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COMMENT

PATENTING THE FINGERPRINT OF GOD: HOW GENE PATENTS VIOLATE THE PRODUCTS OF NATURE DOCTRINE

Timothy M. Todd[†]

I. INTRODUCTION

Lisbeth Ceriani is a single mother with an eight-year-old daughter.¹ In May 2008, Lisbeth was diagnosed with stage IIA breast cancer.² Due to multiple tumors, she had a double mastectomy, along with chemotherapy and radiation therapy.³ Lisbeth's oncologists along with several genetic counselors unanimously agree that she needs genetic testing. This genetic test will determine whether she has genetic mutations in certain genes (the BRCA genes) to help assess the risks for a potential surgery.⁴ Myriad Genetics has such a genetic test.

[†] Managing Editor of Publication, LIBERTY UNIVERSITY LAW REVIEW, Volume 5. J.D. Candidate (2011); Liberty University School of Law; M.S., B.S., Liberty University. I would like to give all glory and honor to Jesus Christ my Lord and Savior. I would also like to thank my beautiful wife, Regan, whose patience, love, and sacrifice has made this Comment and my law school career possible—she is the epitome of *Proverbs* 31:10-31. Finally, thanks to all those dedicated students on the Liberty University Law Review for their time and effort, especially Mr. Andrew Connors, whose direction and insight were invaluable.

1. Brendan L. Smith, *Wrangling Genes: As the Law Changes and New Medical Frontiers Open, the Dispute Over Genetic Patents Intensifies*, A.B.A. J., Jul. 2009, at 56, 57, 59.

2. *BRCA-Plaintiff Statements*, ACLU (May 12, 2009), http://www.aclu.org/free-speech_womens-rights/brca-plaintiff-statements#ceriani. Stage IIA breast cancer is when: [N]o tumor is found in the breast, but cancer is found in the axillary lymph nodes (lymph nodes under the arm); or the tumor is 2 centimeters or smaller and has spread to the axillary lymph nodes; or the tumor is larger than 2 centimeters but not larger than 5 centimeters and has not spread to the axillary lymph nodes.

Stages of Breast Cancer, NATIONAL CANCER INSTITUTE, (Sept. 09, 2010), <http://www.cancer.gov/cancertopics/pdq/treatment/breast/Patient/page2#Keypoint11>.

3. ACLU, *supra* note 2.

4. *Id.* A mutation in the BRCA1 gene indicates an increased risk for breast and ovarian cancer. See *Low-Penetrance Predisposition to Breast and Ovarian Cancer*, NATIONAL CANCER INSTITUTE (Oct. 08, 2010), <http://www.cancer.gov/cancertopics/pdq/genetics/breast-and-ovarian/HealthProfessional/page3>.

Lisbeth's insurance company fully covers Myriad Genetics's BRCA genetic testing but only if performed by a contracted provider.⁵ The problem, however, is that there is only one lab in the country that performs this particular genetic test—Myriad's own lab in Utah.⁶ Myriad has refused to contract with Lisbeth's insurance for the genetic testing.⁷ There are no other alternatives for Lisbeth, or similarly situated patients, because Myriad holds patents on the underlying human BRCA genes.⁸ Therefore, no other laboratory, company, university, or even non-profit entity can use the genes to develop alternative and better tests, or to create cures that use these genes.

Thousands of human genes have been patented.⁹ Patented genes range from those with little utility to those that have vital utility—for instance, the ability to detect a predisposition toward breast cancer.¹⁰ Since patent holders have the right to preclude others from using their “inventions,” the patenting of genes has stymied research, restricted access to medical tests, and granted monopolies to the building blocks of life.¹¹ This Comment addresses the patenting of human genes and focuses on the BRCA1 and BRCA2 genes, which are invaluable in breast cancer research and detection.¹² The BRCA1 and BRCA2 genes are patented by Myriad Genetics.¹³ Thus, Myriad may prevent others from using the genes in a manner covered by the claims of the patent.¹⁴ This preventative ability means that Myriad, or its lucky licensees, are the only individuals who can use these genes in developing medical tests to detect breast cancer and to research a potential cure. This problem, however, is not limited to Myriad and breast cancer. There are gene patents that cover a multitude of

5. ACLU, *supra* note 2.

6. *Id.*

7. *Id.*

8. Myriad holds patents on the “purified and isolated forms” of the BRCA1 and BRCA2 genes. U.S. Patent No. 5,837,492 (filed Apr. 29, 1996) (patent on isolated BRCA2 DNA); U.S. Patent No. 5,747,282 (filed June 7, 1995) (patent on isolated BRCA1 DNA).

9. John F. Merz & Mildred K. Cho, *What Are Gene Patents and Why Are People Worried About Them?*, 8 COMMUNITY GENETICS 203 (2005).

10. *E.g.*, U.S. Patent No. 5,837,492 (filed Apr. 29, 1996) (patent on isolated BRCA2 DNA); U.S. Patent No. 5,747,282 (filed June 7, 1995) (patent on isolated BRCA1 DNA).

11. *See infra* Part III.D (discussing how patents on human genes stymie research).

12. *See supra* note 10.

13. *Id.*

14. 35 U.S.C. § 271 (2010); *see* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1021 (1989).

diseases.¹⁵ Thus, scientists, researchers, and medical professionals are limited in their research and treatment of these diseases because of patented human genes.¹⁶

The Founders gave the federal government the power to grant patents because they recognized that the public could ultimately benefit from limited monopolies.¹⁷ They realized that without patent protection, an inventor might not reveal his discovery to the public, but with the promise of a time-constrained monopoly, that calculus changes.¹⁸ Instead, the inventor will unleash his or her genius to the public, and then the public will have use of the invention after the patent expires.¹⁹ Hence, the United States Supreme Court has explained that to receive a patent an invention must be “a product of human ingenuity,” thus excluding anything that occurs naturally from patent eligibility.²⁰ This is known as the “products of nature” doctrine.

In its current form, the patenting of human genes tramples on the venerable “products of nature” doctrine. Because of the United States Patent and Trademark Office’s (PTO) misapplication of the products of nature doctrine, research has slowed and human life devalued,²¹ among other consequences.²² The current gene patent framework posits that human genes²³ are patentable so long as the gene is “purified and isolated” and the

15. These patents cover genes associated with other diseases such as Alzheimer's disease, asthma, hemochromatosis, forms of colon cancer, and Canavan disease, *BRCA: Genes and Patents*, ACLU (May 27, 2009), <http://www.aclu.org/freespeech/gen/39556res20090512.html#04>.

16. *See infra* Part III.D.

17. *See* U.S. CONST. art. I, § 8, cl. 8.

18. Beth E. Arnold & Eva Ogielska-Zei, *Patenting Genes and Genetic Research Tools: Good or Bad for Innovation?*, 3 ANN. REV. GENOMICS & HUM. GENETICS 415, 416 (2002).

19. *Id.*

20. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

21. Ownership of human genes infringes upon human dignity because it commercializes body parts. It is equivalent to human ownership, and it cheapens that which defines “human identity.” Mark J. Hanson, *Religious Voices in Biotechnology: The Case of Gene Patenting*, in CLAIMING POWER OVER LIFE 94 (Mark J. Hanson ed., 2001) (citing Baruch A. Brody, *Protecting Human Dignity and the Patenting of Human Genes*, in PERSPECTIVES ON GENETIC PATENTING: RELIGION, SCIENCE, AND INDUSTRY IN DIALOGUE 111-26 (Audrey R. Chapman ed., 1999)).

22. *See infra* Part III.

23. The PTO applies this standard to all genes. *See infra* Part III.C.

utility of the gene is known.²⁴ This framework wildly misconstrues and implicitly rejects the products of nature doctrine.

Therefore, there needs to be a new framework dealing mostly with utility to restore the products of nature doctrine, to treat life with the sanctity it deserves, and to minimize the harsh effects that human gene patents have had on medical research and treatment. This Comment proposes a two-pronged approach to revising the gene patent utility standards: (1) the claimed utility cannot be substantially similar to the utility found in the naturally occurring gene, and (2) that the inventor needs actually to imbue the utility in the gene (i.e., the utility is not due to a natural mutation, or other natural trait, but rather the genius of the inventor). Although this framework is proposed for gene patents, it should also be applied to the gamut of chemical and biological patents to harmonize our current scheme of patent law with its overall purpose of encouraging innovation, while keeping naturally occurring phenomenon in the storehouse of all men.²⁵ This Comment's two-pronged test is needed to: (1) restore the products of nature doctrine; (2) keep important biological information in the storehouse of all men; and (3) respect the sanctity of human life.

This Comment starts with a patent primer, including the constitutional and statutory framework. Next, the Comment introduces the products of nature doctrine and its foundation in American jurisprudence. The Comment then discusses the biological foundation needed to scrutinize gene patents. The Comment addresses the problem presented by the patenting of naturally occurring human genes in a "purified and isolated" form, in particular the BRCA1 and BRCA2 genes. Finally, this Comment proposes that (1) the Patent and Trademark Office should change its utility guidelines, (2) Congress should pass ethics regulations precluding human gene patents, and (3) courts confronted with the validity of human gene patents should apply the proffered rule, likely striking down most gene patents covering purified and isolated forms of naturally occurring human genes.²⁶

24. See *infra* Part III.C (discussing the current utility standard).

25. Thomas Jefferson was a staunch proponent of sharing knowledge. He thought it was a "sure foundation . . . for the preservation of freedom and happiness." Thus, those things of nature, which are the foundation of all other discoveries, Jefferson considered public property. See JEFFREY H. MATSUURA, *JEFFERSON VS. THE PATENT TROLLS* 37-38, 41 (2008).

26. This Comment also asserts that the "march in" rights of the Bayh-Dole Act are inadequate as a solution for publicly funded gene patent research. See *infra* Part IV.E.

