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Invalidating Gene Patents: *Association for Molecular Pathology v. U.S. Patent & Trademark Office*

ASHLEY McHUGH*

Biotechnology companies and research institutions have patented thousands of genes based on the idea that a gene in an isolated and purified form is a patentable invention. The biotechnology industry has since grown to a multibillion dollar industry using gene patents as a basis for targeting new drugs, researching genetic disease, and developing diagnostics. One company, Myriad Genetics, faces the threat of having their patents invalidated because of their monopolistic use of their patents on human breast cancer genes. In Association for Molecular Pathology v. U.S. Patent & Trademark Office, the district court found Myriad's gene patents invalid and unenforceable. If upheld, the decision will invalidate all patents on human genes and potentially many other patents on isolated and purified natural products, having far-reaching implications for health, science, and biotechnology.

This Note questions the district court decision in Association for Molecular Pathology to grant the plaintiffs standing to sue Myriad and the United States Patent & Trademark Office and to invalidate gene patents under existing case law. Opponents of gene patents argue that genes are products of nature and are therefore not patentable subject matter under § 101 of the Patent Act. However, circuit courts have consistently endorsed the principle that isolated and purified products of nature are still inventions and patentable subject matter in certain circumstances. Although the patentability of human genes under § 101 had not been addressed by courts until now, human genes have been upheld as patentable under other requirements of the Patent Act. Because invalidating gene patents will not likely remedy the monopolistic effects of gene patents, this Note reviews several legislative approaches that could serve as a more appropriate vehicle to address the harms that gene patents cause.

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INTRODUCTION

In May 2009, the American Civil Liberties Union (ACLU) filed suit against Myriad Genetics, Inc. and the United States Patent and Trademark Office (USPTO), seeking to invalidate Myriad's patents on two human genes in *Association for Molecular Pathology v. U.S. Patent & Trademark Office*.¹ The United States District Court for the Southern District of New York granted the plaintiffs' motion for summary judgment, declaring Myriad's patents invalid and thus essentially invalidating all existing gene patents.² The decision reversed longstanding

1. 669 F. Supp. 2d 365 (S.D.N.Y. 2009).

2. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 09 Civ. 4515, 2010 U.S. Dist. LEXIS 30629, at *163 (S.D.N.Y. Mar. 29, 2010).

practices of granting and upholding gene patents under USPTO policy and existing case law.³ The ACLU filed suit on behalf of four scientific associations, two women's health groups, eight researchers and genetic counselors, and six breast or ovarian cancer patients.⁴

The plaintiffs sought to invalidate Myriad's claims related to the BRCA 1 and BRCA 2 (together referred to as BRCA 1/2) genes, whose mutated forms are associated with an increased risk for breast or ovarian cancer.⁵ There were fifteen claims-in-suit from seven patents covering the non-mutated and mutated isolated and purified forms of the BRCA 1/2 genes.⁶ The claims also covered methods for detecting a mutation, by comparing a mutated BRCA 1/2 gene with a non-mutated gene, and for analyzing the gene sequences to determine whether the gene contains a mutation associated with a higher risk of cancer.⁷ The case is unique because of the nature and identity of the parties, the novelty of the claims against Myriad and the USPTO, and the impact any decision would have on the biotechnology industry.

The impact that cancer, and breast cancer in particular, has had on society gave the case and its outcome particular importance. Myriad's monopolistic use of its gene patents has had a detrimental impact on potential and existing cancer patients.⁸ Myriad's exclusive right to the BRCA genes has also arguably stunted genetic and diagnostic research on the BRCA genes themselves.⁹ As patent holder of the isolated and purified BRCA 1/2 genes, Myriad created diagnostic tests for individuals to determine their genetic risk for cancer by detecting deleterious mutations in individuals' BRCA genes.¹⁰ Myriad is the sole provider of the BRCA diagnostic test, because it is able to prevent other research institutions from offering BRCA diagnostic testing by enforcing its right to exclude others from using the BRCA genes under its patents.¹¹ As the sole provider of BRCA diagnostic testing, Myriad has been able to arguably exploit patients by charging a high price for the test and to chill research through limited licensing practices.¹² The plaintiffs argued that the practical effect is that patients and society bear too much of the costs of Myriad's monopoly.¹³

3. John Schwartz & Andrew Pollack, *Cancer Genes Cannot Be Patented*, U.S. Judge Rules, N.Y. TIMES, Mar. 30, 2010, at B1.

4. *Ass'n for Molecular Pathology*, 669 F. Supp. 2d at 370-76.

5. *Id.* at 369.

6. *Id.* at 380.

7. *Id.*

8. *Ass'n for Molecular Pathology*, 2010 U.S. Dist. LEXIS 30629, at *64-70.

9. *Id.* at *70-81.

10. *Id.* at *56-57.

11. *See id.* at *60-64, *73.

12. *Id.* at *64-81.

13. *See id.* at *64, *72-73, *76.

Any decision from the Federal Circuit, and perhaps the Supreme Court, on appeal will have widespread consequences for the biotechnology industry. Since the Human Genome Project mapped nearly 25,000 genes, biotechnology companies have been able to patent thousands of genes.¹⁴ Almost twenty percent of human genes are now patented in the United States.¹⁵ Human genes are useful for a number of purposes. They provide a basis for targeting new drugs, researching genetic disease, and developing more efficient drugs and diagnostics.¹⁶ Genomic-based medicine also includes genetic testing, such as Myriad's BRCA diagnostic test. Genetic testing can refer to predictive testing of individuals susceptible to a particular genetic risk associated with a genetic mutation, diagnostic testing of individuals who have symptoms of a particular disease, or genetic testing of individuals diagnosed with a particular disease to optimize drug therapy.¹⁷ Because development and regulatory costs associated with bringing drugs and diagnostics to market are extremely high, intellectual property rights are needed to encourage investments in biotechnology.¹⁸ Gene patents confer a time-limited monopoly, providing incentives for companies to invest substantial time and resources in biotechnology and genetics.¹⁹ If the decision is upheld and companies can no longer patent genes, there will be fewer incentives for companies to develop genetic technology.

This Note examines the district court decision in *Association for Molecular Pathology* under the existing case law surrounding gene patents. Part I discusses how the courts and administrative patent agencies have incorporated genes into modern intellectual property doctrine. Part II explains the current effects that Myriad's gene patents have on patients and researchers. Part III analyzes the district court's decision to grant the plaintiffs standing and to invalidate gene patents under § 101 of the Patent Act.²⁰ Part IV examines what impact the district court decision could have if the Federal Circuit upholds the decision. Finally, Part V suggests legislative approaches as a more practical solution than invalidating gene patents under common law.

14. DAVID KOEPEL, WHO OWNS YOU? THE CORPORATE GOLD RUSH TO PATENT YOUR GENES 3-4 (2009).

15. Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE, 239, 239 (2005).

16. Eileen M. Kane, *Patent-Mediated Standards in Genetic Testing*, 2008 UTAH L. REV. 835, 837.

17. *Id.*

18. See Bryan A. Liang, *Regulating Follow-on Biologics*, 44 HARV. J. ON LEGIS. 363, 363-64 (2007). See generally, Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003) (surveying ten pharmaceutical firms for sixty-eight randomly selected new drugs, and finding that the total capitalized costs for new drugs increases at an annual rate of 7.4%).

19. Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 304 (2002).

20. 35 U.S.C. § 101 (2006).

I. THE PATENTABILITY OF GENES UNDER U.S. PATENT LAW

A. PATENTING DNA

In humans, each cell contains a complete copy of the human genome in the cell nucleus in the form of chromosomes, which are comprised of long, twisting strands of DNA, or deoxyribonucleic acid.²¹ DNA is made of molecules called nucleotides that bind together with a complementary DNA strand creating a double helix.²² Contiguous segments of DNA that “code” for the creation of proteins form a single gene.²³ By dictating the function of each cell, DNA affects how a person grows, develops, and reproduces.²⁴ Genes define physical traits and are responsible for both the inheritance of those traits and the production of proteins.²⁵ Each gene contains regions called exons, which code for the creation of proteins to express phenotypes in the human body.²⁶ A gene also contains noncoding portions called introns, which are interspersed between the exons.²⁷ Before the body’s molecular machinery can synthesize proteins by “reading” the gene, the introns must be spliced out.²⁸ The processes of reading a gene and synthesizing proteins are called transcription and translation.²⁹ During transcription, the DNA double helix splits into a single strand, and an mRNA (messenger ribonucleic acid) is created to complement the single strand of DNA.³⁰ RNA is also made of nucleotides, but differs slightly in structure and chemical composition.³¹ The introns of the complementary mRNA are spliced out, and the result is a molecular transcript ready to be “read” to create proteins.³²

Gene patent holders do not own genes as they exist in a human body; they own an exclusive right to make, use, sell, or offer to sell a laboratory-synthesized form of the gene.³³ Researchers have been able to

21. Mark A. Chavez, *Gene Patenting: Do the Ends Justify the Means?*, 7 *COMPUTER L. REV. & TECH. J.* 255, 256 (2003).

22. LORI B. ANDREWS ET AL., *GENETICS: ETHICS, LAW, AND POLICY* 17 (2002).

23. *Id.* at 22.

24. John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part I)*, 85 *J. PAT. & TRADEMARK OFF. SOC’Y* 301, 309 (2003).

25. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2010 U.S. Dist. LEXIS 30629, at *29–30 (S.D.N.Y. Mar. 29, 2010).

26. ANDREWS ET AL., *supra* note 22, at 22.

27. *Id.*

28. *Id.*

29. Conley & Makowski, *supra* note 24, at 311.

30. *Id.* at 312.

31. *Id.* at 311.

32. *Id.* at 312.

33. *See* 35 U.S.C. § 271 (2006); Utility Examination Guidelines, 66 *Fed. Reg.* 1092, 1093 (Jan. 5, 2001).

patent a gene by cloning a DNA strand, or a cDNA, through an artificial process similar to transcription.³⁴ This process of synthesizing cDNA is referred to as “isolating and purifying” the gene.³⁵ In laboratories, researchers create a cDNA by using an enzyme that causes transcription to occur in reverse, synthesizing a strand of DNA from a mature mRNA.³⁶ Because mRNA does not contain any introns, neither does the cDNA.³⁷ The result is a strand of DNA that contains only coding portions of the gene.³⁸ Thus, the synthesized cDNA differs structurally from naturally occurring DNA, which contains introns and other molecules. Though structurally different, cDNA, mRNA, and naturally occurring DNA all contain the same instructions for the creation of certain proteins. But scientists and researchers can use cDNA for purposes for which they cannot use naturally occurring DNA. The use of cDNA “has revolutionized the fields of molecular biology, biochemistry and genetics” by allowing researchers to use cDNA to control DNA expression to study the effect of a gene on a disease or to create protein-based drugs on a large scale that had been difficult to obtain by purification.³⁹ In many ways, cDNA is a great deal more useful to scientists and researchers than native DNA.

