrates an application of this principle.

The court pointed out in *In re 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]

**>A claim should not be rejected on the ground of "aggregation." *In re Gustafson*, 331 F.2d 905, 141 USPQ 585 (CCPA 1964) (an applicant is entitled to know whether the claims are being rejected under 35 U.S.C. 101, 102, 103, or 112); *In re Collier*, 397 F.2d 1003, 1006, 158 USPQ 266, 268 (CCPA 1968) ("[A] rejection for 'aggregation' is non-statutory.").

If a claim omits essential matter or fails to interrelate essential elements of the invention as defined by applicant(s) in the specification, see MPEP § 2172.01.<

2173.05(m)Prolix

Examiners should reject claims as prolix only when they contain such long recitations or unimportant details that the scope of the claimed invention is rendered indefinite thereby. Claims are rejected as prolix when they contain long recitations that the metes and bounds of the claimed subject matter cannot be determined.

2173.05(n) Multiplicity [R-2]

37 CFR 1.75. Claim(s).

(a) The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery.

(b) More than one claim may be presented provided they differ substantially from each other and are not unduly multiplied.

*****

Where, in view of the nature and scope of applicant's invention, applicant presents an unreasonable number of claims which ** are repetitious and multiplied, the net result of which is to confuse rather than to clarify, a rejection on undue multiplicity based on 35 U.S.C. 112, second paragraph, may be appropriate. As noted by the court in *In re Chandler*, 319 F.2d 211, 225, 138 USPQ 138, 148 (CCPA 1963), "applicants should be allowed reasonable latitude in stating their claims in regard to number and phraseology employed. The right of applicants to freedom of choice in selecting phraseology which truly points out and defines their inventions should not be abridged. Such latitude, however, should not be extended to sanction that degree of repetition and multiplicity which beclouds definition in a maze of confusion. The rule of reason should be practiced and applied on the basis of the relevant facts and circumstances in each individual case." See also *In re Flint*, 411 F.2d 1353, 1357, 162 USPQ 228, 231 (CCPA 1969). Undue multiplicity rejections based on 35 U.S.C. 112, second paragraph, should be applied judiciously and should be rare.

If an undue multiplicity rejection under 35 U.S.C. 112, second paragraph, is appropriate, the examiner should contact applicant by telephone explaining that the claims are unduly multiplied and will be rejected under 35 U.S.C. 112, second paragraph. Note MPEP § 408. The examiner should also request that applicant select a specified number of claims for purpose of examination. If applicant is willing to select, by telephone, the claims for examination, an undue multiplicity rejection on all the claims based on 35 U.S.C. 112, second paragraph, should be made in the next Office action along with an action on the merits on the selected claims. If applicant refuses to comply with the telephone request, an undue multiplicity rejection of all the claims based on 35 U.S.C. 112, second paragraph, should be made in the next Office action. Applicant's reply must include a selection of claims for purpose of examination, the number of which may not be greater than the number specified by the examiner. In response to applicant's reply, if the examiner adheres to the undue multiplicity rejection, it should be repeated and the selected claims will be examined on the merits. This procedure preserves applicant's right to have the rejection on undue multiplicity reviewed by the Board of Patent Appeals and Interferences.

Also, it is possible to reject one claim on an allowed claim if they differ only by subject matter old in the art. This ground of rejection is set forth in *Ex parte Whitelaw*, 1915 C.D. 18, 219 O.G. 1237

(Comm'r Pat. 1914). The *Ex parte Whitelaw* doctrine is restricted to cases where the claims are unduly multiplied or are substantial duplicates. *Ex parte Kochan*, 131 USPQ 204, 206 (Bd. App. 1961).

2173.05(o) Double Inclusion

There is no *per se* rule that "double inclusion" is improper in a claim. *In re Kelly*, 305 F.2d 909, 916, 134 USPQ 397, 402 (CCPA 1962) ("Automatic reliance upon a 'rule against double inclusion' will lead to as many unreasonable interpretations as will automatic reliance upon a 'rule allowing double inclusion'. The governing consideration is not *double inclusion*, but rather is what is a reasonable construction of the language of the claims."). Older cases, such as *Ex parte White*, 759 O.G. 783 (Bd. App. 1958) and *Ex parte Clark*, 174 USPQ 40 (Bd. App. 1971) should be applied with care, according to the facts of each case.

The facts in each case must be evaluated to determine whether or not the multiple inclusion of one or more elements in a claim gives rise to indefiniteness in that claim. The mere fact that a compound may be embraced by more than one member of a Markush group recited in the claim does not lead to any uncertainty as to the scope of that claim for either examination or infringement purposes. On the other hand, where a claim directed to a device can be read to include the same element twice, the claim may be indefinite. *Ex parte Kristensen*, 10 USPQ2d 1701 (Bd. Pat. App. & Inter. 1989).

2173.05(p) Claim Directed to Product-By-Process or Product and Process

There are many situations where claims are permissively drafted to include a reference to more than one statutory class of invention.

I. PRODUCT-BY-PROCESS

A product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper. *In re Luck*, 476 F.2d 650, 177 USPQ 523 (CCPA 1973); *In re Pilkington*, 411 F.2d 1345, 162 USPQ 145 (CCPA 1969); *In re Steppan*, 394 F.2d 1013, 156 USPQ 143 (CCPA 1967). A claim to a device, apparatus, manufacture, or composition of matter may contain a reference to the process in which it is intended to be used without being objectionable under 35 U.S.C. 112, second paragraph, so long as it is clear that the claim is directed to the product and not the process.

An applicant may present claims of varying scope even if it is necessary to describe the claimed product in product-by-process terms. *Ex parte Pantzer*, 176 USPQ 141 (Bd. App. 1972).

II. PRODUCT AND PROCESS IN THE SAME CLAIM

A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. 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

Attempts to claim a process without setting forth any steps involved in the process generally raises an issue of indefiniteness under 35 U.S.C. 112, second paragraph. For example, a claim which read: "A process for using monoclonal antibodies of claim 4 to isolate and purify human fibroblast interferon." was held to be indefinite because it merely recites a use without any active, positive steps delimiting how this use is actually practiced. *Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986).

Other decisions suggest that a more appropriate basis for this type of rejection is 35 U.S.C. 101. In *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967), the Board held the following claim to be an improper definition of a process: "The use of a high carbon austenitic iron alloy having a proportion of free carbon as a vehicle brake part subject to stress by sliding friction." In *Clinical Products Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966), the district court held the following claim was definite, but that it

was not a proper process claim under 35 U.S.C. 101: "The use of a sustained release therapeutic agent in the body of ephedrine absorbed upon polystyrene sulfonic acid."

Although a claim should be interpreted in light of the specification disclosure, it is generally considered improper to read limitations contained in the specification into the claims. See *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969) and *In re Winkhaus*, 527 F.2d 637, 188 USPQ 129 (CCPA 1975), which discuss the premise that one cannot rely on the specification to impart limitations to the claim that are not recited in the claim.

A "USE" CLAIM SHOULD BE REJECTED UNDER ALTERNATIVE GROUNDS BASED ON 35 U.S.C 101 AND 112

In view of the split of authority as discussed above, the most appropriate course of action would be to reject a "use" claim under alternative grounds based on 35 U.S.C. 101 and 112.

BOARD HELD STEP OF "UTILIZING" WAS NOT INDEFINITE

It is often difficult to draw a fine line between what is permissible, and what is objectionable from the perspective of whether a claim is definite. In the case of *Ex parte Porter*, 25 USPQ2d 1144 (Bd. Pat. App. & Inter. 1992), the Board held that a claim which clearly recited the step of "utilizing" was not indefinite under 35 U.S.C. 112, second paragraph. (Claim was to "A method for unloading nonpacked, nonbridging and packed, bridging flowable particle catalyst and bead material from the opened end of a reactor tube which comprises utilizing the nozzle of claim 7.").

2173.05(r) Omnibus Claim

Some applications are filed with an omnibus claim which reads as follows: A device substantially as shown and described. This claim should be rejected under 35 U.S.C. 112, second paragraph, because it is indefinite in that it fails to point out what is included or excluded by the claim language. See *Ex parte Fressola*, 27 USPQ2d 1608 (Bd. Pat. App. & Inter. 1993), for a discussion of the history of omnibus claims and an explanation of why omnibus claims do not comply with the requirements of 35 U.S.C. 112, second paragraph.

