



1-1-2012

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Recommended Citation

Johanna Jacob, *Should Our Genes Be Part of the Patent Bargain?: Maximizing Access to Medical Diagnostic Advances While Ensuring Research Remains Profitable*, 28 SANTA CLARA HIGH TECH. L.J. 403 (2012).

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SHOULD OUR GENES BE PART OF THE PATENT BARGAIN? MAXIMIZING ACCESS TO MEDICAL DIAGNOSTIC ADVANCES WHILE ENSURING RESEARCH REMAINS PROFITABLE

Johanna Jacob[†]

I. INTRODUCTION

The purpose of the United States patent system is “[t]o promote the Progress of Science and useful Arts.”¹ Currently, there is a heated emotional debate about whether patents directed to genetic sequences promote or hinder the progress of science, a debate which may soon find its way to the United States Supreme Court.² Unfortunately, the debate is too often characterized in terms of policy concerns. In *Association for Molecular Pathology v. United States Patent and Trademark Office*, Judge Sweet broke with three decades of United States Patent and Trademark Office (USPTO) precedent,³ declaring the method and system claims to the genetic sequences of BRCA1

[†] Johanna Jacob, Santa Clara Law Student, J.D. Expected May 2012. This comment was selected as the winner of the 2010-2011 Santa Clara Computer & High Technology Law Journal Comment Competition.

^{††} As this issue went to press, the Supreme Court released its opinion in the *Mayo v. Prometheus* case. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, No. 10-1150, slip op. (U.S. Mar. 20, 2012), available at <http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf>. Shortly after, in the *Molecular Pathology v. Myriad Genetics* case the Supreme Court granted the petition for certiorari, vacated the Federal Circuit judgment, and remanded for reconsideration in light of the *Prometheus* decision. Cert. Summ. Dispositions at 2, *Ass’n for Molecular Pathology v. Myriad Genetics*, No. 11-725 (U.S. Mar. 26, 2012) (previously entitled *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*).

1. U.S. CONST. art. I, § 8, cl. 8.

2. See *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010), *aff’d in part, rev’d in part*, 653 F.3d 1329 (Fed. Cir. 2011); see also *Liberate the Breast Cancer Genes*, AM. CIVIL LIBERTIES UNION (Mar. 29, 2010), http://www.aclu.org/free-speech_womens-rights/liberate-breast-cancer-genes (varying opinions on the patentability of genetic sequences).

3. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1367 (Fed. Cir. 2011) (Moore, J., concurring) (“Even before the current guidelines formalized the Patent Office’s position, however, it granted patents to human genes in the early 1980s, and subsequently issued thousands of patents on ‘isolated DNA.’”).

and BRCA2 ineligible for patents.⁴ Judge Sweet created a blanket exception to 35 U.S.C. §101 by characterizing genes under the “law of nature” exception to patentability.⁵ Myriad Genetics Inc. (Myriad) appealed, and the Federal Circuit Court of Appeals ruled on July 29, 2011.⁶ The Federal Circuit reversed Judge Sweet’s ruling by upholding claims directed to isolated genetic sequences as subject matter eligible for patenting under 35 U.S.C. §101.⁷ However, the Federal Circuit invalidated diagnostic method claims that merely compared a genetic sequence to an individual’s native genetic sequence as an abstract mental process.⁸ Both parties filed a petition for rehearing in the Federal Circuit.⁹

The real issue in *Association for Molecular Pathology* is patient access to health care, which should not be achieved through a judicially-created exception to the statutory definition of patent eligible subject matter. While the Federal Circuit focuses on the science, the underlying issues largely guide their interpretation. It is unlikely that agreement on the science and how it applies to patent eligible subject matter will ever be achieved. Judge Moore, in his concurring opinion, rightly states that it is the *policy* that tips the scales towards patentability.¹⁰

Weakening biotechnology patent law by declaring claims to genetic sequences patent ineligible, as products of nature under 35 U.S.C. §101, would negatively impact patient access to biotechnology advances by decreasing the incentive of investors to enter the market more than it could possibly help promote patient access to BRCA1

4. *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 185.

5. *Id.* at 237 (“As determined above, the patents issued by the USPTO are directed to a law of nature and were therefore improperly granted.”).

6. *Ass’n for Molecular Pathology*, 653 F.3d at 1329.

7. *Id.* at 1334.

8. *Id.* at 1334.

9. Plaintiffs-Appellees’ Petition for Panel Rehearing, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2011 WL 5057016; Defendants-Appellants’ Petition for Panel Rehearing, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2011 WL 5057015.

10. *Ass’n for Molecular Pathology*, 653 F.3d at 1367 (Moore, J., concurring) (“I believe we must be particularly wary of expanding the judicial exception to patentable subject matter where both settled expectations and extensive property rights are involved. Combined with my belief that we should defer to Congress, these settled expectations tip the scale in favor of patentability.”).

and BRCA2 diagnostic technologies. Patient access to second opinions, affordable diagnostic technologies, patient counseling, comprehensive genetic testing, and insurance coverage are not aspects of patent law, and are best addressed through meaningful health care reform.

