Patentability of Human Genes: Our Patent System Can Address the Issues Without Modification

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PATENTABILITY OF HUMAN GENES: OUR PATENT SYSTEM CAN ADDRESS THE ISSUES WITHOUT MODIFICATION

I. INTRODUCTION

The scientific field of biotechnology is drastically changing the world in which we live. Tremendous new discoveries this past decade have fundamentally changed the way we think about biotechnology and the way we use it to improve our lives. Many biotechnology uses create legal issues, and patent law is evolving to address these issues. However, because the field of biotechnology is new, the body of case law is small. Furthermore, the United States Patent and Trademark Office (PTO) is rapidly adapting to address issues raised by those seeking to patent biotechnological inventions. It is important that there be certainty in the law so that companies endeavoring to invest large sums of money in research and development are secure in the knowledge that they can protect their costly inventions.

One of the biggest issues involving biotechnology and the law is the patenting of human genes. Because of advances in technology, it is relatively routine to isolate genes and determine their genetic sequence.1 With the recent completion of the Human Genome Project, we now know the entire genetic sequence of the human genome. All that remains is for science to determine which portions of the sequenced genome correspond to actual genes.2 For these reasons, the PTO witnessed a tremendous increase in the number of patent applications for human genes.3 The number of applications more than doubled in the last ten years, from approximately 16,000 applications in 1990 to 33,000 applications in 2000, and in the last twenty years, "the [PTO] has

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1. See generally 1 GENOME ANALYSIS: A LABORATORY MANUAL 1-36 (Bruce Birren et al. eds., 1997) [hereinafter GENOME ANALYSIS] (describing numerous techniques for isolating and analyzing genes).
2. See Leslie Roberts, A History of the Human Genome Project, SCIENCE, Feb. 16, 2001, at 1195. The editors of SCIENCE dedicated this entire issue to the Human Genome Project. Id. The issue contains a publication of the entire sequence of the human genome. See id. at 1304–51. Additionally, there are articles that address some of the issues created by the Human Genome Project. See id. at 1177–1207.
This swell in the number of applications for patents on genes not only increased the workload of the PTO, but also led some to call for an evaluation of the law as it relates to the patentability of biological inventions. For example, Supreme Court Justice Stephen Breyer recently expressed the need for a better understanding of the science behind human genes and its relationship with the law. In a rare appeal, Justice Breyer said, "Rapid developments in genetic research have led to calls for legal change, namely [in] patent law.... But what about granting patents on mere gene fragment [or] for the isolation of cell membrane receptors? I'm frightened to death as I approach words like that." Justice Breyer called for an "ongoing conversation" among lawyers, economists, scientists, and the biotechnology industry that will instruct judges on the likely impact of future court decisions. He further identified "the patenting of genes" as the area of law where the need for this conversation was greatest. While the U.S. Supreme Court has decided few major cases involving gene patents, Justice Breyer obviously anticipates more cases in the future. Many molecular biologists might consider the Justice's fear of patents on gene fragments or cell membrane receptors to be unfounded, but the Justice makes a valid point in stressing that those making legal decisions affecting these types of patents should do so on an informed basis.

This Comment explores and discusses patent law as it relates to human genes. Part II explains the biology behind genes, describing what a gene is and what a gene does. Part III addresses the legal basis for the patenting of human genes derived from the U.S. Constitution, statutory provisions, and case law. Part IV of this Comment discusses some of the arguments and problems expressed by some with regard to the patenting of genes, and it also describes how the law addresses these arguments and problems. In Part V, this Comment delineates some of the changes enacted by the PTO to address potential shortcomings of the law in regard to the patentability of genes. Finally, Part VI discusses whether the law requires further modifications to address concerns expressed by those opposed to the patenting of human genes or whether

4. Id.
5. Richard Willing, Breyer Makes a Rare Appeal: Justice Calls for a 'Conversation' on Genetics and Law, USA TODAY, Nov. 24, 2000, at 10A.
6. Id. (alterations in original).
7. Id.
8. Id.
9. Id.
the law as it currently stands sufficiently addresses the patentability of human genes.

II. A MOLECULAR BIOLOGY PRIMER

An understanding of how our patent system differentially treats the patenting of human genes necessitates an understanding of the molecular biology of genes. All living things use deoxyribonucleic acid (DNA) to pass traits on to their offspring. DNA can be thought of as a "code" composed of four deoxyribonucleotides: adenine (A), guanine (G), cytosine (C), and thymine (T). These four deoxyribonucleotides can be regarded as letters within the code. All life uses this DNA code to spell out information that ultimately results in the expression of a genetic trait. Molecular biologists study how information within the DNA code ultimately results in the expression of a genetic trait.

The path from the DNA code to the expression of the corresponding genetic trait is complex. DNA is organized into units called genes. A gene typically codes for a single protein, and it is this protein that effects the genetic trait. For instance, many genes code for proteins that function as enzymes, which facilitate biochemical reactions in the human body. These biochemical reactions ultimately result in the expression of a genetic trait, and in the case of defective genes, disease. But how does a gene result in the production of a protein? The DNA sequence of the gene instructs the cell to synthesize a protein through a series of complex biochemical steps.