Such a claim can be rejected using Form Paragraph 7.35. See MPEP § 706.03(d).

For cancellation of such a claim by examiner's amendment, see MPEP § 1302.04(b).

2173.05(s) Reference to Figures or Tables

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the recitation of the same element or group of elements in the claims. See MPEP § 608.01(m).

2173.05(t) Chemical Formula

Claims to chemical compounds and compositions containing chemical compounds often use formulas that depict the chemical structure of the compound. These structures should not be considered indefinite nor speculative in the absence of evidence that the assigned formula is in error. The absence of corroborating spectroscopic or other data cannot be the basis for finding the structure indefinite. See *Ex parte Morton*, 134 USPQ 407 (Bd. App. 1961), and *Ex parte Sobin*, 139 USPQ 528 (Bd. App. 1962).

A claim to a chemical compound is not indefinite merely because a structure is not presented or because a partial structure is presented. For example, the claim language at issue in *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) referred to a chemical compound as a "polypeptide of at least 24 amino acids having the following sequence." A rejection under 35 U.S.C. 112, second paragraph, for failure to identify the entire structure was reversed and the court held: "While the absence of such a limitation obviously broadens the claim and raises questions of sufficiency of disclosure, it does not render the claim indefinite." Chemical compounds may be claimed by

a name that adequately describes the material to one skilled in the art. See *Martin v. Johnson*, 454 F.2d 746, 172 USPQ 391 (CCPA 1972). A compound of unknown structure may be claimed by a combination of physical and chemical characteristics. See *Ex parte Brian*, 118 USPQ 242 (Bd. App. 1958). A compound may also be claimed in terms of the process by which it is made without raising an issue of indefiniteness.

2173.05(u) Trademarks or Trade Names in a Claim

The presence of a trademark or trade name in a claim is not, *per se*, improper under 35 U.S.C. 112, second paragraph, but the claim should be carefully analyzed to determine how the mark or name is used in the claim. It is important to recognize that a trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. See definitions of trademark and trade name in MPEP § 608.01(v). A list of some trademarks is found in Appendix I.

If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name.

If a trademark or trade name appears in a claim and is not intended as a limitation in the claim, the question of why it is in the claim should be addressed. Does its presence in the claim cause confusion as to the scope of the claim? If so, the claim should be rejected under 35 U.S.C. 112, second paragraph.

2173.05(v) Mere Function of Machine

Process or method claims are not subject to rejection by U.S. Patent and Trademark Office examiners under 35 U.S.C. 112, second paragraph, solely on the ground that they define the inherent function of a disclosed machine or apparatus. *In re Tarczy-Hornoch*, 397 F.2d 856, 158 USPQ 141 (CCPA 1968). The court in *Tarczy-Hornoch* held that a process claim, otherwise patentable, should not be rejected merely because the application of which it is part discloses apparatus which will inherently carry out the recited steps.

2173.06 Prior Art Rejection of Claim Rejected as Indefinite

All words in a claim must be considered in judging the patentability of a claim against the prior art. *In re Wilson*, 424 F.2d 1382, 165 USPQ 494 (CCPA 1970). The fact that terms may be indefinite does not make the claim obvious over the prior art. When the terms of a claim are considered to be indefinite, at least two approaches to the examination of an indefinite claim relative to the prior art are possible.

First, where the degree of uncertainty is not great, and where the claim is subject to more than one interpretation and at least one interpretation would render the claim unpatentable over the prior art, an appropriate course of action would be for the examiner to enter two rejections: (A) a rejection based on indefiniteness under 35 U.S.C. 112, second paragraph; and (B) a rejection over the prior art based on the interpretation of the claims which renders the prior art applicable. See, e.g., *Ex parte Ionescu*, 222 USPQ 537 (Bd. App. 1984). When making a rejection over prior art in these circumstances, it is important for the examiner to point out how the claim is being interpreted. Second, where there is a great deal of confusion and uncertainty as to the proper interpretation of the limitations of a claim, it would not be proper to reject such a claim on the basis of prior art. As stated in *In re Steele*, 305 F.2d 859, 134 USPQ 292 (CCPA 1962), a rejection under 35 U.S.C. 103 should not be based on considerable speculation about the meaning of terms employed in a claim or assumptions that must be made as to the scope of the claims.

The first approach is recommended from an examination standpoint because it avoids piecemeal examination in the event that the examiner's 35 U.S.C. 112, second paragraph rejection is not affirmed, and may give applicant a better appreciation for relevant prior

art if the claims are redrafted to avoid the 35 U.S.C. 112, second paragraph rejection.

2174 Relationship Between the Requirements of the First and Second Paragraphs of 35 U.S.C. 112

The requirements of the first and second paragraphs of 35 U.S.C. 112 are separate and distinct. If a description or the enabling disclosure of a specification is not commensurate in scope with the subject matter encompassed by a claim, that fact alone does not render the claim imprecise or indefinite or otherwise not in compliance with 35 U.S.C. 112, second paragraph; rather, the claim is based on an insufficient disclosure (35 U.S.C. 112, first paragraph) and should be rejected on that ground. *In re Borkowski*, 422 F.2d 904, 164 USPQ 642 (CCPA 1970). If the specification discloses that a particular feature or element is critical or essential to the practice of the invention, failure to recite or include that particular feature or element in the claims may provide a basis for a rejection based on the ground that those claims are not supported by an enabling disclosure. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). In *Mayhew*, the examiner argued that the only mode of operation of the process disclosed in the specification involved the use of a cooling zone at a particular location in the processing cycle. The claims were rejected because they failed to specify either a cooling step or the location of the step in the process. The court was convinced that the cooling bath and its location were essential, and held that claims which failed to recite the use of a cooling zone, specifically located, were not supported by an enabling disclosure (35 U.S.C. 112, first paragraph).

In addition, if a claim is amended to include an invention that is not described in the application as filed, a rejection of that claim under 35 U.S.C. 112, first paragraph, as being directed to subject matter that is not described in the specification as filed may be appropriate. *In re Simon*, 302 F.2d 737, 133 USPQ 524 (CCPA 1962). In *Simon*, which involved a reissue application containing claims to a reaction product of a composition, applicant presented claims to a reaction product of a composition comprising the subcombination A+B+C, whereas the original claims and description of the invention were directed to a composition comprising the combination A+B+C+D+E. The court found no significant support for the argument that ingredients D+E were not essential to the claimed reaction product and concluded that claims directed to the reaction product of a subcombination A+B+C were not described (35 U.S.C. 112, first paragraph) in the application as filed. See also *In re Panagrossi*, 277 F.2d 181, 125 USPQ 410 (CCPA 1960).

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

This section sets forth guidelines for the examination of 35 U.S.C. 112, sixth paragraph, "means or step plus function" limitations in a claim. These guidelines are based on the Office's current understanding of the law and are believed to be fully consistent with binding precedent of the Supreme Court, the Federal Circuit and the Federal Circuit's predecessor courts. These guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law.

The Court of Appeals for the Federal Circuit, in its *en banc* decision *In re Donaldson Co.*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994), decided that a "means-or-step-plus-function" limitation should be interpreted in a manner different than patent examining practice had previously dictated. The *Donaldson* decision affects only the manner in which the scope of a "means or step plus function" limitation in accordance with 35 U.S.C. 112, sixth paragraph, is interpreted during examination. *Donaldson* does not directly affect the manner in which any other section of the patent statutes is interpreted or applied.

When making a determination of patentability under 35 U.S.C. 102 or 103, past practice was to interpret a "means or step plus function" limitation by giving it the "broadest reasonable interpretation." Under the PTO's long-standing practice this meant interpreting such a limitation as reading on any prior art means or step which performed the function specified in the claim without regard for whether the prior art means or step was equivalent to the corresponding structure, material or acts described in the specification. However, in *Donaldson*, the Federal Circuit stated:

> Per our holding, the "broadest reasonable interpretation" that an examiner may give means-plus-function language is that statutorily mandated in paragraph six. Accordingly, the PTO may not disregard the structure disclosed in the

specification corresponding to such language when rendering a patentability determination.