II. BACKGROUND

A. 35 U.S.C. §101 Patentable Subject Matter

Patentable subject matter, the threshold test for patentability, is defined as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”¹¹ The statute on patentable subject matter, 35 U.S.C. §101, is given broad meaning through the use of the word “any” in describing the type of new and useful processes that are patentable, the legislative history surrounding its enactment, and the interpretation that “anything under the sun that is made by man” is patentable.¹² The proper forum for excluding a specific subject matter from the patent bargain lies with Congress in the legislative body and not the judiciary.¹³

However, courts recognize some subject matter as ineligible for patentability under 35 U.S.C. §101. Exceptions to patentable subject matter include laws of nature, physical phenomena, and abstract ideas.¹⁴ Products of nature should be “free to all men and reserved exclusively to none.”¹⁵ Laws of nature, physical phenomena, and abstract ideas are recognized as a type of scientific discovery, rather than a novel invention. This promotes the policy that a discovery is left to the public domain while an invention benefits from intellectual

11. 35 U.S.C. § 101 (2006).

12. 35 U.S.C. § 101 (2006); *Diamond v. Chakrabarty*, 447 U.S. 303, 307-309 (1980).

13. *See Chakrabarty*, 447 U.S. at 318.

Our task, rather, is a narrow one of determining what Congress meant by the words it used in the statute; once that is done our powers are exhausted. Congress is free to amend §101 so as to exclude from patent protection organisms produced by genetic engineering. . . . But, until Congress takes such action, this Court must construe the language of §101 as it is.

Id.

14. *Id.* at 309.

15. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

property rights.¹⁶

The line between scientific discovery and invention blurs when patent law and biotechnology intersect. In 1948, the Supreme Court held a combination fertilizer with several different naturally occurring bacteria unpatentable, because a natural material, even if combined in a novel fashion, will still be ineligible for patentability if the functionality of the material would occur naturally.¹⁷ Later, in *Chakrabarty*, the Supreme Court held that a genetically modified bacterium engineered to break down crude oil is a “non[-]naturally occurring manufacture or composition of matter” and therefore patentable.¹⁸ The test articulated in *Chakrabarty* was whether the non-naturally occurring composition of matter was a product of human ingenuity with “distinctive name, character and use.”¹⁹ Therefore a composition of matter must be: (1) non-naturally occurring; (2) product of ingenuity; with (3) distinctive name, character and use.²⁰ In finding that the bacteria met that standard of law, the court remarked that the patentee had produced a new bacterium with “markedly different characteristics” from the product as it occurred in nature, with the potential for significant utility.²¹ After *Chakrabarty*, patents on genetic sequences were held to be patentable and over 4,000 patents on genes were issued.²²

The Supreme Court addressed the patentability of an isolated substance in *The American Wood-Paper Co v. Fibre Disintegrating Co.*²³ The Court held purified cellulose is a mere “extract” and is not a new manufacture subject to patentability.²⁴ In contrast, the patentability of a purified naturally-occurring biological compound was addressed by a district court in New York in 1912.²⁵ Judge

16. See *Parker v. Flook*, 437 U.S. 584, 593 (1978).

17. *Funk Bros.*, 333 U.S. at 131.

18. *Chakrabarty*, 447 U.S. at 309-10.

19. *Id.* at 309-10.

20. *Id.*

21. *Id.* at 310.

22. Denise Caruso, *A Challenge to Gene Theory, a Tougher Look at Biotech*, N.Y. TIMES (July 1, 2007),

<https://www.nytimes.com/2007/07/01/business/yourmoney/01frame.html?pagewanted=all>.

23. *Am. Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. (23 Wall.) 566, 593-94 (1874).

24. *Id.* at 594.

25. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912).

Learned Hand found isolated purified adrenaline to be patentable.²⁶ A purified base form of a component was found to be a new thing, both therapeutically and chemically, because it functioned differently in its purified form than it did in nature.²⁷ Currently, courts follow Judge Hand's 1912 ruling in *Parke-Davis* for guidance on the patentability of isolated, naturally-occurring biological substances.²⁸

B. What Are Genes?

"Genes are the 'basic units of heredity' that enable organisms to transmit to future generations the blueprint for all proteins."²⁹ Genes contain the hidden plans and design for development of an organism.³⁰ Deoxyribonucleic acid (DNA) is the carrier of genetic information, and it is a long unbranched polymer composed of four bases: adenine, cytosine, guanine, and thymine.³¹ The bases are attached to a repetitive sugar phosphate chain through chemical bonds, like beads strung to a necklace.³² DNA normally exists as a two-strand "double helix."³³ Each base is bound to its complementary base pair, A-T and G-C. Therefore, when the double helix splits, each strand of the double helix can create its own copy of the original double helix.³⁴ The linear order of the nucleotide bases (A, T, G and C) is referred to as the genetic sequence.³⁵ The human genetic sequence would fill a book of more than 500,000 pages written in the four-letter genetic alphabet.³⁶

The sections of the DNA strand that encode to form proteins or functional molecules are known as genes; not every part of the DNA

26. *Id.*

27. *Id.*

28. Lisa Larrimore Ouellette, Note, *Access to Bio-Knowledge: From Gene Patents to Biomedical Materials*, 2010 STAN. TECH. L. REV. ¶ 13 (2010).