II. BACKGROUND

A. *The Constitutional & Historical Background of Patent Protection*

The Constitution grants Congress 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.”²⁷ Under this authority, Congress passed the first patent Act in 1790.²⁸ The Act created a three-member board of commissioners comprised of the Secretary of State, Secretary of War, and the Attorney General.²⁹ The board had the sole discretion to grant a patent.³⁰ Under the Act, the board issued a patent if the invention was “sufficiently useful and important.”³¹ This statutory scheme proved to be too cumbersome,³² thus, Congress enacted the Patent Act of 1793.³³ This Act created the registration system,³⁴ which is still essentially in use today. Under the Act, only the Secretary of State had the authority to grant patents.³⁵ In addition, the Act required the State Department to maintain a registry of patents.³⁶ The registration system, however, did not establish patent validity; that question was left to the courts.³⁷ Congress went through two more iterations of patent statutes³⁸ before arriving at the current 1952 Act.³⁹

27. U.S. CONST. art. 1, § 8, cl. 8.

28. ROGER SCHECHTER & JOHN THOMAS, *PRINCIPLES OF PATENT LAW* 16 (2d ed. 2004); *see* Act of Apr. 10, 1790, ch. 7, 1 Stat. 109 (1790) (repealed 1793).

29. SCHECHTER & THOMAS, *supra* note 28.

30. Act of Apr. 10, 1790, ch. 7, 1 Stat. at 109-10.

31. *Id.* at 110.

32. The examination process, coupled with their other government duties, proved to be too onerous for the three-member board. *See* SCHECHTER & THOMAS, *supra* note 28.

33. Act of Feb. 21, 1793, ch. 11, 1 Stat. 318 (1793) (repealed 1836).

34. The registration system refers to the process of applying for and registering a patent with the U.S. Patent and Trademark Office. It is only through this *registration* process that patent protection is recognized.

35. Act of Feb. 21, 1793, ch.11, 1 Stat. at 320 (1793).

36. *Id.* at 321.

37. SCHECHTER & THOMAS, *supra* note 28.

38. *See* Act of July 4, 1836, ch. 357, 5 Stat. 117 (1836) (amended 1879) (repealed 1952).

39. Act of July 19, 1952, ch. 950, 66 Stat. 792 (1952) (codified as amended in 35 U.S.C. § 1).

Patent protection is not an American creation; rather, intellectual property protection traces back to Roman law.⁴⁰ Moreover, in England, the Crown granted a “royal patent of privilege” for fourteen years to the inventor of a new manufacture or product.⁴¹ Not all of the Founders, however, were enthusiastic about the national government affording intellectual property protection. Thomas Jefferson, a member of the patent board for several years, disfavored granting patent protection.⁴² Jefferson’s view on patent protection is important to understand because it underlines the impetus behind the products of nature doctrine. Jefferson believed that “ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man, and improvement of his condition.”⁴³ Jefferson was averse to monopolies.⁴⁴ Thus, Jefferson advocated a high standard of patentability.⁴⁵ Jefferson also realized the difference between basic and applied science.⁴⁶ The elements of “basic” science, or the structure and operation of natural forces, are to be protected from patentability because of what is now called the products of nature doctrine. In contrast, applied science, which is the useful application of basic science, is to be the proper subject matter of patents.⁴⁷ Jefferson’s view is crucial to remember because, as he suggested, overly broad patent protection could stymie development.⁴⁸

B. The Statutory Requirements to Receive a Patent

Patents come into existence only via a grant from the government.⁴⁹ The United States Patent and Trademark Office, an agency within the U.S. Department of Commerce, is charged with evaluating patent applications.⁵⁰

40. See 2 WILLIAM BLACKSTONE, COMMENTARIES *406 (alluding to a form of copyright protection in ancient Rome).

41. *Id.* at 408.

42. Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), *reprinted in* 3 THE FOUNDERS’ CONSTITUTION 42, 42-43 (Philip B. Kurland & Ralph Lerner eds., 1987).

43. *Id.* at 42.

44. *Graham v. John Deere Co.*, 383 U.S. 1, 7 (1966).

45. *Id.* at 9.

46. See MATSUURA, *supra* note 25, at 81.

47. *Id.* at 81-82.

48. See *id.*

49. SCHECHTER & THOMAS, *supra* note 28, at 221.

50. *Id.*

Thus, the PTO first examines whether a patent application meets the statutory requirements.

Under the current statutory framework, there are five requirements for patentability: proper subject matter,⁵¹ utility,⁵² novelty,⁵³ non-obviousness,⁵⁴ and sufficient definition.⁵⁵

1. Proper Subject Matter

An inventor can obtain a patent only if his invention fits within a statutorily approved category, as set forth in 35 U.S.C. § 101.⁵⁶ Generally, patentable subject matter can be described as either a product or a process.⁵⁷ Product claims cover tangible things.⁵⁸ Thus, product inventions can be machines, manufactures, or compositions of matter.⁵⁹ Compositions of matter include chemical compounds, mixtures, and alloys.⁶⁰ Therefore, gene patents are product patents. Product patents are described in terms of their structural elements.⁶¹ Process patents, on the other hand, “involve a series of acts performed in order to produce a given result.”⁶² Process patents are described by a list of steps.⁶³ While gene patents are normally product patents, there are gene-based process patents that cover the process to reproduce the gene, and earlier gene patents may cover the actual process used to discover the gene.⁶⁴ The United States Supreme Court has held that patentable subject includes “anything under the sun that is made by man.”⁶⁵

51. See 35 U.S.C. § 101 (2006).

52. See *id.*; *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966); DONALD S. CHISUM, CHISUM ON PATENTS § 4.01 (1997); 69 C.J.S. *Patents* § 59.

53. See 35 U.S.C. § 102(a)-(b) (2006); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 149-50 (1989).

54. See 35 U.S.C. § 103(a) (2006); *Graham v. John Deere Co.*, 383 U.S. 1, 11 (1966).

55. 35 U.S.C. § 112 (2006).

56. 35 U.S.C. § 101 (2006).

57. JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 30 (2005).

58. *Id.*

59. See 35 U.S.C. § 101.

60. THOMAS, *supra* note 57.

61. *Id.* at 31.

62. *Id.*

63. *Id.*

64. See, e.g., U.S. Patent No. 5,837,492 (filed Apr. 29, 1996) (patent on isolated BRCA2 DNA); U.S. Patent No. 5,747,282 (filed June 7, 1995) (patent on isolated BRCA1 DNA).

65. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

But historically, proper subject matter did not include anything made by man that also existed in nature.⁶⁶

2. Utility

The concept of utility, or usefulness, is inherent in the concept of promoting the “Progress of . . . Useful Arts.”⁶⁷ Furthermore, utility is required by statute.⁶⁸ An invention is useful if it provides some identifiable benefit.⁶⁹ To be useful, an invention must also be operable; meaning it must be “capable of being used to effect the object proposed.”⁷⁰ Utility is a relatively low threshold; a patent will be invalid for lack of utility only when it is “totally incapable of achieving a useful result.”⁷¹ Another facet of utility is “practical utility.” Practical utility requires that the invention provide some benefit to the public.⁷² The utility requirement is paramount in biotechnology patents. As the United States Supreme Court has explained, the inventor must know the *specific* utility of a chemical compound (i.e., what the compound actually does) to patent it.⁷³

3. Novelty

To be patentable, the invention must be novel; meaning it must be new.⁷⁴ Accordingly, the invention “must not have been previously known.”⁷⁵ This requires that the invention’s essence has not been disclosed in prior art.⁷⁶ A corollary of the novelty principle is “anticipation.”⁷⁷ Anticipation mitigates novelty when the prior art discloses all the elements of the patent, or their functional equivalents.⁷⁸

66. *See infra* Part II.D.

67. *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966).

68. *See* 35 U.S.C. § 101 (2006) (granting a patent only to an inventor that “invents or discovers any . . . useful process”).

69. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1365 (Fed. Cir. 1999).

70. *Mitchell v. Tilghman*, 86 U.S. (19 Wall.) 287, 396 (1873).

71. *See Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992).

72. *Nelson v. Bowler*, 626 F.2d 853, 856 (C.C.P.A. 1980).

73. *Brenner v. Manson*, 383 U.S. 519, 534-35 (1966).

74. *See* 35 U.S.C. § 102(a) (2006); *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1349 (Fed. Cir. 1998).

75. *C.R. Bard, Inc.*, 157 F.3d at 1349.

76. *Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324, 1332 (7th Cir. 1983).

77. *See* 69 C.J.S. *Patents* § 30 (2010).

78. *Armco, Inc. v. Republic Steel Co.*, 707 F.2d 886, 889 (6th Cir. 1983).

4. Nonobviousness

A patent cannot be issued if the invention was obvious.⁷⁹ Thus, an invention is unpatentable if at the time the invention was made, it would have been “obvious” to a person having ordinary skill in the art or technical field;⁸⁰ this is judged in light of the prior art. The invention must be considered as a whole and the claims in their entirety.⁸¹ Obviousness cannot be based upon hindsight.⁸²

In *Graham v. John Deere Co.*, the United States Supreme Court solidified its position that the patented claims must be the work of an *inventor*, not a *skillful mechanic*.⁸³ Thus, although something may be a *new* invention in the sense it has not been created before, it may nevertheless be unpatentable because the difference between the prior art and the new thing is not sufficient to warrant patent protection.⁸⁴ The *Graham* Court laid out three factual inquiries to be determined under an obviousness analysis: (1) the scope and content of the prior art; (2) the differences between the prior art and the instant claims; and (3) the level of ordinary skill in the pertinent art.⁸⁵ For example, the obviousness requirement, especially under *Graham*, is to preclude the patent protection of a hair comb made of ivory instead of being made of plastic.⁸⁶

More recently in *KSR International Co. v. Teleflex Inc.*,⁸⁷ the Supreme Court further clarified the obviousness requirements under § 103. In *KSR*, the Court held that if a patent is merely a combination of prior art, with no drastic change in its respective function, it is obvious if an ordinary person trained in the field would have combined the articles.⁸⁸ Under the *KSR* framework, if there is a known problem in the field and there are a finite

79. See 35 U.S.C. § 103(a) (2006); *Milgo Elec. Corp. v. United Bus. Commc'ns, Inc.*, 623 F.2d 645, 654 (10th Cir. 1980).

80. 35 U.S.C. § 103(a).

81. *Kahn v. Gen. Motors Corp.*, 135 F.3d 1472, 1479-80 (Fed. Cir. 1998).

82. *Id.* at 1479.

83. *Graham v. John Deere Co.*, 383 U.S. 1, 11 (1966); *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248, 267 (1851) (affirming that a patent was invalid because “there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention. In other words, the improvement is the work of the skilful mechanic, not that of the inventor”).

