OFFICE OF THE PRESIDENT

CHANCELS
LABORATORY DIRECTORS

September 4, 1997

Dear Colleagues:

The enclosed University of California Patent Policy will be effective October 1, 1997. This policy supersedes the November 18, 1985 policy, and rescinds the April 16, 1990 revision to that policy (a one-page Summary of Changes is provided). Inventions reported on or after October 1, 1997 will be subject to the new policy. Inventions reported before the effective date will be governed by the November 18, 1985 policy. Also enclosed is a "Patent Acknowledgment" to be signed by all new employees as of October 1st. This form replaces the "Patent Agreement."

The purpose of the new policy is to simplify and restrict the formula for distributing royalty income from inventions, and to establish a new campus laboratory research allocation. This policy is the result of extensive review and discussion within the University community. Additional information regarding implementation of the new policy will be published in the near future by the Office of Technology Transfer.

The enclosed policy applies to all employees and others specified within the policy, except individuals in the following collective bargaining units: Research Support Professional, Technical, and Police. Until collective bargaining agreements have been ratified by both parties in these units, affected employees will remain subject to the requirements of the April 16, 1990 Patent Policy.

Sincerely,

Richard C. Atkinson
President

Enclosures

cc:

Members, President’s Cabinet
Academic Council Chair Weiss
Members, Technology Transfer
Advisory Committee
Academic Vice Chancellors

Administrative Vice Chancellors
Research Vice Chancellors
Executive Director Peterbom
Special Assistant Gardner
Principal Officers of the Regents

UNIVERSITY OF CALIFORNIA
PATENT POLICY
Effective October 1, 1997

PREAMBLE

STATEMENT OF POLICY
PATENT RESPONSIBILITIES AND ADMINISTRATION

I. PREAMBLE

It is the intent of the President of the University of California, in administering intellectual property rights for the public benefit, to encourage and assist members of the faculty, staff, and others associated with the University in the use of the patent system with respect to their discoveries and inventions in a manner that is equitable to all parties involved.

The University recognizes the need for and desirability of encouraging the broad utilization of the results of University research, not only by scholars but also in practical application for the general public benefit, and acknowledges the importance of the patent system in bringing innovative research findings to practical application.

Within the University, innovative research findings often give rise to patentable inventions as fortuitous by-products, even though the research was conducted for the primary purpose of gaining new knowledge.

The following University of California Patent Policy is adopted to encourage the practical application of University research for the broad public benefit; to appraise and determine relative rights and equities of all parties concerned; to facilitate patent applications, licensing, and the equitable distribution of royalties, if any; to assist in obtaining funds for research; to provide for the use of invention-related income for the further support of research and education; and to provide a uniform procedure in patent matters when the University has a right or equity.

II. STATEMENT OF POLICY

A. An agreement to assign inventions and patents to the University, except those resulting from permissible consulting activities without use of University facilities, shall be mandatory for all employees or persons not employed by the University who use University research facilities, and for those who receive gift, grant, or contract funds through the University. Such an agreement may be in the form of an acknowledgment of obligation to assign. Exemptions from such agreements to assign may be authorized in those circumstances when the mission of the University is better served by such action, provided that overriding obligations to other parties are met and such exemptions are not inconsistent with other University policies.

B. Those individuals who have so agreed to assign inventions and patents shall promptly report and fully disclose the conception and/or reduction to practice of potentially patentable inventions to the Office of Technology Transfer or authorized licensing office. They shall execute such declarations, assignments, or other documents as may be necessary in the course of invention evaluation, patent prosecution, or protection of patent or analogous property rights, to assure that title in such inventions shall be held by the University or by such other parties designated by the University as may be appropriate under the circumstances. Such circumstances would include, but not be limited to, those situations where there are overriding patent obligations of the University arising from gifts, grants, contracts, or other agreements with outside organizations. In the absence of overriding obligations to outside sponsors of research, the University may release patent rights to the inventor in those circumstances when:

(1) the University elects not to file a patent application and the inventor is prepared to do so, or
(2) the equity of the situation clearly indicates such release should be given, provided in either case that no further research or development to develop that invention will be conducted involving University support or facilities, and provided further that a shop right is granted to the University.

C. Subject to restrictions arising from overriding obligations of the University pursuant to gifts, grants, contracts, or other agreements with outside organizations, the University agrees, following said assignment of inventions and patent rights, to pay annually to the named inventor(s), or to the inventor(s) heirs, executors, or assignees, 5% of the net royalties and fees per invention received by the University. An additional 5% of net royalties and fees per invention shall be allocated for research-related.

http://www.ucop.edu/office/patentpolicy/patent.html
purposes on the inventor's campus or Laboratory. Net royalties are defined as gross royalties and fees, less the costs of patenting, protecting, and preserving patent and related property rights, maintaining patents, the licensing of patent and related property rights, and such other costs, taxes, or reimbursements as may be necessary or required by law. Inventor shares paid to University employees pursuant to this paragraph represent an employee benefit.

When there are two or more inventors, each inventor shall share equally in the inventor's share of royalties, unless all inventors previously have agreed in writing to a different distribution of such share.

Distribution of the inventor's share of royalties shall be made annually in November from the amount received during the previous fiscal year ending June 30th, except as provided for in Section II.D. below. In the event of any litigation, actual or imminent, or any other action to protect patent rights, the University may withhold distribution and impound royalties until resolution of the matter.

D. The DOE Laboratories may establish separate royalty distribution formulas, subject to approval by the President. Distribution of the inventor's share of DOE Laboratory royalties shall be made annually in February from the amount received during the previous fiscal year ending September 30th. All other elements of this policy shall continue to apply.

E. Equity received by the University in licensing transactions, whether in the form of stock or any other instrument conveying ownership interest in a corporation, shall be distributed in accordance with the Policy on Accepting Equity When Licensing University Technology.

F. In the disposition of any net income accruing to the University from patents, first consideration shall be given to the support of research.

III. PATENT RESPONSIBILITIES AND ADMINISTRATION

A. Pursuant to Regents' Standing Order 100.4(mm), the President has responsibility for all matters relating to patents in which the University of California is in any way concerned. This policy is an exercise of that responsibility, and the President may make changes to any part of this policy from time to time, including the percentage of net royalties paid to inventors.