29. Brief for the United States as Amicus Curiae Supporting Neither Party, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2010 WL 4853320.

30. BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 98 (3d ed. 1994).

31. *Id.*

32. *Id.* at 98-99.

33. *See id.* at 99.

34. *Id.* at 102.

35. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1336 (Fed. Cir. 2011).

36. BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 102 (3d ed. 1994).

strand codes for a gene.³⁷ The human genome contains approximately 3 billion base pairs, and almost every cell in the human body contains a complete genome.³⁸ Human DNA is arranged into 24 distinct chromosomes, which are physically separate molecules ranging in length from 50-250 million base pairs, with each chromosome containing many genes.³⁹ There are approximately 20,000-25,000 genes, which together contain the physical and functional traits that form a human being.⁴⁰

Ribonucleic Acid (RNA) is like DNA, in that it is a chain of linked nucleotides.⁴¹ However, the RNA molecule is single stranded, composed of the sugar ribose instead of deoxyribose, and consists of the nucleotides adenine, guanine, uracil (which replaces the thymine found in DNA) and cytosine.⁴² Messenger RNA (mRNA) is a type of RNA that transfers the information about DNA's amino acid sequence to the protein synthesis process.⁴³ Complementary DNA (cDNA) is a molecule generated from mRNA through "reverse transcription."⁴⁴ Each base in the cDNA is complementary to the corresponding base in the mRNA it is generated from; and therefore, it contains the same informational content as the original DNA molecule. cDNA is typically generated in a laboratory.⁴⁵ Unlike DNA, cDNA does not contain the non-coding sequences because they

37. BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 104 (3d ed. 1994).

The synthesis of proteins involves copying specific regions of DNA (the *genes*) into polynucleotides of a chemically and functionally different type known as ribonucleic acid, or RNA. . . . Molecules of RNA are synthesized by a process known as DNA transcription, which is similar to DNA replication in that one of the two strands of DNA acts as a template on which the base-pairing abilities of incoming nucleotides are tested.

Id.

38. The Human Genome Project, *The Science Behind the Human Genome Project: Basic Genetics, Genome Draft Sequence, and Post-Genome Science*, OAK RIDGE NAT'L LAB., http://www.ornl.gov/sci/techresources/Human_Genome/project/info.shtml (last modified Mar. 26, 2008).

39. *Id.*

40. *Id.*

41. *RNA Transcription*, NOBEL FOUNDATION, http://www.nobelprize.org/educational/medicine/dna/b/transcription/rna_strand.html (last visited Feb. 28, 2012).

42. *Id.*

43. *Id.*

44. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 198 (S.D.N.Y. 2010).

45. *Id.*

were removed in the creation of the mRNA.⁴⁶

“Isolated DNA” is the result of a laboratory process where the DNA molecule is excised from the genome and separated from its cellular environment.⁴⁷ Courts typically hold that products of nature are different from products that have been altered or enhanced through processes of extraction, concentration, and purification of natural materials.⁴⁸ Isolation is a form of extraction, which may cause genetic sequence patents to cross the line from patent ineligible to patentable.⁴⁹

Although isolation usually tips the scale towards patentability, DNA sequencing methods are rapid and reliable.⁵⁰ DNA has become the easiest macromolecule of the cell to analyze.⁵¹ It is currently possible to excise a specific region of DNA, produce a virtually unlimited amount of copies, and to determine the sequence of the nucleotides at a rate of hundreds of nucleotides a day.⁵² In order to sequence a gene, a chromosome is first broken into much shorter segments through subcloning.⁵³ Templates are generated by creating fragments that differ in length by a single base, and these fragments are then separated by gel electrophoresis.⁵⁴ The final base at the end of each fragment is identified, recreating the 4 letter genetic alphabet base by base.⁵⁵ As scientists’ knowledge of this process and capabilities rapidly evolved, patent applications on human genes were

46. *Id.*

47. Brief for the United States as Amicus Curiae Supporting Neither Party at 3, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2010) (No. 2010-1406), 2010 WL 4853320, at *3.

48. *See id.* at 35-36.

49. *See id.*

50. BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 291 (3d ed. 1994).

From being the most difficult macromolecule of the cell to analyze, DNA has become the easiest. It is now possible to excise a specific region of DNA, to produce a virtually unlimited number of copies of it, and to determine the sequence of its nucleotides at a rate of hundreds of nucleotides a day.

Id.

51. *Id.*

52. *Id.*

53. The Human Genome Project, *The Science Behind the Human Genome Project: Basic Genetics, Genome Draft Sequence, and Post-Genome Science*, OAK RIDGE NAT’L LAB., http://www.ornl.gov/sci/techresources/Human_Genome/project/info.shtml (last modified Mar. 26, 2008).