84. *Graham*, 383 U.S. at 14.

85. *Id.* at 17.

86. See *id.* at 10 n.3.

87. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

88. *Id.* at 420.

number of possible solutions, then an ordinary person in the field would try these possible solutions; thus, the resulting “invention” is not due to *innovation* but rather ordinary skill and common sense.⁸⁹

5. Definability

Finally, a patent application must contain a written description in “full, clear, concise, and exact terms” to allow another person to make and use the invention.⁹⁰ The purpose of this requirement is to allow the public to use the invention after the patent expires.⁹¹

C. Patent Examination Process

A patent application, or the patent instrument, must contain a “specification” that explains the invention.⁹² The PTO has promulgated regulations concerning the contents of the specification.⁹³ The specification contains, *inter alia*, a title, an abstract, a detailed description, and even drawings.⁹⁴ Once an inventor completes a patent application, it is sent to the PTO.⁹⁵ Once received by the PTO, the application is assigned an examiner.⁹⁶ The examiner evaluates the prior art regarding the claims.⁹⁷ After evaluating the prior art, the examiner will determine whether the application has met the statutory requirements.⁹⁸ If the examiner finds that the application meets the statutory requirements, the examiner will issue the patent; however, if the statutory requirements are lacking, the examiner will send a denial notice informing the applicant that the patent is denied.⁹⁹ Upon receipt of such a notice, the applicant can avail himself of the PTO’s administrative procedures and ultimately the courts.¹⁰⁰

89. *Id.* at 421.

90. 35 U.S.C. § 112 (2006).

91. *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 57 (1938).

92. *See* 35 U.S.C. § 112.

93. *See* 37 C.F.R. § 1.77 (2009).

94. SCHECHTER & THOMAS, *supra* note 28, at 183.

95. *Id.* at 225.

96. *Id.*

97. *Id.*

98. *Id.* at 225-26.

99. *Id.* at 226.

100. *Id.*

D. The Products of Nature Doctrine

The “products of nature doctrine” holds that an invention indistinguishable from something occurring in nature is not patentable.¹⁰¹ The products of nature doctrine appears as early as the late nineteenth century.¹⁰² A prime example of the doctrine’s early application is *Ex parte Latimer*.¹⁰³ Latimer applied for two patents: one for his process and one for his product. The Patent Commissioner denied a patent to Latimer’s woven fabric consisting of cellular tissues of the *Pinus Australis* plant.¹⁰⁴ Latimer spun and wove the plant filaments making a fiber.¹⁰⁵ The patent examiner denied the patent because the claim did not “set forth any physical characteristics by which the fiber can be distinguished from other vegetable fibers.”¹⁰⁶ The Patent Commissioner held that nature imbued the fiber with its characteristics, not any novel input or genius by Latimer.¹⁰⁷

The modern degradation of the products of nature doctrine spawns from the misinterpretation of *Diamond v. Chakrabarty*.¹⁰⁸ Chakrabarty was a microbiologist for General Electric.¹⁰⁹ Chakrabarty’s patent application asserted thirty-six claims concerning “a bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.”¹¹⁰ Essentially, Chakrabarty invented a human-made genetically-engineered bacterium capable of breaking down crude oil.¹¹¹ This bacterium was neither found in nature, nor was this particular property exhibited in any naturally occurring bacteria.¹¹² Thus, Chakrabarty

101. See *Parker v. Flook*, 437 U.S. 584, 589 (1978); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

102. See *Ex parte Latimer*, 1889 Dec. Comm’r Pat. 123, 123 (1889).

103. *Id.*

104. *Id.*

105. *Id.*

106. *Id.* at 124.

107. *Id.* at 125.

108. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

109. *Id.* at 305.

110. *Id.*

111. *Id.*

112. *Id.*

engineered a unique bacterium possessing significant value for treating oil spills.¹¹³

The patent examiner denied Chakrabarty's claims on the grounds "(1) that micro-organisms are 'products of nature,' and (2) that as living things they are not patentable subject matter under 35 U.S.C. § 101."¹¹⁴ The Patent Office Board of Appeals affirmed the examiner's decision and concluded that § 101 was not intended to cover living things, including laboratory-created micro-organisms.¹¹⁵

The Supreme Court reversed and held that Chakrabarty's bacterium satisfied the requirements of § 101.¹¹⁶ According to the Court, the issue was whether micro-organisms were patentable subject matter.¹¹⁷ The Court held that "anything under the sun that is made by man" is patentable subject matter.¹¹⁸ The Court reasoned that Congress wanted the patent statutes to be given a wide scope, and therefore Chakrabarty's bacterium was not a product of nature.¹¹⁹

E. A Basic Biological Background

Since this Comment argues against the current practice of patenting human gene sequences, a proper foundation of genetics is appropriate. Every human cell contains forty-six chromosomes.¹²⁰ Each of these chromosomes contains a single deoxyribonucleic acid ("DNA") molecule along with various proteins.¹²¹ Every living organism possesses the information to "copy" itself.¹²² This ability supports the hereditary function, or the passing of genetic information from itself to offspring.¹²³ Therefore, DNA is the material of heredity.¹²⁴ DNA is made of smaller units called

113. *Id.* at 305 & n.2 (noting that Chakrabarty's bacterium promised more efficient and rapid oil-spill control).

114. *Id.* at 306.

115. *Id.*

116. *Id.* at 318.

117. *Id.* at 307.

118. *Id.* at 309.

119. *Id.* at 308.

120. STEVE BOLSOVER ET AL., FROM GENES TO CELLS 75 (1997).

121. *Id.* at 79.

122. RICHARD J. REECE, ANALYSIS OF GENES AND GENOMES 1 (2004).

123. *See id.* at 2.

124. *Id.* at 7.

nucleotides;¹²⁵ thus, DNA is a polynucleotide.¹²⁶ DNA has four nucleotides: adenine (A), guanine (G), thymine (T), and cytosine (C).¹²⁷ The “genetic information” is the combination and order of these nucleotides.¹²⁸ DNA is a double-stranded molecule, forming a double helix, joined by hydrogen bonds.¹²⁹ DNA molecules can be very large; for example, the chromosome of *E. Coli* (a bacteria) comprises two DNA strands, each containing approximately 4.5 million nucleotides.¹³⁰ DNA plays an integral part in “coding” and “decoding” genetic information.¹³¹ The information in the DNA (i.e., the order of the nucleotides) is transferred to its “daughter” by “replication.”¹³² Replication occurs when the cell divides.¹³³ During replication, the double helix unwinds and serves as a template for replication.¹³⁴ DNA directs the creation of proteins with the help of ribonucleic acid (“RNA”).¹³⁵ The DNA transfers its code to the RNA, a process known as transcription.¹³⁶ The RNA is translated into amino acids.¹³⁷ This is the basic process wherein cells divide and form the building blocks of life. This process is used to create proteins, the body’s main building blocks.¹³⁸

F. Basic Gene Biology

The exact definition of a “gene” has bewildered scientists.¹³⁹ Early definitions of genes were used to describe a “unit of inheritance of an

125. JAMES N. THOMPSON ET AL., PRIMER OF GENETIC ANALYSIS: A PROBLEMS APPROACH 1 (2d ed. 1997).

126. NORMAN MACLEAN, GENES AND GENE REGULATION 4 (1989).

127. THOMPSON ET AL., *supra* note 125.

128. *See* BOLSOVER ET AL., *supra* note 120, at 79.

129. MACLEAN, *supra* note 126, at 4.

130. BOLSOVER ET AL., *supra* note 120.

131. THOMPSON ET AL., *supra* note 125, at 16.

132. BOLSOVER ET AL., *supra* note 120, at 79.

133. *Id.* at 133.

134. *Id.*

135. *Id.* at 79.

136. *Id.*

137. *Id.*

138. *How Genes Work*, NAT’L INST. OF GEN. MED. SCIS., (2006), <http://publications.nigms.nih.gov/thenewgenetics/chapter1.html> (last updated Apr. 2010).

139. JEREMY DALE & MALCOM VON SCHANTZ, FROM GENES TO GENOMES: CONCEPTS AND APPLICATIONS OF DNA TECHNOLOGY 15-16 (2d ed. 2007).

observable characteristic,” known as a “phenotype.”¹⁴⁰ As the science of genetics progressed, so did the nomenclature; genes were later defined as a DNA sequence coding for a specific polypeptide.¹⁴¹ This definition, however, ignores certain gene types that are used for certain RNA molecules.¹⁴²

In modern science, a “gene” is a “sequence of DNA [deoxyribonucleic acid] that carries the code for a protein or RNA [ribonucleic acid] molecule, and frequently includes regulatory regions at either or both ends.”¹⁴³ Basically, genes are a unique part of a chromosome that determine a particular characteristic.¹⁴⁴

III. THE GENE PATENT PROBLEM

Unfortunately, the PTO has ignored the products of nature doctrine and has been issuing thousands of patents encompassing human gene sequences that are effectively the same as those existing naturally in the body. Patenting genes has many troubling consequences, namely, slowing research and devaluing human life.¹⁴⁵ Concerning human gene patents in particular, Dr. John E. Sulston, the 2002 Nobel Laureate in Medicine, contends that human gene patents have slowed the rate of medical and scientific advancement.¹⁴⁶

In the early 1990s, large amounts of money, both in public and private funds, were invested in biotechnology and genetic research.¹⁴⁷ The public funds expended on the Human Genome Project alone are estimated at more than \$3 billion dollars.¹⁴⁸ The biotechnology sector invested \$15.6 billion dollars in research and development in 2001.¹⁴⁹ A 2005 study found that 4,382 of the nearly 24,000 human genes have express intellectual property

140. *Id.* at 15; see MACLEAN, *supra* note 126, at 1 (noting that the first use of “gene” was used to describe Mendel’s observations on peas).

141. DALE & VON SCHANTZ, *supra* note 139, at 15.

142. *Id.*

143. MACLEAN, *supra* note 126, at 3.

144. REECE, *supra* note 122, at 40.

145. The PTO, however, contends that gene patents do not inhibit the rate of research. See Utility Examination Guidelines, 66 Fed. Reg. 1092, 1094 (Jan. 5, 2001).