B. The President is advised on such matters by the Technology Transfer Advisory Committee (TTAC), which is chaired by the Senior Vice President--Business and Finance. The membership of TTAC includes the Provost and Senior Vice President--Academic Affairs, the Director of the Office of Technology Transfer, and representatives from the campuses, DOE Laboratories, Academic Senate, the Division of Agriculture and Natural Resources and the Office of the General Counsel. TTAC is responsible for:

1. reviewing and proposing University policy on intellectual property matters including patents, copyrights, trademarks, and tangible research products;
2. reviewing the administration of intellectual property operations to ensure consistent application of policy and effective progress toward program objectives; and
3. advising the President on related matters as requested.

C. The Senior Vice President--Business and Finance is responsible for implementation of this Policy, including the following:

1. Evaluating inventions and discoveries for patentability, as well as scientific merit and practical application, and requesting the filing and prosecution of patent applications.
2. Evaluating the patent or analogous property rights or equities held by the University in an invention, and negotiating agreements with cooperating organizations, if any, with respect to such rights or equities.
3. Negotiating licenses and license option agreements with other parties concerning patent and or analogous property rights held by the University.
4. Directing and arranging for the collection and appropriate distribution of royalties and fees.
5. Assisting University officers in negotiating agreements with cooperating organizations concerning prospective rights to patentable inventions or discoveries made as a result of research carried out under gifts, grants, contracts, or other agreements to be funded in whole or in part by such cooperating organizations, and negotiating with Federal agencies regarding the disposition of patent rights.
6. Approving exemptions from the agreement to assign inventions and patents to the University as required by Section II.A. above.
7. Approving exceptions to University policy on intellectual property matters including patents, copyrights, trademarks, and tangible research products.
Who owns your genes? The original question

1. Genes in YOUR body exist in NATURE and are **NOT PATENT ELIGIBLE OR PATENTABLE.**
   
   :: No one owns the intellectual property associated with your genes in your body — there is none!

2. You **own** the genes in your body. You do not have to give a sample of your genes to anyone except (a) voluntarily or (b) by a Search Warrant (II amendment — right of people to be secure in their persons).

3. **Purified genes** are **PATENT ELIGIBLE** because they do not exist in purified form in nature and have been altered by "the hand of man." But must satisfy non-obviousness — particular "useful, substantial, credible" utility.

4. Patents on **PURIFIED GENES** do not cover genes in YOUR body — you do not infringe on **Patent Use!!**

5. Who owns your genes if voluntarily give them? They belong to doctor or hospital — Moore vs. Regents of UC (1970) — for policy reasons.
   Moore vs. Regents of UC (1970) — for policy reasons promoting medical research, person (you) do not retain ownership of cells, tissues (our) taken with informed consent — innovative step outside law.
In what form do genes or DNA sequences appear in patent claims?

Patent claims may assert rights over DNA in various ways, for example, they may claim one or more of the following:

- the DNA sequence, whether comprising a complete or partial gene
- promoters
- enhancers
- individual exons
- expressed sequences as expressed sequence tags (ESTs) or cDNAs
- whole transcribed genes as cDNAs
- individual mutations known to cause disease
- variation between people not associated with disease (polymorphisms)
- cloning vectors, formed from bacterial DNA, which are used to replicate DNA sequences
- expression vectors, also formed from bacterial DNA, which are used to express proteins in replicated DNA sequences
- isolated host cells transformed with expression vectors, which are cells that have been created to express particular proteins
- amino acid sequences (proteins)
- the use of such proteins as medicines
- antibodies, which are used as markers
- nucleic acid probes, which are fragments of DNA that are used to locate particular parts of DNA sequences
- methods of identifying the existence of a DNA sequence or a mutation or deletion in an individual
- testing kits for detecting genetic mutations
- whole genomes
Can Life Be Patented?

Bacteria

Plant

Should life be patentable?
Can Living Organisms Be Patented?

1. Purified Microbial Cultures do not exist in nature and are patentable - Patent Eligible

   In re Bergy (1977) - Streptomyces vellosus producing antibiotics

   Louis Pasteur Patent # 145,072 (1872) - Purified yeast free of organic gums or disease

2. Human-Made Non-Natural Microorganism

   Diamond vs. Chakrabarty (1980) - Genetically Altered Bacteria to Cause Avian Oil -

   Supreme Court - "Anything under the sun that is made by man" is patentable

3. Harvard Mouse


   "Applies to a transgenic non-human mammal whose germ cells contain recombinant activated oncogene, or an ancestor of said mammal"

   Harvard Mouse - Put in 12/2002 Canadian Supreme Court said Mouse itself cannot be patented - gene sequence a process getting it into germ cells can.

4. Transgenic Plants/Hybrid Plants

   Pioneer-Hybrid
In 1980, the U.S. Supreme Court defined a patentable invention as one that included "anything under the sun that is made by man." In 1988, a transgenic mouse was the first genetically engineered animal to be patented. In this case, the transgene consisted of a cancer-causing gene (oncogene) driven by a promoter in the long terminal repeat of the mouse mammary tumor virus (MMTV LTR). The oncogene was the myc gene from the chicken myelocytomatosis OK10 virus. The invention entailed cloning an MMTV LTR-myc fusion gene into a plasmid, injecting linearized plasmid DNA into the male pronuclei of fertilized one-celled mouse eggs, identifying offspring that expressed the myc gene, and establishing transgenic mouse lines. In some of these lines the myc gene was expressed in several different tissues, and in other lines it was limited to one or a few tissues. The integration of the MMTV LTR-myc gene construct, according to Leder and Stewart, "increases the probability of the development of neoplasms (particularly malignant tumors) in the animal." These transgenic organisms can be used to test whether a compound either causes or prevents cancer and as a source of cell lines from cells of various tissues such as the heart that are difficult to culture. Since 1989, Du Pont has been selling one of these lines of transgenic mice under the trade name Oncomice. More generically, others prefer to call this mouse line the "Harvard Oncomouse" or, for short, just "oncomouse."

The granting of U.S. patent 4,736,866 was contentious, with much of the concern directed at the ethical implications of such patents. Those who oppose the patenting of transgenic animals argue that this type of patent violates the sanctity of life, threatens the integrity of species, and fosters inhumane treatment of animals. Notwithstanding these allegations, since 1988, a large number of patents have been granted in the United States for various transgenic organisms. For example, there are now, to name a few, patents for transgenic animals that act as models for benign prostatic disease, inflammatory disease, altered fat tissue metabolism, and thrombocytopenia. To date, neither the U.S. courts nor the U.S. government has suggested that, in principle, any of these patents is inappropriate. The patenting of transgenic organisms is no longer an issue in the United States. By contrast, in Europe and elsewhere, it remains a serious question that has not been completely resolved, although the Harvard Oncomouse has been patented by the European Patent Office. In their decision, the examiners concluded that the benefit to humankind of this transgenic system outweighed other factors that would have made it unacceptable for patenting. However, public interest groups and political parties are continuing to challenge this judgment.