54. *Id.*

55. *Id.*

filed in increasing numbers.⁵⁶

III. ASSOCIATION FOR MOLECULAR PATHOLOGY V. U.S. PATENT AND TRADEMARK OFFICE: THE CONTROVERSY AND UNDERLYING ISSUES

Myriad's patents are controversial for several reasons. First, Myriad's patents deal with breast cancer—a widespread disease that crosses all racial and socioeconomic groups.⁵⁷ Second, Myriad's business plan relies on stringent enforcement of their patent rights, leaving them the sole provider of an important diagnostic test.⁵⁸ Myriad's business practices also caused issues relating to patient access, treatment, and counseling.⁵⁹ Third, negative publicity through advocacy groups framed the debate as patenting human blueprints.⁶⁰ The ACLU made a tactical decision to attack patentability, rather than frame this issue in terms of patient health care reform, which would have addressed patient concerns without implicating long standing patent law policies.⁶¹

A. *BRCA1 and BRCA2 Are Important Tools in the Diagnosis of Breast Cancer and Ovarian Cancer*

Breast cancer is the second most common cancer among women in the United States,⁶² with approximately one in eight U.S. women developing breast cancer over her lifetime.⁶³ Breast cancer is one of the leading causes of cancer death among women of all races and

56. Jon F. Merz & Mildred K. Cho, *What Are Gene Patents and Why Are People Worried About Them?*, 8 CMTY. GENETICS 203, 204 (Oct. 2005).

57. See *Breast Cancer Statistics*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 23, 2010), <http://www.cdc.gov/cancer/breast/statistics/>.

58. See E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS IN MED. S39, S41-43 (2010).

59. See *id.* at S45-48; see also Complaint at 2, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 1:09-cv-04515-RWS), 2009 WL 1343027.

60. See, e.g., Michael Crichton, Op-Ed., *Patenting Life*, N.Y. TIMES, Feb. 13, 2007, at A23, available at <http://www.nytimes.com/2007/02/13/opinion/13crichton.html>; *Liberate the Breach Cancer Genes*, *supra* note 2.

61. See Complaint, *supra* note 59, at 3.

62. *Breast Cancer Statistics*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Nov. 23, 2010), <http://www.cdc.gov/cancer/breast/statistics/>.

63. See *Cancer Among Women*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Feb. 10, 2011), <http://www.cdc.gov/cancer/dcpc/data/women.htm>.

populations in the U.S.⁶⁴ Per year approximately 202,964 women are diagnosed with breast cancer and 40,598 women die from it.⁶⁵ Ovarian cancer is the fifth most common cancer among females in the U.S. and it is the leading cause of death among reproductive cancers.⁶⁶

BRCA1 and BRCA2 are important diagnostic tools in the treatment of breast cancer and ovarian cancer.⁶⁷ Estimates place breast cancer occurrence in a BRCA1 or BRCA2 mutation carrier between 3% and 10%.⁶⁸ Women with BRCA1 and BRCA2 mutations face up to an 85% increased risk of developing breast cancer, and up to 50% increased risk of developing ovarian cancer.⁶⁹ Therefore, BRCA1 and BRCA2 diagnostics are important tools in prophylactic treatment for women with dominantly transmitted BRCA1 and BRCA2 mutations.⁷⁰ The pervasiveness of breast cancer and ovarian cancer in the lives of many Americans sets the emotional back-drop for the debate over control of diagnostic technologies surrounding the treatment of these diseases.

B. *Myriad's Business Practices*

Nearly all of the patented genetic sequences relate to genes associated with human health, including genes relating to diabetes, obesity, and cancer.⁷¹ The holders of these patents, under U.S. patent law, are not required to grant licenses on their patent; however, the majority of these patent holders willingly issue licenses to diagnostic

64. *Breast Cancer Statistics*, *supra* note 62.

65. *Id.*

66. *Ovarian Cancer*, PUBMED HEALTH (Dec. 28, 2010), <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001891/>.

67. *See e.g., id.; BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NAT'L CANCER INST. (May 29, 2009), <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA>.

68. Gold & Carbone, *supra* note 58, at S39.

Of all cases of breast cancer, the estimates of affected women who are carriers of a mutated allele dominantly transmitted and associated with a high risk of breast cancer ranges between 5% and 10%. Estimates of breast cancer cases occurring in BRCA1 or BRCA2 mutation carriers vary from between 3% and 10%.

Id.

69. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 203 (S.D.N.Y. 2010).

70. *See* Gold & Carbone, *supra* note 58, at S39.

71. Olga Bogard, Comment, *Patenting the Human Body: The Constitutionality of Gene Patents and Suggested Remedies for Reform*, 63 SMU L. REV. 1319, 1326 (2010).

laboratories.⁷² The willing grant of these licenses to diagnostic labs results in greater access to diagnostic testing, second opinions, price reductions, and acceptance of insurance providers.⁷³ Myriad, however, chose an “unprecedented [path] in the field of genetic testing,” by exercising their legal right to exclude others from using their invention on the diagnostic tests relating to a predisposition of breast cancer and ovarian cancer in women.⁷⁴

Marc Skolnick headed Myriad’s “unprecedented path” into the successful commercialization of genetic testing. This path began at the University of Utah’s Center for Genetic Epidemiology, where Marc Skolnick led a team of researchers who were working to identify the genetic sequence of BRCA1.⁷⁵ Skolnick’s work relied on an extensive database of Mormon families (200,000), which he cross-referenced with a Utah cancer registry that provided him with 40,000 cross-linked entries that “spurred much of Myriad’s future research”.⁷⁶

In 1990, Dr. Skolnick concluded additional resources were needed in order to remain competitive with another team of researchers who had received a substantial grant from the National Institute of Health (NIH).⁷⁷ In 1991, Dr. Skolnick founded Myriad through a local venture capital group, with the goal of raising the necessary funding to complete his research.⁷⁸ Myriad received significant funding from Eli Lilly and Co.; at least \$1 million in equity and another \$1.8 million over three years, the former part of a \$10 million private stock offering.⁷⁹ Additionally, the NIH contributed \$5 million to the University of Utah research team.⁸⁰ One analysis suggested that the NIH contributed one-third of the funding for the identification of BRCA1.⁸¹

Myriad’s business model focused on being the leading

72. *Id.*

73. *Id.*

74. *Id.* at 1327.

