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COMMENT

CONTRARY TO FIRST IMPRESSION, GENES ARE PATENTABLE: SHOULD THERE BE LIMITATIONS?

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I. INTRODUCTION

The Human Genome Project was designed in 1988 to discover the entire DNA sequence (deoxyribonucleic acid) of the genome.¹ The U.S. Government, which launched the project, expected the project to take 15 years and cost three billion dollars.² The hope is that the discovery of the entire genome will lead to the development of new methods of medical treatment.³ The rate of future treatment development will depend on gene patenting.⁴ Patents, including gene patents, are issued by United States Patent and Trademark Office (USPTO). Gene patents can include both the physical aspects of DNA and the methods of using a gene or protein.⁵ The USPTO has issued several thousand gene patents in recent years.⁶ However, because the primary focus has been on the results of the patent, the process by which the patentability of genes emerged has received less emphasis. To that end, this comment provides an overview of the patent system and its underlying policies, and the statutory requirements that must be met for a patent to issue to a gene sequencer. Following a brief overview of gene isolation, as well as the legality of gene patenting, its many implications are considered. Because the benefits arising from gene patents overcome the objections to their patenting, Congress should impose compulsory licensing on gene patent owners in order to promote continued research and development.

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1. Byron v. Olsen, *The Biotechnology Balancing Act: Patents For Gene Fragments, and Licensing the "Useful Arts,"* 7 ALB. L.J. SCI. & TECH. 295, *297 (1997) WL 7 ALBLJST 295.

2. *Id.*

3. *Id.* at 3.

4. James Bradshaw, *Gene Patent Policy: Does Issuing Gene Patents Accord With The Purposes of the U.S. Patent System?*, 37 WILLAMETTE L. REV. 637, *638 (2001) WL 37 WMTLR 637.

5. *Id.* at *639-40.

6. *Id.* at *640.

II. OVERVIEW OF THE PATENT SYSTEM

A. Introduction and Procedure

A patent grants the owner exclusive rights over an invention for a period of twenty years.⁷ In addition, a patent precludes other people who have subsequently developed the same technology, any right to use, make or commercialize the invention.⁸ In the course of filing a patent application, the inventor must disclose the invention in exchange for a period of exclusivity over the invention.⁹

There are three kinds of patents: utility, design and plant.¹⁰ Utility patents can either be product patents, which grant rights over a particular product itself, or process patents which grant rights on the process of making a product.¹¹ Design patents are granted for aesthetic appearance, not for the functional parts of a product itself or the process by which it is made.¹² Plants may be protected under a utility application, but they are also protected under the Plant Patent Act and the Plant Variety Act.¹³ The remainder of this comment will focus on utility patents.

In order for the USPTO to grant a patent, the patent application must satisfy the statutory requirements set forth by Congress in 35 U.S.C., also known as the Patent Act.¹⁴ The congressional requirements include: patentable subject matter, novelty, utility, enablement and disclosure, and non-obviousness.¹⁵ Moral or philosophical considerations have no determinative weight in the examination of an application.¹⁶

A patent application must traverse several steps before a patent will issue. First, the applicant (or his attorney) drafts a patent application and files with the

7. See Department of Commerce and USPTO, *Manual Of Patent Examining Procedure*, §2701 (8th ed. 2001), [hereinafter MPEP]. The term of twenty years starts from the filing date of the patent application, not the issue date. *Id.*

8. David B. Resnik, *DNA Patents and Human Dignity*, 29 J.L. MED. & ETHICS 152, *153 (2001) WL 29 JLMEDETH 152.

9. See Matthew Erramouspe, *Staking Patent Claims on the Human Blueprint: Reward and Rent-dissipating Races*, 43 UCLA L. REV. 961, *973-76 (1996) WL 43 UCLALR 961.

10. See generally MPEP, *supra* note 7, at §§ 1500, 1600.

11. See generally *id.* An example of a product patent would be a patent on a particular chemical, whereas a process patent would be on the process for making a particular chemical, not on the chemical itself.

12. ROBERT P. MERGES ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 333 (2d ed. 2000).

13. *Id.* at 339. The statutory requirements for plant and design patents differ from those for utility patents. *Id.* at 339-42.

14. See generally 35 U.S.C. (2000). Title 37 of the Code of Federal Regulations also governs patents. See generally 37 C.F.R (2002).

15. 35 U.S.C. §§ 101-3, 112 (2000).

16. Resnik, *supra* note 8, at *153.

USPTO.¹⁷ A patent examiner reviews the application and sends notification as to whether the invention is patentable.¹⁸ The applicant (or his attorney) can make changes to the application in order to overcome the examiners' rejections. The applicant (or his attorney) cannot add any new material to the application while modifying it. Decisions of the examiner are reviewable and can be appealed to the Board of Patent Appeals.¹⁹ After the Board makes a final rejection of the application, the applicant can appeal to a federal district court and then to a United States Court of Appeals for the Federal Circuit. Alternatively, the applicant can proceed directly to the United States Court of Appeals for the Federal Circuit, and from there the applicant can appeal to the U.S. Supreme Court.²⁰

B. *The Policy Rationale Behind Patenting*

1. *Incentive to Invent (The Reward Theory)*

When the Constitution was drafted, the framers wanted to reward inventors for their efforts at ingenuity. Article I, § 8, cl. 8 of the Constitution states that the purpose of a patent is to promote progress in science by providing a monopoly over the invention to the inventor or patent owner.²¹ The intention is that the award of the patent would incentivize inventors to invent.²² Without incentives to promote innovation, future development would be stagnate. Unchallenged inventors could become preoccupied with reproducing designs of their counterparts instead of pushing the scientific envelope further down the road of discovery.²³ Furthermore, without a mechanism to protect an invention, capital investment in research and development is a risky proposition. The monopoly granted by a patent encourages other inventors to invent around an already patented invention.²⁴ The potential reward of a patent incentivizes people to invest in risky research that may not otherwise be attempted.²⁵ Without the commercial rewards that result in the patenting of biotechnology, the technology would not progress as rapidly as it has.