146. See John Sulston, *Beyond Release: The Equitable Use of Genomic Information*, 362 THE LANCET 400, 400-02 (2003).

147. Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L. J. 123, 124 (2002).

148. *Id.*

149. *Id.*

claims.¹⁵⁰ Thus, roughly twenty percent of the human genome has been patented,¹⁵¹ including genes associated with an array of diseases such as Alzheimer's disease, asthma, hemochromatosis, forms of colon cancer, and Canavan disease.¹⁵² Even U.S. government agencies, such as the National Institutes of Health, have sought patent protection for human genes.¹⁵³

Thousands of human genes have been patented in the United States.¹⁵⁴ Currently, "isolated"¹⁵⁵ full-length genes are patentable in the United States.¹⁵⁶ A gene patent owner possesses a negative right that enables him or her to enjoin others from using the gene sequence without the patent holder's permission.¹⁵⁷ This ability to prevent and enjoin arises in research and medical venues when researchers cannot utilize a particular gene sequence because the isolated and purified form of the gene has been patented.¹⁵⁸ In patent law, a gene is treated as a normal chemical compound,¹⁵⁹ despite performing dual roles as a physical substance and a

150. *BRCA: Genes & Patents*, ACLU, (May 27, 2009), http://www.aclu.org/free-speech/brca-genes-and-patents#_ftnref2. (citing Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 *SCIENCE* 239-40 (2005)).

151. The economic incentive to patent a human gene is staggering. For example, the holder of a patent relating to Down syndrome estimates his royalties to be at least over \$100 million for the term of the patent. See Jon F. Merz, *Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine*, 45 *CLINICAL CHEMISTRY* 324, 324 (1999).

152. *BRCA: Genes & Patents*, ACLU (May 27, 2009), <http://www.aclu.org/freespeech/gen/39556res20090512.html#04>.

153. In 1995, the National Institutes of Health (NIH) received a patent on a cell line originating from a member of the Hagahai tribe in Papua New Guinea. U.S. Patent No. 5,397,696 (filed Aug. 12, 1991). The NIH posited that the cell line could be used to make vaccines for T-cell leukemia; but, the NIH abandoned the patent because of international outcry alleging this amounted to "genetic theft." See Lindsey Singeo, *The Patentability of the Native Hawaiian Genome*, 33 *AM. J.L. & MED.* 119, 124 (2007).

154. John F. Merz & Mildred K. Cho, *What Are Gene Patents and Why Are People Worried About Them?*, 8 *COMMUNITY GENETICS* 203, 203 (2005).

155. See *infra* note 199.

156. See Beth E. Arnold & Eva Ogielska-Zei, *Patenting Genes and Genetic Research Tools: Good or Bad for Innovation?*, 3 *ANN. REV. GENOMICS & HUM. GENETICS* 415, 420 (2002).

157. Merz & Cho, *supra* note 154, at 204.

158. See *infra* note 212.

159. *Amgen v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991) ("A gene is a chemical compound, albeit a complex one.").

biological database.¹⁶⁰ Thus, gene patents are actually patents on certain DNA sequences, including their inherent biological databases.¹⁶¹ A gene patent's claim will actually list out the nucleotides that compose the gene, at least in its "purified and isolated form."¹⁶²

A. Myriad's Patent on the Breast Cancer Gene

Breast cancer is a common non-skin cancer affecting vast numbers of women and even men.¹⁶³ Treatment options for breast cancer depend on multiple factors including the type, size, and location of the cancer within the breast.¹⁶⁴ Some women who are diagnosed with breast cancer have inherited particular genes associated with increased risk of developing the cancer—the BRCA1 and BRCA2 genes.¹⁶⁵ The BRCA1 and BRCA2 genes have been "strongly associated with hereditary breast cancer."¹⁶⁶ Mutations in the BRCA1 gene are also associated with "cervical, uterine, pancreatic, and colon cancer . . ."¹⁶⁷ In men, BRCA1 mutations are associated with male breast cancer, pancreatic cancer, and testicular cancer.¹⁶⁸ The BRCA1 gene is on chromosome seventeen with 5,592 base pairs that code for a protein of 1,863 amino acids.¹⁶⁹ This protein is critical for DNA repairing and other functions; thus, when the gene is altered due to a mutation, it

160. Roger D. Klein, *Gene Patents and Genetic Testing in the United States*, 25 NATURE BIOTECHNOLOGY 989, 990 (2007); see also *Amgen*, 927 F.2d at 1206. There are also other concerns surrounding the significance of what is a "gene." For example, if it is merely a chemical, then arguably it should not receive special treatment; however, if a human gene is more ethically significant, then a more heightened standard is warranted. See *infra* Part IV.C; see also Mark J. Hanson, *Religious Voices in Biotechnology: The Case of Gene Patenting*, in CLAIMING POWER OVER LIFE: RELIGION AND BIOTECHNOLOGY POLICY 72 (Mark J. Hanson ed., 2001) (exploring how framing the significance of a gene can affect the policy debate).

161. David Resnik, *Are DNA Patents Bad for Medicine?*, 65 HEALTH POL'Y 181, 183 (2003).

162. See U.S. Patent No. 5,747,282 fig.10A (filed June 7, 1995).

163. Williams-Jones, *supra* note 147, at 127.

164. *Id.*

165. *Id.*

166. *Id.*

167. *BRCA 1 and BRCA 2: Cancer Risk and Genetic Testing*, NATIONAL CANCER INSTITUTE (last updated May 29, 2009), <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA#a2>.

168. *Id.*

169. Williams-Jones, *supra* note 147, at 127.

leads to abnormal cellular gene expression.¹⁷⁰ The BRCA2 gene is located on chromosome thirteen and is even larger with 10,254 base pairs that code for a protein of 3,418 amino acids.¹⁷¹ The functions of the BRCA2 gene are similar to the BRCA1 gene, except that BRCA2 tumors and mutations exhibit different cellular expression.¹⁷² Individuals with the requisite BRCA1 and BRCA2 mutations are estimated to have a lifetime risk of forty to eighty-five percent for developing breast cancer, and sixteen to forty percent for developing ovarian cancer.¹⁷³ The children of parents with BRCA mutations have a fifty percent chance of inheriting the gene mutation.¹⁷⁴

Myriad Genetics (Myriad), a Salt Lake City based biopharmaceutical company, has patents on both the BRCA1 and BRCA2 genes.¹⁷⁵ In addition to the BRCA genes,¹⁷⁶ Myriad has been involved in discovering other disease susceptibility genes¹⁷⁷ and developing tests to exploit those genetic mutations.¹⁷⁸ Due to its patent, Myriad has also developed a genetic test that uses the BRCA genes to detect their presence.¹⁷⁹ The BRCA test consists of three subtests that can be used depending on the medical situation.¹⁸⁰

170. *Id.*

171. *Id.*

172. *Id.*

173. *Id.* at 128.

174. *Id.*

175. U.S. Patent No. 5,837,492 (filed Apr. 29, 1996) (patent on isolated BRCA2 DNA); U.S. Patent No. 5,747,282 (filed June 7, 1995) (patent on isolated BRCA1 DNA).

176. Interestingly, the Mormon Church has amassed one of the world's most extensive genealogical databases. Myriad was able access this data, which helped it to identify the BRCA1 gene. See PHILLIP W. GRUBB, PATENTS FOR CHEMICALS, PHARMACEUTICALS, AND BIOTECHNOLOGY 302 (5th ed. 2010).

177. Disease gene patents "claim the observation of an individual's genetic makeup at a disease-associated locus when done for the purpose of diagnosis." Merz, *supra* note 151. A study found that diagnostic type patents to be the most prevalent type of gene sequence patents. *Id.*

178. Williams-Jones, *supra* note 147, at 130. For example, Myriad also has genetic tests for hereditary non-polyposis colorectal cancer, cardiovascular disease, and melanoma, and has a test in development for prostate cancer. *Id.*

179. *Id.* at 133. Myriad also has patents on the testing applications of this gene, as exemplified in the ACLU lawsuit.

180. *Id.* at 133-34. The "Single site BRACAnalysis" is approximately \$250; "Multisite 3 BRACAnalysis" is approximately \$450; and the "Comprehensive BRACAnalysis" is approximately \$2,600 (dollar figures as of 2002). *Id.*

B. What Exactly Do the Patents Cover?

The “claims” of the patent are the most important part of the patent instrument.¹⁸¹ The claims set forth the rights that are possessed by the patentee.¹⁸² Essentially, the claims define the invention.¹⁸³ The BRCA1 patent has claims that encompass the nucleotide sequence of the gene, a method to produce the sequence, and a kit to test for the gene.¹⁸⁴ The first claim of the BRCA1 gene patent is a composition of matter claim that covers “[a]n isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.”¹⁸⁵ The BRCA2 patent has similar language.¹⁸⁶ SEQ ID NO:2 in the BRCA1 gene lists the amino acids composing the gene; the other claims refer to various mutations and configurations of the gene.¹⁸⁷ Thus, Myriad currently has a patent on a string of nucleotides, regardless of where they are found, as long as they exist in the sequence found in the patent.¹⁸⁸

In May 2009, the American Civil Liberties Union and the Public Patent Foundation (collectively “ACLU”) filed suit in the Southern District of New York challenging the validity of Myriad’s BRCA patents.¹⁸⁹ In the

181. SCHECHTER & THOMAS, *supra* note 28, at 200.

182. *Id.*

183. *Id.*; see *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004) (holding that during examination, “[patent] claims . . . are to be given their broadest reasonable interpretation consistent with the specification, and . . . claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art”).

184. U.S. Patent No. 5,747,282 col.153 l.55 (filed June 7, 1995). The thrust of this Comment is on composition of matter claims for nucleotide sequences; therefore, the production and test kit claims are not of concern for this Comment.

185. *Id.*

186. See U.S. Patent No. 5,837,492 col.167 l.15 (filed Apr. 29, 1996). Claim 1 reads “An isolated DNA molecule coding for a BRCA2 polypeptide, said DNA molecule comprising a nucleic acid sequence encoding the amino acid sequence set forth in SEQ ID NO:2.” *Id.*

187. ’282 Patent col.153 l.55.