75. Gold & Carbone, *supra* note 58, at S41.

76. *Id.*

77. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 201 (S.D.N.Y. 2010).

78. *Id.*; Gold & Carbone, *supra* note 58, at S41.

79. Gold & Carbone, *supra* note 58, at S44.

80. *Id.*

81. *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 202.

biopharmaceutical diagnostic company.⁸² Myriad planned to build a strong and successful relationship with providers, laboratories and insurers as the go to genetic diagnostic tester.⁸³ They wanted to be considered a leading market player to be used for future discovered genetic testing.⁸⁴ Myriad's goal was to quickly and effectively integrate the diagnostic tests into the market, since they were not subject to FDA clinical trials, in order to generate funds for further drug discovery.⁸⁵ Although Myriad's business model may have differed from other companies in the health care sector, it was fully supported by rights granted under patent law.

Myriad marketed several different diagnostic tests.⁸⁶ The comprehensive test, which provided the full sequence of both BRCA1 and BRCA2 genes, initially cost \$2400.⁸⁷ "Myriad only offered [their] testing services through physicians."⁸⁸ Myriad relied on genetic counselors to screen potential test subjects; however, there were not enough genetic counselors to satisfy market demand and Myriad ended up having to train and sponsor physicians.⁸⁹ Myriad did not require genetic counseling once the patient received the results, although the hospital was responsible for signing an informed consent.⁹⁰

Myriad sent cease and desist letters to other laboratories that were performing BRCA1 and BRCA2 diagnostic sequencing.⁹¹ The letters specified that the cease and desist notification did not apply to research testing for non-commercial research programs where the results were not provided to the patient and where no money was received in consideration for the test.⁹² Despite Myriad's business plan, Myriad has yet to make a profit from its diagnostic business.⁹³

82. Gold & Carbone, *supra* note 58, at S42.

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.*

89. *Id.*

90. *Id.*

91. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 187 (S.D.N.Y. 2010).

92. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1340 (Fed. Cir. 2011).

93. Gold & Carbone, *supra* note 58, at S47.

C. *Both the Negative Publicity Surrounding the Patentability of Genes and the ACLU's Complaint, Focused on Patient's Access to Diagnostic Tests and Treatments*

Publicity fueled the public debate, which characterized Myriad as owning a patent on a piece of the human body.⁹⁴ Myriad's patents sparked significant newspaper coverage, and the majority of articles (77.6%) were negative.⁹⁵ In contrast, only 6.9% were positive and only around 50% of the news coverage showed more than one perspective.⁹⁶ "The story was primarily framed as a social dilemma"⁹⁷, as evidenced by the ACLU's many published articles and videos.⁹⁸ The ACLU publications included "Tell Congress: My Genes Aren't For Sale" and "Liberate the Breast Cancer Genes."⁹⁹ The ACLU and other patient advocacy organizations focused on the inability of patients to receive second opinions, access the test, and the misinformation in the process.¹⁰⁰ Even science-fiction author Michael Crichton in a New York Times opinion piece warned, "You, or someone you love, may die because of a gene patent that should never have been granted in the first place."¹⁰¹

With so many conflicting interests intersecting, the plaintiffs that filed the complaint in the Southern District of New York were varied and each asserted their own reasons for standing.¹⁰² The plaintiffs can be categorized into four groups: national organizations, doctors, patient support and advocacy groups, and individual patients.¹⁰³

94. See, e.g., Elizabeth Landau, *How Human Genes Become Patented*, CNN (May 13, 2009), http://articles.cnn.com/2009-05-13/health/genes.patent.myriad_1_human-genes-brca1-trademark-office?s=PM:HEALTH.

95. Timothy Caulfield et al., *Myriad and the mass media: the covering of a gene patent controversy*, 9 GENETICS IN MED. 850, 852 (2007).

96. *Id.*

97. *Id.* at 853.

98. See Search Results for Myriad, AM. CIVIL LIBERTIES UNION, <http://www.aclu.org/search/Myriad?type=blog> (last visited Sept. 15, 2011).

99. Sandra Fulton, *Tell Congress: My Genes Aren't for Sale*, AM. CIVIL LIBERTIES UNION (Apr. 27, 2010, 4:37 PM), <http://www.aclu.org/blog/free-speech-womens-rights/tell-congress-my-genes-arent-sale/>; Joel Engardio, *Liberate the Breast Cancer Genes*, AM. CIVIL LIBERTIES UNION (May 13, 2009, 8:26 AM), <http://www.aclu.org/2009/05/13/liberate-the-breast-cancer-genes/>.