B. NOVELTY, OBVIOUSNESS, AND THE PURIFICATION DOCTRINE

The purpose of U.S. patent law is “[t]o promote the [p]rogress of [s]cience and useful [a]rts” by granting inventors time-limited exclusive rights to inventions as an incentive to invest in new research and technology.⁴⁰ Patent law must balance this right with the negative effect a monopoly will have on scientific progress. In order to maintain this balance, Congress statutorily imposed four major patentability requirements: patentable subject matter, novelty, usefulness, and nonobviousness.⁴¹

Patent law generally excludes laws of nature, mental processes, and abstract ideas from patent protection, reflecting the concern that granting such protection would hinder scientific progress by expanding

34. Conley & Makowski, *supra* note 24, at 314.

35. Utility Examination Guidelines, 66 Fed. Reg. at 1093.

36. Conley & Makowski, *supra* note 24, at 314.

37. *Id.*

38. *Id.*

39. Sherry F. Grissom et al., *A Qualitative Assessment of Direct-Labeled cDNA Products Prior to Microarray Analysis*, 6 BMC GENOMICS 36 (2005), <http://www.biomedcentral.com/content/pdf/1471-2164-6-36.pdf>; see also Memorandum of Law in Support of Defendant U.S. Patent & Trademark Office’s Motion for Judgment on the Pleadings and in Opposition to Plaintiffs’ Motion for Summary Judgment at 23 n.6, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2010 U.S. Dist. LEXIS 30629 (S.D.N.Y. Mar. 29, 2010).

40. U.S. CONST. art. I, § 8, cl. 8.

41. 35 U.S.C. §§ 101–103, 112 (2006).

patent monopolies too far.⁴² The 1853 Supreme Court case *O'Reilly v. Morse* exemplifies this fundamental principle.⁴³ In *O'Reilly*, the inventor of the telegraph tried to claim the use of electromagnetism for long-distance communication.⁴⁴ The Court invalidated the claim because “[t]he mere discovery of a new element, or law, or principle of nature, without any valuable application of it to the arts, is not the subject of a patent.”⁴⁵ About a century later, in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, the Court upheld this same principle to invalidate a patent claiming the mixture of naturally existing bacteria capable of inoculating the seeds of leguminous plants.⁴⁶ The Court’s decision to invalidate the patent was based on the same reasoning as that of *O'Reilly*:

The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. 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.⁴⁷

The fundamental principle that natural phenomena, laws of nature, and abstract ideas are not patentable inventions remains a constant tenet of U.S. patent law.⁴⁸ As emerging technological fields such as biotechnology and genetics arose toward the end of the twentieth century, the line between phenomena of nature and actual invention began to fade.

Past legal challenges to the validity of gene patents concerned the novelty and nonobviousness requirements for patentability.⁴⁹ Prior to the Patent Act of 1952, courts often confused the requirements of novelty, nonobviousness, and patentable subject matter and their relation to each other.⁵⁰ While novelty and utility were always requirements, the case law

42. See *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 127 (2006) (Breyer, J., dissenting).

43. 56 U.S. (15 How.) 62 (1853).

44. *Id.* at 64.

45. *Id.* at 132.

46. 333 U.S. 127, 131 (1948).

47. *Id.* at 130.

48. See *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *Parker v. Flook*, 437 U.S. 584, 589 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

49. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2010 U.S. Dist. LEXIS 30629, at *111 (S.D.N.Y. Mar. 29, 2010).

50. See *Demaine & Fellmeth*, *supra* note 19, at 360–61 (“The disjunction between historical precedent in the Supreme Court and CCPA, and the modern practice of most circuit courts in evaluating biotechnology patents, has created a simmering conflict over the proper interpretation of sections 101 through 103 in evaluating many biotechnology patent applications. . . . Indeed, the CCPA even criticized the Supreme Court’s decision in *Parker v. Flook*, claiming that the Court confused the requirements of novelty and nonobviousness with the patentable class issue in section 101” (footnote omitted)).

prior to 1952 developed a concept of “invention” later codified as obviousness, although courts occasionally merged all three concepts under the umbrella of “invention.”⁵¹ Under the current Patent Act of 1952, for an invention to be novel, it must significantly differ from any previous inventions or prior art.⁵² An invention is obvious if the invention as a whole would have been obvious at the time it was created to a person having ordinary skill in the art or relevant field of the invention.⁵³ A common argument against granting patents on human gene patents is that genes are products of nature and are, therefore, an unpatentable discovery.⁵⁴ But long before scientists mapped the human genome, the legal system upheld patents claiming natural products through the purification doctrine.

The purification doctrine holds that purified products of nature are novel when they differ significantly from their naturally occurring counterparts.⁵⁵ The Supreme Court first addressed a patent claiming a purified product of nature in 1874, in *American Wood-Paper Co. v. Fibre Disintegrating Co.*⁵⁶ The Court initially rejected the purification argument, holding that a patent for purified cellulose to create paper did not significantly differ in kind or in substance from the naturally occurring cellulose, and it was therefore void for lack of novelty.⁵⁷ This requirement of a significant difference created room for later courts to uphold patents claiming purified products that had significantly better therapeutic and commercial effects than the impure product.⁵⁸ Not all courts agreed on the validity of this newly founded distinction for therapeutically valuable purified products. A circuit split arose in the early twentieth century where the Third Circuit, the Court of Customs and Patent Appeals (CCPA), and the Board of Patent Appeals all rejected this principle and invalidated patents claiming purified products of nature.⁵⁹

51. *See id.* at 365.

52. 35 U.S.C. § 102 (2006); PHILIPPE G. DUCOR, PATENTING THE RECOMBINANT PRODUCTS OF BIOTECHNOLOGY AND OTHER MOLECULES 11 (1998).

53. 35 U.S.C. § 103.

54. *Ass'n for Molecular Pathology*, 2010 U.S. Dist. LEXIS 30629, at *2.

55. Demaine & Fellmeth, *supra* note 19, at 332–33.

56. 90 U.S. 566 (1874).

57. *Id.* at 593–96.

58. *See Kuehmsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701, 704–05 (7th Cir. 1910) (upholding the validity of a patent claiming purified acetyl salicylic acid, or “aspirin,” because purified aspirin had significantly greater therapeutic value than unpurified forms of aspirin); *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95, 115 (S.D.N.Y. 1911), *aff'd*, 196 F. 496 (2d Cir. 1912) (holding a patent claiming purified adrenaline did not fail for lack of novelty, because it was more therapeutically effective than the prior art).

59. *See Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641, 650 (3d Cir. 1928) (rejecting a patent claiming purified tungsten); *In re King*, 107 F.2d 618, 619 (C.C.P.A. 1939) (rejecting a patent claiming purified vitamin C); *In re Merz*, 97 F.2d 599, 601 (C.C.P.A. 1938) (rejecting a patent claiming purified

After the enactment of the 1952 Patent Act, the Fourth Circuit in *Merck & Co. v. Olin Mathieson Chemical Corp.* upheld the validity of a patent claiming purified vitamin B-12 because of its therapeutic effectiveness and commercial value.⁶⁰ Pointing to an absence of statutory direction in the 1952 Patent Act, the court noted, “There is nothing in the language of the Act which precludes the issuance of a patent upon a ‘product of nature’ when it is a ‘new and useful composition of matter’ and there is compliance with the specified conditions for patentability.”⁶¹ The court emphasized the idea that, to a certain extent, all products used to make inventions are from nature.⁶² New and useful inventions comprised of matter necessarily include natural products.⁶³ Under the Fourth Circuit’s line of reasoning, one cannot draw a line between products of nature and man-made inventions.⁶⁴ After the *Merck* decision, the Board of Patent Appeals and CCPA reversed themselves, and courts gradually accepted and upheld patents claiming purified natural products.⁶⁵

C. MODERN ACCEPTANCE OF GENE PATENTS

In the past, gene patents were granted and upheld under the purification doctrine, and no one had challenged them as nonpatentable subject matter under § 101 of the Patent Act until *Association for Molecular Pathology*. Patentable subject matter under § 101 includes “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”⁶⁶ Much of the past debate around the validity of gene patents had focused on the other requirements for patentability, especially novelty and nonobviousness, in the context of genes being naturally occurring products.⁶⁷ The closest the Supreme Court has come to a decision about patentable subject matter under § 101 relating to gene patents was in 1980, when the Court ruled on the patentability of a genetically engineered living organism in *Diamond v. Chakrabarty*.⁶⁸

ultramarine dye); *In re Ridgway*, 76 F.2d 602, 603 (C.C.P.A. 1935) (rejecting a patent claiming the abrasive chemical, crystalline alpha alumina); *Ex parte Reed*, 135 U.S.P.Q. (BNA) 34, 36 (Pat. Off. Bd. App. 1961), *rev’d on reconsideration*, 135 U.S.P.Q. (BNA) 105 (Pat. Off. Bd. App. 1961).

60. 253 F.2d 156, 164 (4th Cir. 1958).

61. *Id.* at 161.

62. *Id.* at 162.

63. *Id.*

64. Demaine & Fellmeth, *supra* note 19, at 353.

65. *Id.* at 356. See *In re Bergstrom*, 427 F.2d 1394, 1401–02 (C.C.P.A. 1970); *Ex parte Reed*, 135 U.S.P.Q. (BNA) at 36.

66. 35 U.S.C. § 101 (2006).

67. See, e.g., *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1205–09 (Fed. Cir. 1991).

68. 447 U.S. 303, 305 (1980).

In *Chakrabarty*, the Patent Office rejected Chakrabarty's application for a patent claiming a genetically engineered bacterium because the definition of patentable under § 101 was not intended to cover living organisms.⁶⁹ The Court held that the bacterium was patentable subject matter as a "manufacture" or "composition of matter" because it exhibited characteristics that did not exist in the original bacterium, even though the bacterium itself existed naturally.⁷⁰ The Court distinguished the genetically engineered bacterium from *Funk Bros.*, because there, the mixture of bacteria's "use in combination does not improve in any way their natural functioning."⁷¹ But in *Chakrabarty*, the bacterium had "markedly different characteristics from any found in nature and one having the potential for significant utility."⁷² *Chakrabarty* confirmed that inventors can patent products of nature, but they must have markedly different characteristics from their naturally occurring counterparts. Since then, however, the Supreme Court has not ruled on the purification doctrine in light of the "markedly different characteristics" requirement delineated in *Chakrabarty*.

