EXHIBIT 2

Manual of PATENT PAMINING PROCEDURE

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MANUAL OF PATENT EXAMINING PROCEDURE Seventh Edition

The enclosed is the Seventh Edition to the Manual of Patent Examining Procedure. The Manual has been revised extensively to incorporate the changes necessitated by the final rules, "Changes to Patent Practice and Procedure," which became effective as of December 1, 1997. Changes are highlighted on the following pages.

This Edition of the Manual was prepared with the assistance of the Senior Legal Advisors of the Special Program Law Office. Their efforts are greatly appreciated.

Magdalen Y. C. Greenlief, Editor Manual of Patent Examining Procedure

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2105 Patentable Subject Matter — Living Subject Matter

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. "Inchoosing 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 Actembodied 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=mc²; 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=mc²; 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 determina-

tion. In addition, the requirements of 35 U.S.C. 112 must also be met. In this regard, see MPEP § 608.01(p).

Following this analysis by the Supreme Court of the scope of 35 U.S.C. 101, the Board of Patent Appeals and Interferences has determined that plant subject matter or an animal may be protected under 35 U.S.C. 101. In Ex parte Hibberd, 227 USPQ 443 (Bd. Pat. App. & Inter. 1985) the Board held that plant subject matter may be the proper subject of a patent under 35 U.S.C. 101 even though such subject matter may be protected under the Plant Patent Act (35 U.S.C. 161 - 164) or the Plant Variety Protection Act (7 U.S.C. 2321 et seq.). In Ex parte Allen, 2 USPQ2d 1425 (Bd. Pat. App. & Inter. 1987), the Board decided that a polyploid Pacific coast oyster could have been the proper subject of a patent under 35 U.S.C. 101 if all the criteria for patentability were satisfied. Shortly after the Allen decision, the Commissioner of Patents and Trademarks issued a notice (Animals - Patentability, 1077 O.G. 24, April 21, 1987) that the Patent and Trademark Office would now consider nonnaturally occurring, nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101.

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

I. INTRODUCTION

These Examination Guidelines for Computer—Related Inventions ("Guidelines") are to assist Office personnel in the examination of applications drawn to computer—related inventions. "Computer—related inventions" include inventions implemented in a computer and inventions employing computer—readable media. The Guidelines are based on the Office's current understanding of the law and are believed to be fully consistent with binding precedent of the Supreme Court, the Federal Circuit and the Federal Circuit's predecessor courts.

These Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of

law. These Guidelines have been designed to assist Office personnel in analyzing claimed subject matter for compliance with substantive law. Rejections will be based upon the substantive law and it is these rejections which are appealable. Consequently, any failure by Office personnel to follow the Guidelines is neither appealable nor petitionable.

The Guidelines alter the procedures Office personnel will follow when examining applications drawn to computer—related inventions and are equally applicable to claimed inventions implemented in either hardware or software. The Guidelines also clarify the Office's position on certain patentability standards related to this field of technology. Office personnel are to rely on these Guidelines in the event of any inconsistent treatment of issues between these Guidelines and any earlier provided guidance from the Office.

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

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

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

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

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

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

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

The subject matter sought to be patented must be a "useful" process, machine, manufacture, or composition of matter; i.e., it must have a practical application. The purpose of this requirement is to limit patent protection to inventions that possess a certain level of "real world" value, as opposed to subject matter that represents nothing more than an idea or concept, or is simply a starting point for future investigation or research (*Brenner Manson*, 383 U.S. 519, 528-36, 148 USPQ 689, 693-96 (1966); *In re Ziegler*, 992 F.2d 1197, 1200-03, 26 USPQ2d 1600, 1603-06 (Fed. Cir. 1993)). Accordingly, a complete disclosure should contain some indication of the practical application for the claimed invention, i.e., why the applicant believes the claimed invention is useful.

The utility of an invention must be within the "technological" arts. See, e.g., Musgrave, 431 E2d at 893,

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167 USPQ at 289-90, cited with approval in Schrader, 22 F.3d at 297, 30 USPQ2d at 1461 (Newman, J., dissenting). (The definition of "technology" is the "application of science and engineering to the development of machines and procedures in order to enhance or improve human conditions, or at least to improve human efficiency in some respect." Computer Dictionary 384 (Microsoft Press, 2d ed. 1994).) A computer-related invention is within the technological arts. A practical application of a computer-related invention is statutory subject matter. This requirement can be discerned from the variously phrased prohibitions against the patenting of abstract ideas, laws of nature or natural phenomena. An invention that has a practical application in the technological arts satisfies the utility requirement. See, e.g., In re Alappat, 33 F.3d 1526, 1543, 31 USPQ2d 1545, 1556-57 (Fed. Cir. 1994) (in banc) (quoting Diamond v. Diehr, 450 U.S. 175, 192, 209 USPQ 1, 10 (1981)). See also Alappat at 1569, 31 USPQ2d at 1578-79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing O'Reilly v. Morse, 56 U.S. (15 How.) 62, 114-19 (1854)); Arrhythmia, 958 F.2d at 1056, 22 USPQ2d at 1036; Musgrave, 431 F2d at 893, 167 USPQ at 289-90 ("All that is necessary, in our view, to make a sequence of operational steps a statutory 'process' within 35 U.S.C. 101 is that it be in the technological arts so as to be in consonance with the Constitutional purpose to promote the progress of 'useful arts.' Const. Art. 1, sec. 8.").