100. See Complaint, *supra* note 59, at 2.

101. Crichton, *supra* note 60.

102. See Complaint, *supra* note 59, at 4-13.

103. See *id.*

National organizations asserted that they represented members, some of whom are “ready, willing, and able to engage in research and clinical practice involving the BRCA1 and BRCA2 genes if the patents were invalidated.”¹⁰⁴ Individual doctors asserted that they were “ready, willing, and able” to engage in testing or utilize alternative testing facilities if the patents were invalidated.¹⁰⁵ Patient advocacy groups maintained they would benefit from increased research and members would benefit from information provided from multiple laboratory testing.¹⁰⁶ Individual female patients complained of the following issues: Myriad’s denial of MassHealth care coverage;¹⁰⁷ increased research into genetic variants of unknown significance¹⁰⁸; availability of a second opinion which would help make significant medical decisions; and a need for greater medical insurance acceptance and affordability.¹⁰⁹

IV. THE CLAIMS AT ISSUE IN *ASSOCIATION FOR MOLECULAR PATHOLOGY V. U.S. PATENT AND TRADEMARK OFFICE*

There are several types of patent claims on genes. The claims at issue in *Myriad* included: composition of matter, diagnostic, and functional uses.¹¹⁰

A. *Composition of Matter*

Compositions of matter claims to genetic sequences include the isolated and purified genetic sequence and all derivative products.¹¹¹ This type of claim can include the genetic sequence, the virus or vector containing the claimed sequence, transfected cell lines, and the

104. *Id.* at 4-5.

105. *Id.* at 9-10.

106. *Id.*

107. *Id.* at 10. Masshealth is Massachusetts’s public health insurance program for low and medium-income residents. See Massachusetts Health Care Program, MASSRESOURCES.ORG, <http://www.massresources.org/masshealth.html> (last visited Feb. 28, 2012).

108. There are many variants of the BRCA1/BRCA2 beyond those, which the Myriad diagnostic test covered. Some variants of the BRCA1/BRCA2 are still of unknown significance. For example, Plaintiff Runi Limary received the result “genetic variant of uncertain significance”. She sought the invalidation of Myriad’s patents in order to access additional resources for testing and research in order to reveal the significance of her variant gene and its correlation with cancer. Complaint, *supra* note 59, at 11.

109. Complaint, *supra* note 59, at 11.

110. Merz & Cho, *supra* note 56, at 204.

111. *Id.* at 205.

proteins or other therapeutic products associated with the gene.¹¹²

The following claims in Patent 5,747,282 ('282) are illustrative of the composition of matter claims at issue:

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO: 2.
2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1 . . .
5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.
6. An isolated DNA having at least 15 nucleotides of the DNA of claim 2.¹¹³

There are three types of isolated DNA molecules claimed: (1) isolated sequences identical to naturally occurring genetic sequences which encompass both the full length gene sequence (Claim 1, '282); (2) shorter isolated DNA strains with as few as fifteen nucleotides found on the chromosome (Claim 5, '282); and (3) cDNA molecules which differ from the natural gene sequence because the non-coding sequences are removed and the nucleotide sequence is the complementary sequence of the naturally occurring RNA (equivalent to mRNA) (Claim 2, '282).¹¹⁴

B. Diagnostic Method Claims

Diagnostic gene patents characterize an individual's genetic makeup at a disease-associated location of the individual's DNA, and these types of patents cover all known methods of testing for genetic differences.¹¹⁵ A single gene may have multiple patent applications claiming different diagnostics of mutations or differences in the

112. *Id.* at 206.

113. U.S. Patent No. 5,747,282 (filed June 7, 1995).

114. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1364 (Fed. Cir. 2011) (Moore, J., concurring).

115. Merz & Cho, *supra* note 56, at 204.

sequence.¹¹⁶ Some diseases are caused by mutations in multiple genes, therefore creating issues if different companies hold patents on different diagnostic genetic sequences.¹¹⁷ Additionally, patents can issue on the same type of diagnostic genetic test, if the same mutation is responsible for different types of genetic disorders.¹¹⁸ These types of diagnostic disease patents can monopolize a diagnostic test, since the patents typically claim all methods of testing for a specific gene.¹¹⁹

Claim 1 in Patent 5,709,999 ('999), which looks for mutations in natural human genes, is illustrative of the diagnostic claims at issue:

1. A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.¹²⁰

C. *Functional Use Method Claims*

Claims to the functional use of a gene are based on the discovery of the role genes play in a certain disease or cellular function.¹²¹ Claim 20 in Patent '282 is the sole functional use claim at issue:

20. A method for screening potential cancer therapeutics which comprises: growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, growing said transformed eukaryotic host cell in the absence of said compound, determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.¹²²

116. *Id.*

117. *Id.* at 204-205.

118. *Id.* at 205.

119. *Id.* at 204.

120. U.S. Patent No. 5,709, 999 (filed Nov. 21, 1991).

121. *See Merz & Cho, supra* note 56, at 206.