188. The patent protection, however, is limited by the isolated and purified standards. See *infra* note 203.

189. See *ACLU Challenges Patents on Breast Cancer Genes*, ACLU (Sept. 22, 2010), http://www.aclu.org/free-speech_womens-rights/aclu-challenges-patents-breast-cancer-genes; see also Complaint at 1, Ass’n. for Molecular Pathology v. U.S. Patent & Trademark Office, 09 Civ. 4515 (S.D.N.Y. filed May 12, 2009). This Comment was completed, submitted, and selected for publication before the trial court’s ultimate disposition of the case. On March 29, 2010, the district court declared the patents invalid because, among other things, the isolated patent claims covered products of nature. See Ass’n for Molecular

lawsuit, the ACLU represents approximately 150,000 researchers, pathologists, and medical professionals¹⁹⁰ suing the U.S. Patent and Trademark Office, Myriad Genetics, and the University of Utah Research Foundation.¹⁹¹ Interestingly, the ACLU lawsuit is the first to allege a First Amendment challenge to a gene patent.¹⁹² The lawsuit alleges, among other things, that Myriad's patents reach into natural human genes, natural gene mutations, and claims over thoughts or abstract ideas; thus, the patents are invalid because they represent "products of nature, laws of nature and/or natural phenomena, and abstract ideas or basic human knowledge or thought."¹⁹³

C. *The PTO & Gene Patents*

The PTO has fully embraced human genes patents; it has not waited for congressional approval on the subject.¹⁹⁴ However, in light of the increase of DNA and gene patent applications,¹⁹⁵ the PTO amended its utility standards. In 2001, the PTO adopted new utility guidelines.¹⁹⁶ Its purpose was to ameliorate fears of overly broad DNA patents while concurrently embracing the "legality" of gene patents.¹⁹⁷ The new utility guidelines require the inventor to disclose a "specific" and "substantial" utility.¹⁹⁸ Essentially, with regard to gene patents, the applicant must disclose the *utility* of the gene (i.e., what the gene does). In other words, the applicant cannot merely describe the chemical composition of the DNA sequence; rather, the applicant must identify a useful purpose of the gene (e.g., a mutation in the gene that correlates with an increased risk of breast cancer). The term "specific" according to the PTO means the utility is particular to

Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010). The government has appealed the ruling to the Court of Appeals for the Federal Circuit.

190. ACLU, *supra* note 189.

191. *Id.*

192. *See id.*

193. Complaint at 29, Ass'n. for Molecular Pathology v. U.S. Patent & Trademark Office, 09 Civ. 4515 (S.D.N.Y. filed May 12, 2009).

194. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

195. The number of applications for human genes increased from 16,000 in 1990 to 33,000 in 2000. M. Scott McBride, Comment, *Patentability of Human Genes: Our Patent System Can Address the Issues Without Modification*, 85 MARQ. L. REV 511, 511 (2001).

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

197. *See id.*

198. *See id.*

the subject matter claimed.¹⁹⁹ Thus, a general statement of diagnostic utility would not suffice.²⁰⁰ The term “substantial” means a utility that has a “real world” use.²⁰¹ The real world use cannot be further research per se, but rather a practical use.²⁰²

The PTO, Myriad, and all other gene patent holders justify the validity of their patented genes on the premise that the genes are “purified and isolated.” Thus, they argue that the patented genetic sequences do not occur in nature. But what exactly does this mean? Essentially, purified and isolated means that “the gene has been removed from the human body and the non-coding regions of the gene stripped away.”²⁰³

The PTO relies on its own historic practices to justify gene patents. For example, the PTO proffers Louis Pasteur’s patent on “new” yeast as justification.²⁰⁴ In addition, the PTO relies heavily on a string of cases beginning with *Merck & Co., Inc. v. Olin Mathieson Chemical Corp.*,²⁰⁵ which held that “a new and useful product [that] is the result of processes of extraction, concentration and purification of natural materials does not defeat its patentability.”²⁰⁶ Further, *In re Bergy*²⁰⁷ held that a bacterial

199. *Gene Patents and Other Genomic Inventions: Hearing Before the Subcomm. on Courts and Intellectual Property of the H. Comm. on the Judiciary*, 106th Cong. 28 (2000) (statement of Q. Todd Dickinson, Dir. of the U.S. Patent and Trademark Office).

200. *Id.*

201. *Id.*

202. *Id.*

203. *BRCA: Genes & Patents*, ACLU (May 27, 2009), <http://www.aclu.org/free-speech/brca-genes-and-patents#06>. One commentator has compared the phrase “isolated and purified” to the following analogy:

Compare a field of grass to a strand of DNA. Furthermore, compare a blade of grass to a gene. While the blade of grass remains in the field, it is in its natural environment. Similarly, while a gene is attached to its DNA strand, it also is in its natural environment. Both the blade of grass as well as the gene can be said to be naturally occurring. When the blade of grass is plucked from its root, it has been isolated from the rest of the field. Comparably, a gene becomes isolated when it is purified from its DNA strand.

Stephanie Arcuri, *They Call That Natural? An Analysis of the Term “Naturally Occurring” and the Application of Genes to the Patent Act*, 40 VAL. U. L. REV. 743, 745 (2006) (citations omitted).

204. U.S. Patent No. 141,072 (filed May 3, 1873); *see also* Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

205. 253 F.2d 156 (4th Cir. 1958).

206. *Id.* at 163.

207. 596 F.2d 952 (C.C.P.A. 1979), *vacated sub nom.* *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980).

culture is nonetheless patentable because the culture did not exist in nature in its pure form and could only be produced in a laboratory under certain circumstances.²⁰⁸ The Federal Circuit has also upheld purified and isolated DNA patents.²⁰⁹

Finally, with the advent of the new utility standards, the PTO firmly defends its gene patent stance. Even with the PTO's new standards, however, it has been evinced that naturally occurring sequences could still be patented, so long they are isolated.²¹⁰ This is why a new standard is needed.

D. Gene Patents Have Stymied Medical Research

One of the overarching purposes of the products of nature doctrine is to keep in the storehouse of all men the basic natural principles that are the bases of other discoveries.²¹¹ Thus, the economic purpose behind the products of nature doctrine, like that of the patent system in general, is to encourage innovation. By keeping the basics of science free to all, it allows all to use them in their research. Gene patents, however, have had the opposite effect.²¹² Gene patent holders can, among other things, prevent a doctor from testing a patient's blood for the gene; stop other scientists from

208. *Id.* at 987.

209. *See, e.g.*, *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991) (noting the legal difference between naturally occurring genes and "purified and isolated" genes).

210. The PTO's current standard for an isolated and purified gene is:

An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.

Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

211. *See Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *see also* Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives With Health Needs*, 2 HOUS. J. HEALTH L. & POL'Y 65, 67-68 (2002).

212. For example, one survey of 2,100 life scientists found that that at least twenty percent of scientists have delayed publishing research for patenting-related issues. Donald Willison & Stuart M. MacLeod, *Patenting of Genetic Material: Are the Benefits to Society Being Realized?*, 167 CAN. MED. ASS'N J. 259, 260 (2002).

doing research to improve a genetic test; or preclude others from developing gene therapies based upon the gene.²¹³

Gene patents have also inhibited research. Variations or mutations in a gene can cause various diseases.²¹⁴ Therefore, when one company has a patent on a gene sequence, it prevents other researchers from discovering disease-associated mutations.²¹⁵ One salient example is the search for an autism-related gene. The search was impeded because American universities would not share DNA samples with other researchers because the universities wanted to be able to profit from the discovery and patenting of the “autism gene.”²¹⁶

Another salient example, in addition to Myriad and BRCA genes, is Athena Diagnostics,²¹⁷ which holds the patent on a gene associated with Alzheimer’s disease.²¹⁸ In the past, Athena has not allowed any laboratory, except its own, to screen for mutations in that gene.²¹⁹ In another instance, the PTO granted a patent for a gene related to hemochromatosis (an autosomal recessive disease), and subsequently thirty percent of surveyed U.S. laboratories stopped developing genetic tests around that gene.²²⁰ The survey concluded that the issuance of the patent had a measurable effect on the development and availability of testing services for the gene in the United States.²²¹ Another study found that twenty-five percent of surveyed laboratories had stopped or were prevented from providing clinical tests due to notification of infringement by a gene patent holder.²²² Also, gene

213. Lori B. Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 NAT. REV. GENETICS 803, 804 (2002).

214. *Id.*

215. *Id.*

216. *Id.*

217. Athena Diagnostics has at various times been associated with and done business as Athena Neurosciences, Inc. As of February 2000, Athena Neurosciences, Inc. began doing business as Athena Diagnostics. See ATHENA DIAGNOSTICS, <http://www.athenadiagnostics.com/content/about/>.

218. See *Methods of Screening for Alzheimer’s Disease*, U.S. Patent No. 5,508,167 (filed Apr. 13, 1994); see also 15(3) BIOTECHNOLOGY LAW REPORT 434, 36 (2009).

219. Andrews, *supra* note 211, at 89.

220. Jon F. Merz, Antigone G. Kriss, Debra G.B. Leonard, & Mildred Cho, *Diagnostic Testing Fails the Test: The Pitfalls of Patents Are Illustrated by Hemochromatosis*, 415 NATURE 577, 577 (2002).

221. *Id.*

222. Mildred Cho, Samantha Illangasekare, Meredith A. Weaver, Debra G.B. Leonard, & Jon F. Merz, *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 5 (2003).

patents increase the costs associated with genetic research because now researchers have to pay license fees to patent holders to use the gene sequences even in the research setting.²²³ Not only does the patent increase research costs (due to the required license fees), but it also increases the costs of the final usable product (e.g., a test for breast cancer) to the consumer.²²⁴ Thus, gene patenting inhibits gene related research and products.²²⁵

IV. SOLUTION

A. The PTO Should Amend Its Utility Requirements and Adopt a Higher Utility Threshold

The solution to the mounting patentability of human life is to return to the spirit of the products of nature doctrine—simply, that if the product or manufacture is found in nature, then it cannot be patented. To comport with the products of nature doctrine, the proper utility requirements should be that (1) the claimed utility cannot be substantially similar to the utility found in the naturally occurring gene and (2) the inventor actually needs to imbue the utility in the gene, i.e., the utility is not due to natural mutation, or other natural trait, but rather the genius of the inventor. Some commentators have proposed that the PTO should only look to the claimed utility.²²⁶ Specifically, if the utility being claimed is substantially similar to that found in nature, then the patent should not be granted.²²⁷ Thus, under this “substantially similar” approach, if the isolated and purified gene’s utility is substantially similar to the naturally occurring utility, then the patent claim would fail the statutory utility guideline.²²⁸ While this is a good start and does seemingly resurrect the products of nature doctrine, this test is not enough.