The process whereby the sequence in a gene is used to create a protein can be divided into two steps—"transcription" and

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10. See BENJAMIN LEWIN, GENES VI 71-76 (6th ed. 1997). Lewin also indicates that some viruses use RNA as their genetic material. See id. at 76. In addition, some infectious agents called "prions" may consist only of protein. See PRION BIOLOGY AND DISEASES 3-5 (Stanley B. Prusiner ed., 1999). However, it is debatable whether viruses and prions are living entities because they are the obligate parasites, and thus are totally reliant on the cell they infect for their replication. See id. at 3-4; S.J. FLINT ET AL., PRINCIPLES OF VIROLOGY: MOLECULAR BIOLOGY, PATHOGENESIS AND CONTROL 11 (2000).
11. LEWIN, supra note 10, at 76-79.
12. Id. at 71-74.
13. Id. at 51-95, 135-40, 335.
14. Id. at 61-63.
15. One such enzyme, phenylalanine hydroxylase, converts the amino acid phenylalanine to tyrosine, and those with a mutant gene that produces an enzyme incapable of this metabolic conversion have the disease called "phenylketonuria" or PKU. This defect results in a toxic accumulation of phenylalanine within the body, and mental retardation can result. Id. at 51.
"translation." During transcription, the sequence within the DNA is used to create a copy composed of ribonucleic acid (RNA). RNA is similar to DNA except that RNA is composed of ribonucleotides rather than deoxyribonucleotides, and RNA uses uracil (U) in place of thymine (T). This RNA copy of the gene serves as a template for the process of translation—the next step in the production of a protein from a gene. During translation, the body's cellular machinery reads the RNA sequence, which then produces a protein based on this sequence. Once a protein is synthesized and becomes functional, it can catalyze important biochemical reactions within the cell. These reactions ultimately result in a genetic trait.

Proteins are composed of amino acids, and a protein can be viewed as a long chain of different amino acids. One protein differs from another based on the sequence of amino acids, and it is this sequence of amino acids that determines the protein's ultimate function. As mentioned, RNA is comprised of four different nucleotides (A,G,C,U); in contrast, proteins may be comprised of as many as twenty different amino acids. How can these four nucleotides be used to indicate twenty amino acids? The answer is that the four nucleotides are actually read in triplets to indicate a particular amino acid. Because they are read in triplets, there are over sixty-four different possible combinations. Further, because there are more possible triplets than amino acids, more than one triplet can specify a particular amino acid. Therefore, there is redundancy in the genetic code. For example, one amino acid, leucine, can be specified by six different triplets.

Obviously, this primer is not meant to give the reader a comprehensive understanding of molecular biology, but the reader should recognize one important principle: while genetic traits can have
severe repercussions, especially when they result in disease, they all have a basis in a DNA code that is very simple—four different molecules that are linked in a composition that is a gene.

III. LEGAL BASIS FOR PATENTING HUMAN GENES

A patentee has the right to exclude others from using the claimed invention and thus permits the patentee to create a monopoly. 29 While the right to create a monopoly runs counter to our nation's longstanding economic policy—most visibly embodied in the Sherman Antitrust Act 30—the drafters of the U.S. Constitution recognized that an inventor should have the right to patent his invention. 31 For instance, the Constitution states that Congress shall have the 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." 32 While our forefathers did not likely foresee the advances witnessed in science, the United States Supreme Court has interpreted Article I, Section 8, Clause 8 as permitting Congress to allow a broad range of subject matter that may be patented. 33 The Patent Act of 1952 sets forth the requirements to obtain a patent and the rights of the patentee. 34 In particular, section 101 indicates what subject matter is patentable by stating that "[w]hoever 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." 35 Consequently, the PTO not only permits patents for genes, but also for other life in the form of bacteria, 36 plants, 37 and even mammals. 38 The rapid proliferation

31. THE FEDERALIST, No. 43, at 294 (James Madison) (1947) (stating that "The right to useful inventions seems . . . to belong to the inventors.").
35. Id. § 101.
36. See, e.g., U.S. Patent No. 4,259,444 (issued Mar. 31, 1981). Chakrabarty's patent on oil-degrading bacteria is probably the most famous bacteria patent because it did not issue until after a protracted court battle that ultimately led to the Supreme Court's monumental holding in Diamond v. Chakrabarty, 447 U.S. 303 (1980).
37. See, e.g., U.S. Patent No. PP4,278 (issued July 11, 1978) (patent on a miniature rose
of patents for genes leads some to question whether the PTO should impose more restrictive requirements before issuing patents for genes or whether it should issue patents for genes at all.  

IV. ARGUMENTS AGAINST THE PATENTING OF HUMAN GENES

There are numerous arguments against the patenting of human genes. This Comment divides these arguments into three broad categories: (A) legal arguments, (B) policy arguments, and (C) ethical arguments. The legal arguments are based on interpretations of the Constitution, the Patent Act, and applicable case law. The policy arguments are based on the perceived goals of our patent system. Finally, ethical arguments are based on the author's feelings about the nature of genes and how genes contribute to what makes us human.

A. Legal Arguments

As stated in Part III, the origin of patent rights is in the U.S. Constitution at Article 1, Section 8, Clause 8, which states that "Congress shall have the 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." Congress exercised this power by passing the Patent Act. Under the Patent Act, a patent gives one the right to exclude others from making, using, selling, or importing the patented invention in the United States "beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed."

40. Many of the arguments presented in this Comment were offered in response to a request for comments by the PTO in regard to its "Revised Interim Utility Examination Guidelines." See Public Comments on the United States Patent and Trademark Office "Revised Interim Utility Examination Guidelines," 64 Fed. Reg. 71,440 (Dec. 27, 1999). The PTO responded to some of these comments when it published its revised utility examination guidelines. 66 Fed. Reg. 1092–99 (Jan. 5, 2001) [hereinafter "Comments and Response"].
41. For a similar organization and analysis of arguments against the patenting of human genes, see Rebecca S. Eisenberg, Genetics and the Law: Patenting the Human Genome, 39 EMORY L.J. 721 (1990).
42. U.S. CONST. art. I, § 8, cl. 1, 8.
44. Id. § 271(a).
45. Id. § 154(a)(2).
In order to receive a patent under the Patent Act, the inventor must comply with certain statutory requirements. For example, section 101 of the Patent Act requires that the invention or discovery fall within a category of statutory subject matter and that the invention or discovery has a certain threshold of utility. Section 101 states that "[w]hoever 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." In addition to meeting this degree of utility, the invention must also be "novel." Section 102 requires that the invention not be "known or used by others in this country... before the invention thereof by the applicant." Section 103 goes further, requiring that the invention not be "obvious." Section 103 states that "[a] patent may not be obtained... if the differences between the [invention] and the prior art are such that the [invention] would have been obvious at the time the invention was made to a person having ordinary skill in the art."