17. See generally MPEP, *supra* note 7.

18. *Id.*

19. See MPEP, *supra* note 7, at § 1201.

20. *Id.* at § 1216.

21. U.S. CONST. art. I, § 8, cl. 8 ("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.").

22. Erramouspe, *supra* note 9, at *973.

23. See *id.* (explaining central tenet of reward theory).

24. See *id.* at *976 (explaining consequences of system that only rewards first inventor).

25. Bradshaw, *supra* note 4, at *653.

2. *Incentive to Commercialize*

Congress and the Supreme Court “hope” that patents will have a positive effect on society through the introduction of new products in the market, just as the framers of the Constitution intended.²⁶ Patents encourage the commercial implementation of research, which in turn allows more products to reach the public.²⁷ The monopoly a patent grants allows inventors to commercially produce their products without having to compete, which can have both positive and negative repercussions.²⁸ On the negative side, the lack of competitors can inflate the price of a product because the inventor has sole control of the market. On the other hand, the elimination of competitors can also allow the inventor to reduce costs while producing the product.²⁹ Irrespective of the plausible repercussions, however, another competitor may emerge and create a similar or better product. Therefore the inventor is encouraged to commercialize quickly or lose his window of opportunity. Given the fact that numerous inventors are faced with this challenge of producing quickly, or face rising cost as others enter the market, a greater selection of products are produced for consumers.

3. *The Incentives to Disclose*

Although one of the cornerstone purposes of the patent system is to promote inventiveness, the system also requires the disclosure of the knowledge to the public.³⁰ This disclosure of knowledge in turn encourages other inventors to invent around patented inventions, or to make improvements on an existing invention.³¹ The disclosure of a new invention will also stop the duplicative efforts that may be in progress.

Before it was envisioned that patents would be applicable to genes or other medical research, inventors published their inventions as a means to receive personal recognition as “the first” to invent.³² Conversely, in the present patent system, although there remains the incentive to be “the first” to invent, research that is ready to be published may not be ready to be patented.³³ This motivation

26. *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980) (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974)).

27. *See id.*

28. Olsen, *supra* note 1, at *312.

29. Bradshaw, *supra* note 4, at *657.

30. *Id.* at *656.

31. *See id.*

32. *Id.*

33. *Id.*

works against the theory of public disclosure because publication may be delayed until a patent application is filed.³⁴

Prior to the amendment of 35 U.S.C §122 in 1999, an application was not published until the patent issued.³⁵ Under current rules, an application is published 18 months after filing the application with USPTO unless the applicant “foregoes” the opportunity to file in foreign countries.³⁶ The new rules encourage early disclosure of an invention, though there remain some situations in which the USPTO will not publish an application because it pertains to military intelligence or other matters of national security.³⁷

C. Statutory Requirements

1. Patentable Subject Matter

Patentable subject matter is the first of the statutory hurdles that need to be cleared. Patentable subject matter is defined in 35 U.S.C. §101 as “any new or useful process, machine, manufacture, or composition of matter, or any new useful improvement thereof.”³⁸ Materials that are naturally occurring or are result from a natural phenomena cannot be patented because they are never new or novel.³⁹ The courts have broadly interpreted the statute and have held that materials that are purified from their natural form may be patented if they also meet the remaining statutory requirements.⁴⁰ The broad interpretation of the statute allows for bacteria, which are not found in nature, to be patentable, as well as purified vitamins and genes.⁴¹ To reiterate, the morality of the invention is not assessed during the review of a patent application. Instead, an application is assessed solely on whether the invention meets the statutory requirements.⁴²

2. Novelty

In order for an invention to be afforded a patent, it must be novel. The statutory novelty requirement is set forth in 35 U.S.C. §102. The invention must not have been available to the public, or used or known to others for more than one

34. *Id.* at *657.

35. See 35 U.S.C. § 122 (b)(1) (2000); MERGES ET AL., *supra* note 12, at 321.

36. MERGES ET AL., *supra* note 12, at 321.

37. See MPEP, *supra* note 7, at § 101.

38. 35 U.S.C. § 101 (2000).