223. In one survey, fourteen out of twenty-seven gene patent holders stated they would require licenses for researchers to study gene mutations in their patented sequences. *See* Andrews, *supra* note 211, at 81.

224. *See* Merz et al., *supra* note 220, at 579.

225. In a recent study, sixty-five percent of surveyed laboratories (out of 211 surveyed, with a sixty-three percent response rate), had been contacted by a patent holder contending that the laboratory had possibly infringed on a patent. *Id.*

226. *E.g.*, Sean C. Pippen, *Dollars and Lives: Finding Balance in the Patent “Gene Utility” Doctrine*, 12 B.U. J. SCI. & TECH. L. 193, 223 (2006).

227. *See id.*

228. *Id.*

Rather, the proper test to use is the substantially similar framework as the beginning, but to add an additional layer of analysis asking: who imbued the utility? Was it the inventor or was it nature? For example, solely under a substantially similar framework, a gene mutation may still be patentable. A gene that naturally mutates can exhibit a new utility or usefulness. This “new” utility, however, is not imbued or instilled by any man. Rather, it is a latent iteration of the gene’s DNA sequence; thus, it is still a product of nature.

Therefore, the PTO should adopt a two-pronged approach to gene and DNA patents and require that (1) the claimed utility is not substantially similar to that found in nature, and (2) it is the inventor who imbued the utility through his or her inventiveness. By adopting this proposed two-pronged test, the PTO would actually be harmonizing its gene patent stance with its other standards regarding naturally occurring phenomena.²²⁹

The current Manual of Patent Examining Procedures (“MPEP”) precludes, in theory at least, patenting of naturally occurring phenomena²³⁰ except gene patents.²³¹ According to the MPEP, “a thing occurring in nature, which is substantially unaltered, is not a ‘manufacture.’”²³² The MPEP gives an example of “[a] shrimp with the head and digestive tract removed is an example [of a naturally occurring article].”²³³ It is illogical to assert that the current practice of gene patenting is anything but the beheaded shrimp in modern technological terms. An isolated and purified gene is not substantially altered; while it may be different in terms of exact sequence (due to the excision of non-coding regions), it nonetheless operates *exactly* the same as the naturally occurring gene.²³⁴ Thus, the MPEP is contradictory and expressly disregards the products of nature doctrine insofar as gene and other DNA patents are concerned.

Therefore, the PTO should once again amend its utility guidelines to comport with this approach. The current approach, the “specific and substantial” approach, merely allows a scientist to jot down the DNA’s naturally occurring utility. With the advent of the Human Genome Project,

229. See PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE (8th ed. 2006) § 706.03(a)(I)(B) [hereinafter MPEP].

230. See *id.*

231. For examination guidelines for micro-organisms, the MPEP references § 2105 (citing *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)).

232. MPEP, *supra* note 229.

233. *Id.*

234. *Id.*

among other genetic breakthroughs, the obviousness of such future DNA and genetic patents should be questioned as well.²³⁵

B. The Courts Should Adopt This Two Pronged Test

Even if, however, the PTO does not amend its own utility standards, courts should still adopt this Comment's proposed utility standard. The PTO is merely the "gatekeeper" of the patent system. While the PTO makes initial and administrative determinations of the patentability of inventions, the final decision still rests with the courts. Thus, if the PTO were still to grant patents under its current utility regime, the courts should still hold most gene patents invalid.

The proposed two-pronged utility standard is founded in case law. The products of nature doctrine became increasingly important in the industrial revolution and the scientific breakthroughs occurring in the first few decades of the twentieth century. In *General Electric Co. v. De Forest Radio Co.*,²³⁶ the United States Court of Appeals for the Third Circuit used *Latimer*-based reasoning regarding purported tungsten patent claims. In *General Electric*, the issue was whether a purported tungsten invention was a new metal, or varied significantly enough from naturally occurring tungsten to make it patentable. Coolridge, the inventor of the "new" tungsten, took naturally occurring tungsten and "purified" it.²³⁷ Coolridge purified the tungsten (or WO₃, tungstic oxide) by heating it in a furnace allowing the metal to free from oxygen, carbon, and other impurities, after which he submitted the tungsten to other various heating methods.²³⁸ After the heating, the tungsten was "purified," leaving it with "ductility and high tensile strength."²³⁹ It was this "product" that Coolridge claimed, among others, in his patent. The Court of Appeals affirmed the finding that this claim was invalid because it was a product of nature.²⁴⁰

The court's analysis in *General Electric* embodies a true products of nature test. While the court was scrutinizing Coolridge's claim to

235. Granted, this is beyond the scope of the Comment. However, the author does feel that in light of the modern genetic milieu, "obviousness" will be the forefront of future lawsuits in this field.

236. 28 F.2d 641 (3d Cir. 1928).

237. *Id.* at 642.

238. *Id.*

239. *Id.*

240. *Id.* at 643.

“substantially pure tungsten,” it asked “who created pure tungsten.”²⁴¹ Of course, the court found that Coolidge did not create pure tungsten; rather, it existed in nature for centuries. The court stated that “[t]he fact that no one before Coolidge found it there does not negat[e] its origin or existence.”²⁴² The court focused on the creator of the product. Next, the court analyzed his claim to “having ductility and high tensile strength.”²⁴³ Once again, the court asked whether Coolidge imbued those qualities to his “pure tungsten.” And again, the court found in the negative: Coolidge did not imbue the special characteristics of pure tungsten; rather, they existed naturally in tungsten the entire time.²⁴⁴ Therefore, the court found that this claim to “substantially pure tungsten” was over a product of nature and thus unpatentable.²⁴⁵

The importance of *General Electric*, however, reaches beyond the Third Circuit. In *In re Marden*,²⁴⁶ the Court of Customs and Patent Appeals²⁴⁷ adopted the Third Circuit’s rationale in *General Electric*. In *Marden*, the inventor was seeking patent protection of claims to “ductile uranium.”²⁴⁸ The court found the reasoning in *General Electric* to be the standard by which to gauge the products of nature analysis. In *Marden*, the court held that the “inventor” is not entitled to patent “the same, or upon any of the inherent natural qualities of [uranium].”²⁴⁹ The importance of *Marden* was that the Court of Customs and Patent Appeals, the predecessor to the current Court of Appeals for the Federal Circuit, adopted the *General Electric* standard for products of nature; the *General Electric* standard being that the court should examine: (1) who created the product and (2) who imbued the special characteristics meriting patent protection.²⁵⁰

This analysis has its basis in the classical notion of the products of nature doctrine set forth in *Latimer*.²⁵¹ In *Latimer*, the Patent Commissioner held that Latimer was not entitled to patent protection because he ascertained the

241. *Id.*

242. *Id.*

243. *Id.*

244. *Id.*

245. *Id.*

246. 47 F.2d 957, 957 (C.C.P.A. 1931).

247. The Court of Customs and Patent Appeals no longer exists and was replaced by the Court of Appeals for the Federal Circuit.

248. *Marden*, 47 F.2d at 957.

249. *Id.*

250. *Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641, 643 (3d Cir. 1928).

251. *Ex parte Latimer*, 1889 Dec. Pat. Comm’r. 123, 125 (1889).

character or quality of the composition.²⁵² The Commissioner likened Latimer's purported claim to a discoverer who finds a new gem in the earth would be entitled to all like gems subsequently found.²⁵³ Granting a patent on the plant fiber would be akin to allowing patent protection to "one who gathers the pebbles along the seashore, where the forces of nature have placed them."²⁵⁴ The Commissioner, however, did articulate that if Latimer's process had in some way imbued the fiber with something new or different, then it would qualify as a product or manufacture under the patent act.²⁵⁵

Economic pressures in granting patents are not new. In *Latimer*, the Commissioner was plagued by pressures to grant the patent.²⁵⁶ The Commissioner lamented that "[t]he alleged invention is unquestionably very valuable . . . [and] of immense benefit . . . [but] the invention resides, I am compelled to say, exclusively in the process and not at all in the product."²⁵⁷ Therefore, as early as *Latimer*, the patent office recognized that the inventor had to do something special, not the claimed product, even if the invention was valuable.

Similarly, in *Chakrabarty*, the genesis of DNA patents, the Supreme Court went to great lengths to show the novelty of Chakrabarty's bacteria. The Court pointed to the fact that the bacterium is "a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'"²⁵⁸ Furthermore, the Court emphasized that Chakrabarty's bacterium "[has] markedly different characteristics from any found in nature and . . . is not nature's handiwork, but his own."²⁵⁹ Thus, the critical reason for holding the bacteria patentable was its uniqueness insofar as it did not exist in nature, it could not be created in nature, and it had a property not found in nature. Therefore, in *Chakrabarty* the analysis focused on that it was Chakrabarty's ingenuity

252. *Id.* ("[B]ecause the mere ascertaining of the character or quality of trees that grow in the forest and the construction of the woody fiber and tissue of which they are composed is not a patentable invention, recognized by the statute.").

253. *Id.*

254. *Id.* at 126.

255. *Id.*

256. *Id.* at 127.

257. *Id.*

258. *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980) (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

259. *Id.* at 310.

that imbued the bacteria with its properties (adding the two distinct bacterium together), not any handiwork of nature.