Other statutory requirements can be thought of as "consideration" for receiving a patent. For example, before receiving a patent, the inventor must comply with the disclosure requirements of section 112 and provide an adequate "written description" of the invention. The written description requirement of 35 U.S.C. § 112 states:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The requirement of an adequate written description ensures that the invention is disclosed to the public before the inventor receives the right to exclude others from making, using, selling, or importing the invention.

46. Id. § 101.
47. Id.
48. See id. § 102.
49. Id. § 102(a).
50. Id. § 103.
51. Id. § 103(a).
52. Id. § 112.
53. Id.
in the United States. The policy behind this requirement is to reward invention and discovery by granting patent rights while promoting the dissemination of information to further research.

These requirements under the Patent Act raise various arguments that the patenting of genes violates the spirit, if not the letter of the law.

1. Genes are Not "Inventions"

Many argue that genes are not "inventions," but rather they are "discoveries" which do not require an inventive effort. Because the discovery of genes does not require an inventive effort, the PTO should not issue patents for genes. In the same regard, because genes are "discoveries" and not new "compositions," genes should not be patented because they are not "novel," as required by section 102. For example, human genes have existed as long as the existence of humanity; therefore, an inventor can never discover a gene and claim that it is "novel." Finally, carrying patent law to its extreme, some argue that anyone containing patented genes within his or her body could be considered an infringer, because he or she is "using" a patented gene merely by being alive.

To address the first argument—that genes should not be patentable because they are discoveries and not inventions—it should be noted that the drafters of the Constitution clearly stated in Article 1, Section 8,

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54. See CHISUM ON PATENTS § 7.02 (2d ed. 2000) (citing Grant v. Raymond, 31 U.S. (6 Pet.) 218 (1832)).

The third section requires, as preliminary to a patent, a correct specification and description of the thing discovered. This is necessary in order to give the public, after the privilege shall expire, the advantage for which the privilege is allowed, and is the foundation of the power to issue the patent.

Id. (emphasis omitted).

55. See id.

56. Comments and Response, supra note 40; Eisenberg, supra note 41; Hettinger, supra note 39.


59. See Comments and Response, supra note 40, at 1093; Eisenberg, supra note 41, at 725–29.

60. See Hettinger, supra note 39, at 286.

61. Comments and Response, supra note 40, at 1093. The comment apparently refers to a concern that by merely being alive, one may be guilty of using a patented gene without authority as proscribed by statute. 35 U.S.C. § 271(a) (1994).
Clause 8 that Congress may extend to "[i]nventors the exclusive Right to their respective . . . Discoveries." As such, the drafters expressed no intent to distinguish between inventions and discoveries.

Federal case law has addressed the second argument—that because genes are isolated from nature, they are not "novel." An early case implied that genes might not satisfy the novelty requirement of our patent system. In Funk Brothers Seed Co. v. Kalo Inoculant Co., the patent involved a process for inoculating leguminous plants with strains of naturally occurring bacteria to allow the plants to fix nitrogen from the air. The U.S. Supreme Court stated, "[P]atents cannot issue for the discovery of phenomena of nature," and "these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none." One can argue that genes, like the bacteria in Funk Brothers, are a "discovery of the phenomena of nature," and therefore genes should not be patentable. A gene is not an "invention" in the same sense that a machine is an "invention." However, while the Court never explicitly overruled Funk Brothers, it limited its holding in a subsequent decision.

In Diamond v. Chakrabarty, the Court held that bacteria, which had been genetically modified to degrade oil, could be patented. The distinguishing factor in Chakrabarty, as compared to Funk Brothers, appeared to be that in Chakrabarty the bacteria had been altered by human intervention. In light of these cases, how would the Court analyze a challenge to the patenting of genes? A gene isolated for patenting is not altered in the same way as the bacteria in Chakrabarty, but it is purified and amplified. The Court has never answered whether this distinction is sufficient to qualify a human gene as patentable subject matter, but the PTO in its Comments and Response has stated that "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.

64. Id.
65. Id. at 128–30.
67. Id. See also Eisenberg, supra note 41, at 726. "[T]he relevant inquiry for distinguishing between patentable subject matter and unpatentable products of nature is whether the claimed invention is the result of human intervention . . . . [As such, a human gene] should not be patentable unless it has been altered somehow by human intervention." Id.
through purifying steps that separate the gene from other molecules naturally associated with it." This opinion of the PTO corresponds to case law subsequent to *Funk Brothers*, which "seems to represent the high-water mark in the 'products of nature' doctrine." For example, in *In re Bergstrom*, a federal court of appeals held that scientists could patent purified forms of two human hormones called prostaglandins because the purified forms do not naturally occur in nature.

The PTO specifically addressed the final argument—that anyone who carries patented genes within his body can be considered to be an infringer—in its published guidelines. PTO guidelines state that the PTO cannot charge an individual with infringement for carrying a patented gene within one's body, because "[a] patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature." However, as scientists and physicians become more adept at using gene therapy to manipulate and modify genes within a patient's body, the courts may test this *in situ* distinction. At that point, the courts and the PTO may re-analyze what constitutes infringement in the context of *in situ* use, although it seems preposterous from a public policy standpoint to envision a patentee of a gene suing all of humanity for infringement. Furthermore, patent claims on gene therapies would likely focus on a process or method, rather than on a particular gene itself.