In 1991, the Federal Circuit addressed the patentability of purified DNA in *Amgen, Inc. v. Chugai Pharmaceutical Co.*⁷³ In *Amgen*, Amgen owned a patent covering isolated and purified DNA sequences coding for the production of human erythropoietin (EPO).⁷⁴ This protein stimulates the production of red blood cells and is used in the treatment of anemias or other blood disorders.⁷⁵ Amgen sued Chugai and Genetics Institute for direct infringement by producing recombinant human EPO through DNA technology.⁷⁶ Chugai raised several affirmative defenses, including the invalidity of Amgen's patent for lack of novelty.⁷⁷ While the court was careful to note that "neither [party] invented EPO or the EPO gene," it emphasized that "[t]he subject matter of [one of Amgen's patent claims] was the novel *purified and isolated* sequence which codes for EPO"⁷⁸ The Federal Circuit upheld the validity of Amgen's patent claims on the DNA sequences, because the gene was isolated and purified and, therefore, novel.⁷⁹ Since *Amgen*, courts have generally upheld isolated and purified genes as novel and nonobvious.⁸⁰

69. *Id.* at 306.

70. *Id.* at 308-09, 318.

71. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948).

72. *Chakrabarty*, 447 U.S. at 310.

73. 927 F.2d 1200 (Fed. Cir. 1991).

74. *Id.* at 1203-04.

75. *Id.* at 1203.

76. *Id.* at 1204.

77. *Id.*

78. *Id.* at 1206.

79. *Id.* at 1206, 1219.

80. *Demaine & Fellmeth, supra* note 19, at 408.

II. MYRIAD'S BRCA PATENTS AND THEIR EFFECT

Prior USPTO policy of granting gene patents allowed Myriad to obtain patents claiming two important genes associated with breast and ovarian cancer: BRCA 1 and BRCA 2. Everyone carries the BRCA 1/2 genes; however, individuals with a mutated BRCA 1 or BRCA 2 gene may have an increased risk of developing breast and ovarian cancer.⁸¹ Depending on the type of mutation and family history, individuals carrying a BRCA mutation have a forty to eighty-five percent chance of developing breast cancer and a sixteen to forty percent chance of developing ovarian cancer during their lifetimes.⁸² Roughly five to ten percent of women with breast and ovarian cancer are likely to have inherited a mutated BRCA 1 or BRCA 2 gene.⁸³ Given the large role the BRCA genes can play in breast and ovarian cancer, Myriad's patents are extremely important and valuable intellectual property.

A. THE HISTORY AND IMPORTANCE OF BRCA

Many parties recognized the value and importance of the BRCA 1/2 genes almost immediately after they were discovered. In 1990, a team led by Mary-Claire King, a human geneticist on faculty at the University of California, Berkeley, recognized that a mutated form of BRCA 1 increased the risk of developing breast cancer.⁸⁴ Mark Skolnick, co-founder of Myriad, sequenced BRCA 1 with help from researchers at Myriad and the University of Utah, the U.S. National Institutes of Health (NIH), and McGill University.⁸⁵ Shortly thereafter, it became apparent that another gene, BRCA 2, was also linked with increased risk of breast and ovarian cancer.⁸⁶ Skolnick raced against a group of U.K. researchers to discover, sequence, and patent BRCA 2.⁸⁷ Myriad filed for a patent claiming BRCA 2 in the U.S. while CRC Technology, a U.K. research institution, filed for a patent in the U.K.⁸⁸ Around that same time, the National Institute of Health (NIH), Myriad, and another gene discovery company, OncorMed, Inc., all filed overlapping patents

81. *Ass'n for Molecular Pathology v. U. S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 378 (S.D.N.Y. 2009).

82. *Id.* (breast cancer); Abram Katz, *Breast Cancer Gene Test Disputed*, NEW HAVEN REG., Sept. 30, 2007, <http://www.nhregister.com/articles/2007/09/30/import/18868796.prt> (ovarian cancer).

83. *Id.*

84. Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L.J. 123, 131 (2002).

85. *Id.* In 1991, Mark Skolnick, Adjunct Professor in the Department of Medical Informatics at the University of Utah, co-founded Myriad with Walter Gilbert, 1980 Nobel Laureate in Chemistry and Professor in the Department of Molecular and Cellular Biology at Harvard University, and Peter Meldrum, past President and CEO of a company called Agridyne. *Id.* at 129.

86. *Id.* at 132.

87. *Id.*

88. *Id.*

claiming BRCA 1.⁸⁹ The NIH withdrew its patent application once two of their researchers were named on Myriad's BRCA 1 patent, and Myriad eventually purchased an exclusive license to OncorMed's patents in a lawsuit settlement.⁹⁰ By the end of the race, Myriad owned patent rights to both the BRCA 1 and BRCA 2 genes in the U.S.⁹¹

Before 1996, Myriad had not yet asserted its exclusivity rights over the BRCA 1/2 genes. Other research institutions offered cheaper BRCA diagnostic testing.⁹² Some researchers were even given the test free of charge.⁹³ These tests varied in methodology, the part of the gene being tested, and who could be tested based on population.⁹⁴ In the late 1990s, Myriad offered various researchers a limited license agreement to perform the test only on patients of Ashkenazi Jewish descent.⁹⁵ Because Myriad owned patents on the mutated and non-mutated BRCA genes, it was able to require all researchers to pay a royalty fee under a license agreement in order to conduct genetic tests, regardless of differences methodologies.⁹⁶ The researchers declined the offer because it was too narrow a license to perform any meaningful BRCA 1/2 testing.⁹⁷ Myriad subsequently issued cease-and-desist letters to the research institutions that were providing unlicensed genetic BRCA testing to female patients.⁹⁸ The researchers could not continue to use their own separate diagnostic tests or to create new, improved diagnostic tests.⁹⁹

Myriad now owns patents claiming all forms of the isolated BRCA 1/2 genes themselves, any mutations thereof, all methods comparing or analyzing the two BRCA sequences to see if a mutation exists or to screen for potential cancer therapeutics, and several other related claims.¹⁰⁰ Myriad currently provides two genetic diagnostic tests to detect

89. *Id.*

90. *Id.* at 132–33.

91. *Id.*

92. *Id.* at 135.

93. *Id.* at 134–35.

94. *Id.*

95. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2010 U.S. Dist. LEXIS 30629, at *61–62 (S.D.N.Y. Mar. 29, 2010).

96. *See id.* at *61–63.

97. *Id.* at *62.

98. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 378–79 (S.D.N.Y. 2009).

99. There is a common law research exception to patent infringement, but the defense is “very narrow and limited to actions performed ‘for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.’ Further, use does not qualify for the experimental use defense when it is undertaken in the ‘guise of scientific inquiry’ but has ‘definite, cognizable, and not insubstantial commercial purposes.’” *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (citation omitted) (quoting *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000)). The exception would not apply to researchers who are working to develop diagnostic tests for BRCA, because any test created would have commercial value.

100. Complaint at 20–24, *Ass'n for Molecular Pathology*, 669 F. Supp. 2d 365 (No. 09 Civ. 4515).

the presence or absence of mutations in the BRCA 1/2 genes. The first test, the Comprehensive BRCAAnalysis Test costs more than \$3000 per test.¹⁰¹ The second test, the BRCAAnalysis Rearrangement Test, searches for large genetic mutations not caught by the standard Comprehensive BRCAAnalysis Test.¹⁰² The BRCAAnalysis Rearrangement Test costs approximately \$650, but Myriad conducts the test for women who meet certain criteria at no additional cost.¹⁰³

B. THE NEGATIVE EFFECTS OF MYRIAD'S PATENTS

Myriad's patents have had a number of negative effects on both patients and on the scientific community. As the sole provider of full sequencing of the BRCA 1/2 genes, Myriad is able to charge over \$3000 per test.¹⁰⁴ For some women, such as several of the plaintiffs, Myriad will not accept their insurance, so they need to pay the full amount to find out whether they have a genetic predisposition to cancer.¹⁰⁵ Despite oncologists' and genetic counselors' recommendations, these women cannot be tested if they cannot afford the full price of the test.¹⁰⁶ In addition, due to the nature of patenting a gene itself, there is no available workaround for researchers to develop improved diagnostic tests.¹⁰⁷ This is because a genetic diagnostic test requires the exact patented gene segment, such as BRCA 1. There is no substitute for that gene, so "the [inability] to use the patent-protected gene would, by definition, result in an incomplete and clinically unacceptable test since all of those individuals with the disease who have a mutation in the patented gene would go undetected and undiagnosed."¹⁰⁸ Thus, researchers cannot even develop independent, alternative ways of testing for BRCA mutations.

Alternative tests would help patients and researchers in many ways. They would spur competition, which would improve the quality of the tests and lower costs of diagnostic testing. Alternative tests also would allow patients diagnosed with a cancer-predisposing mutation to receive confirmatory testing before making major medical decisions about invasive preventative treatment, such as a mastectomy or oophorectomy.¹⁰⁹

101. *Id.* at 27.

102. *Id.*

103. *Id.* at 28.

104. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2010 U.S. Dist. LEXIS 30629, at *57 (S.D.N.Y. Mar. 29, 2010).

105. *Id.* at *14-16.

106. *Id.*

107. SEC'Y'S ADVISORY COMM. ON GENETICS, HEALTH, & SOC'Y, GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 15 (2010) [hereinafter SACGHS REPORT] ("Inventing around a technology involves making an invention that accomplishes the same thing as the original patented invention but that does not infringe the patented invention.").

108. *Id.*

109. *Id.* at 44.

Confirmatory testing by alternative tests would control for false negatives generated from Myriad's BRCAAnalysis. While there are a few laboratories that conduct confirmatory BRCA 1/2 testing pursuant to patent license agreements with Myriad, testing "is limited to the confirmation of certain, specific positive test results; the remaining types of positive test results as well as all negative test results are excluded from such testing services."¹¹⁰ A 2006 study in the Journal of the American Medical Association revealed that twelve percent of the participants from families with high risk breast cancer received negative results from Myriad's test, but actually carried cancer-predisposing mutations in one of their genes tested.¹¹¹ Those who receive a falsely negative result from Myriad's test are led to believe they are not genetically at risk for breast cancer and would have little reason to pursue any preventative measures. Moreover, Myriad's tests do not look for all known mutations correlated with breast and ovarian cancer, but because of its patent claiming the isolated BRCA sequences themselves, Myriad is able to bar other researchers from developing diagnostic tests that could identify further such mutations.¹¹² As a result, Myriad's BRCA patents have had a detrimental impact on patients and researchers by barring the development of alternative diagnostic tests for BRCA mutations.