This Comment's proposed utility test comports with Supreme Court precedent. The Court applied a similar test in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*,²⁶⁰ at the height of the products of nature doctrine.²⁶¹ In *Funk Brothers*, the Court reviewed a Court of Appeals decision that affirmed the validity of a product patent.²⁶² The patent claimed a mixed culture of Rhizobia (a bacteria) capable of inoculating the seeds of plants that otherwise could not be inoculated efficiently.²⁶³ The inventor, Bond, discovered that by mixing certain strains of different species of plants he could bypass some of the biological inhibitors.²⁶⁴ The key to Bond's invention was the use of "inhibitors."²⁶⁵ The Court reversed the Court of Appeals and held that the patent was invalid.²⁶⁶

The Court held that Bond's invention was a product of nature and thus unpatentable.²⁶⁷ First, the Court examined whether Bond created the utility.²⁶⁸ The Court stated that the sought after quality (inhibition or non-inhibition) is the work of nature.²⁶⁹ According to the Court, "Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature."²⁷⁰ The crux of this rationale was that the bacteria's qualities "are part of the storehouse of knowledge of all men."²⁷¹ Manifestations of the laws of nature (e.g., a bacteria's qualities in *Funk*) are "free to all men and reserved exclusively to none."²⁷² The Court acknowledged the incredible commercial value of Bond's bacteria, but

260. 333 U.S. 127 (1948).

261. Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union*, 76 N.Y.U. L. REV. 1623, 1640 (2001).

262. *Funk Bros. Seed Co.*, 333 U.S. at 128.

263. *Id.* at 128-130.

264. *Id.* at 130.

265. *Id.*

266. *Id.* at 132.

267. *Id.* at 130.

268. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (noting that the patent holder did not "create a state of inhibition or of non-inhibition in the bacteria").

269. *Id.*

270. *Id.*

271. *Id.*

272. *Id.*

because it was the “discovery of some of the handiwork of nature,” it was not patentable, regardless of value.²⁷³

The *Funk* holding does not preclude all biotechnology patents, nor does this Comment’s test; but, what they seek to accomplish is harmonization between patentable subject matter and the purpose of the patent system. The *Funk* Court did recognize that there are circumstances where biotechnological patents are completely valid. The Court stated in *Funk*, “If there is to be invention from such a discovery, it *must* come from the *application* of the law of nature to a *new* and *useful* end.”²⁷⁴ The Court found that Bond’s bacteria did not acquire a different use from the naturally occurring function.²⁷⁵ Next, the Court found that the bacteria performed in their *natural way*.²⁷⁶ In sum, Bond’s new and improved bacteria did not improve their natural functioning and served the ends or purposes that nature originally intended.²⁷⁷

Detractors of this new utility test may assert that it would completely nullify thousands of biotechnology patents, but this is not true. Under this Comment’s proposed two-pronged test, all of the discussed cases would have the same outcome. While their holdings would be the same, the proposed two-pronged test would invalidate patents that should have never received patent protection and concomitantly harmonize the patent system with its purpose of encouraging ingenuity but keeping products of nature in the “storehouse of all men.”

In *Latimer*, the patent would still be denied. First, the utility was substantially similar to that found in nature (the strength of the fibers),²⁷⁸ and second, as the Patent Commissioner pointed out, *Latimer* did not imbue the strings with his inventiveness.²⁷⁹ Rather, *Latimer* merely identified the naturally imbued properties of the fibers. In *Chakrabarty*, the patent would still have been deemed valid. First, *Chakrabarty* was neither patenting any product with a natural analogue, nor was that specific utility found in nature (e.g., an oil-consuming bacteria). Second, it was the inventiveness of

273. *Id.* at 131.

274. *Id.* at 130 (emphasis added).

275. *Id.* at 131. In other words, the bacteria was still used to inoculate plants—exactly what it was being used for before Bond’s improvement.

276. *Id.* This would be analogous to the “substantially similar” test espoused by this Comment.

277. *Id.* The Court expressly focused on whether the invention acted independent of what it would in nature due to the effort of the patentee.

278. *Ex parte Latimer*, 1889 Dec. Pat. Comm’r. 123, 123 (1889).

279. *Id.*

Chakrabarty that imbued the bacteria with their utility. In other words, it was the combination of products, due to Chakrabarty's genius, that gave the bacteria their utility, not a naturally occurring phenomenon. In *Funk*, the patent would still be invalid. The Court held that the function was too similar to its naturally occurring function, and that the inventor did not imbue the invention with the utility.²⁸⁰ Thus, the proposed two-pronged test would keep the hallmarks of biotechnology cases unperturbed and restore the integrity of the patent system.

C. Ethics Regulations Should Be Adopted to Invalidate Human Gene Patents

Another avenue to invalidate human gene patents is ethics regulations. Human life is special and unique.²⁸¹ Human gene patenting is not just a legal issue: it is a legal, economic, and even a religious issue.²⁸² Human life is a gift from God.²⁸³ Thus, life and the human body are not just the sum of chemical formulas, but rather a special divine work. Therefore, the patenting of anything that can amount to human life should be prohibited.²⁸⁴ Also, by allowing a select few to have the right to preclude others from

280. *Chakrabarty*, 447 U.S. at 306

281. See *Genesis* 1:26 (NASB) (God said, "Let Us make man in Our image, according to Our likeness; and let them rule over the fish of the sea and over the birds of the sky and over the cattle and over all the earth, and over every creeping thing that creeps on the earth."); *Job* 10:12 (NASB) ("You have granted me life and lovingkindness; And Your care has preserved my spirit."); *Jeremiah* 1:4-5a (NASB) ("Now the word of the LORD came to me saying, 'Before I formed you in the womb I knew you, And before you were born I consecrated you; I have appointed you a prophet to the nations.'"); 1 *Corinthians* 6:19-20 (NASB) ("Or do you not know that your body is a temple of the Holy Spirit who is in you, whom you have from God, and that you are not your own? For you have been bought with a price: therefore glorify God in your body.").

282. See Mark J. Hanson, *Religious Voices in Biotechnology: The Case of Gene Patenting*, in CLAIMING POWER OVER LIFE 73 (Mark J. Hanson ed., 2001). The ethical debate around gene patents encompasses not only the law, but also a clash of worldviews. *Id.* A worldview is a set of beliefs and ideas that influences how one evaluates the world. *Id.* Under a Christian worldview, the patenting of isolated genes that are based upon naturally occurring human genes presents a seeming infringement upon God's handiwork. But for the person who believes that humans are the end result of eons of random chemical mutations, it makes complete sense that human DNA is a chemical compound like any other.

283. See *Genesis* 1:26; *Job* 10:12; *Jeremiah* 1:4-5a; 1 *Corinthians* 6:19-20.

284. One commentator, however, has suggested that a *Roe v. Wade* framework should be used to determine whether genes qualify as a living entity. See M. Scott McBride, *Patentability of Human Genes: Our Patent System Can Address the Issues Without Modification*, 85 MARQ. L. REV 511, 529 (2001).

using certain DNA sequences for research and other societal benefit is morally wrong and reprehensible.²⁸⁵

Allowing the continued patenting of human genes may even be the first step to human “commodification.”²⁸⁶ In the broad sense of the word, commodification occurs when one “conceives of human attributes (properties of a person) as fungible owned objects (the property of the person).”²⁸⁷ Religious commentators equate gene patenting with wrongfully transferring ownership of the creation from the Creator (God) to the creation (man).²⁸⁸ This commodification manifests in attempts to patent specific gene or cell lines of people with abnormal immunity or other special genetic traits.²⁸⁹ Some individuals have even applied for patents on their own entire genome.²⁹⁰ The PTO, however, has shrugged off any attempts to use morals or ethics as a roadblock to gene patenting.²⁹¹

285. President Bill Clinton and British Prime Minister Tony Blair issued a joint statement concerning gene patents stating, “[R]aw fundamental data on the human genome, including the human DNA sequence and its variations, should be made freely available to scientists everywhere.” Gitter, *supra* note 261, at 1629.

286. See Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 440 (2002) (noting that Kant’s Categorical Imperative posits that humans should not be used for one’s own end).

287. MARGARET JANE RADIN, *CONTESTED COMMODITIES* 13 (1996).

288. For example, one commentator has stated:

Human beings are pre-owned. We belong to the sovereign Creator. We are, therefore, not to be killed without adequate justification (e.g., in self-defense) nor are we, or our body parts, to be bought and sold in the marketplace. Yet the patenting of human genetic material attempts to wrest ownership from God and commodifies human biological materials and, potentially, human beings themselves. Admittedly, a single human gene or a cell line is not a human being; but a human gene or cell line is undeniably human and warrants different treatment than all nonhuman genes or cell lines. The image of God pervades human life in all of its parts. Furthermore, the right to own one part of a human being is *ceteris paribus* the right to own all the parts of a human being. This right must not be transferred from the Creator to the creature.

Richard D. Lane & C. Ben Mitchell, *Patenting Life: No*, 63 FIRST THINGS (May 1996), available at <http://www.firstthings.com/article/2007/10/005-patenting-life-no-4>. But see Ted Peters, *Patenting Life: Yes*, 63 FIRST THINGS (May 1996), available at <http://www.firstthings.com/article/2007/10/004-patenting-life-yes-24>.

289. See *supra* note 153 (discussing the patenting of the gene sequences of Hawaiian and Papua New Guinea people).

290. See Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives With Health Needs*, 2 HOUS. J. HEALTH L. & POL’Y 65, 65 (2002). In 2000, Donna

Ethics regulations regarding intellectual property are not uncommon. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), an international intellectual property agreement, allows member countries to exclude from TRIPS protection patents that are contrary to public order or morality.²⁹² The TRIPS Agreement expressly allows exceptions to protect human life.²⁹³ In addition, the European Patent Organization and its thirty-four member countries have the Biotechnology Directive.²⁹⁴ The Biotechnology Directive has a morality exception that precludes any intellectual property protection that contravenes public policy or morality.²⁹⁵ The Biotechnology Directive also expressly precludes the patenting of certain biotechnology inventions or processes, for example, the cloning of human life.²⁹⁶

Rawlinson MacLean filed a patent application with the British Patent Office entitled “Myself” wherein she purported to patent her own genetic sequence. *Id.*

291. See Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (rejecting express proposals that argued genes are “at the core of what it means to be human”).

292. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, ¶ 2, Apr. 15, 1994, 1869 U.N.T.S. 299 [hereinafter TRIPS].

293. *Id.* While TRIPS does not expressly preclude “gene patents,” it does contain language allowing for preclusion of patents to protect human life or morals; this language arguably allows for gene patent preclusion.

294. Council Directive 98/44, art.1, 1998 O.J. (L 213) 1, 2 (EC) [hereinafter Biotechnology Directive]; see Erin Bryan, *Gene Protection: How Much Is Too Much?*, 9 J. HIGH TECH L. 52, 56-57 (2009); see also Franz-Josef Zimmer & Svenja Sethmann, *Act Implementing the Directive on the Legal Protection of Biotechnological Inventions in Germany*, 24 BIOTECH. L. REP. 561 (2005).