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

The USPTO must apply 35 U.S.C. 112, sixth paragraph in appropriate cases, and give claims their broadest reasonable interpretation, in light of and consistent with the written description of the invention in the application. See *Donaldson*, 16 F.3d at 1194, 29 USPQ2d at 1850 (stating that 35 U.S.C. 112, sixth paragraph "merely sets a limit on how broadly the PTO may construe means-plus-function language under the rubric of reasonable interpretation.'"). The Federal Circuit has held that applicants (and reexamination patentees) before the USPTO have the opportunity and the obligation to define their inventions precisely during proceedings before the PTO. See *In re Morris*, 127 F.3d 1048, 1056–57, 44 USPQ2d 1023, 1029–30 (Fed. Cir. 1997) (35 U.S.C. 112, second paragraph places the burden of precise claim drafting on the applicant); *In re Zletz*, 893 F.2d 319, 322, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (manner of claim interpretation that is used by courts in litigation is not the manner of claim interpretation that is applicable during prosecution of a pending application before the PTO); *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1425, 44 USPQ2d 1103, 1107 (Fed. Cir. 1997) (patentee who had a clear opportunity to negotiate broader claims during prosecution but did not do so, may not seek to expand the claims through the doctrine of equivalents, for it is the patentee, not the public, who must bear the cost of failure to seek protection for this foreseeable alteration of its claimed structure). Applicants and reexamination patentees before the USPTO have an opportunity and obligation to specify, consistent with these guidelines, when a claim limitation invokes 35 U.S.C. 112, sixth paragraph.

A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

(A) the claim limitations must use the phrase "means for" or "step for;"

(B) the "means for" or "step for" must be modified by functional language; and

(C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

With respect to the first prong of this analysis, a claim element that does not include the phrase "means for" or "step for" will not be considered to invoke 35 U.S.C. 112, sixth paragraph. If an applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant must either: (A) amend the claim to include the phrase "means for" or "step for" in accordance with these guidelines; or (B) show that even though the phrase "means for" or "step for" is not used, the claim limitation is written as a function to be performed and does not recite sufficient structure, material, or acts which would preclude application of 35 U.S.C. 112, sixth paragraph. See *Watts v. XL Systems, Inc.*, 232 F.3d 877, 56 USPQ2d 1836 (Fed. Cir. 2000) (Claim limitations were held not to invoke 35 U.S.C. 112, sixth paragraph, because the absence of the term "means" raised the presumption that the limitations were not in means-plus-function form, nor was the presumption rebutted.); see also *Masco Corp. v. United States*, 303 F.3d 1316, 1327, 64 USPQ2d 1182, 1189 (Fed. Cir. 2002) ("[W]here a method claim does not contain the term 'step[s] for,' a limitation of that claim cannot be construed as a step-plus-function limitation without a showing that the limitation contains no act.").

While traditional "means for" or "step for" language does not automatically make an element a means-(or step-) plus-function element, conversely, lack of such language does not prevent a limitation from being construed as a means-(or step-) plus-function limitation. See *Signtech USA, Ltd. v. Vutek, Inc.*, 174 F.3d 1352, 1356, 50 USPQ2d 1372, 1374– 75 (Fed. Cir.1999) ("ink delivery means positioned on …" invokes 35 U.S.C. 112, sixth paragraph since the phrase "ink delivery means" is equivalent to "means for ink delivery"); *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1317-19, 50 USPQ2d 1161, 1166-67 (Fed. Cir. 1999) (although the claim elements "eyeglass hanger member" and "eyeglass contacting member" include a function, these claim elements do not invoke 35 U.S.C. 112, sixth paragraph because the claims themselves contain sufficient structural limitations for performing these functions); *Seal-Flex, Inc. v. Athletic Track and Court Construction*, 172 F.3d 836, 850, 50 USPQ2d 1225, 1234 (Fed. Cir. 1999) (Radar, J.,

concurring) ("claim elements without express step-plus-function language may nevertheless fall within 112 6 if they merely claim the underlying function without recitation of acts for performing that function…In general terms, the underlying function' of a method claim element corresponds to *what* that element ultimately accomplishes in relationship to what the other elements of the claim and the claim as a whole accomplish. Acts,' on the other hand, correspond to *how* the function is accomplished…If the claim element uses the phrase step for,' then § 112, 6 is presumed to apply…On the other hand, the term step' alone and the phrase steps of' tend to show that § 112, 6 does not govern that limitation."); *Personalized Media Communications LLC v. ITC*, 161 F.3d 696, 703– 04, 48 USPQ2d 1880, 1886– 87 (Fed. Cir. 1998); *Mas-Hamilton Group v. LaGard Inc.*, 156 F.3d 1206, 1213, 48 USPQ2d 1010, 1016 (Fed. Cir. 1998) ("lever moving element for moving the lever" and "movable link member for holding the lever…and for releasing the lever" were construed as means-plus-function limitations invoking 35 U.S.C. 112, sixth paragraph since the claimed limitations were described in terms of their function not their mechanical structure); *Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1463, 45 USPQ2d 1545, 1550 (Fed. Cir. 1998) ("use of the word means 'gives rise to a presumption that the inventor used the term advisedly to invoke the statutory mandates for means-plus-function clauses'"); *O.I. Corp. v. Tekmar*, 115 F.3d 1576, 1583, 42 USPQ2d 1777, 1782 (Fed. Cir. 1997) (method claim that paralleled means-plus-function apparatus claim but lacked "step for" language did not invoke 35 U.S.C. 112, sixth paragraph). Thus, absent an express recitation of "means for" or "step for" in the limitation, the broadest reasonable interpretation will not be limited to "corresponding structure…and equivalents thereof." *Morris*, 127 F.3d at 1055, 44 USPQ2d at 1028 ("no comparable mandate in the patent statute that relates the claim scope of non-§ 112 paragraph 6 claims to particular matter found in the specification").

With respect to the second prong of this analysis, see *York Prod., Inc. v. Central Tractor Farm & Family Center*, 99 F.3d 1568, 1574, 40 USPQ2d 1619, 1624 (Fed. Cir. 1996) (holding that a claim limitation containing the term "means" does not invoke 35 U.S.C. 112, sixth paragraph, if the claim limitation does not link the term "means" to a specific function). It must be clear that the element in the claims is set forth, at least in part, by the function it performs as opposed to the specific structure, material, or acts that perform the function. See 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."); *O.I. Corp.*, 115 F.3d at 1582-83, 42 USPQ2d at 1782 (With respect to process claims, "[35 U.S.C. 112, sixth paragraph] is implicated only when steps *plus function* without acts are present…If we were to construe every process claim containing steps described by an 'ing' verb, such as passing, heating, reacting, transferring, etc., into a step-plus-function, we would be limiting process claims in a manner never intended by Congress." (Emphasis in original).). However, "the fact that a particular mechanism…is defined in functional terms is not sufficient to convert a claim element containing that term into a 'means for performing a specified function' within the meaning of section 112(6)." *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583, 39 USPQ2d 1783, 1786 (Fed. Cir. 1996) ("detent mechanism" defined in functional terms was not intended to invoke 35 U.S.C. 112, sixth paragraph). See also *Al-Site Corp. v. VSI International Inc.*, 174 F.3d 1308, 1318, 50 USPQ2d 1161, 1166–67 (Fed. Cir. 1999) (although the claim elements "eyeglass hanger member" and "eyeglass contacting member" include a function, these claim elements do not invoke 35 U.S.C. 112, sixth paragraph, because the claims themselves contain sufficient structural limitations for performing those functions). Also, a statement of function appearing only in the claim preamble is generally insufficient to invoke 35 U.S.C. 112, sixth paragraph. *O.I. Corp.*, 115 F.3d at 1583, 42 USPQ2d at 1782 ("[A] statement in a preamble of a result that necessarily follows from performing a series of steps does not convert each of those steps into step- plus-function clauses. The steps of 'passing' are not individually associated in the claims with functions performed by the steps of passing.").