C. THE LAWSUIT AGAINST MYRIAD

The plaintiffs in the suit against Myriad sought a declaratory judgment that Myriad's patent claims were invalid and/or unenforceable, and an injunction against defendants from taking actions to enforce the patents.¹¹³ The complaint challenged the validity of Myriad's patents claiming the isolated mutated and non-mutated forms of BRCA 1 and BRCA 2, the method of analyzing an individual's BRCA 1 gene to determine if an inherited mutation exists, and the method of comparing BRCA 1 and BRCA 2 sequences containing mutations with normal sequences to determine whether the difference indicates a predisposition to breast or ovarian cancer.¹¹⁴ The plaintiffs challenged Myriad's patent claims as nonpatentable subject matter under § 101 of the Patent Act and as unconstitutional under Article I, section 8, clause 8 of the United States Constitution, as well as the First and Fourteenth Amendments.¹¹⁵

¹¹⁰. *Ass'n for Molecular Pathology*, 2010 U.S. Dist. LEXIS 30629, at *69.

¹¹¹. See Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 JAMA 1379, 1386 (2006).

¹¹². *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 381 (S.D.N.Y. 2009).

¹¹³. Complaint at 30, *Ass'n for Molecular Pathology*, 669 F. Supp. 2d 365 (No. 09 Civ. 4515).

¹¹⁴. *Ass'n for Molecular Pathology*, 669 F. Supp. 2d at 380.

¹¹⁵. *Id.* at 369-70.

On March 29, 2010, the United States District Court for the Southern District of New York granted the plaintiffs' motion for summary judgment and invalidated Myriad's BRCA and related method patents under § 101 as nonpatentable subject matter, finding that the patented genes do not markedly differ from genes as they exist in nature.¹¹⁶ The court dismissed the constitutional claims under the doctrine of constitutional avoidance.¹¹⁷

Since the inception of recombinant DNA technology, thousands of isolated and purified genes have been patented.¹¹⁸ This decision, if upheld, will have a tremendous impact on the biotechnology sector by invalidating all existing gene patents and, potentially, other related or similar patents.

III. INVALIDATING GENE PATENTS

While the case is "unique in the identity of the parties, the scope and significance of the issues presented, and the consequences of the remedy sought," the decision to invalidate Myriad's BRCA patents should not be upheld.¹¹⁹ In applying the "markedly different

116. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2010 U.S. Dist. LEXIS 30629, at *145, *163 (S.D.N.Y. Mar. 29, 2010).

117. *Id.* at *161-62 (quoting *Ashwander v. TVA*, 297 U.S. 288, 347 (1936) (Brandeis, J., concurring)) ("[I]f a case can be decided on either of two grounds, one involving a constitutional question, the other a question of statutory construction or general law, the Court will decide only the latter." (alteration in original) (internal quotation marks omitted)). The district court also granted the USPTO's motion to dismiss for judgment on the pleadings because the only claims against the USPTO were constitutional claims. *Id.* at *163.

118. *Demaine & Fellmeth*, *supra* note 19, at 359.

119. *Ass'n for Molecular Pathology*, 669 F. Supp. 2d at 370. This Note will address the district court opinion invalidating the gene patents alone and will not address the decision to invalidate Myriad's method patents. The district court invalidated Myriad's method patents in light of the Federal Circuit's decisions in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009), and *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), *aff'd sub nom. Bilski v. Kappos*, 130 S. Ct. 3218 (2010). The Federal Circuit in *Bilski* articulated the "machine or transformation" test for patentability under § 101 for method patents. 545 F.3d at 954. According to the Federal Circuit decision in *Bilski*, a method is patentable under § 101 "if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." *Id.* *Prometheus* involved the validity of patent claims for methods determining the proper dosage of thiopurine drugs by measuring metabolite levels in patients' blood. 581 F.3d at 1339. In *Prometheus*, the Federal Circuit held that the claimed methods satisfied the "machine or transformation" test, because determining metabolite levels included the extraction of metabolites by using some form of manipulation, which was a transformative step central to the claimed method. *Id.* at 1347. The district court distinguished *Prometheus* in *Association for Molecular Pathology*, holding that Myriad's methods of analyzing or comparing BRCA sequences to determine a genetic mutation were invalid because the methods of "comparing" and "analyzing" were directed only toward the abstract mental processes of comparing and analyzing gene sequences, which is not transformative in nature. 2010 U.S. Dist. LEXIS 30629, at *151-53. However, the recent Supreme Court decision in *Bilski* stated that the Federal Circuit's "machine or transformation" test is not the exclusive test for defining processes under § 101. 130 S. Ct. at 3226. This important distinction may affect whether the district court decision to invalidate Myriad's diagnostic method patents is upheld.

characteristics” test from *Chakrabarty*, the district court did not adequately reconcile invalidating the BRCA patents as nonpatentable subject matter under § 101 with the prior case law establishing and upholding the purification doctrine. Even if the district court decision to invalidate gene patents under § 101 is upheld, all the plaintiffs except those who actually received cease-and-desist letters lacked standing to sue Myriad. While the negative impact of gene patents on patients and the scientific community is real and important, the court should not relax the standing requirements to remedy the negative effects of Myriad’s patents.

A. CONSTITUTIONAL STANDING TO SUE THE USPTO

Even though the district court resolved the plaintiffs’ constitutional claims in favor of the USPTO, that does not render moot the standing issue: none of the plaintiffs had standing to bring their claims against the USPTO in the first place. Under Article III, there must be a justiciable case or controversy for a plaintiff to have standing for the court to hear his or her case.¹²⁰ To have standing, a plaintiff must satisfy the constitutional requirement by showing (1) actual or threatened injury as a result of the defendant’s actions, (2) that the injury is fairly traceable to the defendant’s actions, and (3) that the plaintiff’s injury can be redressed by a favorable decision.¹²¹ In addition, the plaintiff must satisfy the prudential requirement by asserting his or her own legal interest, rather than a generalized grievance shared by a larger class.¹²²

The court found that the plaintiffs satisfied the constitutional requirement by showing that their injury resulted from the USPTO’s policy to grant patents claiming DNA.¹²³ If it were not for the USPTO allowing Myriad to monopolize the BRCA 1/2 genes, researchers could provide BRCA diagnostic testing, and the patients would not be deprived of adequate and cost effective diagnostic tests. In addition, plaintiffs’ injuries could be remedied by a favorable decision from the court. Invalidating the patents would allow researchers to be free to research the gene, and other companies could provide diagnostic testing, which would lower the cost of being tested for patients. Therefore, the plaintiffs satisfied the constitutional requirement for standing.

The plaintiffs, however, did not satisfy the prudential requirement, because their injuries constitute a generalized grievance shared by a large

120. *Allen v. Wright*, 468 U.S. 737, 750 (1984).

121. *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 472 (1982).

122. *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 804 (1985); *Warth v. Seldin*, 422 U.S. 490, 499 (1975).

123. *Ass’n for Molecular Pathology*, 669 F. Supp. 2d at 385.

class of citizens. Every person has a BRCA gene,¹²⁴ and the cost and availability of Myriad's tests affects any person who wants to be tested. In addition, Myriad's patents prevent anyone from conducting research on the BRCA genes, or from providing BRCA diagnostic testing. In support of this contention, the defendants cited *Animal Legal Defense Fund v. Quigg*, which involved a challenge to the issuance of a notice by the Commissioner of Patents & Trademarks that non-naturally occurring substances such as animals could be patented.¹²⁵ The plaintiffs in that case claimed that the Commissioner violated the Administrative Procedure Act (APA)¹²⁶ by failing to comply with the requirements of the APA's public notice provision.¹²⁷ They also claimed he acted in excess of statutory authority under the Patent Act.¹²⁸ The Federal Circuit dismissed the claim for lack of standing, because the plaintiffs asserted "no adverse effect on any individual's rights to benefits under the patent statute. Rather, they assert[ed] that the general public has an interest in the statutory limitations to patentability."¹²⁹ Similarly, the plaintiffs in *Association for Molecular Pathology* asserted an interest shared by a larger class, as well as the entire scientific, research, and medical communities.¹³⁰ Their shared interest was in remedying the monopolistic effect of Myriad's patents by limiting research and medicine. Technically, any consumer, patient, or researcher who would like to test or be tested for a BRCA mutation would have the same interest.

Although the district court distinguished *Animal Legal Defense Fund*, it failed to recognize the plaintiffs' interests as widely shared. The court distinguished *Animal Legal Defense Fund* because the decision turned on a lack of a legally cognizable right under the specific provisions of the APA.¹³¹ Additionally, the claimed harm in *Animal Legal Defense Fund* was merely speculative, because a patent claiming an animal had not actually been granted.¹³² In contrast, the court stated that because Myriad actually owns existing patents claiming the BRCA 1/2 genes granted by the USPTO, the plaintiffs' harm is not speculative as Myriad

124. *Id.* at 378.

125. *Id.* at 392 & n.20 (citing *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 922 (Fed. Cir. 1991)).

126. 5 U.S.C. §§ 551–559, 701–06 (2006).

127. *Animal Legal Def. Fund*, 932 F.2d at 925–26.

128. *Id.* at 931.

129. *Id.* at 929.

130. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2010 U.S. Dist. LEXIS 30629, at *7–16. (S.D.N.Y. Mar. 29, 2010).

131. *Ass'n for Molecular Pathology*, 669 F. Supp. 2d at 384 n.11; see *Animal Legal Def. Fund*, 932 F.2d at 931 ("Having reviewed all of appellants' arguments, we are persuaded that the Commissioner's Notice falls within the 'interpretative' exception to the section 553 public notice and comment procedures. Appellants thus have no standing to assert Count I of the Complaint by reason of 'procedural harm.'").

132. *Ass'n for Molecular Pathology*, 669 F. Supp. 2d at 384 n.11.

actively prevents breast cancer patients from obtaining diagnostic tests.¹³³ However, even if the plaintiffs' harms are substantiated, their harms are still a generalized grievance shared by a larger class. Dicta in *Animal Legal Defense Fund* supported the decision to dismiss for lack of standing, even if an animal patent had been granted, giving rise to a cognizable harm:

Moreover, we find nothing in the law which gives rise to a right in nonapplicants to object to the way in which patent applications of others are prosecuted. A third party has no right to intervene in the prosecution of a particular patent application to prevent issuance of an allegedly invalid patent.¹³⁴

The district court in *Association for Molecular Pathology* justified the plaintiffs' standing even though their harms were generalized grievances, based on the fact that the plaintiffs asserted constitutionality claims against Myriad's patents.¹³⁵ Nevertheless, asserting the harm as a constitutional violation should not counteract the prudential requirement for standing. The prudential standing requirement is a separate requirement in addition to that of a legally cognizable harm under constitutional standing doctrine.¹³⁶ While the plaintiffs have experienced actual harm, the harm is still a generalized grievance shared by all researchers and patients in the scientific community who are interested in engaging in clinical analysis of the BRCA genes.