2. It was Not Congress's Intent to Include Genes as Patentable Subject Matter

Another argument proffered by those opposed to the patenting of genes is that Congress did not intend to include genes as patentable

68. Comments and Response, *supra* note 40, at 1083 (citing Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911); *In re Bergstrom*, 427 F.2d 1394, 1397 (C.C.P.A. 1970) (both holding that proteins purified from their natural setting were patentable)).

69. *See* Eisenberg, *supra* note 41, at 725–29 (discussing Diamond v. Chakrabarty, 447 U.S. 303 (1980)); Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156 (4th Cir. 1958) (holding that a purified form of vitamin B12 could be patented); *In re Bergstrom*, 427 F.2d at 1396, 1401–02 n.2 (C.C.P.A. 1970) (holding that prostaglandins, hormones purified from "animals such as fish, birds, and mammals, for example, chickens, pigs, sheep, cattle, and man" are patentable). This author notes that the court was incorrect in identifying chickens as mammals.

70. Eisenberg, *supra* note 41, at 725.

71. 427 F.2d at 1401–02.


73. *Id.*

74. For a discussion of the state of science with regard to gene therapy, see generally *THE DEVELOPMENT OF HUMAN GENE THERAPY* (Theodore Friedmann ed., 1999).
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subject matter. For instance, because the discovery and isolation of genes was neither possible nor foreseeable at the time the Constitution was drafted, the drafters could not have intended for biological discoveries such as genes to be patentable subject matter. Therefore, in passing the Patent Act of 1952, the 82nd Congress could not have intended that genes be included as patentable subject matter.

Chief Justice Burger, writing for the majority in Diamond v. Chakrabarty, determined that statutory subject matter under the Patent Act could include genetically modified bacteria. In support of his determination, Justice Burger noted that the legislative history of the earliest patent act, the Patent Act of 1793, supported a broad definition of statutory subject matter. Further, Justice Burger stated that "[t]he Committee Reports accompanying the 1952 [Patent] Act inform us that Congress intended statutory subject matter to 'include anything under the sun that is made by man.'" Justice Burger concluded by stating that the term "'composition of matter'" within section 101 may include "'all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.'"

A gene is the result of a chemical union of solids—a gene is merely a polymer of nucleotides—therefore, it can be considered a "composite article." But can a gene be considered to be something that is "made by man"? Lower federal courts have held that through the process of isolating and purifying a hormone, the hormone "becomes for every practical purpose a new thing .... That is a good ground for a patent." The PTO follows the same line of reasoning by permitting patents on genes as "new compositions" made by man, where a researcher has isolated and purified a gene from its natural setting.

Therefore, by isolating and purifying a gene from its natural setting, the

75. Comments and Response, supra note 40, at 1093.
76. Id.
77. Id.
78. 447 U.S. 303, 308-09 (1980).
79. Id. at 308.
82. See supra Part II.
84. See Comments and Response, supra note 40, at 1093.
researcher "transforms" the gene into something made by man.85

3. Sequencing DNA is so Routine that it is No Longer Inventive

Some argue that because of recent advances in the isolation, purification, and sequencing of genes, 86 it may take only a few days to determine the sequence of a particular gene. 87 Therefore, the relative ease of determining the sequence of a particular gene should preclude patenting of the gene because obtaining the sequence is obvious.88

However, patent law is not concerned with the ease at which an inventor achieves an invention or discovery. 89 For example, section 103(c) states that "patentability shall not be negatived by the manner in which the invention was made."90 In this regard, patent law is more concerned that the invention or discovery contributes to the growing body of knowledge instead of how that knowledge is obtained. If an invention contributes non-obvious information to the scientific body of knowledge, how we acquired the information should not concern us. The Federal Circuit Court of Appeals stated that the non-obvious test for DNA molecules depends on whether a molecule having a particular structure would have been obvious to one of ordinary skill in the art at the time the invention was made.91 In In re Deuel, the court of appeals stated that "the existence of a general method of isolating [DNA] is essentially irrelevant to the question whether the specific molecules themselves would have been obvious."92 Therefore, the court of appeals appears to be saying that when patenting a gene, the sequence of the gene itself must be obvious, and the method for determining the sequence is largely irrelevant to the test of non-obviousness.

4. A DNA Sequence by Itself has Little Utility

Some argue that "because a DNA sequence by itself has little

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85. Id.
86. See generally GENOME ANALYSIS, supra note 1.
87. See Sara Dastgheib-Vinarov, A Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill, 4 MARQ. INTELL. PROP. L. REV. 143, 154–57 (2000) (analyzing In re Deuel, 51 F.3d 1552 (Fed. Cir. 1995) and arguing how the ease in obtaining a DNA sequence should preclude patenting of that sequence as obvious).
88. Id.
90. Id. § 103(a).
91. In re Deuel, 51 F.3d at 1557–58.
92. Id. at 1559.
utility," genes should not receive patents. After all, a DNA sequence is just information that describes the corresponding gene, and because a gene consists of a DNA sequence, it therefore has little practical utility and is not patentable under section 101.

It is indeed arguable that a DNA sequence, by itself, has little utility. However, an isolated, purified, and sequenced gene is more than just a DNA sequence, and its utility goes beyond the information in its DNA sequence. Countless experiments use isolated, purified, and sequenced genes. The PTO guidelines for assessing "utility" require that an invention or discovery have "specific, substantial, and credible" utility. The guidelines further state that "[c]redibility is assessed from the perspective of one of ordinary skill in the art." By this measure, the utility requirement appears to be minimal, and an isolated and purified gene meets this requirement. Federal courts say as much by holding that an assertion of utility within a patent application is presumed correct. In In re Brana, the federal circuit stated that "the PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure ...." [The burden is satisfied upon a] showing that one of ordinary skill in the art would reasonably doubt the asserted utility" of the claimed invention. Because a gene is presumed to have utility and because a scientist could not reasonably doubt that a gene has utility, a gene satisfies the utility requirement of our patent system.