With respect to the third prong of this analysis, see *Seal-Flex*, 172 F.3d at 849, 50 USPQ2d at 1234 (Radar, J., concurring) ("Even when a claim element

uses language that generally falls under the step-plus-function format, however, 112 ¶ 6 still does not apply when the claim limitation itself recites sufficient acts for performing the specified function."); *Envirco Corp. v. Clestra Cleanroom, Inc.*, 209 F.3d 1360, 54 USPQ2d 1449 (Fed. Cir. 2000) (holding "second baffle means" does not invoke 35 U.S.C. 112, sixth paragraph, because the word "baffle" itself imparts structure and the claim further recites the structure of the baffle); *Rodime PLC v. Seagate Technology, Inc.*, 174 F.3d 1294, 1303–04, 50 USPQ2d 1429, 1435–36 (Fed. Cir. 1999) (holding "positioning means for moving" does not invoke 35 U.S.C. 112, sixth paragraph, because the claim further provides a list of the structure underlying the means and the detailed recitation of the structure for performing the moving function removes this element from the purview of 35 U.S.C. 112, sixth paragraph); *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531, 41 USPQ2d 1001, 1006 (Fed. Cir. 1996) (holding "perforation means…for tearing" does not invoke 35 U.S.C. 112, sixth paragraph, because the claim describes the structure supporting the tearing function (i.e., perforation)). In other cases, the Federal Circuit has held otherwise. See *Unidynamics Corp. v. Automatic Prod. Int'l*, 157 F.3d 1311, 1319, 48 USPQ2d 1099, 1104 (Fed. Cir. 1998) (holding "spring means" does invoke 35 U.S.C. 112, sixth paragraph). During examination, however, applicants have the opportunity and the obligation to define their inventions precisely, including whether a claim limitation invokes 35 U.S.C. 112, sixth paragraph. Thus, if the phrase "means for" or "step for" is modified by sufficient structure, material or acts for achieving the specified function, the USPTO will not apply 35 U.S.C. 112, sixth paragraph, until such modifying language is deleted from the claim limitation.

It is necessary to decide on an element by element basis whether 35 U.S.C. 112, sixth paragraph, applies. Not all terms in a means-plus-function or step-plus-function clause are limited to what is disclosed in the written description and equivalents thereof, since 35 U.S.C. 112, sixth paragraph, applies only to the interpretation of the means or step that performs the recited function. See, e.g., *IMS Technology Inc. v. Haas Automation Inc.*, 206 F.3d 1422, 54 USPQ2d 1129 (Fed. Cir. 2000) (the term "data block" in the phrase "means to sequentially display data block inquiries" was not the means that caused the sequential display, and its meaning was not limited to the disclosed embodiment and equivalents thereof.). Each claim must be independently reviewed to determine the applicability of 35 U.S.C. 112, sixth paragraph, even where the application contains substantially similar process and apparatus claims. *O.I. Corp.*, 115 F.3d at 1583-1584, 42 USPQ2d at 1782 ("We understand that the steps in the method claims are essentially in the same language as the limitations in the apparatus claim, albeit without the 'means for' qualification…Each claim must be independently reviewed in order to determine if it is subject to the requirements of section 112, ¶ 6. Interpretation of claims would be confusing indeed if claims that are not means- or step-plus function were to be interpreted as if they were, only because they use language similar to that used in other claims that are subject to this provision.").

>Where a claim limitation meets the 3-prong analysis and is being treated under 35 U.S.C. 112, sixth paragraph, the examiner will include a statement in the Office action that the claim limitation is being treated under 35 U.S.C. 112, sixth paragraph. However, if a claim limitation does not use the phrase "means for" or "step for," that is, the first prong of the 3-prong analysis is not met, the examiner will not treat such a claim limitation under 35 U.S.C. 112, sixth paragraph. It will not be necessary to state in the Office action that 35 U.S.C. 112, sixth paragraph, has not been invoked, since the presumption is that applicant did not intend to invoke the provisions of 35 U.S.C. 112, sixth paragraph, because applicant did not use the specific phrase "means for" or "step for." If a claim limitation does include the phrase "means for" or "step for," that is, the first prong of the 3-prong analysis is met, but the examiner determines that either the second prong or the third prong of the 3-prong analysis is not met, then in these situations, the examiner must include a statement in the Office action explaining the reasons why a claim limitation which uses the phrase "means for" or "step for" is not being treated under 35 U.S.C. 112, sixth paragraph.<

Accordingly, these guidelines provide applicants with the opportunity to either invoke or not invoke 35 U.S.C. 112, sixth paragraph, based upon a clear and simple set of criteria.

**>The following examples illustrate situations where the phrase "means for" or "step for" was not

used but the Board or the courts determined that the claim limitation falls within the scope of 35 U.S.C. 112, sixth paragraph. Note that the examples are fact specific and should not be applied as *per se* rules. As noted above, examiners should apply the 3-prong analysis to determine whether the claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph. A claim element that does not include the phrase "means for" or "step for" will not be considered to invoke 35 U.S.C. 112, sixth paragraph. If an applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant must either amend the claim to include the phrase "means for" or "step for," or show that even though the phrase "means for" or "step for" is not used, the claim limitation is written as a function to be performed and does not recite sufficient structure, material, or acts which would preclude application of 35 U.S.C. 112, sixth paragraph.<

(A) 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);

(B) "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;

(C) force generating means adapted to provide . . . . *De Graffenreid v. United States*, 20 Ct. Cl. 458, 16 USPQ2d 1321 (Ct. Cl. 1990);

(D) 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);

(E) 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

(F) 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.

II. WRITTEN DESCRIPTION NECESSARY TO SUPPORT A CLAIM LIMITATION WHICH INVOKES 35 U.S.C. 112, SIXTH PARAGRAPH

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure…described in the specification and equivalents thereof." "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112." *In re Donaldson Co.*, 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc).

The proper test for meeting the definiteness requirement is that the corresponding structure (or material or acts) of a means (or step)-plus-function limitation must be disclosed in the specification itself in a way that one skilled in the art will understand what structure (or material or acts) will perform the recited function. See *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1381, 53 USPQ2d 1225, 1230 (Fed. Cir. 1999). In *Atmel*, the patentee claimed an apparatus that included a "high voltage generating means" limitation, thereby invoking 35 U.S.C. 112, sixth paragraph. The specification incorporated by reference a non-patent document from a technical journal, which described a particular high voltage generating circuit. The Federal Circuit concluded that the title of the article in the specification may, by itself, be sufficient to indicate to one skilled in the art the precise structure of the means for performing the recited function, and it remanded the case to the district court "to consider the knowledge of one skilled in the art that indicated, based on unrefuted testimony, that the specification disclosed sufficient structure corresponding to the high-voltage means limitation." *Id*. at 1382, 53 USPQ2d at 1231.

The disclosure of the structure (or material or acts) may be implicit or inherent in the specification if it

would have been clear to those skilled in the art what structure (or material or acts) corresponds to the means (or step)-plus-function claim limitation. See *Id*. at 1380, 53 USPQ2d at 1229; *In re Dossel*, 115 F.3d 942, 946-47, 42 USPQ2d 1881, 1885 (Fed. Cir. 1997). If there is no disclosure of structure, material or acts for performing the recited function, the claim fails to satisfy the requirements of 35 U.S.C. 112, second paragraph. *Budde v. Harley-Davidson, Inc*., 250 F.3d 1369, 1376, 58 USPQ2d 1801, 1806 (Fed. Cir. 2001); *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc*., 296 F.3d 1106, 1115-18, 63 USPQ2d 1725, 1731-34 (Fed. Cir. 2002) (Court interpreted the language of the "third monitoring means for monitoring the ECG signal…for activating …" to require the same means to perform both functions and the only entity referenced in the specification that could possibly perform both functions is the physician. The court held that excluding the physician, no structure accomplishes the claimed dual functions. Because no structure disclosed in the embodiments of the invention actually performs the claimed dual functions, the specification lacks corresponding structure as required by 35 U.S.C. 112, sixth paragraph, and fails to comply with 35 U.S.C. 112, second paragraph.).