39. Erramouspe, *supra* note 9, at 968-69.

40. See, e.g., Merck & Co. v. Olin Mathieson Chemical Corp., 253 F.2d 156, 161 (1958).

41. See *id.* at 164-65; See also Diamond v. Chakrabarty, 447 U.S. 303, 309-10 (1980).

42. Resnik, *supra* note 8, at *153.

year prior to the filing of the patent application.⁴³ Nor, can the essential elements be contained in a prior invention.⁴⁴ In contrast, outside of the U.S. most countries require absolute novelty for the issuance of a patent.⁴⁵ This means that the invention must be kept a complete secret before the application is filed.⁴⁶ The United States has relaxed this rule and allows for the information to be disclosed or known within only the one year prior to the filing of an application.⁴⁷ The purpose of the novelty requirement prevents patents on everyday items or processes that are well known to the public but have never been patented. This requirement also prevents the duplicity of patents.

3. Utility

In January 2001, the new Utility Examination Guidelines (Guidelines) were issued by the USPTO.⁴⁸ The utility standard requires "specific, substantial, and credible" utility.⁴⁹ For several years prior to 2001, the court had a relaxed method of enforcing the utility requirement.⁵⁰ In response to the growing number of patent applications for genes and gene segments, the USPTO issued the new Guidelines.⁵¹ The recent change to a stricter requirement was probably made because the USPTO realized that by not enforcing the requirement, a patent could be granted on large unknown areas of scientific knowledge.⁵²

Under 35 U.S.C. §101 the invention must have some practical use or application.⁵³ Furthermore, the statute does not require that the invention be superior to an existing invention.⁵⁴ The Supreme Court has held that a suspected use is not enough to fulfill the requirement.⁵⁵ One reasoning behind the utility requirement is that if the use is unknown the patent may grant rights over a large unknown area and thereby "block" subsequent research and development.⁵⁶ This would lead to one patent controlling the rights for an entire scientific area, and

43. 35 U.S.C. § 102 (2000).

44. *Id.*

45. MERGES ET AL., *supra* note 12, at 315.

46. *Id.*

47. *Id.*

48. Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

49. *Id.* at 1093.

50. Sherizaan Minwalla, *A Modest Proposal to Amend The Patent Code 35 U.S.C. §287(C) to Allow Health Care Providers to Examine Their Patients' DNA*, 26 S. ILL. U. L.J. 471, *479-80 (2002) 26 SILULJ 471.

51. *See generally* Utility Examination Guidelines, *supra* note 48.

52. Minwalla, *supra* note 50.

53. 35 U.S.C. § 101 (2000).

54. *Id.*

55. *Brenner v. Manson*, 383 U.S. 519, 534-35 (1996); Minwalla, *supra* note 50, at *479.

56. *Brenner*, 383 U.S. at 534.

award a monopoly over an invention that the inventor never had true possession over.⁵⁷

The recent Guidelines will effect many changes, both positive and negative. The Guidelines added the "substantial" requirement to utility standards, yet fail to specify what constitutes substantial utility. There is a great likelihood that inequality may result by imposing the new, stricter requirements without specifying what substantial utility entails. However, the Guidelines will serve to combat some of the fears of both double patenting, and patenting of gene sequences that have no utility. Under the new requirements a gene sequence or fragment thereof, must have a specific, real world utility.⁵⁸ Under this heightened standard, raw DNA will not be patentable.

4. Disclosure and Enablement

A patent application must contain a written description of the invention. The written description should include a description of the manner and process of making and using the invention, in clear, concise and exact terms as to enable any person skilled in the art to make and use the invention.⁵⁹ The application must also include the best mode for carrying out the invention, however, a description of every conceivable mode is not required.⁶⁰ The written description demonstrates that inventor had actual possession of the invention.⁶¹

Of the Section 112 requirements, applications are most often rejected for failure to comply with the enablement requirement. The enablement is required to ensure that someone of ordinary skill in the art could actually make and use the invention.⁶² The description does not need to provide a step-by-step guide to make the invention but must allow someone skilled in the art to make and use the invention without undue experimentation.⁶³ It is this public disclosure of the invention, in exchange for the monopoly, that is granted when a patent issues.

57. *Id.*

58. Julie Grisham, *New Rules for Gene Patents*, 18 NATURE 921 (2000), available at http://www.nature.com/cgi-taf/DynaPage.taf?file=/nrg/journal/v18/n9/full/nbt0900_921.html (on file with Journal of Health Care Law & Policy).

59. 35 U.S.C. § 112 (2000).

60. *Id.*

61. *Fiers v. Revel*, 984 F.2d 1664, 1171 (1993).

62. 35 U.S.C. § 112 (2000).

63. See MPEP, *supra* note 7, at § 2164.

5. *Non-obviousness*

Section 103 of the Patent Act describes the parameters of the non-obviousness requirement. This section precludes the granting of a patent if the invention is obvious from an individual prior art,⁶⁴ or from a combination of prior art to someone skilled in the art.⁶⁵

In 1996, the Supreme Court in *Graham v. John Deere Co.*, articulated four factors to determine non-obviousness.⁶⁶ The four factors include: (1) the scope and content of the prior art, (2) the difference between the prior art and the claimed invention, (3) the level of ordinary skill in the art; and (4) other secondary considerations.⁶⁷ Secondary considerations may include commercial success; long felt but unsolved need; unexpected result; other's failure to solve the same problem; licensing by others; and recognition by others in the art.⁶⁸ There must be a nexus between the secondary considerations and the existing patent in order for obviousness to be found.⁶⁹ Although it was decided several years ago, the *Graham* decision remains the guideline in reviewing non-obviousness.