Should Life Be Patented?
Canada Rules That Transgenic Animals are Nonpatentable

Transgenic Organisms Cannot Be Declared "Inventions"

David J. Heller, L.L.B.

In a decision released on December 5 (2002 SCC 76), the Supreme Court of Canada ruled that plants and animals are not patentable in Canada. The Canadian Patent Office had already granted Harvard University a patent for the "process" that created the university's Oncomouse. The question before the court was whether the mouse itself qualified.

Both the majority ruling and the dissent professed to confine their reasons to determining what Parliament did or did not intend 133 years ago when it defined "invention" in the Patent Act. The 5-4 majority decided that higher life forms cannot be patented in Canada unless Parliament explicitly says so, because "the patenting of higher life forms is a highly contentious and complex matter that raises serious practical, ethical, and environmental concerns.'

Life Forms versus Inventions

The Canadian Patent Act defines "invention" as "any new and useful art, process, machine, manufacture, or composition of matter, or any new and useful improvement in any art, process, machine, manufacture, or composition of matter." If an invention fits into this definition and meets the other criteria for patentability, the Commissioner of Patents must grant a patent.

The majority decision by Justice Michel Bastarache ruled that the mouse is not a "manufacture," which is "commonly understood" to be nonliving. They concluded that "composition of matter" can apply to lesser life forms such as yeast, but not to higher life forms, because the phrase must be considered in the context of the other words on the list. Just as 'machine' and 'manufacture' do not imply a living creature, the words 'composition of matter' are best read as not including higher life forms.

The majority conceded that a fertilized egg injected with a cancer-causing gene "may be a mixture of various ingredients," but said the mouse "does not consist of ingredients or substances that have been combined or mixed together by a person." Rather, "animal life forms have numerous unique qualities that transcend the particular matter of which they are composed."

Justice William J.C. Binnie disagreed, saying that the profound cellular changes in the mouse render it "a composition of matter." Writing in dissent, he expressed admiration for the discovery and argued that it was precisely the sort of invention the Patent Act was meant to protect. If the majority acknowledges that the egg itself is an invention, why can't the mouse that grows from the egg be patented?

The Patent Act doesn't exclude the mouse, Justice Binnie contended. Many inventions, including pharmaceutical drugs, also depend on natural processes for their effect and have numerous unique qualities that transcend the particular matter of which they are composed.

The dissent opinion continued, "The proper question is not whether Parliament intended to include 'oncomice' or 'higher life forms' or biotechnology generally in patent legislation," but whether it intended to protect inventions, such as oncomice, when the legislation was established.

Most other industrialized countries, including the U.S., Japan, New Zealand, and most of Europe, have allowed the patenting of higher life forms. They recognize the public interest in encouraging biotechnological research that may lead to the relief of illnesses such as cancer. They recognize the importance of an international patent regime that protects the fruits of such work, and thereby encourages private investment. The Supreme Court decision has put Canada out of step with its major competitors.

Possible Repercussions

The decision may also cast doubt on the ability of transgenic-seed manufacturers to protect their genetically modified plants in Canada. At present, these companies have obtained patents on the genes and seeds containing the genes. In Schmeiser v. Monsanto (2002 Federal Court of Appeal 309), this was seen as sufficient to give rise to infringement by a farmer growing plants that contained the genes.

However, we now have a Supreme Court ruling that denies patents on plants and other higher life forms. Would it not be open to argue that growing a higher life form con...
Genes and Patents

Continued from page 6

The Harvard Mouse case is not only important from the standpoint of the patenting of animals and plants, but potentially has much broader implications on the issue of patentable subject matter in general. Patent claims to higher life forms have been denied on the basis that they were not contemplated by Parliament when the definition of invention was drafted.

As asked by the dissenting opinion, where in the 1869 definition of invention would we find Parliament contemplating the patenting of "moon rockets, antibiotics, telephones, e-mail, or hand-held computers," which now seems to be a prerequisite for patentability? It appears that Canadian infringement defense lawyers have a new tool in their briefcases.

The End for Patenting Transgenic Animals in Canada?

Given that the court's majority would not recognize the Patent Act's wording as open-ended, it is up to the Canadian Parliament to clarify the point and decide whether to amend the law to permit patents on nonhuman higher life forms.

On December 9, 2002, Industry Minister Allan Rock told the House of Commons that the government plans to consult with Canadians and with the Canadian Biotechnology Advisory Committee (CBAC) before deciding what to do. The CBAC is a body of external experts charged with advising the Canadian government on the ethical, social, regulatory, economic, scientific, environmental, and health aspects of biotechnology.

In December 2001, the CBAC issued a Report to the Government of Canada recommending that higher life forms, including plants, seeds, and nonhuman animals, be recognized as patentable subject matter (subject to certain limits) under the existing Patent Act.

In the meantime, companies in Canada are still free to patent individual genes, other useful DNA sequences, cell lines, transgenic fertilized eggs (and presumably seeds), and the processes by which transgenic plants and animals are produced.
What Concerns HAVE BEEN RAISED ABOUT Patenting Genes & Organisms?

1. Genes are part of what it is to be human—no one should be able to own/control genes.
2. Naturally occurring genetic sequences should not be patentable.
3. Patents should not be for discoveries of nature—only marketable inventions.
4. Delay progress of research.
5. Someone else will own our genes.
6. Life forms should not be patented.
7. Higher life forms should not be patented.
8. Hinder genetic testing/diagnosis/treatment—tests based on genes—diagnostic tests.
9. Research tools should not be patented — hinders progress. Enabling patents (e.g., Recombinant DNA).
10. Must show substantial utility—not just a DNA sequence—computational methods & finding.
12. Prevent patented inventions from being used in third world developing countries.
13. Patents on a person's body tissues/cell lines/etc.

But patents guided by Constitution & US Statutes
Change only by Congress
Guided only by statute/law by Congress

Court argues otherwise.
relations with telecommunication industry interests require a clear and consistent policy in this matter. The content of this report is based on dozens of industry and government sources and draws on the collaboration and review of numerous experts in the business, legal and technical arenas.

Once finalized, the fee structure proposed in this report will be used to assess fees (as stated in their respective special use permits) for cables already installed in the Olympic Coast and Stellwagen Bank National Marine Sanctuaries. In addition, this structure will provide the basis for future fair market value assessment of submarine cable permit applications in National Marine Sanctuaries. Comments on the report and peer reviews should focus on the methodology employed and the conclusions that it reached.