Not only did the plaintiffs fail to meet the prudential requirement, existing legislation precludes standing by outlining a specific procedure for third parties to challenge the validity of a patent. In the context of standing, the Supreme Court has held that "when a statute provides a detailed mechanism for judicial consideration of particular issues at the behest of particular persons, judicial review of those issues at the behest of other persons may be found to be impliedly precluded."¹³⁷ Congress has already outlined a statutory procedure for third parties to challenge a patent issued by the USPTO in reexamination proceedings, and the statute does not specifically allow for a private cause of action for third parties.¹³⁸ Once a patent is granted, the Patent Act allows for any third party, at any time, to request a reexamination of the patent from the

133. *Id.*

134. *Animal Legal Def. Fund*, 932 F.2d at 930 (citing *Syntex (U.S.A.), Inc. v. U.S. Patent & Trademark Office*, 882 F.2d 1570, 1574-75 (Fed. Cir. 1989) ("The creation of a right or remedy in a third party to challenge a result favorable to a patent owner after *ex parte* prosecution would be unprecedented, and we conclude that such a right cannot be inferred."); *Chi. Rawhide Mfg. Co. v. Crane Packing Co.*, 523 F.2d 452, 458 n.13 (7th Cir. 1975); *Williams Mfg. Co. v. United Shoe Mach. Corp.*, 121 F.2d 273, 277 (6th Cir. 1941), *aff'd*, 316 U.S. 364 (1942); *Godtfredsen v. Banner*, 503 F. Supp. 642, 646 (D.D.C. 1980).

135. *Ass'n for Molecular Pathology*, 669 F. Supp. 2d at 384-85.

136. *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 804 (1985).

137. *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 349 (1984).

138. *See* 35 U.S.C. §§ 314-15 (2006); 37 C.F.R. § 1.550(g) (2007).

USPTO, but “[t]he active participation of the *ex parte* reexamination requester ends with the reply . . . , and no further submissions on behalf of the reexamination requester will be acknowledged or considered.”¹³⁹ After reexamination proceedings, the third party requesters cannot seek judicial review because the Patent Act specifies that only patent applicants may do so.¹⁴⁰ Thus, under existing legislation, request for reexamination is the only way a third party may challenge the validity of a patent after the USPTO grants the patent. Challenges by third parties to the validity of a patent are limited to a reexamination request or as a defense to an allegation of infringement.

In *Syntex (U.S.A.) Inc. v. U.S. Patent & Trademark Office*, the Federal Circuit applied the Supreme Court’s holding that a statute outlining a detailed mechanism for review of an issue can preclude judicial review of that issue.¹⁴¹ The Federal Circuit dismissed a suit brought against the USPTO to compel the USPTO to reopen the reexamination for lack of standing, because Congress precluded judicial review of reexamination decisions by creating a “comprehensive statutory scheme” for reexamination.¹⁴² The court concluded that “a plaintiff cannot claim standing based on violation of an asserted personal statutorily-created procedural right when Congress intended to grant that plaintiff no such right.”¹⁴³ The district court in *Association for Molecular Pathology* distinguished this case, because the plaintiffs could not file reexamination requests for the alleged constitutional violations, so “the Patent Act provide[d] no remedy” for them.¹⁴⁴ The plaintiffs did not file a reexamination request because reexamination is limited to claims of invalidity based on prior art.¹⁴⁵ Instead, the plaintiffs asserted unique claims based on constitutionality.¹⁴⁶ Therefore, according to the court, the only avenue available to remedy their constitutional harms is by lawsuit. However, the holding in *Syntex* could be extended to the current case because Congress specifically outlined a reexamination framework for claims of invalidity based on the prior art. Congress could have allowed for reexamination by any third party for any reason, but declined to do so. Thus, it is possible that Congress wanted to avoid waves of reexamination proceedings and lawsuits brought by third parties against lawfully granted patents under USPTO policies. Outlining

139. 37 C.F.R. § 1.550(g); *see also* 35 U.S.C. §§ 314–15.

140. *See* 35 U.S.C. § 305; *Boeing Co. v. Comm’r of Patents & Trademarks*, 853 F.2d 878, 881 (Fed. Cir. 1988).

141. 882 F.2d 1570, 1573–74 (Fed. Cir. 1989).

142. *Id.* at 1573.

143. *Id.* (quoting *Banzhaf v. Smith*, 737 F.2d 1167, 1170 n.* (D.C. Cir. 1984)).

144. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 384–85 (S.D.N.Y. 2009).

145. *See* 35 U.S.C. §§ 301, 311.

146. *Ass’n for Molecular Pathology*, 669 F. Supp. 2d at 369.

reexamination procedures for novelty and obviousness claims only could impliedly preclude third party standing to sue to invalidate a patent that has already been reviewed and approved by the USPTO.

Finally, the precedential effects of allowing the plaintiffs to sue the USPTO as third parties seeking to invalidate a patent are an important consideration. Allowing the plaintiffs to file suit for allegedly unconstitutional policies potentially invites the feared and admonished “flood of litigants” to challenge USPTO decisions based on constitutional claims, rather than following the reexamination procedures outlined in the Patent Act. Setting this precedent would also encourage third parties who are unsuccessful in invalidating a patent through reexamination, and consequently precluded from obtaining judicial review, to then file suit claiming constitutional violations. Patents already undergo initial review and approval by the USPTO and are presumed valid.¹⁴⁷ Allowing any third party to sue for a legally granted patent seriously undermines the purpose of the USPTO.

B. DECLARATORY JUDGMENT STANDING TO SUE MYRIAD AND THE UNIVERSITY OF UTAH RESEARCH FOUNDATION

To sue for a declaratory judgment, a plaintiff must satisfy the Supreme Court’s “all circumstances” test. Generally, suits for declaratory judgment relating to patents are filed by potential infringers in anticipation of an infringement action.¹⁴⁸ Potential infringers usually seek a declaratory judgment from the court stating that they do not infringe the patent or that the patent is invalid before the inventor can sue them for infringement.¹⁴⁹ However, *Association for Molecular Pathology* was a unique action, where third party patients, referred to as non-researcher plaintiffs in the district court opinion, and researchers sought to invalidate the patent, rather than potential infringers.¹⁵⁰ In applying the existing declaratory judgment requirements for standing, the district court should not have granted standing for the non-researcher plaintiffs.

The appropriate standard to determine whether a court may hear a declaratory judgment action is the “all circumstances” test from *MedImmune, Inc. v. Genentech, Inc.*¹⁵¹ Under this test, the court must determine whether, under all the circumstances, “there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory

147. 35 U.S.C. § 282.

148. Jennifer Saionz, *Declaratory Judgment Actions in Patent Cases: The Federal Circuit's Response to MedImmune v. Genentech*, 23 BERKELEY TECH. L.J. 161, 165 (2008).

149. *Id.*

150. 669 F. Supp. 2d at 392.

151. 549 U.S. 118, 127 (2007).

judgment.”¹⁵² Plaintiffs must demonstrate there was an actual controversy by showing (1) there were affirmative acts by the defendant to enforce the patent, and (2) that the plaintiffs had engaged in meaningful preparation to conduct the infringing activity.¹⁵³

The court in this case should not have granted the non-researcher plaintiffs standing to sue Myriad and the University of Utah Research Foundation.¹⁵⁴ Myriad sent cease-and-desist letters to various researchers and organizations who were researching the BRCA 1/2 genes and/or were providing commercial diagnostic tests.¹⁵⁵ Sending the letters was a sufficient affirmative act to enforce the patent in satisfaction of the first prong. In satisfaction of the second prong, all the plaintiffs stated they were “ready, willing, and able” to conduct infringing activity consisting of clinical research and practices using BRCA 1/2 genes.¹⁵⁶ The plaintiffs can be divided into two groups: researcher plaintiffs and non-researcher plaintiffs. The researcher plaintiffs, consisting of researchers and science organizations ready to use BRCA 1/2 for diagnostic testing and research activities, satisfied the declaratory judgment standing requirements, because they could provide alternative testing services other than Myriad’s diagnostic tests to potential breast cancer patients. The district court erroneously held that the non-researcher plaintiffs (the breast cancer plaintiffs and women’s health groups) had standing because they were ready, able, and willing to use the diagnostic testing services that the researcher plaintiffs would offer.¹⁵⁷ Although they do not have the potential to directly infringe Myriad’s patents, because they themselves would not be using the isolated and purified BRCA genes, the district court found them to be “potential contributory infringers,” because they were ready, able, and willing be tested by the researcher plaintiffs.¹⁵⁸

In the past, courts have held that potential indirect infringers had standing for a declaratory judgment without a showing of direct

152. *Id.* (quoting *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941) (internal quotation marks omitted)).

153. *Ass’n for Molecular Pathology*, 669 F. Supp. 2d at 386–87.

154. *Id.* at 392.

155. *Id.* at 387 n.13, 390; see Complaint at 19, *Ass’n for Molecular Pathology*, 669 F. Supp. 2d 365 (No. 09 Civ. 4515).

156. *Ass’n for Molecular Pathology*, 669 F. Supp. 2d at 371; Complaint at 3–13, *Ass’n for Molecular Pathology*, 669 F. Supp. 2d 365 (No. 09 Civ. 4515).

157. Complaint at 10–13, *Ass’n for Molecular Pathology*, 669 F. Supp. 2d 365 (No. 09 Civ. 4515); see also *Ass’n for Molecular Pathology*, 669 F. Supp. 2d at 391–92.

158. *Ass’n for Molecular Pathology*, 669 F. Supp. 2d at 392; see also 35 U.S.C. § 271(c) (2006) (“Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.”).

infringement, but only where the patentee directly notified the indirect infringer about enforcing its patents against the indirect infringer.¹⁵⁹ Indirect infringement can include induced infringement or contributory infringement.¹⁶⁰ Both actions involve somehow aiding or causing another person to directly infringe the patent, but a person cannot be liable for indirect infringement without the occurrence of direct infringement.¹⁶¹ In *Fina Research, S.A. v. Baroid Ltd.*, the Federal Circuit held that a manufacturer of a product used in drilling mud had standing to bring a declaratory judgment action against the assignees of drilling mud patents.¹⁶² The plaintiff, Fina Research (FRSA), could only be liable for indirect infringement, because its product could only satisfy one element of the multi-element patent claims.¹⁶³ Baroid tried to argue that FRSA did not have standing, because direct infringement had not actually occurred; thus, FRSA could not have meaningfully prepared to infringe under the second prong of the test for declaratory judgment standing.¹⁶⁴ The Federal Circuit rejected Baroid's contention, holding that a potential indirect infringer could bring an action for declaratory judgment even if no direct infringement had occurred.¹⁶⁵ Similarly, the researcher plaintiffs in *Association for Molecular Pathology* were not required to have directly infringed Myriad's BRCA patents in order to have standing to bring a declaratory judgment action.