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

B. Review the Detailed Disclosure and Specific Embodiments of the Invention to Determine What the Applicant Has Invented

The written description will provide the clearest explanation of the applicant's invention, by exemplifying the invention, explaining how it relates to the prior art and explaining the relative significance of various features of the invention. Accordingly, Office personnel should begin their evaluation of a computer—related invention as follows:

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

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

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

Patent applicants can assist the Office by preparing applications that clearly set forth these aspects of a computer-related invention.

C. Review the Claims

The claims define the property rights provided by a patent, and thus require careful scrutiny. The goal of claim analysis is to identify the boundaries of the protection sought by the applicant and to understand how the claims relate to and define what the applicant has indicated is the invention. Office personnel must thoroughly analyze the language of a claim before determining if the

claim complies with each statutory requirement for patentability.

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

Office personnel are to correlate each claim limitation to all portions of the disclosure that describe the claim limitation. This is to be done in all cases, i.e., whether or not the claimed invention is defined using means or step plus function language. The correlation step will ensure that Office personnel correctly interpret each claim limitation.

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

- (A) statements of intended use or field of use,
- (B) "adapted to" or "adapted for" clauses,
- (C) "wherein" clauses, or
- (D) "whereby" clauses.

This list of examples is not intended to be exhaustive.

Office personnel must rely on the applicant's disclosure to properly determine the meaning of terms used in the claims. Markman v. Westview Instruments, 52 F.3d 967, 980, 34 USPQ2d 1321, 1330 (Fed. Cir.) (en banc), aff'd, U.S., 116 S. Ct. 1384 (1996). An applicant is entitled to be his or her own lexicographer, and in many instances will provide an explicit definition for certain terms used in the claims. Where an explicit definition will control interpretation of the term as it is used in the claim. Office personnel should determine if the original disclosure provides a definition consistent with any assertions made by applicant. See, e.g., In re Paulsen,

30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (inventor may define specific terms used to describe invention, but must do so "with reasonable clarity, deliberateness, and precision" and, if done, must "set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change" in meaning) (quoting *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387–88, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992)). If an applicant does not define a term in the specification, that term will be given its "common meaning." *Paulsen*, at 30 F. 3d 1480, 31 USPQ2d at 1674.

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

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

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

Where means plus function language is used to define the characteristics of a machine or manufacture invention, claim limitations must be interpreted to read on

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

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

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

Disclosure may be express, implicit or inherent. Thus, at the outset, Office personnel must attempt to correlate claimed means to elements set forth in the written description. The written description includes the specification and the drawings. Office personnel are to give the claimed means plus function limitations their broadest reasonable interpretation consistent with all corresponding structures or materials described in the specification and their equivalents. Further guidance in interpreting the scope of equivalents is provided in MPEP § 2181 through § 2186.

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

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

III. CONDUCT A THOROUGH SEARCH OF THE PRIOR ART

Prior to classifying the claimed invention under 35 U.S.C. 101, Office personnel are expected to conduct a thorough search of the prior art. Generally, a thorough search involves reviewing both U.S. and foreign patents and nonpatent literature. In many cases, the result of such a search will contribute to Office personnel's understanding of the invention. Both claimed and unclaimed aspects of the invention described in the specification should be searched if there is a reasonable expectation that the unclaimed aspects may be later claimed. A search must take into account any structure or material described in the specification and its equivalents which correspond to the claimed means plus function limitation, in accordance with 35 U.S.C. 112, sixth paragraph and MPEP § 2181 through § 2186.

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

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

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

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197 (1980). Accordingly, section 101 of title 35, United States Code, provides:

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

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

In choosing such expansive terms as "manufacture" and "composition of matter," modified by the comprehensive "any," Congress plainly contemplated that the patent laws would be given wide scope. The relevant legislative history also supports a broad construction. The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]." Act of Feb. 21, 1793, 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; In re Warmerdam, 33 F.3d 1354, 1358, 31 USPQ2d 1754, 1757 (Fed. Cir. 1994). Second, 35 U.S.C. 101 requires that the subject matter sought to be patented be a "useful" invention. Accordingly, a complete definition of the scope of 35 U.S.C. 101, reflecting Congressional intent, is that any new and useful process, machine, manufacture or composition of matter under the sun that is made by man is the proper subject matter of a patent. Subject matter not within one of the four statutory invention categories or which is not "useful" in a patent sense is, accordingly, not eligible to be patented.