John Oliver,
Chief Financial Officer, National Ocean Service.

[FR Doc. 01–387 Filed 1–4–01; 8:45 am]
BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
[Docket No. 991027289–0263–02]
RIN 0651–AB09
Utility Examination Guidelines

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) is publishing a revised version of guidelines to be used by Office personnel in their review of patent applications for compliance with the “utility” requirement of 35 U.S.C. 101. This revision supersedes the Revised Interim Utility Examination Guidelines that were published at 64 FR 71440, Dec. 21, 1999; 1231 O.G. 136 (2000); and correction at 65 FR 3425, Jan. 21, 2000; 1231 O.G. 67 (2000).

DATES: The Guidelines are effective as of January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Mark Nagumo by telephone at (703) 305–8666, by facsimile at (703) 305–9373, by electronic mail at “mark.nagumo@uspto.gov,” or by mail marked to his attention addressed to the Office of the Solicitor, Box 8, Washington, DC 20231; or Linda Therkorn by telephone at (703) 305–9233, by facsimile at (703) 305–8625, by electronic mail at “linda.therkorn@uspto.gov,” or by mail marked to her attention addressed to Box Comments, Commissioner for Patents, Washington, DC 20231.

SUPPLEMENTARY INFORMATION: As of the publication date of this notice, these Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the “utility” requirement of 35 U.S.C. 101. Because these Guidelines only govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

I. Discussion of Public Comments
The Revised Interim Utility Examination Guidelines published at 64 FR 71440, Dec. 21, 1999; 1231 O.G. 136, Feb. 29, 2000, with a correction at 65 FR 3425, Jan. 21, 2000; 1231 O.G. 67, Feb. 15, 2000, requested comments from the public. Comments were received from 35 individuals and 17 organizations. The written comments have been carefully considered.

Overview of Comments
The majority of comments generally approved of the guidelines and several expressly stated support for the three utility criteria (specific, substantial, and credible) set forth in the Guidelines. A few comments addressed particular concerns with respect to the coordinate examiner training materials that are available for public inspection at the USPTO website, www.uspto.gov. The comments on the training materials will be taken under advisement in the revision of the training materials. Consequently, those comments are not specifically addressed below because they do not impact the content of the Guidelines. Comments received in response to the request for comments on the “Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 ‘Written Description’ Requirement,” 64 FR 71427, Dec. 21, 1999; 1231 O.G. 123, Feb. 29, 2000, which raised issues pertinent to the utility requirement are also addressed below.

Responses to Specific Comments
(1) Comment: Several comments state that while inventions are patentable, discoveries are not patentable. According to the comments, genes are discoveries rather than inventions. These comments urge the USPTO not to issue patents for genes on the ground that genes are not inventions. Response: The suggestion is not adopted. An inventor can patent a discovery when the patent application satisfies the statutory requirements. The U.S.
Constitution uses the word "discoveries" where it authorizes Congress to promote progress made by inventors. The pertinent part of the Constitution is Article 1, section 8, clause 8, which reads: "The Congress shall have power . . . * * * to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

When Congress enacted the patent statutes, it specifically authorized issuing a patent to a person who "invents or discovers" a new and useful composition of matter, among other things. The pertinent statute is 35 U.S.C. 101, which reads: "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." Thus, an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.

If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. But when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the "utility" requirement. That is, where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.

Comment: Several comments state that a gene is not a new composition of matter because it exists in nature, and/or that an inventor who isolates a gene does not actually invent or discover a patentable composition because the gene exists in nature. These comments urge the USPTO not to issue patents for genes on the ground that genes are products of nature. Others state that naturally occurring DNAs are part of our heritage and are not inventions. Another comment expressed concern that a person whose body includes a patented gene could be guilty of patent infringement. Response: The comments are not adopted. A patent claim directed to an isolated and purified DNA molecule could cover, e.g., a gene excised from a natural chromosome or a synthesized DNA molecule. An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound. Patenting compositions or compounds isolated from nature follows well-established principles, and is not a new practice. For example, Louis Pasteur received U.S. Patent 141,072 in 1873, claiming "[t]he least, free from organic germs of disease, as an article of manufacture." Another example is an early patent for adrenaline. In a decision finding the patent valid, the court explained that compounds isolated from nature are patentable: "even if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it [adrenaline] available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent." Parke-Davis & Co. v. H. K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911) (J. Learned Hand).

In a more recent case dealing with the prostaglandins PGE2 and PGE3, extracted from human or animal prostate glands, a patent examiner had rejected the claims, reasoning that "inasmuch as the 'claimed compounds are naturally occurring' * * * they therefore 'are not 'new' within the connotation of the patent statute.'" In re Bergstrom, 427 F.2d 1394, 1397, 166 USPQ 256, 259 (CCPA 1970). The Court reversed the Patent Office and explained the error: "what appellants claim—pure PGE2 and PGE3—is not 'naturally occurring.' Those compounds, as far as the record establishes, do not exist in nature in pure form, and appellants have neither merely discovered, nor claimed sufficiently broadly to encompass, what has previously existed in fact in nature's storehouse, albeit unknown, or what has previously been known to exist." Id. at 1401, 166 USPQ at 261-62. Like other chemical compounds, DNA molecules are eligible for patents when isolated from their natural state and purified or when synthesized in a laboratory from chemical starting materials.

A patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature. Thus, the concern that a person whose body "includes" a patented gene could infringe the patent is misconceived. The body does not contain the patented, isolated and purified gene because genes in the body are not in the patented, isolated and purified form. When the patent issued for purified adrenaline about one hundred years ago, people did not infringe the patent merely because their bodies naturally included unpurified adrenaline.

Comment: Several comments suggested that the USPTO should seek guidance from Congress as to whether naturally occurring genetic sequences are patentable subject matter. Response: The suggestion is not adopted. Congress adopted the current statute defining patentable subject matter (35 U.S.C. 101) in 1952. The legislative history indicates that Congress intended "anything under the sun that is made by man" to be eligible for patenting. S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952). The Supreme Court interprets the statute to cover a "naturally occurring manufacture or composition of matter—a product of human ingenuity." Diamond v. Chakrabarty, 447 U.S. 303, 309, 206 USPQ 193, 197 (1980). Thus, the intent of Congress with regard to patent eligibility for chemical compounds has already been determined: DNA compounds having naturally occurring sequences are eligible for patenting when isolated from their natural state and purified, and when the application meets the statutory criteria for patentability. The genetic sequence data represented by strings of the letters A, T, C and G alone is raw, fundamental sequence data, i.e., nonfunctional descriptive information. While descriptive sequence information alone is not patentable subject matter, a new and useful purified and isolated DNA compound described by the sequence is eligible for patenting, subject to satisfying the other criteria for patentability.