While *Fina Research* establishes that indirect infringers can have declaratory judgment standing, *Fina Research* is easily distinguishable from *Association for Molecular Pathology*. In *Fina Research*, the Federal Circuit recognized the difficulties in determining whether an actual controversy emanates from potential indirect infringement.¹⁶⁶ The court confirmed, "whether a declaratory plaintiff's ability and definite intention to undertake a potentially infringing activity constitutes

159. See *Fina Research, S.A. v. Baroid Ltd.*, 141 F.3d 1479, 1485–86 (Fed. Cir. 1998); *Walker Process Equip., Inc. v. FMC Corp.*, 356 F.2d 449, 451 (7th Cir. 1966); *Unif. Prod. Code Council, Inc. v. Kaslow*, 460 F. Supp. 900, 903–04 (S.D.N.Y. 1978). Recently, the Supreme Court in *MedImmune*, abandoned the Federal Circuit's "reasonable apprehension" test to sue for declaratory judgment, which the Federal Circuit applied in *Fina Research*, as too stringent. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). This decision renders all Federal Circuit opinions decided under the "reasonable apprehension" test questionable, but *Fina Research*, although decided under the "reasonable apprehension" test, is still dispositive of the holding that indirect infringers can have standing to sue for declaratory judgment. If the indirect infringers in *Fina Research* satisfied the Federal Circuit's more stringent test, they would likely satisfy the more relaxed "all circumstances" test under *MedImmune*.

160. See 35 U.S.C. § 271.

161. *Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986).

162. 141 F.3d at 1481–82, 1485–86.

163. *Id.* at 1481–82.

164. *Id.* at 1485.

165. *Id.* at 1485–86.

166. *Id.* at 1485.

sufficient ‘preparation’ is a question of degree to be resolved on a case-by-case basis.”¹⁶⁷ Although the non-researcher plaintiffs in *Association for Molecular Pathology* did not need to show direct infringement, the relationship between non-researcher plaintiffs and Myriad is less pronounced than the relationship between the parties in *Fina Research*. One major factor exemplifying this discrepancy is the nature of the patentee’s affirmative acts to enforce the patent in *Fina Research*. Baroid sent a letter directly to FRSA notifying the plaintiffs that introducing its product into U.S. markets would induce infringement, and that it intended to enforce its patents.¹⁶⁸ Baroid directly notified FRSA that it could enforce its patents, putting the indirect infringers on notice of a potential infringement action to allow them to bring a suit for declaratory judgment.¹⁶⁹ In the current case, Myriad’s actions to enforce its patents were only directed at specific researcher plaintiffs, and not in any way directed toward the non-researcher plaintiffs.¹⁷⁰ The non-researcher plaintiffs might not have even known of Myriad’s efforts to enforce its patents until litigation had been initiated. Therefore, without any notice from the patentee, the non-researcher plaintiffs had no reason to bring a declaratory judgment and should not have had standing.

The Supreme Court decision in *MedImmune* could provide some support for the plaintiffs, but not enough. In *MedImmune*, the Supreme Court abandoned the Federal Circuit’s stringent standing requirement that the declaratory plaintiff have “reasonable apprehension” that he or she will face an infringement suit.¹⁷¹ Now, instead of the “reasonable apprehension of suit” test, courts only need to employ the less stringent “all circumstances” test.¹⁷² However, it is unclear whether the standard has been so relaxed that the declaratory party need not have known of the patentee’s efforts to enforce its patents at all. If the patentee has not made any effort to enforce its patent against a declaratory party, there seems to be no indication that the parties actually have adverse legal interests, or that there is sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Allowing the non-researcher plaintiffs to bring an action for declaratory judgment, in essence, allows any person “able and willing” to use the product of a potential infringer to sue a patentee at any time, so long as there is at least one instance where the patentee has attempted to enforce its patent rights against any

167. *Id.* (alteration in original) (quoting *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988)).

168. *Id.* at 1482.

169. *Id.*

170. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 370–73 (S.D.N.Y. 2009).

171. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127, 132 n.11 (2007).

172. *See supra* text accompanying notes 151–53.

potential infringer. This expands the doctrine of standing for declaratory judgment far beyond its scope. The only parties who should have standing to bring a declaratory judgment action against Myriad for patent invalidity are those research institutions who received cease-and-desist letters, or any direct action from Myriad enforcing its patent rights. Even though the researcher plaintiffs who received cease-and-desist letters from Myriad likely had standing to bring a declaratory judgment, the district court erred in finding that genes are not patentable subject matter.

C. GENE PATENTS UNDER § 101

The district court made two errors in invalidating Myriad's gene patents for lack of § 101 patentable subject matter. First, the court misapplied *Chakrabarty's* "markedly different characteristics" test by ignoring the therapeutic and commercial properties of purified DNA that distinguish it from native DNA. Second, the district court misconstrued the chemical nature of purified DNA to conclude that it does not significantly differ from native DNA. These errors are inconsistent with prior Federal Circuit decisions upholding the patentability of isolated and purified compounds.

1. *Therapeutic and Commercial Value and the "Markedly Different Characteristics" Test*

The district court misapplied the "markedly different characteristics" test from *Chakrabarty* to conclude that isolated and purified genes do not significantly differ from native DNA. For the § 101 requirement, the proper analysis is to determine "(1) whether the claimed invention possesses utility; and (2) whether the claimed invention constitutes statutory subject matter, that is, whether it is a 'process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.'"¹⁷³ Under *Chakrabarty*, patentable subject matter includes products of nature, as long as the new product has "markedly different characteristics from any found in nature and one having the potential for significant utility."¹⁷⁴

The district court relied heavily on the 1931 Supreme Court case, *American Fruit Growers v. Brogdex Co.*, which involved a patent claim on fresh citrus fruit whose skin has been treated with the mineral solution, borax, to prevent molding.¹⁷⁵ The Court rejected the patent and stated:

173. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2010 U.S. Dist. LEXIS 30629, at *107 (S.D.N.Y. Mar. 29, 2010) (quoting 35 U.S.C. § 101 (2006)).

174. *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

175. 283 U.S. 1, 6 (1931).

Addition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property. . . . There is no change in the name, appearance, or general character of the fruit. It remains a fresh orange fit only for the same beneficial uses as theretofore.¹⁷⁶

Similarly, the district court in *Association for Molecular Pathology* emphasized “the overriding importance of DNA’s nucleotide sequence to both its natural biological function as well as the utility associated with DNA in its isolated form,” finding that there was not a significant difference between the natural and isolated DNA.¹⁷⁷ Isolated and purified DNA and natural DNA still serve the same function: coding for proteins. Like the orange in *American Fruit Growers*, the isolated and purified DNA is functionally the same as native DNA, because the two products code for the same proteins.

Myriad relied on Judge Learned Hand’s opinion in *Parke-Davis & Co. v. H. K. Mulford Co.*¹⁷⁸ to show that isolated and purified DNA was similar to other isolated chemicals that were found to be patent-eligible.¹⁷⁹ In *Parke-Davis*, the court considered the validity of a patent claiming purified adrenaline, a natural hormone found in animal glands.¹⁸⁰ The prior art, powdered suprarenal glands, contained some desired therapeutic properties, but could not be safely administered in humans.¹⁸¹ Nevertheless, the court found that the purified adrenaline was novel because it could be administered to humans for therapeutic purposes.¹⁸²

The district court in *Association for Molecular Pathology* distinguished *Parke-Davis* on the grounds that the plaintiffs challenged Parke-Davis’s patent claiming the purified adrenaline for lack of novelty and not for lack of patentable subject matter.¹⁸³ The district court cited subsequent cases establishing that novelty and obviousness considerations should not be taken into account in determining patentable subject matter, because they are “separate requirements,” and that the test for patentable subject matter is whether the invention contains “‘markedly different characteristics’ over products existing in nature.”¹⁸⁴ While novelty and patentable subject matter now are separate

176. *Id.* at 11–12.

177. 2010 U.S. Dist. LEXIS 30629, at *134–35.

178. 189 F. 95, 109 (S.D.N.Y. 1911), *aff’d*, 196 F. 496 (2d Cir. 1912).

179. *Ass’n for Molecular Pathology*, 2010 U.S. Dist. LEXIS 30629, at *121–23 (citing *Parke-Davis*, 189 F. at 97).

180. *Parke-Davis*, 189 F. at 97.

181. *Id.* at 106.

182. *See id.* at 102.

183. 2010 U.S. Dist. LEXIS 30629, at *123–24.

184. *Id.* at *125 (quoting *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1343 (2009); *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)); *see also id.* at *107 (“The Supreme Court subsequently affirmed this understanding of the § 101 analysis in *Diehr*, noting that while it had been

requirements, courts did not distinguish between the requirements before 1952, which created inconsistent qualifications for the novelty and patentable subject matter requirements.¹⁸⁵ Following the district court's reasoning to its logical end, commercial and therapeutic properties are sufficient to satisfy the novelty requirement under *Parke-Davis* but are not markedly different characteristics sufficient to satisfy the patentable subject matter requirement. The court stated that this approach was consistent with the Supreme Court's rejection of patents claiming commercially useful natural products in *American Fruit Growers*, *Funk Bros.*, *American Wood-Paper*, and *O'Reilly* for lack of patentable subject matter.¹⁸⁶ However, the court failed to address a major distinction between cases upholding patents claiming purified products of nature, such as *Parke-Davis* and *Merck*, and cases rejecting patents claiming purified products of nature, such as *Funk Bros.*, *American Fruit Growers*, and *O'Reilly*. The products in the former set of cases differed from their natural counterparts in therapeutic value, while the products in the latter cases did not.