122. U.S. Patent No. 5,747,282 (filed June 7, 1995).

V. JUDGE SWEET'S RULING IN THE S.D.N.Y.

The Association for Molecular Pathology moved for summary judgment to declare fifteen claims out of seven different patents issued to Myriad Genetics invalid.¹²³ In *Association for Molecular Pathology*, molecular biotechnology and patent law collided, presenting the question of whether or not isolated human genomic sequences and their complementary sequences were patentable.¹²⁴ The ruling shocked the patent community, because Judge Sweet ruled against the thousands of patents on genes that the USPTO had issued over three decades, invalidating both compositions of matter and method claims as patent ineligible products of nature under 35 U.S.C. §101.¹²⁵

In concluding that “DNA represents the physical embodiment of biological information,” Judge Sweet’s decision emphasized the similarity between isolated genes and native DNA as a carrier of information.¹²⁶ As carriers of information, DNA has unique characteristics from chemical compounds.¹²⁷ Chemical compounds only transmit the information that relates to their own production, while DNA transmits not only its chemical information, but the genetics that form a unique human being.¹²⁸ Based on this reasoning, genes were held to be products of nature differentiable from other chemical compounds and therefore unpatentable.¹²⁹

Judge Sweet invalidated the diagnostic method claims because they did not specify any other action beyond “analyzing” or “comparing” two gene sequences to determine if differences existed.¹³⁰ Judge Sweet characterized this comparison or analysis of two different sequences as an unpatentable mental process.¹³¹ Judge Sweet also invalidated the singular functional method claim because

123. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 184 (S.D.N.Y. 2010).

124. *Id.* at 185, 198-99.

125. *See id.* at 238.

126. *Id.* at 228.

127. *Id.*

128. *Id.*

129. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 228-29 (S.D.N.Y. 2010).

130. *Id.* at 233-37.

131. *Id.* at 234.

it improperly attempted to patent a basic scientific principle.¹³²

VI. COURT OF APPEALS DECISION

On July 29, 2011, the Federal Circuit issued its ruling, with all three judges writing separately.¹³³

A. *Standing*

Although the district court found broad standing among all the plaintiffs, the Federal Circuit spent significant time in finding that only one plaintiff, Dr. Ostrer, had the necessary standing to maintain declaratory judgment in the suit.¹³⁴ Dr. Ostrer had standing based on the totality of the circumstances: he received a letter from Myriad proposing a collaborative license requiring N.Y.U. to make payments to Myriad for each non-research test performed; he was aware that Myriad was asserting its patent rights against similarly situated parties; and as a result of litigation he was forced to send all patient samples to Myriad.¹³⁵ In addition, Dr. Ostrer maintained he could have proceeded with testing without taking a license due to his belief that the patents are invalid, he intended to undertake BRCA1 testing, and stated unequivocally that he would immediately begin such testing if the patents were ruled invalid.¹³⁶ Furthermore, “Myriad’s challenged composition and method claims undisputedly provide[d] ‘an absolute barrier’ to Dr. Ostrer’s ability to undertake *BRCA* diagnostic testing activities, and a declaration of those claims’ invalidity would remove that barrier.”¹³⁷ The other plaintiffs—patients, advocacy groups, national organizations, and medical organizations—failed to articulate an adverse legal controversy.¹³⁸ Judge Lourie held that “[s]imply disagreeing with the existence of a patent or even suffering an attenuated, non-proximate, effect from the existence of a patent” is not enough to establish standing for

132. *Id.* at 237 (“The recited transformative steps . . . represent nothing more than preparatory, data-gathering steps to obtain growth rate information and not render the claimed mental process patentable under §101.”).

133. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1333 (Fed. Cir. 2011).

134. *Id.* at 1344.

135. *Id.* at 1345.

136. *Id.* at 1345-46.

137. *Id.* at 1348.

138. *Id.*

declaratory judgment.¹³⁹

B. Method Claims

The district court's decision predated *Bilski*'s rejection of the machine-or-transformation test as the exclusive test for determining a patent eligible process.¹⁴⁰ In light of *Bilski*, Judge Lourie determined all the diagnostic method claims were directed to patent-ineligible abstract mental processes and therefore fail the machine-or-transformation test.¹⁴¹

Myriad's diagnostic method claims that "compare" or "analyze" two gene sequences fell outside the scope of §101.¹⁴² The claims recite "nothing more than the abstract mental steps necessary to compare two different nucleotide sequences."¹⁴³ Myriad's claims did not include a step where the BRCA gene sequence must first be "determined."¹⁴⁴ In contrast, Myriad's method claims to potential cancer therapeutics were determined to be a patent-eligible process because they included the step of "determining" the cells' growth rates, which necessarily involves physical manipulation of the cells and are central to the purpose of the claim.¹⁴⁵

C. Composition of Matter Claims: Isolated DNA Molecules

Judge Lourie summarized the debate over the patentability of isolated DNA molecules as a disagreement "on whether and to what degree such molecules fall within the exception for products of nature."¹⁴⁶ The disagreement on whether and what degree such molecules qualify as an exception to patentable subject matter permeated all three different Federal Circuit judicial opinions as well.¹⁴⁷

139. *Id.*

140. *Id.* at 1355.

141. *Id.*

142. *Id.*

143. *Id.* at 1356.

144. *Id.* at 1357.

145. *Id.*

146. *Id.* at 1350.