Whether a claim reciting an element in means- (or step-) plus-function language fails to comply with 35 U.S.C. 112, second paragraph, because the specification does not disclose adequate structure (or material or acts) for performing the recited function is closely related to the question of whether the specification meets the description requirement in 35 U.S.C. 112, first paragraph. See *In re Noll*, 545 F.2d 141, 149, 191 USPQ 721, 727 (CCPA 1976) (unless the means-plus-function language is itself unclear, a claim limitation written in means-plus- function language meets the definiteness requirement in 35 U.S.C. 112, second paragraph, so long as the specification meets the written description requirement in 35 U.S.C. 112, first paragraph). However, 35 U.S.C. 112, sixth paragraph, does not impose any requirements in addition to those imposed by 35 U.S.C. 112, first paragraph. See *In re Knowlton*, 481 F.2d 1357, 1366, 178 USPQ 486, 492–93 (CCPA 1973). Conversely, the invocation of 35 U.S.C. 112, sixth paragraph, does not exempt an applicant from compliance with 35 U.S.C. 112, first and second paragraphs. See *Donaldson*, 16 F.3d at 1195, 29 USPQ2d at 1850; *Knowlton*, 481 F.2d at 1366, 178 USPQ at 493.

Under certain limited circumstances, the written description does not have to explicitly describe the structure (or material or acts) corresponding to a means- (or step-) plus-function limitation to particularly point out and distinctly claim the invention as required by 35 U.S.C. 112, second paragraph. See *Dossel*, 115 F.3d at 946, 42 USPQ2d at 1885. Under proper circumstances, drawings may provide a written description of an invention as required by 35 U.S.C. 112. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1565, 19 USPQ2d 1111, 1118 (Fed. Cir. 1991). Rather, disclosure of structure corresponding to a means-plus-function limitation may be implicit in the written description if it would have been clear to those skilled in the art what structure must perform the function recited in the means-plus-function limitation. See *Atmel Corp. v. Information Storage Devices Inc.*, 198 F.3d 1374, 1379, 53 USPQ2d 1225, 1228 (Fed. Cir. 1999) (stating that the "one skilled in the art" analysis should apply in determining whether sufficient structure has been disclosed to support a means-plus-function limitation and that the USPTO's recently issued proposed Supplemental Guidelines are consistent with the court's holding on this point); *Dossel*, 115 F.3d at 946–47, 42 USPQ2d at 1885 ("Clearly, a unit which receives digital data, performs complex mathematical computations and outputs the results to a display must be implemented by or on a general or special purpose computer (although it is not clear why the written description does not simply state 'computer' or some equivalent phrase.)").

III. DETERMINING 35 U.S.C. 112 SECOND PARAGRAPH COMPLIANCE WHEN 35 U.S.C. 112 SIXTH PARAGRAPH IS INVOKED

The following guidance is provided to determine whether applicant has complied with the requirements of 35 U.S.C. 112, second paragraph, when 35 U.S.C. 112, sixth paragraph, is invoked:

(A) If the corresponding structure, material or acts are described in the specification in specific terms (e.g., an emitter-coupled voltage comparator) and one skilled in the art could identify the structure, material or acts from that description, then the requirements of 35 U.S.C. 112, second and sixth para-

graphs and are satisfied. See *Atmel*, 198 F.3d at 1382, 53 USPQ2d 1231.

(B) If the corresponding structure, material or acts are described in the specification in broad generic terms and the specific details of which are incorporated by reference to another document (e.g., attachment means disclosed in U.S. Patent No. X, which is hereby incorporated by reference, or a comparator as disclosed in the IBM article, which is hereby incorporated by reference), Office personnel must review the description in the specification, without relying on any material from the incorporated document, and apply the "one skilled in the art" analysis to determine whether one skilled in the art could identify the corresponding structure (or material or acts) for performing the recited function to satisfy the definiteness requirement of 35 U.S.C. 112, second paragraph. >See *Default Proof Credit Card System, Inc. v. Home Depot U.S.A., Inc.*, ___F.3d ___, 75 USPQ2d 1116 (Fed. Cir. 2005) ("The inquiry under [35 U.S.C.] § 112, ¶ 2, does not turn on whether a patentee has 'incorporated by reference' material into the specification relating to structure, but instead asks first 'whether structure is described in the specification, and, if so, whether one skilled in the art would identify the structure from that description'").<

(1) If one skilled in the art would be able to identify the structure, material or acts from the description in the specification for performing the recited function, then the requirements of 35 U.S.C. 112, second paragraph, are satisfied. See *Dossel*, 115 F.3d at 946-47, 42 USPQ2d at 1885 (The function recited in the means-plus-function limitation involved "reconstructing" data. The issue was whether the structure underlying this "reconstructing" function was adequately described in the written description to satisfy 35 U.S.C. 112, second paragraph. The court stated that "[n]either the written description nor the claims uses the magic word 'computer,' nor do they quote computer code that may be used in the invention. Nevertheless, when the written description is combined with claims 8 and 9, the disclosure satisfies the requirements of Section 112, Para. 2." The court concluded that based on the specific facts of the case, one skilled in the art would recognize the structure for performing the "reconstructing" function since "a unit which receives digital data, performs complex mathematical computations and outputs the results to a display must be implemented by or on a general or special purpose computer."). See also *Intel Corp. v. VIA Technologies, Inc*, 319 F.3d 1357, 1366, 65 USPQ2d 1934, 1941 (Fed. Cir. 2003) (The "core logic" structure that was modified to perform a particular program was held to be adequate corresponding structure for a claimed function although the specification did not disclose internal circuitry of the core logic to show exactly how it must be modified.)

(2) If one skilled in the art would <u>not</u> be able to identify the structure, material or acts from description in the specification for performing the recited function, then applicant will be required to amend the specification to include the material incorporated by reference and to clearly link or associate the structure, material or acts to the function recited in the claim. Applicant should not be required to insert the subject matter described in the entire referenced document into the specification. To maintain a concise specification, applicant should only include the relevant portions of the referenced document that correspond to the means (or step)-plus-function limitation. See *Atmel*, 198 F.3d at 1382, 53 USPQ2d at 1230 ("All one needs to do…is to recite some structure corresponding to the means in the specification…so that one can readily ascertain what the claim means and comply with the particularity requirement of Para. 2.").

IV. DETERMINING WHETHER 35 U.S.C. 112, FIRST *>PARAGRAPH< SUPPORT EXISTS

The claims must still be analyzed to determine whether there exists corresponding adequate support for such claim under 35 U.S.C. 112, first paragraph. In considering whether there is 35 U.S.C. 112, first paragraph support for the claim limitation, the examiner must consider not only the original disclosure contained in the summary and detailed description of the invention portions of the specification, but also the original claims, abstract, and drawings. See *In re Mott*, 539 F.2d 1291, 1299, 190 USPQ 536, 542–43 (CCPA 1976) (claims); *In re Anderson*, 471 F.2d 1237, 1240, 176 USPQ 331, 333 (CCPA 1973) (claims); *Hill-Rom Co. v. Kinetic Concepts, Inc.*, **>209 F.3d 1337<, 54 USPQ2d 1437 (Fed. Cir. 2000) (unpublished) (abstract); *In re Armbruster*, 512 F.2d 676, 678–79, 185 USPQ 152, 153–54 (CCPA

1975) (abstract); *Anderson*, 471 F.2d at 1240, 176 USPQ at 333 (abstract); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d at 1564, 19 USPQ2d at 1117 (drawings); *In re Wolfensperger*, 302 F.2d 950, 955–57, 133 USPQ 537, 541– 43 (CCPA 1962) (drawings).