Comment: Several comments state that patents should not issue for genes because the sequence of the human genome is at the core of what it means to be human and no person should be able to own/control something so basic. Other comments stated that patents should be for marketable inventions and not for discoveries in nature. Response: The comments are not adopted. Patents do not confer ownership of genes, genetic information, or sequences. The patent system promotes progress by securing a complete disclosure of an invention to the public, in exchange for the inventor's legal right to exclude other people from making, using, offering for sale, selling, or importing
the composition for a limited time. That is, a patent owner can stop infringing activity by others for a limited time. 

Disclosures from nature have led to marketable inventions in the past, but assessing the marketability of an invention is not pertinent to determining if an invention has a specific, substantial, and credible use. [Development of a product to the extent that it is presently commercially salable in the marketplace is not required to establish 'usefulness' within the meaning of § 101."

In re Langer, 503 F.2d 1380, 1393, 183 USPQ 288, 298 (CCPA 1974). Inventors are entitled to patents when they have made the statutory requirements for novelty, nonobviousness and usefulness, and their patent disclosure adequately describes the invention and clearly teaches others how to make and use the invention. The utility requirement, as explained by the courts, only requires that the inventor disclose a practical or real world benefit available from the invention, i.e., a specific, substantial and credible utility. As noted in a response to other comments, it is a long tradition in the United States that discoveries from nature which are transformed into new and useful products are eligible for patents.

(5) Comment: Several comments state that the Guidelines mean that anyone who discovers a gene will be allowed a broad patent covering any number of possible applications even though those uses may be unattainable and unproven. Therefore, according to these comments, gene patents should not be issued. Response: The comment is not adopted. When a patent claiming a new chemical compound issues, the patentee has the right to exclude others from making, using, offering for sale, selling, or importing the compound for a limited time. The patentee is required to disclose only one utility, that is, teach others how to use the invention in at least one way. The patentee is not required to disclose all possible uses, but promoting the subsequent discovery of other uses is one of the benefits of the patent system. When patents for genes are treated the same as for other chemicals, progress is promoted because the original inventor has the possibility to recoup research costs, because others are motivated to invent around the original patent, and because a new chemical is made available as a basis for future research. Other inventors who develop new and nonobvious methods of using the patented compound have the opportunity to patent those methods.

(6) Comment: One comment suggests that the USPTO should not allow the patenting of ESTs because it is contrary to indigenous law, because the Supreme Court's Diamond v. Chakrabarty decision was a bare 5-4 decision, because it would violate the Thirteenth Amendment of the U.S. Constitution, because it violates the novelty requirement of the patent laws, because it will exacerbate tensions between indigenous peoples and western academic/research communities and because it will undermine indigenous peoples' own research and academic institutions. The comment urges the USPTO to institute a moratorium on patenting of life forms and natural processes. Response: The comments are not adopted. Patents on chemical compounds such as ESTs do not implicate the Thirteenth Amendment.

The USPTO must administer the patent statutes as the Supreme Court interprets them. When Congress enacted § 101, it indicated that "anything under the sun that is made by man" is subject matter for a patent. S. Rep. No. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess. 6 (1952). The Supreme Court has interpreted § 101 many times without overturning it. See, e.g., Diamond v. Diehr, 450 U.S. 175, 209 USPQ 1 (1981) (discussing cases construing section 101). Under United States law, a patent applicant is entitled to a patent when an invention meets the patentability criteria of title 35. Thus, ESTs which meet the criteria for utility, novelty, and nonobviousness are eligible for patenting when the application teaches that skill of the art how to make and use the invention. (7) Comment: Several comments state that patents should not issue for genes because patents on genes are delaying medical research and thus there is no social benefit associated with gene patents. Others state that granting patents on genes at any stage of research deprives others of incentives and the ability to continue exploratory research and development. Some comment that patentees will deny access to genes and our property (our genes) will be owned by others. Response: The comments are not adopted. The incentive to make discoveries and inventions is generally spurred, not inhibited, by patents. The disclosure of genetic inventions provides new opportunities for further development. The patent statutes provide that a patent must be granted when at least one specific, substantial and credible utility has been disclosed, and the application satisfies the other statutory requirements. As long as one specific, substantial and credible use is disclosed and the statutory requirements are met, the USPTO is not authorized to withhold the patent until another, or better, use is discovered. Other researchers may discover higher, better or more practical uses, but they are advantaged by the starting point that the original disclosure provides. A patent grants exclusive rights over a patented composition but does not grant ownership of the composition. Patents are not issued on compositions in the natural environment but rather on isolated and purified compositions.

(8) Comment: Several comments stated that DNA should be considered unpatentable because a DNA sequence, by itself has little utility. Response: A DNA sequence—i.e., the sequence of base pairs making up a DNA molecule—is simply one of the properties of a DNA molecule. Like any descriptive property, a DNA sequence itself is not patentable. A purified DNA molecule isolated from its natural environment, on the other hand, is a chemical compound and is patentable if all the statutory requirements are met. An isolated and purified DNA molecule may meet the statutory utility requirement if, e.g., it can be used to produce a useful protein or it hybridizes near and serves as a marker for a disease gene. Therefore, a DNA molecule is not per se unpatentable for lack of utility, and each application claim must be examined on its own facts.

(9) Comment: One comment states that the disclosure of a DNA sequence has inherent value and that possible uses for the DNA appear endless, even if no single use has been worked out. According to the comment, the “basic social contract of the patent deal” requires that such a discovery should be patentable, and that patenting should be “valuable.” Response: The comment is not adopted. The Supreme Court did not find a similar argument persuasive in Brenner v. Manson, 383 U.S. 519 (1966). The courts interpret the statutory term “useful” to require disclosure of at least one available practical benefit to the public. The Guidelines reflect this determination by requiring the disclosure of at least one specific, substantial, and credible utility. If no such utility is disclosed or readily apparent from an application, the Office should reject the claim. The applicant may rebut the Office position by showing that the invention does have a specific, substantial, and credible utility that would have been recognized by one of skill in the art at the time the application was filed.