5. Gene Patents Should Be Limited to "Processes" and Not the DNA Molecule Itself

The final argument in this category relates to the difference between patents on compositions and patents on processes. Patents on

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93. Comments and Response, supra note 40, at 1094.
94. See id.
95. See generally GENOME ANALYSIS, supra note 1 (listing numerous experiments that utilize purified DNA).
96. Id.
98. Id.
99. See id.
101. In re Brana, 51 F.3d at 1566 (citing In re Bundy, 642 F.2d 430, 439 (C.C.P.A. 1980-81)).
102. 35 U.S.C. § 101 (1994). The text of section 101 does not limit patentability to new and useful compositions. It additionally states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ...." Id. (emphasis added).
compositions are considered broader than patents on processes because patents on compositions can cover all processes that use the composition. In order to limit the number of patents for genes, some argue that the PTO should limit patents on genes to processes that utilize the genes, and not the composition of the genes themselves.\(^{103}\)

In response to this argument, section 101 clearly states that patents shall be extended to "composition[s]" as well as "process[es]."\(^{104}\) As a matter of long-standing tradition, the PTO extends patents to chemical compositions, and it is unclear how extending patents to human genes—chemical compositions themselves\(^ {105}\)—distinguishes human genes from other chemical compositions. Further, it is unclear whether this would actually reduce the number of patents involving genes. On the contrary, because patents on processes are not as broad—patents on compositions cover any process that uses the composition—distinguishing human genes from other chemical compositions might force those seeking patent protection to effectively protect the composition of their genes. If they could not file a patent on the gene's composition, they may attempt to file patents on every conceivable process in which the gene might be used. This could result in an even higher workload for the PTO.

6. Summary

The U.S. Supreme Court has yet to confront a case that challenges the legality of patents on human genes. However, the federal courts can certainly uphold such legality under the Patent Act,\(^{106}\) enacted under the authority of Article I, Section 8, Clause 8 of the Constitution. To find that the patenting of genes is not permitted under the Patent Act, federal courts would likely have to re-interpret the Patent Act and distinguish the Court's holding in *Chakrabarty*\(^ {107}\). Of course, federal courts might also find independent authority in the Constitution that forbids the patenting of genes, although such a constitutional argument is difficult to conceive. Therefore, barring any future action by the federal courts or Congress, it appears that the Constitutional and statutory arguments against the patenting of genes are contradicted by

\(^{103}\) Comments and Response, *supra* note 40, at 1094–95.


\(^{105}\) *See supra* Part II.


\(^{107}\) *Diamond v. Chakrabarty*, 447 U.S. 303, 316–17 (1980) (holding that genetically modified bacteria can be patented because it has been altered by human intervention).
case law and current PTO regulations.

B. Policy Arguments

Traditionally, the policy underlying our patent system attempts to create four incentives based on economic goals: "(1) incentive to invent, (2) incentive to disclose, (3) incentive to commercialize, and (4) incentive to design around." These four policies are furthered by the current state of the law as it relates to the patenting of human genes. Before enacting any modification in the law, Congress should consider how the law affects each of these incentives and whether the law needs any change regarding the patenting of human genes.

1. The Patenting of Genes Does Not Discourage Invention

The first goal of our patent system is to provide an incentive to invent. In this regard, the theory underlying our patent system is that the grant of some form of "property right" in exchange for the labor expended in creating the invention maximizes the incentive to invent. Those opposed to the patenting of genes argue that "patents are not necessary to encourage additional discovery and sequencing of genes." Certainly, even without a patent system, some research and discovery of genes would continue, but the underlying reasons for establishing a reward for one's labor, rooted in the Lockean Labor Theory, applies to the discovery of genes as well as to any other discovery. The Lockean Labor Theory posits that one is likely to avoid labor as an unpleasant task and, therefore, to encourage labor, one should receive an award for one's work. In our patent system, an inventor's reward for an invention is the receipt of a patent, which permits the inventor to exclude others from making, using, selling, or importing the invention. The inventor can use this "right to exclude" to commercialize the invention or to license the invention and receive royalties. The "reward" of a patent thereby encourages invention and discovery, and the PTO takes the opinion that "[t]he incentive to make

109. Id. at 62.
110. See id.
111. Comments and Response, supra note 40, at 1095.
112. See CHISUM ET AL., supra note 108, at 35–37 (citing John Locke, Second Treatise on Civil Government, in TWO TREATISES OF GOVERNMENT (Prometheus Books 1986)).
113. See id. But see Hettinger, supra note 39, at 279–81.
discoveries and inventions is generally spurred . . . by patents." Some may argue that research and discovery satisfies an intellectual curiosity, and as such, hardly qualifies as labor. Therefore, intellectual endeavors, such as research and discovery, do not require rewards. Nevertheless, Congress designed our patent system with the underlying premise that reward is required, and it is difficult to envision why the law should distinguish the discovery of genes from other discoveries in this regard.