37 CFR 1.75(d)(1) provides, in part, that "the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." In the situation in which the written description only implicitly or inherently sets forth the structure, materials, or acts corresponding to a means- (or step-) plus-function, and the examiner concludes that one skilled in the art would recognize what structure, materials, or acts perform the function recited in a means- (or step-) plus-function, the examiner should either: (A) have the applicant clarify the record by amending the written description such that it expressly recites what structure, materials, or acts perform the function recited in the claim element; or (B) state on the record what structure, materials, or acts perform the function recited in the means- (or step-) plus-function limitation. Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to a means- (or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the USPTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP § 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, or acts perform the function recited in the claim element. See 35 U.S.C. 112, sixth paragraph ("An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." (emphasis added)); see also *B. Braun Medical*, 124 F.3d at 1424, 43 USPQ2d at 1900 (holding that "pursuant to this provision [35 U.S.C. 112, sixth paragraph], structure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim. This duty to link or associate structure to function is the *quid pro quo* for the convenience of employing 112, paragraph 6."); *Medical Instrumentation and Diagnostic Corp. v. Elekta AB*, 344 F.3d 1205, 1218, 68 USPQ2d 1263, 1268 (Fed. Cir. 2003)(Although one of skill in the art would have been able to write a software program for digital to digital conversion, such software did not fall within the scope of "means for converting" images as claimed because nothing in the specification or prosecution history clearly linked or associated such software with the function of converting images into a selected format.); *Wolfensperger*, 302 F.2d at 955, 133 USPQ at 542 (just because the disclosure provides support for a claim element does not mean that the USPTO cannot enforce its requirement that the terms and phrases used in the claims find clear support or antecedent basis in the written description).

V. SINGLE MEANS CLAIMS

Donaldson does not affect the holding of *In re Hyatt*, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983) to the effect that a single means claim does not comply with the enablement requirement of 35 U.S.C. 112, first paragraph. As *Donaldson* applies only to an interpretation of a limitation drafted to correspond to 35 U.S.C. 112, sixth paragraph, which by its terms is limited to "an element in a claim to a combination," it does not affect a limitation in a claim which is not directed to a combination.

2182 Scope of the Search and Identification of the Prior Art [R-2]

As noted in MPEP § 2181, in *In re Donaldson Co.*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994) the Federal Circuit recognized that it is important to retain the principle that claim language should be given its broadest reasonable interpretation. This principle is important because it helps insure that the statutory presumption of validity attributed to each claim of an issued patent is warranted by the search and examination conducted by the examiner. It is also important from the standpoint that the scope of protection afforded by patents issued prior to *Donaldson* are not unnecessarily limited by the latest interpretation of this statutory provision. Finally, it is important from the standpoint of avoiding the necessity for a patent specification to become a catalogue of existing technology. The specification need not describe the equivalents of the structures, material, or acts corre-

sponding to the means- (or step-) plus-function claim element. See *In re Noll*, 545 F.2d 141, 149-50, 191 USPQ 721, 727 (CCPA 1976) ("The meaning of 'equivalents' is well understood in patent law, … and an applicant need not describe in his specification the full range of equivalents of his invention.") (citation omitted). A patent specification need not teach, and preferably omits, what is well known in the art. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).

The *Donaldson* decision thus does not substantially alter examining practice and procedure relative to the scope of the search. Both before and after *Donaldson*, the application of a prior art reference to a means or step plus function limitation requires that the prior art element perform the identical function specified in the claim. However, if a prior art reference teaches identity of function to that specified in a claim, then under *Donaldson* an examiner carries the initial burden of proof for showing that the prior art structure or step is the same as or equivalent to the structure, material, or acts described in the specification which has been identified as corresponding to the claimed means or step plus function.

The "means or step plus function" limitation should be interpreted in a manner consistent with the specification disclosure. >The Federal Circuit explained the two step analysis involved in construing means-plus-function limitations in *Golight Inc. v. Wal-Mart Stores Inc*., 355 F.3d 1327, 1333-34, 69 USPQ2d 1481, 1486 (Fed. Cir. 2004):

> The first step in construing a means-plus-function claim limitation is to define the particular function of the claim limitation. *Budde v. Harley-Davidson, Inc*., 250 F.3d 1369, 1376 [58 USPQ2d 1801, 1806] (Fed. Cir. 2001). "The court must construe the function of a means-plus-function limitation to include the limitations contained in the claim language, and only those limitations." *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1113 [63 USPQ2d 1725, 1730] (Fed. Cir. 2002)…. The next step in construing a means-plus-function claim limitation is to look to the specification and identify the corresponding structure for that function. "Under this second step, 'structure disclosed in the specification is "corresponding" structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim.'" *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1210 [68 USPQ2d 1263, 1267] (Fed. Cir. 2003) (quoting *B. Braun Med. Inc. v. Abbott Labs*., 124 F.3d 1419, 1424 [43 USPQ2d 1896, 1900] (Fed. Cir. 1997)).<

If the specification defines what is meant by the limitation for the purposes of the claimed invention, the examiner should interpret the limitation as having that meaning. If no definition is provided, some judgment must be exercised in determining the scope of the limitation. See, e.g., *B. Braun Medical, Inc. v. Abbott Labs*., 124 F.3d 1419, 1424, 43 USPQ2d 1896, 1900 (Fed. Cir. 1997) ("We hold that, pursuant to [35 U.S.C. 112, sixth paragraph], structure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim. This duty to link or associate structure to function is the *quid pro quo* for the convenience of employing 112, paragraph 6." The court refused to interpret a means-plus-function limitation as corresponding to a disclosed valve seat structure, as argued by patentee, since there was no indication in the specification or prosecution history that this structure corresponds to the recited function, and there was an explicitly clear association between that function and a traverse cross section bar structure disclosed in the specification.).

2183 Making a *Prima Facie* Case of Equivalence

If the examiner finds that a prior art element

(A) performs the function specified in the claim,

(B) is not excluded by any explicit definition provided in the specification for an equivalent, and

(C) is an equivalent of the means- (or step-) plus-function limitation,

the examiner should provide an explanation and rationale in the Office action as to why the prior art element is an equivalent. Factors that will support a conclusion that the prior art element is an equivalent are:

(A) the prior art element performs the identical function specified in the claim in substantially the same way, and produces substantially the same results as the corresponding element disclosed in the specification. *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000) (An internal adhesive sealing the inner surfaces of an

envelope pocket was not held to be equivalent to an adhesive on a flap which attached to the outside of the pocket. Both the claimed invention and the accused device performed the same function of closing the envelope. But the accused device performed it in a substantially different way (by an internal adhesive on the inside of the pocket) with a substantially different result (the adhesive attached the inner surfaces of both sides of the pocket)); *Odetics Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267, 51 USPQ2d 1225, 1229-30 (Fed. Cir. 1999); *Lockheed Aircraft Corp. v. United States*, 193 USPQ 449, 461 (Ct. Cl. 1977). The concepts of equivalents as set forth in *Graver Tank & Mfg. Co. v. Linde Air Products*, 339 U.S. 605, 85 USPQ 328 (1950) are relevant to any "equivalents" determination. *Polumbo v. Don-Joy Co.*, 762 F.2d 969, 975 n.4, 226 USPQ 5, 8-9 n.4 (Fed. Cir. 1985).

(B) a person of ordinary skill in the art would have recognized the interchangeability of the element shown in the prior art for the corresponding element disclosed in the specification. *Caterpillar Inc. v. Deere & Co.*, 224 F.3d 1374, 56 USPQ2d 1305 (Fed. Cir. 2000); *Al-Site Corp. v. VSI Int' l, Inc.*, 174 F.3d 1308, 1316, 50 USPQ2d 1161, 1165 (Fed. Cir. 1999); *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus. Inc.*, 145 F.3d 1303, 1309, 46 USPQ2d 1752, 1757 (Fed. Cir. 1998); *Lockheed Aircraft Corp. v. United States*, 193 USPQ 449, 461 (Ct. Cl. 1977*); Data Line Corp. v. Micro Technologies, Inc.*, 813 F.2d 1196, 1 USPQ2d 2052 (Fed. Cir. 1987).

(C) there are insubstantial differences between the prior art element and the corresponding element disclosed in the specification. *IMS Technology, Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1436, 54 USPQ2d 1129, 1138 (Fed. Cir. 2000); *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 117 S. Ct. 1040, 41 USPQ2d 1865, 1875 (1997); *Valmont Industries, Inc. v. Reinke Mfg. Co.*, 983 F.2d 1039, 25 USPQ2d 1451 (Fed. Cir. 1993). See also *Caterpillar Inc. v. Deere & Co.*, 224 F.3d 1374, 56 USPQ2d 1305 (Fed. Cir. 2000) (A structure lacking several components of the overall structure corresponding to the claimed function and also differing in the number and size of the parts may be insubstantially different from the disclosed structure. The limitation in a means-plus-function claim is the overall structure corresponding to the claimed function. The individual components of an overall structure that corresponds to the claimed function are not claim limitations. Also, potential advantages of a structure that do not relate to the claimed function should not be considered in an equivalents determination under 35 U.S.C. 112, sixth paragraph).