(10) Comment: Several comments stated that the scope of patent claims directed to DNA should be limited to applications or methods of using DNA, and should not be allowed to
encompass the DNA itself. Response: The comment is not adopted. Patentable subject matter includes both "process(es)" and "composition(s) of matter." 35 U.S.C. 101. Patent law provides no basis for treating DNA differently from other chemical compounds that are compositions of matter. If a patent application claims a composition of matter comprising DNA, and the claims meet all the statutory requirements of patentability, there is no legal basis for rejecting the application.

(11) Comment: Several comments stated that DNA patent claim scope should be limited to uses that are disclosed in the patent application and that allowing patent claims that encompass DNA itself would enable the inventor to assert claims to "speculative" uses of the DNA that were not foreseen at the time the patent application was filed. Response: The comment is not adopted. A patent on a composition gives exclusive rights to the composition for a limited time, even if the inventor disclosed only a single use for the composition. Thus, a patent granted on an isolated and purified DNA composition confers the right to exclude others from any method of using that DNA composition, for up to 20 years from the filing date. This result flows from the language of the statute itself. When the utility requirement and other requirements are satisfied by the application, a patent granted provides a patentee with the right to exclude others from, inter alia, "using" the patented composition of matter. See 35 U.S.C. 154. Where a new use is discovered for a patented DNA composition, that new use may qualify for its own process patent, notwithstanding that the DNA composition itself is patented.

By statute, a patent is required to disclose one practical utility. If a well-established utility is readily apparent, the disclosure is deemed to be implicit. If an application fails to disclose one specific, substantial, and credible utility, and the examiner discerns no well-established utility, the examiner will reject the claim under section 101. The rejection shifts the burden to the applicant to show that the examiner erred, or that a well-established utility would have been readily apparent to one of skill in the art. The applicant cannot rebut the rejection by relying on a utility that would not have been readily apparent at the time the application was filed. See, e.g., In re Wright, 999 F.2d 1557, 1562-63, 27 USPQ2d 1510, 1514 (Fed. Cir. 1993) ("developments occurring after the filing date of an application are of no ordinary skill in the art at the time the invention was made. See, e.g., In re Deuel, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995) ("[T]he existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious."); see also, In re Bell, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993).

(13) Comment: Several comments stated that DNA should be freely available for research. Some of these comments suggested that patents are not necessary to encourage additional discovery and sequencing of genes. Some comments suggested that patenting of DNA inhibits biomedical research by allowing a single person or company to control the claimed DNA. Another comment expressed concern that patenting ESTs will preclude complete characterization of genes and delay or restrict exploration of genetic materials for the public good. Response: The scope of subject matter that is eligible for a patent, the requirements that must be met in order to be granted a patent, and the legal rights that are conveyed by an issued patent, are all controlled by statutes which the USPTO must administer. "Whoever invents or discovers any new and useful * * * composition of matter * * * may obtain a patent therefor." 35 U.S.C. 101. Congress creates the law and the Federal judiciary interprets the law. The USPTO must administer the laws as Congress has enacted them and as the Federal courts have interpreted them. Current law provides that when the statutory patentability requirements are met, there is no basis to deny patent applications claiming DNA compositions, or to limit a patent's scope in order to allow free access to the use of the invention during the patent term.

(13) Comment: Several comments suggested that DNA sequences should be considered unpatentable because sequencing DNA has become so routine that determining the sequence of a DNA molecule is not inventive. Response: The comments are not adopted. A DNA sequence is not patentable because a sequence is merely descriptive information about a molecule. An isolated and purified DNA molecule may be patentable because a molecule is a "composition of matter," one of the four classes of invention authorized by 35 U.S.C. 101. A DNA molecule must be nonobvious in order to be patentable. Obviousness does not depend on the amount of work required to characterize the DNA molecule. See 35 U.S.C. 103(a) ("Patentability shall not be negated by the manner in which the invention was made."). As the nonobviousness requirement has been interpreted by the U.S. Court of Appeals for the Federal Circuit, whether a claimed DNA molecule would have been obvious depends on whether a molecule having the particular structure of the DNA would have been obvious to one of ordinary skill in the art at the time the invention was made. See, e.g., In re Deuel, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995) ("[T]he existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious."); see also, In re Bell, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993).

(14) Comment: One comment suggested that genes ought to be patentable only when the complete sequence of the gene is disclosed and a function for the gene product has been determined. Response: The suggestion is not adopted. To obtain a patent on a chemical compound such as DNA, a patent applicant must adequately describe the compound and must disclose how to make and use the compound. 35 U.S.C. 101, 112. "An adequate written description of a DNA * * * requires a precise definition, such as by structure, formula, chemical name, or physical properties." Univ. of California v. Eli Lilly & Co., 119 F.3d 1559, 1556, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997) (emphasis added, internal quote omitted). Thus, describing the complete chemical structure, i.e., the DNA sequence, is one method of describing a DNA molecule but it is not the only method. In addition, the utility of a claimed DNA does not necessarily depend on the function of the encoded gene product. A claimed DNA may have a specific and substantial utility because, e.g., it hybridizes near a disease-associated gene or it has a gene-regulating activity.

(15) Comment: One comment stated that the specification should "disclose the invention," including why the invention works and how it was developed. Response: The comment is not adopted. The comment is directed more to the requirements imposed by 35 U.S.C. 112 than to those of 35 U.S.C. 101. To satisfy the enablement requirement of 35 U.S.C. 112, § 1, an application must disclose the claimed invention in sufficient detail to enable a person of ordinary skill in the art to make and use the claimed invention. To satisfy the written description requirement of 35 U.S.C. 112, § 1, the description must show that the applicant was in possession of the claimed invention at the time of filing. If all the requirements under 35 U.S.C. 112, § 1, are met, there is no statutory basis to require disclosure of why an invention works or how it was developed. "[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works." Newman v. Quigg.
assignment does not provide information regarding the actual biological activity of an encoded protein and therefore patent claims drawn to such nucleic acids should be limited to method of use claims that are explicitly supported by the as-filed specification(s). These comments also state that if homology-based utilities are acceptable, then the nucleic acids, and proteins encoded thereby, should be considered as obvious over the prior art nucleic acids. On the other hand, one comment stated that homology is a standard, art-accepted basis for predicting utility, while another comment stated that any level of homology to a protein with known utility should be accepted as indicative of utility. Response: The suggestions to adopt a per se rule rejecting homology-based assertions of utility are not adopted. An applicant is entitled to a patent to the subject matter claimed unless statutory requirements are not met (35 U.S.C. 101, 102, 103, 112). When the USPTO denies a patent, the Office must set forth at least a prima facie case as to why an applicant has not met the statutory requirements. The inquiries involved in assessing utility are fact dependent, and the determinations must be made on the basis of scientific evidence. Reliance on the commenters' per se rule, rather than a fact dependent inquiry, is impermissible because the commenters provide no scientific evidence that homology-based assertions of utility are inherently unbelievable or involve implausible scientific principles. See, e.g., In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (rejection of claims improper where claims did "not suggest an inherently unbelievable undertaking or involve implausible scientific principles" and where "prior art * * * discloses structurally similar compounds to those claimed by the applicants which have been proven * * * to be effective"). A patent examiner must accept a utility asserted by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. The examiner's decision must be supported by a preponderance of all the evidence of record. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion. "A rigorous correlation need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." Fujikawa v. Wattanasin, 93 F.3d 1559, 1565, 39 USPQ2d 1895, 1900 (Fed. Cir. 1996).