III. GENETICS BASICS

A. *Overview of DNA*

It is an organisms' DNA that determines its characteristics. Every chromosome is a unique individual strand of DNA. A whole copy of an organism's DNA resides in each individual cell.⁷⁰ DNA is comprised of two rungs which are connected together, like those of a ladder.⁷¹ The ladder twists around itself into a spiral, and each rung consists of a sugar, and a phosphate group which contains a nitrogenous base.⁷² There are four different nitrogenous bases that work in complimentary pairs. The nitrogenous bases of each side of the DNA are matched up with the corresponding complimentary bases on the other side of the ladder.⁷³ The arrangement of the nitrogenous bases on the DNA strands is what makes an organism's genetic code distinct.⁷⁴ Any mismatch in the

64. Prior art is an existing patent or other publication.

65. 35 U.S.C. § 103 (2000).

66. 383 U.S. 1 (1996).

67. *Id.* at 17-18.

68. *Id.*

69. *Id.*

70. Olsen, *supra* note 1, at *297.

71. Erramouspe, *supra* note 9, at *980.

72. *Id.*

73. *Id.*

74. *Id.*

nitrogenous base pairs could possibly lead to an abnormality. The different, small segments of sequences of nucleic acids make up individual genes and are the units that make up our inheritance.⁷⁵

B. Gene Expression

A gene is usually expressed in the form of proteins which control most of the activities in cells including function, structure and other activity.⁷⁶ Three nucleic acids translate into a single amino acid.⁷⁷ A sequence of amino acids codes for a particular protein, and a gene is comprised of a sequence of nucleic acids which translates into codons (the sequence of three nucleic acids), which in turn translate into amino acids which finally comprise a protein.⁷⁸

C. Gene Isolation

There are two distinct methods of gene isolation.⁷⁹ The two methods include copy DNA (cDNA) sequencing and genetic sequencing.⁸⁰ The method of cDNA starts with the premise that a person's exact genetic sequence does not directly code for a gene that later is translated into a protein.⁸¹ The DNA molecule is first translated into an RNA (ribonucleic acid) molecule which is later transcribed into a messenger RNA (mRNA) sequence.⁸² The mRNA molecule translates into the elements that build the protein, and is a copy of the DNA without the introns.⁸³ Reverse transcriptase allows for the translation of mRNA back into DNA.⁸⁴ When the DNA molecule is made it does not include the introns that have previously been spliced out.⁸⁵ Gel electrophoresis is then performed on the DNA sequence, giving the exact nucleic acid sequence.⁸⁶ The disadvantage of this method is that it does not allow for the sequencing of the introns, so the overall sequence of a

75. *Id.*; Olsen, *supra* note 1, at *301.

76. Erramouspe, *supra* note 9, at *982.

77. *Id.*

78. *Id.*

79. Olsen, *supra* note 1, at *302.

80. *Id.*

81. *Id.* at *303.

82. *Id.* at *303-04.

83. *Id.* at *303-04. An intron is a region of DNA that does not code for a protein. These regions are edited out of the DNA before the protein is made. Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing The Double Helix: A Novel And Nonobvious Reconceptualization of The Biotechnology Patent*, 55 STAN. L. REV. 303, *408 (2002) WL 55 STNLR 303 [hereinafter Demaine & Fellmeth].

84. Olsen, *supra* note 1, at *303-04.

85. *Id.*

86. *Id.*

chromosome or gene cannot be determined.⁸⁷ The exons may provide valuable information about the expression of the genes themselves.⁸⁸

Genetic sequencing is the slower, more traditional method of gene isolation. First a large genetic fragment is identified.⁸⁹ Subsequently, the fragment is cut into smaller sequences using a restriction endonuclease.⁹⁰ After the pieces of DNA have been shortened, they go through gel electrophoresis.⁹¹ The electrophoresis allows for the nucleic acid sequence to be identified.⁹² By repeating this process and comparing the results, researchers are able to determine the genomic DNA sequence.⁹³

IV. WHY ARE GENES PATENTABLE?

A. *Are the Statutory Requirements Met?*

Gene patents must satisfy all of the statutory requirements that all other patent applications must fulfill, including patentable subject matter, novelty, utility, enablement and disclosure, and non-obviousness.⁹⁴ A common assumption is that genes are not patentable because they are naturally occurring. But the Supreme Court has held that purified forms of naturally occurring substances are in fact patentable.⁹⁵ The USPTO will grant a patent for a purified and isolated gene that demonstrates new utility and was not previously known, discovered or suggested.⁹⁶ The Court has reasoned that the purified forms do not naturally exist and that human ingenuity is required to actually purify and identify the sequence.⁹⁷

B. *Evolution of the Case Law Leading to the Patenting of Genes*

At the inception of the patent system, the first court decisions regarding patents were decided by the federal district courts. Beginning in 1982, Congress created the Court of Appeals for the Federal Circuit in order to address the

87. *Id.*

88. *Id.* An exon is a region of DNA that does code for a protein. See also Demaine & Fellmeth, *supra* note 83, at *408.

89. Olsen, *supra* note 1, at *302-03.

90. *Id.* at *303.

91. *Id.*

92. *Id.*

93. *Id.*

94. 35 U.S.C. §§ 101-3, 112 (2000).