(D) the prior art element is a structural equivalent of the corresponding element disclosed in the specification. *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.

A showing of at least one of the above-noted factors by the examiner should be sufficient to support a conclusion that the prior art element is an equivalent. The examiner should then conclude that the claimed limitation is met by the prior art element. In addition to the conclusion that the prior art element is an equivalent, examiners should also demonstrate, where appropriate, why it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute applicant's described structure, material, or acts for that described in the prior art reference. See *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). The burden then shifts to applicant to show that the element shown in the prior art is not an equivalent of the structure, material or acts disclosed in the application. *In re Mulder*, 716 F.2d 1542, 219 USPQ 189 (Fed. Cir. 1983). No further analysis of equivalents is required of the examiner until applicant disagrees with the examiner's conclusion, and provides reasons why the prior art element should not be considered an equivalent. See also, *In re Walter*, 618 F.2d 758, 768, 205 USPQ 397, 407-08 (CCPA 1980) (a case treating 35 U.S.C. 112, sixth paragraph, in the context of a determination of statutory subject matter and noting "If the functionally-defined disclosed means and their equivalents are so broad that they encompass any and every means for performing the recited functions . . . the burden must be placed on the applicant to demonstrate that the claims are truly drawn to specific apparatus distinct from other apparatus capable of performing the identical functions"); *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 229 (CCPA 1971) (a case in which the court treated as improper a rejection under 35 U.S.C. 112, second paragraph, of

functional language, but noted that "where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristics relied on"); and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980) (a case indicating that the burden of proof can be shifted to the applicant to show that the subject matter of the prior art does not possess the characteristic relied on whether the rejection is based on inherency under 35 U.S.C. 102 or obviousness under 35 U.S.C. 103).

See MPEP § 2184 when determining whether the applicant has successfully met the burden of proving that the prior art element is not equivalent to the structure, material or acts described in the applicant's specification.

IF NONEQUIVALENCE SHOWN, EXAMINER MUST CONSIDER OBVIOUSNESS

However, even where the applicant has met that burden of proof and has shown that the prior art element is not equivalent to the structure, material or acts described in the applicant's specification, the examiner must still make a 35 U.S.C. 103 analysis to determine if the claimed means or step plus function is obvious from the prior art to one of ordinary skill in the art. Thus, while a finding of nonequivalence prevents a prior art element from anticipating a means or step plus function limitation in a claim, it does not prevent the prior art element from rendering the claim limitation obvious to one of ordinary skill in the art. Because the exact scope of an "equivalent" may be uncertain, it would be appropriate to apply a 35 U.S.C. 102/103 rejection where the balance of the claim limitations are anticipated by the prior art relied on. A similar approach is authorized in the case of product-by-process claims because the exact identity of the claimed product or the prior art product cannot be determined by the examiner. *In re Brown*, 450 F.2d 531, 173 USPQ 685 (CCPA 1972). In addition, although it is normally the best practice to rely on only the best prior art references in rejecting a claim, alternative grounds of rejection may be appropriate where the prior art shows elements that are different from each other, and different from the specific structure, material or acts described in the specification, yet perform the function specified in the claim.

2184 Determining Whether an Applicant Has Met the Burden of Proving Nonequivalence After a *Prima Facie* Case Is Made [R-2]

The specification need not describe the equivalents of the structures, material, or acts corresponding to the means-(or step-) plus-function claim element. See *In re Noll*, 545 F.2d 141, 149-50, 191 USPQ 721, 727 (CCPA 1976) (the meaning of equivalents is well understood in patent law, and an applicant need not describe in his specification the full range of equivalents of his invention) (citation omitted). *Cf. Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986) ("a patent need not teach, and preferably omits, what is well known in the art"). Where, however, the specification is silent as to what constitutes equivalents and the examiner has made out a *prima facie* case of equivalence, the burden is placed upon the applicant to show that a prior art element which performs the claimed function is not an equivalent of the structure, material, or acts disclosed in the specification. See *In re Mulder*, 716 F.2d 1542, 1549, 219 USPQ 189, 196 (Fed. Cir. 1983).

If the applicant disagrees with the inference of equivalence drawn from a prior art reference, the applicant may provide reasons why the applicant believes the prior art element should not be considered an equivalent to the specific structure, material or acts disclosed in the specification. Such reasons may include, but are not limited to:

(A) Teachings in the specification that particular prior art is not equivalent;

(B) Teachings in the prior art reference itself that may tend to show nonequivalence; or

(C) 37 CFR 1.132 affidavit evidence of facts tending to show nonequivalence.

>

I. < TEACHINGS IN APPLICANT'S SPECIFICATION

When the applicant relies on teachings in applicant's own specification, the examiner must make

sure that the applicant is interpreting the "means or step plus function" limitation in the claim in a manner which is consistent with the disclosure in the specification. If the specification defines what is meant by "equivalents" to the disclosed embodiments for the purpose of the claimed means or step plus function, the examiner should interpret the limitation as having that meaning. If no definition is provided, some judgment must be exercised in determining the scope of "equivalents." Generally, an "equivalent" is interpreted as embracing more than the specific elements described in the specification for performing the specified function, but less than any element that performs the function specified in the claim. >See, e.g., *NOMOS Corp. v. BrainLAB USA Inc*., 357 F.3d, 1364, 1368, 69 USPQ2d 1853, 1856 (Fed. Cir. 2004) (only one embodiment is described, therefore the corresponding structure is limited to that embodiment and equivalents thereof).< To interpret "means plus function" limitations as limited to a particular means set forth in the specification would nullify the provisions of 35 U.S.C. 112 requiring that the limitation shall be construed to cover the structure described in the specification and equivalents thereof. *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1574, 225 USPQ 236, 238 (Fed. Cir. 1985).

The scope of equivalents embraced by a claim limitation is dependent on the interpretation of an "equivalent." The interpretation will vary depending on how the element is described in the supporting specification. The claim may or may not be limited to particular structure, material or acts (e.g., steps) as opposed to any and all structure, material or acts performing the claimed function, depending on how the specification treats that question. See, e.g., *Ishida Co. v. Taylor*, 221 F.3d 1310, 55 USPQ2d 1449 (Fed. Cir. 2000) (The court construed the scope of a means-plus-function claim element where the specification disclosed two structurally very different embodiments for performing the claimed function by looking separately to each embodiment to determine corresponding structures. The court declined to adopt a single claim construction encompassing both embodiments since it would be so broad as to describe systems both with and without the fundamental structural features of each embodiment.).

If the disclosure is so broad as to encompass any and all structure, material or acts for performing the claimed function, the claims must be read accordingly when determining patentability. When this happens the limitation otherwise provided by "equivalents" ceases to be a limitation on the scope of the claim in that an equivalent would be any structure, material or act other than the ones described in the specification that perform the claimed function. For example, this situation will often be found in cases where (A) the claimed invention is a combination of elements, one or more of which are selected from elements that are old, *per se*, or (B) apparatus claims are treated as indistinguishable from method claims. See, for example, *In re Meyer*, 688 F.2d 789, 215 USPQ 193 (CCPA 1982); *In re Abele*, 684 F.2d 902, 909, 214 USPQ 682, 688 (CCPA 1982); *In re Walter*, 618 F.2d 758, 767, 205 USPQ 397, 406-07 (CCPA 1980); *In re Maucorps*, 609 F.2d 481, 203 USPQ 812 (CCPA 1979); *In re Johnson*, 589 F.2d 1070, 200 USPQ 199 (CCPA 1978); and *In re Freeman*, 573 F.2d 1237, 1246, 197 USPQ 464, 471 (CCPA 1978).

On the other end of the spectrum, the "equivalents" limitation as applied to a claim may also operate to constrict the claim scope to the point of covering virtually only the disclosed embodiments. This can happen in circumstances where the specification describes the invention only in the context of a specific structure, material or act that is used to perform the function specified in the claim.