A second argument within this category is that the patenting of genes discourages others from performing research and discovery. Under our patent system, after a researcher discovers and patents a gene, the researcher, as an inventor, may exclude others from using the gene. When a second researcher studies a particular disease and the patented gene's role in that disease, it may be difficult to design an experiment that does not require the gene. In order to use the gene, the second researcher must seek a license from the patentee, undoubtedly requiring a fee in the form of a royalty. Some argue that this is a waste of valuable resources that could be used for research, rather than royalties, and therefore all human genes should be in the public domain. This is a compelling argument because it is difficult for a molecular biologist studying a particular gene or protein to conceive of experiments that do not require use of the gene itself. In this regard, perhaps it is better to view this perceived problem not as creating a disincentive to invent, but rather as impeding scientific progress. However, this argument is not unique to the patenting of genes. In fact, one could argue that a patent on any invention might similarly impede scientific progress.

Regardless, the PTO is of the opinion that "[t]he incentive to make discoveries and inventions is generally spurred, not inhibited, by patents." Furthermore, the fact that there is a limited exemption

115. Comments and Response, supra note 40, at 1094.
116. See id.
118. See Comments and Response, supra note 40, at 1094–95. See also Eisenberg, supra note 41, at 740–44; Stephen P. Hoffert, PTO Issues Biotech Patent Guidelines, THE SCIENTIST, July 6, 1998, at 1 (citing Professor Jonathan A. King, an outspoken critic of gene patents who describes another cost of gene patents). For instance, Professor King opines how any revenue generated by patents is largely consumed by court battles to defend the patent from infringement. King states that "[t]hese kinds of tit-for-tat court battles have almost become the norm in the area of gene patents . . . . As soon as a patent is issued, you can expect one company to sue another to defend their claims. You have to wonder if this is the best way to spend money and devote resources in scientific endeavor." Id.
119. Comments and Response, supra note 40, at 1094 (emphasis added).
PATENTABILITY OF HUMAN GENES

against patent infringement for research purposes somewhat tempers any concern that the patenting of genes might impede scientific progress.  

Additionally, when a researcher requires the use of a gene and seeks a license from the patentee, "[m]ost inventions [including genes] are made available to academic researchers on very favorable licensing terms." Further, when a second researcher discovers a new use for a patentee's gene without having a license to use the gene's composition, the second researcher may patent the process itself.  

If the patentee of the gene's composition desires to use the second researcher's process, the first patentee must then seek a license from the second patentee, and this may place the two in equipoise in bargaining negotiations for a cross-license agreement.  

Finally, while it is difficult for a molecular biologist to envision experiments that do not require the use of any particular gene, this difficulty may actually further another goal of our patent law—the incentive to design around. After all, the greater the need for a particular tool in studying a problem, the greater the incentive is for designing around the required tool. It is often said that necessity is the mother of invention.

2. The Patenting of Genes Does Not Discourage Disclosure

Much of the research performed by the scientific community relies on free access to information, and some argue that the possibility of obtaining patent rights might hinder communication among scientists. For instance, section 102 creates a statutory bar to patentability where an "invention was . . . described in a printed publication . . . more than one year prior to the date of the application for patent." This requirement might inhibit free exchange of information, at least until the inventor files the application or has no apprehension about failing to meet the statutory bar.

However, the purpose behind this statutory bar is to encourage the

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120. See 35 U.S.C. §§ 163, 271(a), (e).
121. Comments and Response, supra note 40, at 1096.
123. For a contrary view, see Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. CHI. L. REV. 1017 (1989).
124. Comments and Response, supra note 40, at 1095.
125. 35 U.S.C. § 102(b).
inventor to timely file a patent application, and the ultimate goal of our patent system is full disclosure. The written description requirement ensures that the invention is adequately described such that one of ordinary skill in the art can make and practice the invention. Furthermore, under section 122, applications must be published eighteen months from the earliest filing date. While disclosure may ultimately occur later under the patent system, the system ensures that anyone seeking to acquire a patent must fulfill a disclosure requirement. In fact, it is likely that less disclosure would occur without our patent system, because scientists, unprotected by a patent, would then have to rely on secrecy to protect their discoveries. Regardless, the incentive for full disclosure does not create unique issues for the patenting of human genes in comparison to other inventions, although the written description requirement is a highly litigated issue that will be discussed in Part V.

3. The Patenting of Genes Does Not Frustrate the Incentives to Commercialize or "Design Around"

This author is unaware of any arguments put forward to claim that the patenting of genes frustrates the final two incentives—commercialization and "designing around." On the contrary, one can argue that it is precisely because of the patent system that inventors are encouraged to commercialize inventions that rely on human genes. Without patent protection, few would be willing to invest resources in developing inventions that rely on human genes. Similarly, as discussed in Part IV.B.1 supra, the patent system provides a strong incentive to "design around" because of the difficulty in performing experiments in molecular biology without the use of the particular gene that the inventor chose to study.

129. 35 U.S.C. § 122. Section 122 provides an exception to this publication requirement if the applicant certifies that he has no intent to file in a foreign country. Id. § 122 (b)(2)(B)(i).
130. Eisenberg, supra note 41, at 741.
C. Ethical Arguments

Ethical arguments, the final category, is the most difficult to marshal and address. As such, this author will briefly address only the two most common arguments against the patenting of genes.

One of the most common ethical arguments is that the government should not issue patents on human genes because genes belong to all humankind, and therefore no single group should have the exclusive property right to exclude others from their use. However, gene patents are not owned in the same sense as property is owned. A patent is intangible property, and therefore, granting a patent on a human gene does not deprive humankind of "property" in the traditional or tangible sense. A gene patent only deprives other researchers, often attempting to realize a financial gain, from its use.