95. See generally, *Diamond*, *supra* note 41.

96. See generally, *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

97. See generally, *Fiers*, *supra* note 61.

complex subject of patenting.⁹⁸ One reason behind the creation of the Federal Circuit is to ensure consistency of the holdings in patent cases.⁹⁹ Over the years it is evident that both the Circuit decisions, as well as those from the Supreme Court, progressively opened the door to the patenting of biological material.

In 1948, the Supreme Court in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*¹⁰⁰ held that the combination of several species of existing bacteria was not patentable because all the elements of the invention were known and exist in nature.¹⁰¹ The mere fact the applicant combined products of nature does not render the combination a "patentable" invention because the individual components of the invention are naturally occurring.¹⁰² As such the Court distinguished between the discovery of a patentable sequence, and the newly discovered natural principle resulting from combining products of nature.¹⁰³

The next influential case in the area of gene patenting was decided by the Fourth Circuit in 1958. In *Merk & Co. v. Olin Mathieson Chemical Corp.*,¹⁰⁴ the court allowed for a purified vitamin to be patented.¹⁰⁵ One of the considerations that the court took into account was that the vitamin as found in nature had no utility.¹⁰⁶ The governing statute, 35 U.S.C. § 101, does not specify that a product of nature *that is transformed* to a new and useful composition cannot be patented.¹⁰⁷ Here, because an element of an invention occurs in nature, it was not interpreted to mean that the whole invention was not patentable.¹⁰⁸ There was also nothing in the prior art to suggest, or from which to anticipate, the vitamin.¹⁰⁹

The next decision from the U.S. Supreme Court regarding the patentability of genes came 22 years later in *Diamond v. Chakrabarty*.¹¹⁰ In a 5-4 decision, the Court held that living organisms can be patented.¹¹¹ The issue before the Court was whether or not a micro-bacteria that was not present in nature, was capable of being patented.¹¹² The Court determined that a patent could be granted because the organisms at issue did not naturally occur in nature, a decision that paved the way

98. 28 U.S.C. § 1295 (2000).

99. Pauline Newman, *The Federal Circuit— A Reminiscence*, 14 GEO. MASON U. L. REV. 513, *525 (1992) WL 14 GMULR 513.

100. 333 U.S. 127 (1948).

101. *Id.* at 132.

102. *Id.*

103. *Id.*

104. 253 F.2d 156 (1958).

105. *Id.* at 164.

106. *Id.*

107. *Id.*

108. *Id.* at 162.

109. *Id.* at 164.

110. 447 U.S. 303 (1980).

111. *Id.* at 318.

112. *Id.* at 305.

for gene patents. The Court determined that 35 U.S.C. § 101 has traditionally be interpreted very broadly, and thus the Court should continue to do so.¹¹³ It is the broad interpretation that allowed for the patent to issue.¹¹⁴ The Court struggled with whether bacteria should fall within § 101, yet referenced congressional reports which indicated that it fit within the statutory definition in § 101, given that the bacteria could not be reproduced in nature.¹¹⁵

Several years later, in 1991, there was another evolution in the patenting of genes—this time at the United States Court of Appeals for the Federal Circuit. In *Amgen, Inc. v. Chugai Pharmaceutical*,¹¹⁶ the court allowed a patent to issue for the genetic sequence of a blood protein.¹¹⁷ The application was found to be enabling by the disclosure of the full DNA sequence of the blood protein.¹¹⁸ But the court failed to consider the obviousness of the protein itself.¹¹⁹ This same court, in 1993, took a different approach in *In re Bell*.¹²⁰ There, the court considered whether a prior art that disclosed an amino acid sequence of a protein would make the DNA sequence of that protein obvious.¹²¹ Although a protein sequence makes the process for finding a corresponding gene easier by allowing the researcher to hypothesize possible sequences, in this case it produced 1,036 different nucleotide sequences.¹²² Bell did not claim all of these possibilities, which may have been found to be obvious, but instead claimed only one sequence which coded for a particular gene.¹²³ The court found that when the protein sequence is known, the DNA sequence may be found to be obvious depending on whether the amino acids are specified by unique codons.¹²⁴

More recently, the Federal Circuit in its 1993 decision in *Fiers v. Revel*¹²⁵ stressed the importance of disclosure of the gene sequence on a patent application. This case was an interference proceeding, in which the court specified the priority date of the Fiers application and then looked at a foreign filed application to determine if it met the statutory requirements.¹²⁶ The court determined that it did not meet the statutory requirement because the application was not enabling.¹²⁷

113. *Id.* at 316-17.

114. *Id.*

115. *Id.* at 313 (citing to H.R. 1129, and S.Res. 315).

116. 927 F.2d 1200 (1991).

117. *See generally id.*

118. *Id.*

119. *Id.*

120. 991 F.2d 781 (1993).

121. *Id.* at 783.

122. *Id.* at 784.

123. *Id.*

124. *Id.*

125. 984 F.2d 1164 (1993).

126. *Id.*

127. *Id.* at 1170-71.

Although the application was for a gene patent, it did not specify the gene sequence itself.¹²⁸ The court determined that an application must specify more than just the functional utility of the gene to be patentable.¹²⁹ In short, the DNA sequence itself must be disclosed.

C. Consideration for the Patenting of Genes

With the feasibility of gene patenting recognized by both the Supreme Court, and at the circuit level as discussed above, we turn from a discussion of the legal possibility of gene patenting, to a consideration of the practical implications of granting patents in this area.