The Office will take into account both the nature and degree of the homology. When a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial, and credible utility to the assigned protein. If the preponderance of the evidence of record, or of sound scientific reasoning, casts doubt upon such an asserted utility, the examiner should reject the claim for lack of utility under 35 U.S.C. 101. For example, where a class of proteins is defined by common structural features, but evidence shows that the members of the class do not share a specific, substantial functional attribute or utility, despite having structural features in common, membership in the class may not impute a specific, substantial, and credible utility to a new member of the class. When there is a reason to doubt the functional protein assignment, the utility examination may turn to whether or not the asserted protein encoded by a claimed nucleic acid has a well-established use. If there is a well-established utility for the protein and the claimed nucleic acid, the claim would meet the requirements for utility under 35 U.S.C. 101. If not, the burden shifts to the applicant to provide evidence supporting a well-established utility. There is no per se rule regarding homology, and each application must be judged on its own merits.

The comment indicating that if a homology-based utility could meet the requirements set forth under 35 U.S.C. 101, then the invention would have been obvious, is not adopted. Assessing nonobviousness under 35 U.S.C. 103 is separate from analyzing the utility requirements under 35 U.S.C. 101. When a claim to a nucleic acid supported by a homology-based utility meets the utility requirements of section 101, it does not follow that the claimed nucleic acid would have been prima facie obvious over the nucleic acids to which it is homologous. "[S]ection 103 requires a fact-intensive comparison of the [claim] with the prior art rather than the mechanical application of one or another per se rule." In re Ochoa, 71 F.3d 1565, 1571, 37 USPQ2d 1127, 1132 (Fed. Cir. 1995). Nonobviousness must be determined according to the analysis
in Graham v. John Deere, 383 U.S. 1, 148 USPQ 459 (1966). See also, In re Dillon, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (in banc) ("structural similarity between claimed and prior art subject matter, * * * where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness") (emphasis added).

Where "the prior art teaches a specific, structurally-definable compound [] the question becomes whether the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention." In re Deuel, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995).

(20) Comment: Several comments indicated that in situations where a well-established utility is relied upon for compliance with 35 U.S.C. 101, the record should reflect what that utility is. One comment stated that the record should reflect whether the examiner accepted an asserted utility or relied upon a well-established utility after dismissing all asserted utilities. Another comment stated that when the examiner relies on a well-established utility not explicitly asserted by the applicant, the written record should clearly identify this utility and the rationale for considering it specific and substantial. Response: The comments are not adopted. Only one specific, substantial and credible utility is required to satisfy the statutory requirement. Where one or more well-established utilities would have been readily apparent to those of skill in the art at the time of the invention, an applicant may rely on any one of those utilities without prejudice. The record of any issued patent typically reflects consideration of a number of references in the prior art that the applicant or the examiner considered material to the claimed invention. These references often indicate uses for related inventions, and any patents listed typically disclose utilities for those applications. Thus, even when the examiner does not identify a well-established utility, the record as a whole will likely disclose readily apparent utilities. Just as the examiner without comment may accept a properly asserted utility, there is no need for an examiner to comment on the existence of a well-established utility. However, the Guidelines have been revised to clarify that a well-established utility is a specific, substantial, and credible utility that must be readily apparent to one skilled in the art. Most often, the closest prior art cited and applied in the course of examining the application will demonstrate a well-established utility for the invention.

(21) Comment: Several comments stated that the Guidelines erroneously burden the examiner with proving that a person of skill in the art would not be aware of a well-established utility. One comment stated that this requires the examiner to prove a negative. Another comment stated that the Guidelines should direct examiners that if a specific utility has not been disclosed, the applicant should be required to identify a specific utility. Response: The comments have been adopted in part. The Guidelines have been revised to indicate that where the applicant has not asserted a specific, substantial, and credible utility, and the examiner does not perceive a well-established utility, a rejection under § 101 should be entered. That is, if a well-established utility is not readily apparent and an invention is not otherwise supported by an asserted specific, substantial, and credible utility, the burden will be shifted to applicant to show either that the specification discloses an adequate utility, or to show that a well-established utility exists for the claimed invention. Again, most often the search of the closest prior art will reveal whether there is a well-established utility for the claimed invention.

(22) Comment: Several comments suggested that further clarification was required with regard to the examiner's determination that there is an adequate nexus between a showing supporting a well-established utility and the application as filed. The comments indicated that the meaning of this "nexus" was unclear. Response: The Guidelines have been modified to reflect that evidence provided by an applicant is to be analyzed with regard to a concordance between the showing and the full scope and content of the claimed invention as disclosed in the application as filed. In situations where the showing provides adequate evidence that the claim is supported by at least one asserted specific, substantial, and credible or well-established utility, the rejections under 35 U.S.C. 101 and 112, first paragraph, will be withdrawn. However, the examiner is instructed to consider whether or not the specification, in light of applicant's showing, is evident in the use of the full scope of the claimed invention. Many times prior patents and printed publications provided by applicant will clearly demonstrate that a well-established utility exists.

(23) Comment: One comment states that the Office is using an improper standard in assessing "specific" utility. According to the comment, a distinction between "specific" and "general" utilities is an overreaching interpretation of the specificity requirement in the case law because "unique" or "particular" utilities have never been required by the law. The comment states that the specificity requirement concerns sufficiency of disclosure, i.e., teaching how to make and use a claimed invention, not the utility requirement. The comment states that the specificity requirement is to be distinguished from the "substantial" utility requirement, and that the Brenner v. Manson decision concerned only a "substantial" utility issue, not specificity. Response: The comment is not adopted. The disclosure of only a general utility rather than a particular utility is insufficient to meet statutory requirements. Although the specificity requirement is relevant to § 112, it is not severable from the utility requirement.