While commercial value alone may be insufficient to constitute a markedly different characteristic, it is a relevant consideration. The circuit courts have held that when a product's purification gives it significant commercial and therapeutic value, the purified product is patentable subject matter.¹⁸⁷ *Merck*, decided after the enactment of the Patent Act of 1952, applied Judge Hand's reasoning in *Parke-Davis* to patentable subject matter under § 101.¹⁸⁸ The court upheld a patent claiming purified vitamin B-12 as patentable subject matter because of its increased therapeutic value.¹⁸⁹ The court stated that a § 101 inquiry should be considered in two steps:

- (1) that a patent may not be granted upon an old product though it be derived from a new source by a new and patentable process, and
- (2) that every step in the purification of a product is not a patentable advance, except, perhaps, as to the process, if the new product differs from the old 'merely in degree, and not in kind.'¹⁹⁰

Under the first step, no one had ever produced a comparable product to the purified B-12, because it had such advantageous characteristics over

argued that 'novelty is an appropriate consideration under § 101,' '[t]he question . . . of whether a particular invention is novel is wholly apart from whether . . . the invention falls into a category of statutory subject matter.'" (quoting *Diamond v. Diehr*, 450 U.S. 175, 189-90 (1981) (alteration in original) (internal quotation marks omitted))).

185. See *supra* notes 50-51 and accompanying text.

186. *Ass'n for Molecular Pathology*, 2010 U.S. Dist. LEXIS 30629, at *113, *125-26.

187. See *Merck & Co., Inc. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 164 (4th Cir. 1958); *Parke-Davis*, 189 F. at 115; *Kuehmsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701, 705 (7th Cir. 1910).

188. *Merck*, 253 F.2d at 163.

189. *Id.*

190. *Id.* at 162.

other vitamin B products.¹⁹¹ Under the second step, the purified B-12 differed in kind and not just in degree.¹⁹² The court stated that the new product was more than a “mere advance in degree of purity,” and it differed in kind, because “products of great therapeutic and commercial worth have been developed. The new products [were] not the same as the old, but new and useful compositions entitled to the protection of the patent.”¹⁹³ This language suggests that the purified B-12 differed in kind from the old product because of its great therapeutic and commercial worth.

The Seventh Circuit case, *Kuehmsted v. Farbenfabriken of Elberfeld Co.*, also supports the commercial and therapeutic value distinction. The court upheld a patent claiming purified aspirin as “a new article of manufacture” because the purified aspirin was therapeutically effective.¹⁹⁴ Although the only difference between the two products was purification, the court emphasized that the purified aspirin was patentable because of its therapeutic use.¹⁹⁵ Thus, therapeutic value is a characteristic that makes a purified product a novel invention capable of patent protection under the Seventh and Fourth Circuit’s reasoning.

Similarly, isolated and purified cDNA are therapeutically and commercially significant. Like the naturally occurring adrenaline and vitamin B, genes as they exist in nature cannot be used in a medically meaningful way. Isolation and purification of the gene is a necessary step in order to utilize the gene to diagnose mutations in people to determine predisposed risk for genetic disease. In emphasizing the “markedly different characteristics” test from *Chakrabarty*, the court in *Association for Molecular Pathology* ignores this distinction made in prior cases reviewed under a patentable subject matter analysis. The district court’s analysis suggests that if *Parke-Davis* or *Kuehmsted* were decided under *Chakrabarty*’s “markedly different characteristics” test under § 101, they would be overturned because simply extracting a product of nature for improved therapeutic use is not a sufficient change to satisfy the patentable subject matter requirement. This application of the “markedly different characteristics” test would invalidate all purified products that are patentable, because of their increased therapeutic and commercial properties. This was most likely not the outcome intended by *Chakrabarty* when the Supreme Court stated, “in choosing such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any,’ Congress plainly contemplated that the

191. *Id.* at 162–63.

192. *Id.* at 164.

193. *Id.*

194. 179 F. 701, 705 (7th Cir. 1910).

195. *Id.*

patent laws would be given wide scope.”¹⁹⁶ In ignoring the therapeutic value distinction made in prior case law, the district court misapplied the “markedly different characteristics” test.

2. *Isolated Genes and Natural DNA as Genetic Instructions Instead of Chemical Compounds*

The district court also incorrectly categorized DNA as information and not as a chemical compound in order to conclude that isolated and purified DNA is no different than native DNA and therefore not patentable subject matter. The district court found that DNA’s unique status as the “physical embodiment of information” remains the same for naturally occurring DNA and for isolated and purified DNA.¹⁹⁷ Genes serve “as the physical embodiment of laws of nature—those that define the construction of the human body.”¹⁹⁸ An isolated and purified gene still codes for proteins to define physical traits.¹⁹⁹ Therefore, according to the court, steps to isolate and purify DNA do not render the patented gene markedly different, because both forms serve as instructions for the coding of proteins.²⁰⁰

Myriad tried to argue that DNA was similar to all biological chemicals, in that all chemicals convey some sort of information in the body, but the court distinguished DNA from other chemical compounds, because chemical compounds embody information about their own molecular structure for their own biological function.²⁰¹ DNA, on the other hand, directs the synthesis of other molecules.²⁰² The district court reasoned that because both isolated and purified DNA and native DNA have the same coding properties and functions, their defining characteristic remains the same.²⁰³ In addition, the court emphasized that the physical coding sequences of cDNA are the same as those of spliced, mature mRNA.²⁰⁴ Therefore, because the basis for isolated and purified DNA’s utility stems from the same functional property contained in native DNA, the court found that isolated and purified genes do not markedly differ from native DNA.²⁰⁵

The district court’s view of DNA is too narrow and directly contradicts the Federal Circuit’s classification of DNA. In upholding Amgen’s patent on an isolated and purified gene, the Federal Circuit

196. *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

197. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2010 U.S. Dist. LEXIS 30629, at *134–35 (S.D.N.Y. Mar. 29, 2010).

198. *Id.* at *134.

199. *Id.* at *143.

200. *Id.* at *134.

201. *Id.* at *131–32.

202. *Id.* at *133–34.

203. *Id.* at *138–39.

204. *Id.*

205. *Id.* at *134.

stated, “[a] gene is a chemical compound, albeit a complex one.”²⁰⁶ By classifying DNA as the embodiment of information and finding that purified DNA does not differ from native DNA because of their shared functional property of conveying genetic instruction, the district court essentially identified what constituted “important” or “essential” property of DNA, and decided that cDNA does not markedly differ from native DNA. However, cDNA has important uses for which native DNA is unsuitable. Those functions include diagnostic testing, using cDNA to study the effect of a gene on a disease for therapeutic purposes, or creating protein-based drugs on a large scale that were difficult to obtain by purification.²⁰⁷ Genetic instruction is not the only property of DNA and should not be the only factor to consider when applying the “markedly different characteristics” test.

While the district court distinguished DNA from other chemical compounds by its “unique qualities as a physical embodiment of information,” the court does not clearly state how this difference renders cDNA not patentable, while other purified chemical compounds are patentable.²⁰⁸ If the issue is functionality of the compound itself, all patents on purified products would be invalidated under the district court’s reasoning. Like isolated DNA, purified adrenaline and vitamin B-12 have the same chemical function as those existing in an impure form. Their use in purified form necessarily relies on similar chemical properties to the impure form. For example, adrenaline as it existed in the powdered gland form still contained blood-pressure-raising properties, which necessarily stemmed from adrenaline’s chemical composition.²⁰⁹ The pure form simply allowed it to be safely and effectively administered in humans.²¹⁰ Vitamin B as it existed in cattle liver still could treat pernicious anemia.²¹¹ Purification of the vitamin simply yielded a more effective treatment.²¹² Similarly, isolated genes could be the same product in native DNA as they are in cDNA. However, isolating the gene and extracting it from human cells gives it significant therapeutic value. That genes contain the same functional properties as information carriers whether they are isolated or native should not be the only consideration in determining whether isolated genes contain markedly different characteristics from native genes. The district court reasoning thus suggests that purification in general is simply

206. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991).

207. *Ass’n for Molecular Pathology*, 2010 U.S. Dist. LEXIS 30629, at *42, *140–42.

208. *Id.* at *135.

209. *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95, 109 (S.D.N.Y. 1911), *aff’d*, 196 F. 496 (2d Cir. 1912).

210. *Id.* at 115.

211. *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 158 (4th Cir. 1958).

212. *Id.* at 164.

not an inventive step yielding patentable subject matter. This narrow view of purified products, including DNA, does not follow prior circuit court precedent, and therefore the district court decision should be overturned.

IV. IMPACT OF INVALIDATING GENE PATENTS

Invalidating gene patents not only may fail to remedy many of the harms suffered by patients as a result of Myriad's monopoly on diagnostic tests, but doing so may also lead to the invalidation of other patents that were granted based on the purification doctrine. A major concern is that thousands of patents will be invalidated and millions of dollars lost if the Federal Circuit upholds the district court decision.²¹³ Depending on how the court frames the decision, these concerns may be well-founded if the plaintiffs prevail. Even if a court were to render most gene patents invalid, it is unlikely companies will lose the plethora of intellectual property rights and billions of dollars they are afraid of losing as a result of the pending litigation. Most gene patents, like Myriad's, do not just claim the isolated and purified DNA sequence; they also claim diagnostic tests and methods for using or analyzing the sequence. If using genes for specific diagnostic or therapeutic purposes could still be patented, then companies could possibly still monopolize diagnostic tests with other patents effectively blocking use of the genes anyway.²¹⁴ Nevertheless, the district court's opinion is quite broad and could potentially invalidate other types of patents. If upheld, the district court's decision might not even remedy the problems the plaintiffs experienced, but it could have the unintended consequence of invalidating other types of patents.

If the district court's decision in *Association for Molecular Pathology* is upheld, it could potentially invalidate an entire set of first-generation biotechnology patents. Although many of those patents are expiring or expired, the patents that are still in effect will be invalidated and future patents with similar bases will not be granted. Many of these first-generation biotechnology patents consist of claims covering naturally occurring, therapeutically useful molecules or an isolated DNA sequence that codes for the production of naturally occurring, therapeutically useful molecules. For example, Amgen's patent, the subject of litigation in 1991, was a patent claiming the sequence coding for the production of erythropoietin (EPO), a hormone used as a therapeutic agent for blood disorders.²¹⁵ A similar example would be Scripps's patent covering purified Factor VIII:C, a naturally occurring

213. KOEPESELL, *supra* note 14, at 114; see Schwartz & Pollack, *supra* note 3.

214. See KOEPESELL, *supra* note 14, at 144.

215. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1203 (Fed. Cir. 1991).

protein that is essential for blood clotting.²¹⁶ Applying Judge Sweet's reasoning from *Association for Molecular Pathology*, both these patents and thousands of other similar patents would be invalid, because they claim molecules in their isolated form that are really no different from the naturally occurring molecules—except that isolating them allows them to be used in a therapeutically significant way. Such a result could detrimentally impact the biotechnology sector by removing incentives to purify and commercialize therapeutically useful, naturally occurring products.