1. Arguments for the Patenting of Genes

a. The Medical Infringement Exception

One of the overarching goals of the patent system is to drive discovery.¹³⁰ The reward theory incentivizes researchers to determine the sequences for genes in order to secure a patent, disclosure of which may lead to the development of new medical treatments. The combination of the incentive to invent and the sharing of information promotes necessary medical progress.¹³¹ In 1996, Congress adapted the Patent Act to allow for the infringement of medical process patents.¹³² This adaptation fosters medical treatments despite infringement, and continues to encourage innovation. This medical treatment infringement exception is a one-of-a-kind and the patented process cannot be used in any other manner. The policy behind this 1996 congressional adaptation is to continue the encouragement of invention, but at the same time it ensures that the public is not deprived of the newest medical treatments, and achieves the necessary balance between protecting both public and private interests.¹³³

b. Commercialization: A Necessary Evil

Many of the companies searching for gene sequences depend on the commercialization of the patent in order to survive financially.¹³⁴ There is no race to improve a gene patent because the gene is already fully purified and disclosed.

128. *Id.* at 1171.

129. *Id.* at 1169.

130. Bradshaw, *supra* note 4, at *645.

131. Robin E. Margolis, *Patenting Human Genes: Sheer Lunacy or Sound Legal Protection?*, 9 NO. 10 HEALTHSPAN 14, *15 (1992) WL 9 No. 10 HTHSP 14.

132. Minwalla, *supra* note 50, at *488.

133. *Id.* at *487.

134. Olsen, *supra* note 1, at *309.

Many companies would not be able to research and develop new technology without the profits that they receive from licensing their patents; in that sense unfair advantages or excessive profits are the price of continued progress.¹³⁵ Genetic research is inherently expensive, and without the possible reward of the limited monopoly, it would be close to impossible to solicit funding. Many of the companies may borrow money in order to carry out the research and cannot survive without the revenue generated from licensing their patent. It is also unlikely that there would be such a rush to find the possible cures to genetically created health problems without the reward received.

2. Considerations Against Patenting Genes

a. Double Patenting

One of the greatest fears weighing against the patenting of genes is that double patenting of gene sequences will occur, especially given the patenting of gene segments.¹³⁶ Thousands of applications for genes and gene fragments applications have been filed, and the USPTO has found itself overwhelmed by these applications and mounting demand.¹³⁷ This, in turn, may lead to an increase in the likelihood of double patenting because of the rush to process these applications quickly.¹³⁸ Due to conflicting rights granted by overlapping patents, the costs of obtaining a license to use the patented sequence could be driven up by having to acquire multiple licenses.¹³⁹ This could lead to the curtailing of research and possible medical treatments.¹⁴⁰

Another argument against the patenting of genes is that it encourages duplicative efforts.¹⁴¹ Due to the desire of different companies and the government to obtain gene patents, many companies are trying to discover the same gene sequences.¹⁴² But some companies that cannot afford the effort will not be able to

135. *Id.* at *322.

136. *Id.* at *322-23. The fear with patenting gene sequences is that when a later applicant wants to patent the entire gene they will not be able to, or in the alternative, several people will have a patent for the same sequence which is clearly against the novelty requirement of 35 U.S.C. (2000). *Id.* Yet another option is that they will have to receive a license from the prior patent holder to use their own patent. *Id.* Although the original purpose of the Human Genome Project was for a collaborative effort to be undertaken, the desire of individual companies to acquire as many patents as possible may stop the collaboration in its tracks. *Id.* The free flow of information will also be jeopardized, thereby hindering the quick advancement of technology. The duplicative efforts of researchers also may increase. *Id.*

137. John Murray, *Owning Genes: Disputes Involving DNA Sequence Patents*, 75 CHI.-KENT L. REV. 231, *231 (1999) WL 75 CHIKLR 231; see also Olsen, *supra* note 1, at *326.

138. Olsen, *supra* note 1, at *326.

139. *Id.* at *323.

140. *Id.*

141. Erramouspe, *supra* note 9, at *964-65.

142. Murray, *supra* note 137, at *254.

compete due to the costs of the research that is driven up through the “race” to patent the human genome.¹⁴³ This will ultimately lead to only a few companies having all the gene patents and this will lead to the exploitation of gene sequences.

b. Health Concerns

Additionally, health related concerns weigh against gene patenting. It has been shown that many laboratories may test for a particular gene abnormality while the patent is pending or not yet patented.¹⁴⁴ Once the patent issues, the labs that once conducted the tests for reasonable prices will find themselves embroiled in licensing fees, which they will either be unwilling to pay, or will pay despite exorbitant costs that will have to be absorbed elsewhere. Many patients, therefore, may be forced to pay the costs passed onto them, or seek less effective, less reliable, or perhaps unconventional methods of treatment. The exclusive right granted by the monopoly can also “impede” research because it makes it difficult for other companies/institutions who want to find a new treatment to use the patented gene in research. This limits research on patented genes to only those companies that have licensed the patent from the inventor, his assignee, or to the inventor himself.¹⁴⁵

c. Statutory Concerns

One of the strongest arguments against the patenting of genes is that it violates the statutory requirements set forth in the Patent Act. Some have asserted that even though gene patents are issued on a purified gene, the gene is the same as the naturally occurring sequence.¹⁴⁶ Some bolster this argument by suggesting that gene patents should be statutorily barred due to the fact that they occur in nature, and that natural form is prior art.¹⁴⁷ Another such argument is that genes contain information, and as such the patenting of useful information is a departure from the patent rules.¹⁴⁸ Under these arguments the patenting of genes would be impermissible.