The second most common argument against the patenting of human genes is that researchers derive a human gene from a human being, which violates our society's 150-year prohibition on humans having property rights in another human being. However, should a human gene qualify as a human being or a living entity? The U.S. Supreme Court has offered a potential framework for analyzing whether a gene should qualify as a living entity. In Roe v. Wade, the Court held that the State did not have a "compelling" interest in proscribing abortion where a fetus was not viable. While this author does not wish to equate a woman's right to seek an abortion with an inventor's right to patent a biological product, the "viability" test that was expressed in Roe v. Wade may have applicability in determining whether a human gene qualifies as a living entity. The "viability" test established by Roe v. Wade was whether the fetus could have a "meaningful life outside the mother's womb." Human genes fail this test for viability because


135. Id.

136. Id.
human genes are inanimate compositions of matter. Even with all the recent scientific advances, creation of a human being in vitro from the entire human genome is scientific fantasy.

However, even if human genes are not viable, some may argue that patents should not be issued for genes for the same reason that it is illegal to market other human products such as organs. Clearly, society believes that some human products should not be for sale, although, society somewhat relaxes this policy by allowing one to "donate" certain bodily fluids, such as plasma, for money. The underlying concern for this ban on the sale of organs may be to protect those that are impoverished from sacrificing vital organs for financial gain, but this policy is not particularly applicable to the patenting of human genes. First, one can argue that patenting of genes is distinguishable in that there is not a market for genes similar to the market for human organs. Second, one may be able to isolate, amplify, and sequence a gene from a single cell. Thus, a patentee that patents his or her own genes is not deprived of a vital organ in the same way as an organ donor.

Undoubtedly, there are additional ethical arguments against the patenting of genes. Ultimately, however, society determines what is ethical, and consequently whether the patenting of genes meets our ethical standard.


Recently, in response to particular arguments against the patenting of genes, the PTO issued new examination guidelines regarding the

137. See supra Part II.

138. Arguably, scientists will never be able to create a human being in vitro from the human genome because human life may require the pre-existence of a single cell, or at least certain organelles within the cell. See VIRGINIA WALBOT & NIGEL HOLDER, DEVELOPMENTAL BIOLOGY 2-3 (1987).

139. 42 U.S.C. § 274e(a) (1994). This section states that "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration." Id.

140. See Note, Regulating the Sale of Human Organs, 71 VA. L. REV. 1015, 1034 (1985) (stating that "[A] monetary inducement to donate is so coercive that it deprives some sellers of the ability to give informed consent.").

141. Theoretically, one can amplify a gene from a single DNA molecule by using a process called polymerase chain reaction (PCR). See generally GENOME ANALYSIS, supra note 1. Therefore, a gene can be isolated from a single cell.
interpretation of the utility requirement\textsuperscript{142} and the written description requirement.\textsuperscript{143} These new guidelines address some of the concerns of those opposed to the patenting of human genes.

The utility requirement, as described in Part IV, derived from 35 U.S.C. § 101, states that "[w]hoever 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 therefore, subject to the conditions and requirements of this title."\textsuperscript{144} Arguably, the PTO previously applied the utility requirement very liberally, but the Human Genome Project created what some perceived as a problem with the liberal application of the utility requirement.

In attempting to sequence the human genome, scientists first sequenced short stretches of human DNA called Express Sequence Tags (EST) to use as tools for sequencing entire genes.\textsuperscript{145} These ESTs contained only short portions of the DNA sequence of unknown genes rather than the entire DNA sequence.\textsuperscript{146} However, ESTs are useful tools for obtaining the entire sequence of genes.\textsuperscript{147} Because ESTs had this utility, albeit limited, the National Institute of Health (NIH) filed many patents for various ESTs in the 1990s,\textsuperscript{148} despite the fact that the inventors of ESTs did not know to which genes these ESTs corresponded.\textsuperscript{149} This created concern in the scientific community that the PTO would grant patents on short stretches of these unknown genes, and thereby preclude others from patenting the entire gene.\textsuperscript{150} For example, after someone patents the short stretch of a gene as an EST, this patente would own the patent rights to that portion of the gene. Even if someone later isolates and sequences the entire gene, the inventor could only patent the portions of the gene not previously patented as an EST because the portion of the gene corresponding to

\begin{thebibliography}{99}
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\item\textsuperscript{142} Comments and Response, supra note 40, at 1092–99.
\item\textsuperscript{143} Written Description Guidelines, 66 Fed. Reg. 1099–1111 (Jan. 5, 2001) [hereinafter Written Description Guidelines].
\item\textsuperscript{144} 35 U.S.C. § 101 (1994).
\item\textsuperscript{145} For a discussion of ESTs and patent law, see Dorothy R. Auth, Are ESTs Patentable?, 15 NATURE BIOTECHNOLOGY 911, 912 (1997); Rebecca S. Eisenberg & Robert P. Merges, Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences, 23 AIPLA Q. J. 1 (1995).
\item\textsuperscript{146} See Eisenberg & Merges, supra note 145, at 13–14.
\item\textsuperscript{147} Id.
\item\textsuperscript{148} Id. at 2–3.
\item\textsuperscript{149} Id. at 18.
\item\textsuperscript{150} Comments and Response, supra note 40, at 1095.
\end{small}
the EST would not be novel. Therefore, patenting of ESTs could create a disincentive to isolate and sequence entire genes, and "could create a very serious limitation on the freedom of researchers to determine the functionality of genes."152

In response to this perceived problem, the PTO clarified the utility standard.153 This clarified standard requires that "[a] claimed invention must have a specific and substantial utility."154 This requirement precludes the inventor of an EST from patenting the EST without providing a substantial utility.155 Presumably, under the new standard, this would likely require that the inventor know the identity of the gene that corresponds to the EST.156 Therefore, this new standard is likely to protect researchers performing bona fide research on particular genes against those who patent ESTs to lay claim to those genes of which they have no knowledge.