>

II. < FACTORS TO BE CONSIDERED IN DECIDING EQUIVALENCE

When deciding whether an applicant has met the burden of proof with respect to showing nonequivalence of a prior art element that performs the claimed function, the following factors may be considered. First, unless an element performs the identical function specified in the claim, it cannot be an equivalent for the purposes of 35 U.S.C. 112, sixth paragraph. *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 4 USPQ2d 1737 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 961 (1988).

Second, while there is no litmus test for an "equivalent" that can be applied with absolute certainty and predictability, there are several indicia that are sufficient to support a conclusion that one element is or is not an "equivalent" of a different element in the context of 35 U.S.C. 112, sixth paragraph. Among the

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

(A) Whether the prior art element performs the identical function specified in the claim in substantially the same way, and produces substantially the same results as the corresponding element disclosed in the specification. *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000) (An internal adhesive sealing the inner surfaces of an envelope pocket was not held to be equivalent to an adhesive on a flap which attached to the outside of the pocket. Both the claimed invention and the accused device performed the same function of closing the envelope. But the accused device performed it in a substantially different way (by an internal adhesive on the inside of the pocket) with a substantially different result (the adhesive attached the inner surfaces of both sides of the pocket)); *Odetics Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267, 51 USPQ2d 1225, 1229-30 (Fed. Cir. 1999); *Lockheed Aircraft Corp. v. United States*, 193 USPQ 449, 461 (Ct. Cl. 1977). The concepts of equivalents as set forth in *Graver Tank & Mfg. Co. v. Linde Air Prod*ucts, 339 U.S. 605, 85 USPQ 328 (1950) are relevant to any "equivalents" determination. *Polumbo v. Don-Joy Co.*, 762 F.2d 969, 975, n. 4, 226 USPQ 5, 8-9, n. 4 (Fed. Cir. 1985).

(B) 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. *Caterpillar Inc. v. Deere & Co.*, 224 F.3d 1374, 56 USPQ2d 1305 (Fed. Cir. 2000); *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1316, 50 USPQ2d 1161, 1165 (Fed. Cir. 1999); *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus. Inc.*, 145 F.3d 1303, 1309, 46 USPQ2d 1752, 1757 (Fed. Cir. 1998); *Lockheed Aircraft Corp. v. United States*, 193 USPQ 449, 461 (Ct. Cl. 1977*); Data Line Corp. v. Micro Technologies, Inc.*, 813 F.2d 1196, 1 USPQ2d 2052 (Fed. Cir. 1987).

(C) Whether there are insubstantial differences between the prior art element and the corresponding element disclosed in the specification. *IMS Technology, Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1436, 54 USPQ2d 1129, 1138 (Fed. Cir. 2000); *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 117 S. Ct. 1040, 41 USPQ2d 1865, 1875 (1997); *Valmont Industries, Inc. v. Reinke Mfg. Co.*, 983 F.2d 1039, 25 USPQ2d 1451 (Fed. Cir. 1993). See also *Caterpillar Inc. v. Deere & Co.*, 224 F.3d 1374, 56 USPQ2d 1305 (Fed. Cir. 2000) (A structure lacking several components of the overall structure corresponding to the claimed function and also differing in the number and size of the parts may be insubstantially different from the disclosed structure. The limitation in a means-plus-function claim is the overall structure corresponding to the claimed function. The individual components of an overall structure that corresponds to the claimed function are not claim limitations. Also, potential advantages of a structure that do not relate to the claimed function should not be considered in an equivalents determination under 35 U.S.C. 112, sixth paragraph).

(D) Whether the prior art element is a structural equivalent of the corresponding element disclosed in the specification. *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.

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.
>

III. < MERE ALLEGATIONS OF NONEQUIVALENCE ARE NOT SUFFICIENT

In determining whether arguments or 37 CFR 1.132 evidence presented by an applicant are persuasive that the element shown in the prior art is not an equivalent, the examiner should consider and weigh as many of the above-indicated or other indicia as are presented by applicant, and should determine whether, on balance, the applicant has met the burden of proof to show nonequivalence. However, under no circumstance should an examiner accept as persuasive a bare statement or opinion that the element shown in the prior art is not an equivalent embraced by the claim limitation. Moreover, if an applicant argues that the

"means" or "step" plus function language in a claim is limited to certain specific structural or additional functional characteristics (as opposed to "equivalents" thereof) where the specification does not describe the invention as being only those specific characteristics, the claim should not be allowed until the claim is amended to recite those specific structural or additional functional characteristics. Otherwise, a claim could be allowed having broad functional language which, in reality, is limited to only the specific structure or steps disclosed in the specification. This would be contrary to public policy of granting patents which provide adequate notice to the public as to a claim's true scope.
>

IV. < APPLICANT MAY AMEND CLAIMS

Finally, as in the past, applicant has the opportunity during proceedings before the Office to amend the claims so that the claimed invention meets all the statutory criteria for patentability. An applicant may choose to amend the claim by further limiting the function so that there is no longer identity of function with that taught by the prior art element, or the applicant may choose to replace the claimed means plus function limitation with specific structure, material or acts that are not described in the prior art.

2185 Related Issues Under 35 U.S.C. 112, First or Second Paragraphs [R-1] [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 first paragraph or the definiteness requirement of the second paragraph of 35 U.S.C. 112. *In re Knowlton*, 481 F.2d 1357, 178 USPQ 486 (CCPA 1973).

If a "means or step plus function" limitation recited in a claim is not supported by corresponding structure, material or acts in the specification disclosure, the following rejections should be considered:

(A) under 35 U.S.C. 112, first paragraph, as not being supported by an enabling disclosure because the person skilled in the art would not know how to make and use the invention without a description of elements to perform the function. The description of an apparatus with block diagrams describing the function, but not the structure, of the apparatus is not fatal under the enablement requirement of 35 U.S.C. 112, first paragraph, as long as the structure is conventional and can be determined without an undue amount of experimentation. *In re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971);

(B) under 35 U.S.C. 112, second paragraph, as being indefinite. >See< *In re Dossel*, 115 F.3d 942, 946, 42 USPQ2d 1881, 1884 (Fed. Cir. 1997) >and MPEP § 2181<; and

(C) under 35 U.S.C. 102 or 103 where the prior art anticipates or renders obvious the claimed subject matter including the means or step that performs the function specified in the claim, the theory being that since there is no corresponding structure, etc., in the specification to limit the means or step plus function limitation, an equivalent is any element that performs the specified function.

2186 Relationship to the Doctrine of Equivalents

The doctrine of equivalents arises in the context of an infringement action. If an accused product or process does not literally infringe a patented invention, the accused product or process may be found to infringe under the doctrine of equivalents. The essential objective inquiry is: "Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention?" *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 117 S. Ct. 1040, 41 USPQ2d 1865, 1875 (1997). In determining equivalence, "[a]n analysis of the role played by each element in the context of the specific patent claim will thus inform the inquiry as to whether a substitute element matches the function, way, and result of the claimed element, or whether the substitute plays a role substantially different from the claimed element." 41 USPQ2d at 1875.

35 U.S.C. 112, sixth paragraph, permits "means or step plus function" limitations in claims to combinations, "with the proviso that application of the broad literal language of such claims must be limited to only

those means that are 'equivalent' to the actual means shown in the patent specification. This is an application of the doctrine of equivalents in a restrictive role, narrowing the application of broad literal claim elements." 41 USPQ2d at 1870. Accordingly, decisions involving the doctrine of equivalents should be considered, but should not unduly influence a determination under 35 U.S.C. 112, sixth paragraph, during *ex parte* examination.

>

2190 Prosecution Laches [R-1]

The Federal Circuit affirmed a rejection of claims in a patent application on the ground that applicant had forfeited his right to a patent under the doctrine of prosecution history laches for unreasonable and undue delay in prosecution. *In re Bogese*, 303 F.3d 1362, 1369, 64 USPQ2d 1448, 1453 (Fed. Cir. 2002) (Applicant "filed twelve continuation applications over an eight-year period and did not substantively advance prosecution when required and given an opportunity to do so by the PTO."). An examiner should obtain approval from the TC Director before making a rejection on the grounds of prosecution history laches.<

●●●●●●●●●●●●●●●●●●●●●●●●●●●●●●