143. Erramouspe, *supra* note 9, at *964.

144. Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL’Y 65 (2002).

145. See Lori B. Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 NATURE REV. GENETICS 803 (2002), available at <http://www.nature.com/cgi-taf/DynaPage.taf?file=/nrg/journal/v3/n10/index.html> (presenting an overview and critique of the public health and research concerns involved in human gene patents) (on file with Journal of Health Care Law & Policy).

146. Resnik, *supra* note 8, at *154.

147. *Id.*

148. Rebecca S. Eisenberg, *Re-examining the Role in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783, *794 (2000) WL 49 EMORYLJ 783.

d. Moral Standards

Finally, there are weighty moral arguments against gene patenting.¹⁴⁹ Each person has his or her own property rights to his or her genes; but a gene patent is essentially patenting the chromosomes of an individual's cells.¹⁵⁰ A person may violate a patent when he/she donates their DNA, and yet research is reliant on individuals' willingness to donate.¹⁵¹ Individuals who donate their DNA as samples do not receive any direct benefit from doing so.¹⁵² Some argue that the patenting of DNA is commoditization of human beings and therefore violates fundamental morality because "human beings should not be used simply as a means to one's own ends."¹⁵³ There are also arguments that the genome shapes the person and thus the patenting of DNA violates a person's dignity.¹⁵⁴ In *Moore v. Regents of the University of California*,¹⁵⁵ a university developed a cell line from the patient's cancer cells which was very profitable.¹⁵⁶ This type of exploitation is precisely the type that opponents to DNA patenting are worried about. Erosion of respect for human life and the exploitation of human beings are major moral concerns.¹⁵⁷

V. ANALYSIS

At first blush, the benefits of gene patenting—such as the necessary funding gained from commercialization that provides funding for ongoing developments, and the infringement exception for medical treatments—appear outweighed by possible negative impacts ranging from health and moral concerns to duplicative efforts. Yet of all considerations, the central question must be whether an appropriate balance is struck between public and private interest in the current patent system, specifically as it applies to genomic material.

149. Murray, *supra* note 137, at *232.

150. *Id.*

151. *Id.*

152. *Id.* at *254-55.

153. Demaine & Fellmeth, *supra* note 83, at *413 (discussing the Kantian view that it is a fundamental principle of morality that human beings not be used "simply as a means to one's own end."); See also Resnik, *supra* note 8, at *157. The author suggests that human dignity is violated when people are treated only for market value and that most violations of human dignity are immoral. If the only value of an invention is its commercial use, then human beings are rendered a complete commodity. Patenting DNA has been analogized to slavery because both treat people as complete commodities. *Id.*

154. Resnik, *supra* note 8, at *159.

155. 793 P.2d 479 (Cal. 1990).

156. See generally *id.*

157. Resnik, *supra* note 8, at *162.

An important consideration is whether the appropriate balance between the public's interest and private patent holder's interest is supported by the current patent system regarding the patenting of genomic material. The public's interest is in securing new medicines and treatments.¹⁵⁸ It is important to remember that the patent system was initially designed to promote inventions not investments.¹⁵⁹ There are many different considerations that must be weighed by the legislature in order to make sure that the health and safety of the country does not suffer due to the restrictions that are caused by the granting of patents on DNA or uses for it.

The legislatures should consider compulsory licensing, which would require patent owners to license their patents to everyone. The government could regulate the process so that a "reasonable" licensing fee is paid by the licensee.¹⁶⁰ Although compulsory licensing will not overcome all of the opposition to genomic patents, it could help address many of the problems that are keeping useful medical treatment away from the public, while continuing to promote more research and development.

First, the fear of double patenting and the ensuing problems can be overcome by compulsory licensing. The nature of compulsory licensing enables anyone to receive a license on a patent and thereby use an invention. Because reasonable royalties can be set by the government, even if a company must obtain multiple licenses to guard against double patenting, they will not be forced to pay exorbitant royalty rates which may lead them to abandon using the technology. Although this is perhaps not the ideal way to overcome the USPTO's failure to ensure that an invention is not patented twice, it would alleviate many of the economic hardships associated with double patenting.

Secondly, the cost of regulation and the increased availability of desired technology if compulsory licensing is implemented, will likely mute many health concerns. Compulsory licensing would allow for companies to do research and development on technology to which they may otherwise not have access due to either the cost of obtaining a license or the patent owner's unwillingness to license. Many newly developed treatments also would be made available to patients more quickly and at a much lower cost. It is these treatments that otherwise might be abandoned, for less reliable, less efficient or more unconventional treatments. It is evident that compulsory licensing would possibly lead to more treatments in the future and increase the availability of better treatments to the public.

158. Sandy M. Thomas et al., *Shares in The Human Genome—The Future of Patenting DNA*, 20 NATURE BIOTECHNOLOGY 1185 (2002) available at <http://www.nature.com/cgi-taf/dynapage.taf?file=/nbt/journal/v20/n12/index.html> (on file with the Journal of Health Care Law & Policy).