295. See Bryan, *supra* note 294, at 58. The Biotechnology Directive provides, among other things, “Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.” Biotechnology Directive, *supra* note 294, art. 6, ¶ 1.

296. Biotechnology Directive, *supra* note 294. In fact, the following are precluded under the Biotechnology Directive:

On the basis of paragraph 1, the following, in particular, shall be considered unpatentable: (a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Id. at art. 6, ¶ 2.

The German Patent Act, however, only allows for partial protection of human gene sequences.²⁹⁷ Under German law, gene patent protection is only given for *functions* as compared to DNA sequences.²⁹⁸ Such restrained protection is different from the American and other European patent systems. The American system requires disclosure of a function to grant protection to the *entire* DNA sequence, including any other useable functions; whereas, the German system would only offer protection for the identified function.²⁹⁹ Germany reasoned that the absolute protection of human DNA sequences should not be granted.³⁰⁰ The German approach still allows others to use the gene sequences so long as it is not for the function in the patent; the PTO has expressly rejected this compromise.³⁰¹

There have been proposals, albeit unsuccessful ones, to pass similar legislation in the United States.³⁰² In 2007, Congressman Xavier Becarra (D-CA)³⁰³ introduced “The Genomic Research and Accessibility Act.”³⁰⁴ The Act was quite simple: it sought to amend Title 35 of the U.S. Code and provided, “Notwithstanding any other provision of law, no patent may be obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies.”³⁰⁵ Congressman Becarra introduced and referred the Bill to both the House Judiciary Committee and the House Judiciary Subcommittee on Courts, the Internet, and Intellectual Property. The Bill, however, has not made any progress at becoming law.

D. Congress Should Enact a Human Gene Patent Fair-Use Exemption

If the courts³⁰⁶ and the PTO are unwilling to honor the products of nature doctrine, Congress can still ameliorate the threats of gene patents to

297. See Bryan, *supra* note 294, at 60; see also Zimmer & Sethmann, *supra* note 294.

298. See Bryan, *supra* note 294, at 60. While Germany has stricter (more restrictive) DNA patent laws, it cannot enforce these laws against European Patent Office granted patents. *Id.*

299. *Id.*

300. *Id.*

301. See Utility Examination Guidelines, 66 Fed. Reg. 1092, 1095 (Jan. 5, 2001).

302. See Roger D. Klein, *Gene Patents and Genetic Testing in the United States*, 25 NATURE BIOTECHNOLOGY 989, 989 (2007).

303. The bill was also co-sponsored by Congressmen Weldon (R-FL), Stark (D-CA), Carson (D-IN), Shea-Porter (D-NH), Degette (D-CO), and Sanchez (D-CA).

304. H.R. 977, 110th Cong. (2007).

305. *Id.* § 2(a).

306. There have been courts that have recognized, at least in theory, the promise of a patent fair use exemption. See *Whittmore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass.

research by creating fair-use type exemptions³⁰⁷ for research.³⁰⁸ Attempts to enact such an exemption thus far have failed. In 1990, Congress proposed the “Research, Experimentation, and Competitiveness Act.”³⁰⁹ The Act provided that “It shall not be an act of infringement to make or use a patented invention solely for research or experimentation purposes unless the patented invention has a primary purpose of research or experimentation.”³¹⁰ Again in 2002, Congress tried to create a specific genetic sequence information exemption.³¹¹ This Act would have provided, “It shall not be an act of infringement for any individual or entity to use any patent for or patented use of genetic sequence information for purposes of research.”³¹² The most recent attempt, in 2007, would simply preclude all patents for nucleotide sequences.³¹³ Regardless of the attempts to provide fair-use exemptions, such attempts would not be necessary if the products of nature doctrine was properly understood and applied because such patents covering the utility of naturally occurring genes (and DNA sequences) would be invalid.

1813) (“[I]t could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”); *see also* *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (holding that an “experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement is not an infringement of the rights of the patentee”). However, the purported judicially created experimentation fair use defense has not been effective in practice. *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1023 (1989).

307. In copyright law, there is a “fair use” exemption from copyright infringement. If a copyrighted work is used for certain purposes (such as “criticism, comment, news reporting, teaching . . . scholarship or research”), the use is not an infringement of a copyright. 17 U.S.C. § 107 (2006).

308. Without such a fair use exemption, even “innocent” infringement is still prohibited under patent law. *See* Eisenberg, *supra* note 306. Thus, if there are two research laboratories, and one has a gene patent and the other stumbles upon the isolated sequence and starts to develop innovative products around the gene, the former laboratory can preclude the latter from development. *See id.* at 1021.

309. H.R. 5598, 101st Cong. § 402 (1990) (proposing to amend 35 U.S.C. § 271(j)).

310. *Id.*

311. Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. § 2 (2002) (proposing to amend 35 U.S.C. § 271(j)(1)).

312. *Id.*

313. Genomic Research and Accessibility Act, H.R. 977, 110th Cong. § 2 (2007) (proposing to amend 35 U.S.C. § 106).

E. Bayh-Dole's "March-In" Rights Are Neither a Viable Nor Realistic Solution

The Bayh-Dole Act³¹⁴ allows certain entities, including non-profit organizations and universities, to retain ownership over patents that arise from the use of federal funds.³¹⁵ Before Bayh-Dole, if federal funds were used to create a patented invention, the federal agency doling out the funds retained ownership over the patent.³¹⁶ In theory, the purpose of the Bayh-Dole Act is to improve technology transfers by incentivizing qualified entities to create technology by reaping the royalties and license fees.³¹⁷ One caveat of the Act, however, is the "march-in" rights provision.³¹⁸ Under march-in rights, if the patent holder fails to commercialize the invention, or if the invention is needed for "health or safety needs," the federal agency can "march-in" and grant a license to a petitioner.³¹⁹ Thus, march-in rights are purported to keep the balance between the monopoly granted under the patent and the idea that public funds should be used for the public good.³²⁰ Therefore, if a gene patent holder was at least partially federally-funded, the government could "march-in" and grant others licenses to use the gene sequences.³²¹

314. 35 U.S.C. §§ 200–212 (2006) (Patent and Trademark Act Amendments of 1980, also known as the Bayh-Dole Act).

315. 35 U.S.C. § 202 (2006). *See generally* Mary Eberle, *March-In Rights Under the Bayh-Dole Act*, 3 MARQ. INTELL. PROP. L. REV. 155 (1999).

316. *See* Eberle, *supra* note 315, at 155-56.

317. *Id.*

318. 35 U.S.C. § 203 (2006).

319. *See id.*

320. *See* 35 U.S.C. § 200 (2006).

321. The government would have to find that at least one of the four criteria in 35 U.S.C. § 203 is been satisfied. The criteria in § 203 are:

- (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
- (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
- (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
- (4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

A recent study found that when universities and research institutes, who hold many gene patents, regularly enforce their patent rights, laboratories are discouraged from performing further research and experimentation.³²² Of those universities and research institutes, more than half of the gene patents were, at least in part, federally-funded.³²³ Despite the seeming promise of march-in rights, they have been unsuccessful in application.³²⁴ In fact, there has not yet been one case of the United States exercising its Bayh-Dole march-in rights.³²⁵ Thus, it appears as though the public's right to benefit from public research funds is doubtful.³²⁶ Therefore, arguments contending that Bayh-Dole is sufficient to protect the rights of the people to access important research, e.g., a gene sequence for detecting breast cancer, are tenuous at best.

F. The Two-Pronged Utility Solution Proposed Does Not Invalidate Gene Patents Per Se

This Comment does not argue that all DNA or gene patents should be invalid per se. Rather, the purposes of the proposed two-pronged utility test are three-fold: (1) to restore the products of nature doctrine; (2) to keep important biological information in the storehouse of all men; and (3) to respect the sanctity of human life. There are instances under the two-pronged framework where many DNA and gene patents could still be patented, and rightly so, and yet still conform to the proposed test and the purpose of the patent system. For instance, suppose an inventor takes Gene A and splices some of the DNA with Gene B to create Gene C. Now, assuming *arguendo* that if Gene C has no natural analogue and has no utility substantially similar to a naturally occurring gene, Gene C would be patentable. First, Gene C passes the substantial similarity prong, and second, it also passes prong two insofar as the inventor through his creative genius of splicing the genes together actually imbued the utility in Gene C. This is essentially what the Supreme Court approved in *Chakrabarty*.

35 U.S.C. § 203 (2006)

322. Mildred K. Cho, Samantha Illangasekare, Meredith A. Weaver, Debra G. B. Leonard & Jon F. Merz, *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 6 (2003).

323. *See id.*

324. *See id.*

325. Eberle, *supra* note 315, at 160.

326. *Id.*

Also, neither this Comment nor its two-pronged test would invalidate gene-testing products. One of the main aims of genetic research is developing tests that detect the presence of certain genes and their mutations. This Comment does not foreclose the patenting of these tests. An inventor, for example Myriad, could still properly have a product patent on its gene-detecting test, but not on the underlying gene itself. This is a reasonable approach that still offers the incentive for genetic research, yet keeps the actual purified and isolated gene in the public domain for research and other reasons.³²⁷ Thus, new biotechnological inventions such as medicine or DNA therapies could still be properly patentable, and this test would not implode the biotechnological sector.

V. CONCLUSION

In conclusion, the PTO should amend its gene utility requirements to require that (1) the claimed utility is not substantially similar to that found in nature, and (2) it is the inventor who imbued the utility through his or her work. Even if the PTO did not adopt this standard, courts should still use this test to invalidate certain gene patents. This test would work to alleviate the many pressures and conflicts surrounding the gene patent debate; would align the utility requirement with decades of case law; and would still support the holdings of the classic cases of *Latimer*, *Funk*, and *Chakrabarty*. This test would restore the products of nature doctrine, keep important biological information in the storehouse of all men, and respect the sanctity of human life. Without the adoption of this test, many women like Lisbeth Ceriani will be foreclosed from the medical treatment they desperately need.

327. The position of allowing the validity of the product claim for detection kits, among others, but not the underlying gene flows naturally from this Comment's approach.