The subject matter courts have found to be outside the four statutory categories of invention is limited to abstract ideas, laws of nature and natural phenomena. While this is easily stated, determining whether an applicant is seeking to patent an abstract idea, a law of nature or a natural phenomenon has proven to be challenging. These three exclusions recognize that subject matter that is not a practical application or use of an idea, a law of nature or a natural phenomenon is not patentable. See, e.g., Rubber-Tip Pencil Co. v. Howard, 87 U.S. (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.

L. Nonstatutory Subject Matter

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

Both types of "descriptive material" are nonstatutory when claimed as descriptive material per se. When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases. Compare In re Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure that increases computer efficiency held statutory) and Warmerdam, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having specific memory held statutory product-by-process claim) with Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory). When nonfunctional descriptive material is recorded on some computer-readable medium, it is not structurally and functionally interrelated to the medium but is merely carried by the medium. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory. Such a result would exalt form over substance. In re Sarkar, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978)("[E]ach invention must be evaluated as claimed; yet semantogenic considerations preclude a determination based solely on words appearing in the claims. In the final analysis under 101, the claimed invention, as a whole, must be evaluated for what it is.") (quoted with approval in Abele, 684 F2d at 907, 214 USPQ at 687). See also In re Johnson, 589 E2d 1070, 1077, 200 USPQ 199, 206 (CCPA 1978) ("form of

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the claim is often an exercise in drafting"). Thus, nonstatutory music does not become statutory by merely recording it on a compact disk. Protection for this type of work is provided under the copyright law.

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

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

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

Similarly, computer programs claimed as computer listings per se, i.e., the descriptions or expressions of the programs, are not physical "things," nor are they statutory processes, as they are not "acts" being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed aspects of the invention which permit the computer program's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a computer program defines structural and functional interrelationships between the computer program and the medium which permit the computer program's functionality to be realized, and is thus statutory. Accordingly, it is important to distinguish claims that define descriptive material per se from claims that define statutory inventions.

Computer programs are often recited as part of a claim. Office personnel should determine whether the computer program is being claimed as part of an otherwise statutory manufacture or machine. In such a case,

the claim remains statutory irrespective of the fact that a computer program is included in the claim. The same result occurs when a computer program is used in a computerized process where the computer executes the instructions set forth in the computer program. Only when the claimed invention taken as a whole is directed to a mere program listing, i.e., to only its description or expression, is it descriptive material *per se* and hence non-statutory.

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

(b) Nonfunctional Descriptive Material

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

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

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

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

(c) Natural Phenomena Such as Electricity and Magnetism

Claims that recite nothing but the physical characteristics of a form of energy, such as a frequency, voltage, or the strength of a magnetic field, define energy or magnetism, per se, and as such are nonstatutory natural phenomena. O'Reilly v. Morse, 56 U.S. (15 How.) at 112–114. However, a claim directed to a practical application of a natural phenomenon such as energy or magnetism is statutory. Id. at 114–119.

2. Statutory Subject Matter

(a) Statutory Product Claims

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

A machine is "a concrete thing, consisting of parts or of certain devices and combinations of devices." Burr v. Duryee, 68 U.S. (1 Wall.) 531, 570 (1863).

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

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

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

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

Claims That Encompass Any Machine or Manufacture Embodiment of a Process

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

(A) define the physical characteristics of a computer or computer component exclusively as functions or steps to be performed on or by a computer, and

(B) encompass <u>any and every</u> product in the stated class (e.g., computer, computer-readable memory) <u>configured in any manner</u> to perform that process.

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

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

If a claim is found to encompass any and every product embodiment of the underlying process, and if the underlying process is statutory, the product claim should be classified as a statutory product. By the same token, if the underlying process invention is found to be nonstatutory, Office personnel should classify the "product" claim as a "nonstatutory product." If the product claim is classified as being a nonstatutory product on the basis of the underlying process, Office personnel should emphasize that they have considered all claim limitations and are basing their finding on the analysis of the underlying process.

Product Claims — Claims Directed to Specific Machines and Manufactures

If a product claim does not encompass any and every computer—implementation of a process, then it must be treated as a specific machine or manufacture. Claims that define a computer—related invention as a specific machine or specific article of manufacture must define the physical structure of the machine or manufacture in

terms of its hardware or hardware and "specific software." ("Specific software" is defined as a set of instructions implemented in a specific program code segment. See Computer Dictionary 78 (Microsoft Press, 2d ed. 1994) for definition of "code segment.") The applicant may define the physical structure of a programmed computer or its hardware or software components in any manner that can be clearly understood by a person skilled in the relevant art. Generally a claim drawn to a particular programmed computer should identify the elements of the computer and indicate how those elements are configured in either hardware or a combination of hardware and specific software.

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

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

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

Two applicants present a claim to the following process:

A process for determining and displaying the structure of a chemical compound comprising:

- (a) solving the wavefunction parameters for the compound to determine the structure of a compound; and
- (b) displaying the structure of the compound determined in step (a).

Each applicant also presents a claim to the following apparatus:

A computer system for determining the three dimensional structure of a chemical compound comprising:

- (a) means for determining the three dimensional structure of a compound; and
- (b) means for creating and displaying an image representing a three-dimensional perspective of the compound.

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