159. *Id.*

160. Andrews, *supra* note 144, at 103.

The statutory concerns discussed above are outweighed by the fact that the incentive to invent is necessary to promote science. As previously mentioned, without the incentive to invent, U.S. innovation would not prove as fruitful and it would not come as quickly. Thus, vital public access to medical treatments would likely be delayed by several years. Compulsory licensing is an avenue that may help alleviate delays, and yet will not circumvent the requisite statutory hurdles to gene patenting.

In order for a patent to issue, all of the statutory requirements *must* have been met. The USPTO has not relaxed any of its standards for genomic patents. The real hurdle against gene patenting, when considering the statutory requirements, is qualifying as patentable subject matter because naturally occurring items are not patentable. The courts and the USPTO have held that genes and other biological material as found in nature are *not* in fact patentable. Conversely a purified form, which does not exist in nature, is patentable. The novelty, utility, disclosure and enablement requirements work the same for any invention—be it a gene or otherwise—and genes can just as easily be expected to meet these requirements as any other invention. Furthermore, purified genes are obvious and thus distinguishable from genes as they occur in nature.

Therefore, if one considers the requirements for non-obviousness set forth by the Court in *Graham*, it is clear that all of the factors are fulfilled by gene patents. The first two factors to consider are the scope and content of the prior art and the difference between the prior art and the claimed invention.¹⁶¹ Genes as they occur in nature are within the body and their sequence is unknown. In contrast, sequences to be patented have been extracted, purified and have undergone sequencing. The sequence sought to be patented is not naturally occurring.

The third consideration is the level of ordinary skill in the art.¹⁶² The great race to be the first to purify a gene sequence has filled the vacuum of the race to discover the entire genomic sequence. It is evident that although some of the processes to discover and sequence genes may have become routine, new processes are being developed during the race to sequence. The race to sequence is evidence that this information is still unknown and is *not* obvious in light of any prior art.

Secondary considerations include: commercial success, long felt but unresolved need, unexpected results, others' failure to solve the same problem, licensing by others, and recognition by others in the art. These must be considered on a case-by-case basis, but many will be fulfilled by the uses that purified gene sequences provide and the need for the development of new medical treatments. The USPTO's insistence that the same statutory requirements that must be met for

161. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

162. *Id.*

a patent to issue for *any* other invention, must be met for a patent to issue on a gene sequence, should therefore quell objections regarding the statutory requirements.

Finally, compulsory licensing is unlikely to satisfy the breadth of moral concerns and will only partially alleviate some of the particular moral concerns surrounding gene patenting. However, this forced licensing will ensure that exploitive commodization of DNA and gene sequences does not occur because access will be available to the general public.

Although pronounced moral concerns no doubt stem from sincere convictions, arguments concerning the potential “harm” resulting from the patenting of genes may be made on a faulty foundation.¹⁶³ Moreover, for many years the U.S. has permitted the patenting of the different molecules that occur in the human body; there have been few moral objections to these patents and publicized fears of abuse have not come to pass.¹⁶⁴ In other words, just as we allow marketing of other properties of the human body, genes and gene sequences may be treated as complete commodities without treating the whole human body as such.

Furthermore, although it may be of little comfort to those whose moral objections to gene patenting are rooted in religious or deeply philosophical beliefs, it is important to note that the USPTO’s treatment of DNA as a chemical compound, is similar to its treatment of any other chemical invention, and is not a marked departure from previous patent practices, nor was it entirely unpredictable.¹⁶⁵ One could argue that DNA patents are akin to property rights in other markets,¹⁶⁶ and yet their commodization is vastly more important precisely because of the moral implications of *restricting* access to gene patents. One of the biggest benefits received from donating one’s DNA to research is the possible medical advances that may be developed as a result of the donation. Because compulsory licensing can guard against future abuses, carefully limiting access to gene sequences is arguably less morally objectionable than preventing the patenting of genes altogether.

163. See Demaine & Fellmeth, *supra* note 83, at *455. The authors identify a conceptual problem with the idea that the patent system is designed to redress “harm,” what they characterize as an equitable concept. *Id.* They note that key prohibitions in the patent act are legal requirements, and “do not stem from a concern for fairness to Mother Nature,” but instead are intended to “prevent applicants from taking something out of the public sphere that the applicants did not themselves create in any meaningful sense.” *Id.*

164. Resnik, *supra* note 8, at *158 (pointing out that in the United States, a person’s body, voice, face, or figure are all commonly marketed body properties).

165. Resnik, *supra* note 8, at *152.

166. Resnik, *supra* note 8, at *159.

VI. CONCLUSION

As demonstrated above, compulsory licensing will help overcome many of the objections against the patenting of genes including those of double patenting, health concerns and even to a more limited degree, some of the moral objections. The USPTO and the courts have repeatedly held that genes are patentable provided that the necessary statutory requirements are met. The benefits received from gene patenting, including the incentive to invent and the disclosure of new sequences, outweigh the considerations against gene patenting. Compulsory licensing could prove to be a valuable tool in the federal legislature's arsenal as it strives to strike a balance between public and private interests, and to reinforce a patent system that is now called upon to protect both innovation and investments.