V. LEGISLATIVE ALTERNATIVES

Invalidating gene patents might be too narrow a reaction to remedy the larger problems that harmed plaintiffs in *Association for Molecular Pathology*. A meta-analysis of all available empirical evidence relating to the negative effects of gene patents indicates that the problems have less to do with patenting and more to do with the nature of commercialization in research and medicine in general.²¹⁷ Even if gene patents themselves were invalid, pharmaceutical companies, universities, and clinical laboratories could still monopolize diagnostic tests through other patents on platform technologies or methods of use. Given the findings of the study, it seems unlikely that invalidating Myriad's BRCA patents would resolve the major concern of limiting scientific progress. To invalidate gene patents in this case, the district court has incorrectly applied the requirements for patentable subject matter and has expanded the doctrine of standing by allowing third parties to bring a declaratory judgment action without direct notice of enforcement of the patents-in-suit. Rather than bend legal doctrine to meet a socially justifiable end, a more plausible solution would be to urge Congress to create some sort of statutory exemption for research or patient medical services that would otherwise infringe gene patents.

A. STATUTORY EXEMPTIONS SUGGESTED BY SACGHS

In response to the current litigation, the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) issued a revised report assessing the effects of gene patenting and licensing practices on patient and clinical access to genetic tests.²¹⁸ The report draws on law and

216. See *Scripps Clinic & Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379, 1382 (N.D. Cal. 1987).

217. Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1093 (2006).

218. SACGHS REPORT, *supra* note 107, at ix. SACGHS advises the Secretary of Health and Human Services on medical, ethical, legal and social issues raised by technological developments in human genetics. *Id.* One of the specific issues that SACGHS was chartered to examine is "current patent policy and licensing practices [and] their impact on access to genetic technologies." *Id.*

policy, policy studies, and existing legal frameworks, to conclude that obstacles in research development are the result of the decreasing capacity of laws to mitigate the problems plaintiffs cite.²¹⁹ Accordingly, the Committee made six recommendations relating to fostering better research and licensing practices, two of which suggest narrow statutory exemptions for infringing gene patents. The first statutory change is an “exemption from liability for anyone who infringes a patent on a gene while making, using, ordering, offering for sale, or selling a genetic test for patient care purposes.”²²⁰ The second is an exemption for the use of patent-protected genes in the pursuit of research.²²¹

Under an exemption from infringement liability for patient care purposes, researchers could create and sell an existing diagnostic test that would otherwise be exclusively offered by the patent holder.²²² This exemption proposes to improve the availability and quality of genetic tests by restoring basic free market conditions for genetic tests.²²³ There are several diseases where unencumbered use of a gene patent has allowed for greater, more cost-efficient access to genetic tests for patients. For example, patents related to hereditary nonpolyposis colorectal cancer have not been enforced, allowing at least fifteen different laboratories to develop genetic testing.²²⁴ Similar results have occurred with cystic fibrosis and Huntington’s disease, because exclusivity has not been enforced with those diseases.²²⁵ Rather than eliminate gene patents altogether, this exemption addresses patient access concerns by introducing competition to lower costs and increase the likelihood that patients will find a provider that accepts their insurance.²²⁶ Multiple providers would also lead to availability of confirmatory testing, which would improve the quality of testing patients receive.²²⁷

However, this exemption might be too narrow. The exemption still allows for patents claiming methods of genetic analysis and platform technologies that could block the use of existing diagnostic tests. If other labs created and sold Myriad’s breast cancer diagnostic test, they may be exempt from infringement liability for infringing the gene patent, but they would still infringe any valid method patents and any potential platform technology patents. Thus, the exemption could have little to no practical effect on increasing patient access to genetic tests.

219. *Id.* at 89.

220. *Id.* at 94.

221. *Id.* at 95.

222. *Id.* at 94.

223. *Id.*

224. *Id.*

225. *Id.*

226. *Id.*

227. *Id.*

The second exemption aims to allow researchers to develop new genetic tests and therapeutics without being liable for infringement. This recommendation seeks to promote the progress of science and the useful arts.²²⁸ Using patented genes for research purposes often does not satisfy the experimental research exemption, because there is usually, if not always, a commercial interest in such research and not merely “idle curiosity.”²²⁹ Rather than focus on the availability of current genetic tests, this exemption would allow researchers to use patent-protected genes to develop new prognosis and risk assessment methods that would provide patients with more effective testing and diagnostic services.²³⁰

While more plausible than the first, this exemption could also be circumvented by a patent claiming an essential method for analyzing the gene. For example, Myriad could still exclude other laboratories from developing alternative diagnostic tests if there was no workaround to analyzing a BRCA gene for mutations to determine genetic risk for breast cancer. If companies can patent a broad method of analyzing the gene that is essential to developing any diagnostic test, this exception could also have no practical effect.

B. CREATE AN EXCEPTION SIMILAR TO EXISTING LEGISLATION

If an exception to gene patents alone is too narrow to allow researchers to feasibly practice diagnostic testing without infringing related patents, a broader exception for a more specific and limited purpose could be more appropriate. An exception similar to the current medical and surgical procedure exception under 35 U.S.C. § 287(c) could be more effective.²³¹ Enacted in 1996 in response to litigation surrounding the infringement of “a sutureless method of closing eye incisions following cataract surgery,”²³² the exception states:

(c)(1) With respect to a medical practitioner’s performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity. . . .

. . . .

(A) [T]he term “medical activity” means the performance of a medical or surgical procedure on a body, but shall not include . . . the practice of a process in violation of a biotechnology patent.²³³

228. *Id.* at 95.

229. *Id.* at 59.

230. *Id.* at 89.

231. Michele Westhoff, *Gene Patents: Ethical Dilemmas and Possible Solutions*, 20 HEALTH L. 1, 9–10 (2008).

232. *Id.* at 9.

233. 35 U.S.C. § 287(c) (2006).

Section 287(c) was enacted “[b]ecause the ‘medical community had a longstanding tradition of freely sharing information about advancements in healthcare, and [because] the practice of building upon trial and error promoted rather than stifled medical and surgical methods.’”²³⁴ Although § 287(c) specifically excludes biotechnology patents, concerns about how detrimental gene patents could be for patients were not realized and brought to the public’s attention until *Association for Molecular Pathology*. Concerns about gene patents limiting patient access to diagnostic tests are also similar to those that initiated the creation of an exception for medical and surgical procedures. Rather than create an exception for gene patents specifically, an amendment could be written similarly to § 287(c), where any infringement by a medical practitioner for purposes of genetic diagnosis would be exempt from liability.²³⁵ This type of legislation is a compromise between industry, research, and clinical medicine. It would allow companies to enforce their patents against researchers and scientists who would attempt to commercialize any tests using patented genes or methods, while granting more efficient, lower-cost patient access to diagnostic tests.²³⁶

C. MODEL AFTER OTHER COUNTRIES’ LAWS

Congress could enact legislation similar to that of other countries either by excluding diagnostic, therapeutic, or surgical methods from patentability, or by denying patentability to an invention on moral grounds. Both of these exceptions are listed as possible options for countries to adopt under the Trade-Related Intellectual Property Rights (TRIPS) agreement, which outlines specific minimum standards for its member countries for the harmonization of international intellectual property laws.²³⁷ It seems unlikely that Congress would implement legislation excluding DNA or diagnostic methods from patentability on moral grounds, because in the U.S., there is generally no accepted exclusion from patentability based on morality.²³⁸ However, Congress could implement legislation similar to that of other countries that allow for the exclusion of diagnostic methods from patentability. For example, the U.K. and Germany exclude from patentability methods for treating

234. Westhoff, *supra* note 231, at 9–10 (quoting *Medical Procedures Innovation and Affordability Act and Inventor Protection Act of 1995: Hearing on H.R. 1127 and H.R. 2419 Before the H. Comm. on the Judiciary*, 104th Cong. 24 (1995) (statement of Rep. Greg Ganske)).

235. *See id.* at 10.

236. 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, 503–04 (2002).

237. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 1197, 1197–98 (1994) [hereinafter TRIPS].

238. Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1651 (2001).

humans or animals by surgery or therapy, as well as diagnostic methods.²³⁹ However, this restriction does not apply to research tools and would therefore, not apply to the patented gene sequences themselves. On the other hand, other provisions in TRIPS might allow for a specific exclusion of gene sequences from patentability for diagnostic purposes. Article 30 of TRIPS allows for limited exceptions that do not unreasonably prejudice the interests of the patent holder.²⁴⁰ Under this exemption, France and Belgium permit the grant of a compulsory license over patents claiming diagnostic methods.²⁴¹ Thus, it is possible that Congress could allow for a very narrow exclusion, or possibly a compulsory license, and still comply with international intellectual property agreements. Congress could model similar exceptions or grants of compulsory licenses after other countries that have already implemented such limitations.

CONCLUSION

Gene patenting has incited legal and ethical debate since its inception, but the debate has been exacerbated by Myriad's limited licensing practices and high costs for diagnostic tests involving the BRCA 1/2 genes. Although the plaintiffs' harms are serious, the district court should not have erroneously granted standing to the plaintiffs and misapplied the "markedly different characteristics" test to address the harms resulting from Myriad's monopolistic exercise of its BRCA patent rights. As a practical matter, granting standing to third-party consumers to sue for harms resulting from the commercialization of medical technologies would also invite many more parties to sue patent holders and the USPTO for exercising their patent rights. Moreover, in light of the fact that invalidating gene patents might not solve many of the patients' harms, a legislative exception seems to be a more effective and practical solution. Rather than invalidating gene patents under the common law, Congress should adopt a legislative limitation or compulsory license to remedy the harms patenting human genes can cause.

239. Patentgesetz [Patent Act], Dec. 16, 1980, BGBL. I at 1, last amended by Gesetz [G], July 31, 2009, BGBL. I at 2521, §§ 1a, 5 (Ger.); Patents Act, (1977) § 4A, 19(2A) HALS. STAT. (4th ed.) 380 (U.K.).

240. See TRIPS, *supra* note 237, at 209.

241. Loi sur les brevets d'invention [Patents Act] of Mar. 28, 1984, MONITEUR BELGE [M.B.] [OFFICIAL GAZETTE OF BELGIUM] as amended on Apr. 28, 2005, <http://www.staatsblad.be>; Loi 2004-800 du 6 août 2004 relative à la bioéthique (1), [Law 2004-800 of Aug. 4, 2004 on Relating to Bioethics], 182 JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] [OFFICIAL GAZETTE OF FRANCE], Aug. 6, 2004, p. 14040.