[Surely Congress intended § 112 to presuppose full satisfaction of the requirements of § 101. 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. As this court stated in Diederich, quoting with approval from the decision of the board: "We do not believe it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates." As the Supreme Court said in Brenner v. Manson, *** * a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.]


II. Guidelines for Examination of Applications for Compliance With the Utility Requirement

A. 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.

B. 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.

1. Read the claims and the supporting written description.
   (a) Determine what the applicant has claimed, noting any specific embodiments of the invention.
   (b) Ensure that the claims define statutory subject matter (i.e., a process, machine, manufacture, composition of matter, or improvement thereof).
   (c) 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 (1) if 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 (2) the utility is specific, substantial, and credible.

2. 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:
   (a) 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.
   (1) 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.

   (2) 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.

   (b) 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 § 101 on the grounds that the invention as claimed lacks utility. Also reject the claims under § 112, first paragraph, on the basis that the disclosure fails to teach how to use the invention as claimed. The § 112, first paragraph, rejection imposed in conjunction with a § 101 rejection should incorporate by reference the grounds of the corresponding § 101 rejection.

   (c) 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 § 101, emphasizing that the applicant has not disclosed a specific and substantial utility for the invention. Also impose a separate rejection under § 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 §§ 101 and 112 rejections shift the burden of coming forward with evidence to the applicant to:
      (1) Explicitly identify a specific and substantial utility for the claimed invention; and
      (2) 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 information 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.

   3. 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.

   (a) 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:
      (1) 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;
      (2) Support for factual findings relied upon in reaching this conclusion; and
      (3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

   (b) 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:
      (1) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;
      (2) Support for factual findings relied upon in reaching this conclusion; and
      (3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

   (c) 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.

4. 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 §101, withdraw the §101 rejection and the corresponding rejection imposed under §112, first paragraph.


Q. Todd Dickinson,
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
[Docket No. 991027288–0264–02]
RIN 0651–AB10


ACTION: Notice.

SUMMARY: These Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the “written description” requirement of 35 U.S.C. 112, ¶ 1. These Guidelines supersede the “Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 ‘Written Description’ Requirement” that were published in the *Federal Register* at 64 FR 71427, Dec. 21, 1999, and in the Official Gazette at 1231 O.G. 123, Feb. 29, 2000. These Guidelines reflect the current understanding of the USPTO regarding the written description requirement of 35 U.S.C. 112, ¶ 1, and are applicable to all technologies.

DATES: The Guidelines are effective as of January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Stephen Walsh by telephone at (703) 305–9035, by facsimile at (703) 305–9373, by mail to his attention addressed to United States Patent and Trademark Office, Box 8, Washington, DC 20231, or by electronic mail at “stephen.walsh@uspto.gov”; or Linda Therkorn by telephone at (703) 305–8800, by facsimile at (703) 305–8825, by mail addressed to Box Comments, Commissioner for Patents, Washington, DC 20231, or by electronic mail at “linda.therkorn@uspto.gov.”

SUPPLEMENTARY INFORMATION: As of the publication date of this notice, these Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the “written description” requirement of 35 U.S.C. 112, ¶ 1. Because these Guidelines only govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

Discussion of Public Comments

Comments were received from 48 individuals and 18 organizations in response to the request for comments on the “Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 ‘Written Description’ Requirement” published in the *Federal Register* at 64 FR 71427, Dec. 21, 1999, and in the Official Gazette at 1231 O.G. 123, Feb. 29, 2000. The written comments have been carefully considered.

Overview of Comments

The majority of comments favored issuance of final written description guidelines with minor revisions. Comments pertaining to the written description guidelines are addressed in detail below. A few comments addressed particular concerns with respect to the associated examiner training materials that are available for public inspection at the USPTO web site (www.uspto.gov). Such comments will be taken under advisement in the review of the training materials; consequently, these comments are not specifically addressed below as they do not impact the content of the Guidelines. Several comments raised issues pertaining to the patentability of ESTs, genes, or genomic inventions with respect to subject matter eligibility (35 U.S.C. 101), novelty (35 U.S.C. 102), or obviousness (35 U.S.C. 103). As these comments do not pertain to the written description requirement under 35 U.S.C. 112, they have not been addressed. However, the aforementioned comments are fully addressed in the “Discussion of Public Comments” in the “Utility Examination Guidelines” Final Notice, which will be published at or about the same time as the present Guidelines.

Responses to Specific Comments

(1) Comment: One comment stated that the Guidelines instruct the patent examiner to determine the correspondence between what applicant has described as the essential identifying characteristic features of the invention and what applicant has claimed, and that such analysis will lead to error. According to the comment, the examiner may decide what applicant should have claimed and reject the claim for failure to claim what the examiner considers to be the invention. Another comment suggested that the Guidelines should clarify what is meant by “essential features of the invention.” Another comment suggested that what applicant has identified as the “essential distinguishing characteristics” of the invention should be understood in terms of *Fiers v. Revel*, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993) ("Conception of a substance claimed per se without reference to a process requires conception of its structure, name,
PATENTS GRANTED ACCORDING TO CRITERIA SET BY CONGRESS

USC 35 101, 102, 103, 112

1. Patent Eligible
2. Useful
3. Novel
4. Non-Obvious
5. Written Description
6. Best Mode of Practice

If utility is specific, substantial, a credible patent must be issued by law—

To change requires change by Congress
A Common Misperception...

Patents inhibit free exchange of information.
TO THE CONTRARY...

The patent laws require DISCLOSURE of the structure of the invention, how to make and use it and the best mode of the invention. (35 U.S.C. § 112, first paragraph.)

Patent applications are typically PUBLISHED 18 months after filing and in any event upon issue.

An applicant is free to DISCLOSE the invention any time after the application is filed without jeopardizing patentability.
US VS. JAPAN PATENTS

1. US - First to Invent
2. US Patent - Only in US
3. US - Inventor Benefits First, Then Society 18 Months Later Published
4. US - Applicant must be US or foreigner whose country allows US applicant (not Japan)
6. Compulsory License - US none
7. Term - US - 20 years from filing
8. US - First to File
9. Japan - in Japan & Europe
10. Japan - Same
11. Japan - NOT recognize US natural must be Japanese
12. Japan - When Published is used by others (before issued)
13. Japan - If Patent not used in 3 years or if in public interest
14. Japan - Same
So......

Patents?

Patent Life?

What Kind of Life?

Mause, Bacteria, Cell Lines, Cancer? Plant? Own Cell Line?