However, the new utility standard does not preclude the patenting of ESTs per se,157 and the inventor of the EST need not describe a utility for the EST other than its use in the isolation of the entire corresponding gene.158 Regardless, because the inventor is required to know the gene to which an EST corresponds, it is probable that another inventor already sequenced the corresponding gene and reported it, if not patented it. If a prior inventor already reported the gene's sequence, the EST's inventor is precluded from patenting the EST as a new composition because the sequence of the EST is not novel.159 Similarly, the law precludes the discoverer of the gene from patenting the EST for use in obtaining the entire gene because that use would be obvious.160 This policy encourages the reporting of new genetic sequences while maintaining the right of bona fide researchers to seek a patent.

The PTO also issued new guidelines for assessing compliance with the written description requirement of section 112.161 Under the

154. Id. at 1098.
155. Id.
156. See id.
157. See id. at 1095.
158. See id.
160. Id. § 103(a).
161. Written Description Guidelines, supra note 143, at 1099–1111.
authority of the written description requirement, some urge the PTO to require the disclosure of the sequence of a gene for patentability.\textsuperscript{162} Presumably, this would limit the number of patents on human genes and increase dissemination of the sequence of the human genome.\textsuperscript{163} The PTO refused to follow this suggestion.\textsuperscript{164} Even if the PTO were to require the reporting of the sequence of a gene for patentability, this requirement would have little practical effect on the number of patent applications, because the most practical and common way to satisfy the written description requirement is to report the DNA sequence.\textsuperscript{165}

The primary purpose of the written description requirement is to ensure that the inventor is in possession of the invention at the time of filing and to prevent the inventor from claiming subject matter that was not filed in the patent application.\textsuperscript{166} Courts require that in order to conceive of a gene, the inventor must sufficiently describe the gene.\textsuperscript{167} This indicates that the inventor possesses the gene at the time he or she files the patent. In \textit{Eli Lilly}, the Federal Circuit Court of Appeals held that an applicant was not in possession of a gene when the application did not disclose the sequence of the gene.\textsuperscript{168} It was not sufficient that the patent's specification disclosed the sequence of a related gene and a method for obtaining the sequence of the claimed gene.\textsuperscript{169} Further, the court of appeals stated that "an adequate written description of a DNA . . . requires . . . a description of the DNA itself,"\textsuperscript{170} and that an adequate description is "usually achieved by means of the recitation of the sequence of nucleotides that make up the [DNA]."\textsuperscript{171}

However, the court of appeals was not willing to make reporting of a DNA sequence an absolute requirement for patentability, and accordingly, the PTO incorporated this opinion into its examination

\begin{itemize}
\item\textsuperscript{162} \textit{Id.}
\item\textsuperscript{163} Comments and Response, \textit{supra} note 40, at 1095.
\item\textsuperscript{164} \textit{Id.}
\item\textsuperscript{165} \textit{See generally} \textit{GENOME ANALYSIS, supra} note 1. There are other ways to characterize a gene, for example by its molecular weight. \textit{Id.} The best way to distinguish and characterize DNA is, however, to sequence it, and because of the relative ease at which sequencing is performed, there is no reason not to sequence a gene. \textit{Id.}
\item\textsuperscript{166} \textit{See} Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560-61 (Fed. Cir. 1991) (quoting Evans v. Eaton, 20 U.S. (7 Wheat.) 356 (1822)).
\item\textsuperscript{167} \textit{See}, e.g., Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997).
\item\textsuperscript{168} \textit{Id.} at 1567-69.
\item\textsuperscript{169} \textit{Id.} at 1562-63.
\item\textsuperscript{170} \textit{Id.} at 1566-67 (citing Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993)).
\item\textsuperscript{171} \textit{Id.} at 1569 (emphasis added) (citation omitted).
\end{itemize}
guidelines for satisfying the written description requirement. The PTO stated that while reporting "the DNA sequence[] is one method of describing a DNA molecule[,] ... it is not the only method." Again, the most practical and common way for an inventor to satisfy the written description requirement is to simply report the DNA sequence of the gene.

VI. CONCLUSION

This Comment intends to impart an understanding of how patent law relates to the patenting of genes. In addition, this Comment seeks to explain some of the perceived problems and provide a framework to analyze proposed solutions to these problems. Under the Court's current analysis of the Constitution and the Patent Act, the patenting of genes is probably permissible, and any prohibition on the patenting of genes would likely require the Court to revisit prior holdings or for Congress to amend the Patent Act.

The most important policy question relates to our patent system's goal of creating an incentive to invent and whether the patenting of genes promotes or impedes scientific progress. If we concede, contrary to the PTO's opinion, that gene patents do impede scientific progress, or that the patenting of genes should be distinguished and treated differently than other patents because gene patents relate to human medicine, there are a number of solutions. For example, in the extreme, Congress could amend the Patent Act to prohibit the patenting of genes altogether as contrary to the public interest, or in a more moderate action, Congress could create a system of compulsory licensing. Of course, both of these solutions might impair the patent system's incentive to invent.

Finally, regarding ethical arguments proffered against the patenting of genes, society will ultimately decide whether the patenting of genes contradicts our ethical standards. In making such a decision, it is important to note that gene patents are not tangible property; thus, the law should not equate owning a gene patent with owning a part of "humankind." Additionally, because genes are not living entities, the law should not equate a human gene patent to a patent on any living part of a human being.

Our expanding knowledge of the human genome presents many

172. Written Description Guidelines, supra note 143, at 1104-11.
173. Comments and Response, supra note 40, at 1095 (emphasis added).
174. See supra note 165.
opportunities for us to improve our lives through advances in human medicine. We can and should use our patent system as a tool to promote these discoveries to create a better world. As it currently stands, our patent system provides a statutory framework for addressing most issues that arise from the patenting of human genes. Upon addressing these issues in the future, we should remember the old adage: "if it ain't broke, don't fix it." 175

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175. Lema v. United States, 987 F.2d 48, 54 (1st Cir. 1993).

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