147. *See generally id.*

1. Majority Opinion, Judge Lourie

Judge Lourie, in applying the *Chakrabarty-Funk Brothers* “markedly different” framework, held that isolated DNA molecules are markedly different due to their distinctive chemical identity and nature from molecules that exist in nature.¹⁴⁸ Judge Lourie stressed that chemical covalent bonds must be broken in order to form an isolated DNA segment and that isolated DNA segments can be independently synthesized.¹⁴⁹ Judge Lourie distinguished isolated DNA molecules from purification, describing purification as a process resulting in an identical molecule in pure form.¹⁵⁰ Judge Lourie suggested DNA is not purified in its isolated form, because isolated genetic sequences do not exist within a physical mixture from which it can be purified—they must be chemically cleaved from their chemical composition with other genetic material.¹⁵¹

Judge Lourie also indicated that Judge Sweet wrongly determined patentability based on DNA’s genetic function—transformation of information—rather than what it is: a distinct chemical entity.¹⁵² The majority opinion emphasized deference to the legislature and long-standing USPTO practice.¹⁵³ Judge Lourie noted that the Supreme Court has “more than once cautioned that courts ‘should not read into the patent laws limitations and conditions which

148. *Id.* at 1351.

Native DNA exists in the body as one of forty-six large, contiguous DNA molecules. Each DNA molecule is itself an integral part of a larger structural complex, a chromosome. In each chromosome the DNA molecule is packaged around histone proteins into a structure called chromatin, which in turn is packaged into the chromosomal structure. Isolated DNA, in contrast, is a free standing portion of a native DNA molecule, frequently a single gene. Isolated DNA has been cleaved (*i.e.*, had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule.

Id.

149. *Id.* at 1352-1353.

150. *Id.* at 1352.

151. *Id.*

152. *Id.* at 1353 (“Uses of chemical substances may be relevant to the non-obviousness of these substances or to method claims embodying those uses but the patent eligibility of an isolated DNA is not negated because it has similar informational properties to a different more complex natural material that embodies it.”).

153. *Id.* at 1354-55 (Because of the thousands of genetic patents and longstanding USPTO practice of granting these type of patents, Judge Lourie noted that a categorical exclusion to patentable subject matter should come from Congress and not the Judiciary).

the legislature has not expressed.”¹⁵⁴

2. Concurring Opinion, Judge Moore

In his concurring opinion, Judge Moore emphasized that he did not believe that the different chemical structure emphasized by Judge Lourie rendered the isolated DNA *per se* patentable.¹⁵⁵ Judge Moore also suggested that an isolated genetic sequence is not *per se* unpatentable as a law of nature, as Judge Sweet held, given the chemical differences highlighted by Judge Lourie.¹⁵⁶ Judge Moore framed the issue as whether the chemical differences in the isolated genetic sequences impart a new utility, which makes the molecule markedly different than they occur in nature.¹⁵⁷

Judge Moore easily found claims to shorter isolated genetic molecules patentable, because they can be used as primers in diagnostic screening processes to detect gene mutations, or as probes with isolated radiolabeled sequences mirroring those on the chromosome.¹⁵⁸ In contrast, naturally occurring DNA cannot be used to accomplish either of these two functions.¹⁵⁹ Judge Moore found longer strands of isolated DNA presented a “closer case” than shorter isolated DNA strands.¹⁶⁰ A fully sequenced isolated gene maintains the same chemical differences as a shorter strand of isolated DNA; however, it is too long to be used as a probe and is unsuitable as a primer; therefore, larger strands of isolated DNA do not enlarge the range of utility.¹⁶¹ Judge Moore found that the settled expectations of

154. *Id.* at 1353.

155. *Id.* at 1364-65 (Moore, J., concurring in part).

156. *Id.* at 1365.

157. *Id.*

158. *See id.*

The ability to use isolated DNA molecules as the basis for diagnostic genetic testing is clearly an “enlargement of the range of . . . utility” as compared to nature. . . . Because the different chemical structure of the isolated DNA, which is a product of the intervention of man, leads to a different and beneficial utility, I believe small, isolated DNA fragments are patentable subject matter. . . . Man has whittled the chromosomal DNA molecule down to a 15 nucleotide sequence—defining the parts to be retained and discarded. And the result is a product with a function (primer or probe) that is entirely different from the full gene from which it was obtained.

Id.

159. *Id.*

160. *Id.* at 1366.

161. *See id.*

patent law “tip the scale in favor of patentability.”¹⁶²

3. Dissenting Opinion, Judge Bryson

Judge Bryson held that isolated genetic sequences are categorically unpatentable as composition of matter claims.¹⁶³ Judge Bryson framed the issue as whether an inventor could obtain a patent on a human gene.¹⁶⁴ The dissent compared the isolated genetic sequences to minerals that are hard to extract from a natural setting, and compared the cleaving of a covalent bond to the cleaning of a diamond with water or solvent to remove dirt or grime.¹⁶⁵ Judge Bryson’s reasoning was similar to Judge Sweet’s reasoning in the district court opinion. Judge Bryson based his holding on the belief that the structural differences are irrelevant because the function of the genetic sequence is the same as the native DNA—both transfer information, whether it is being used in the body to code a protein or used as a primer or a probe in diagnostic technologies.¹⁶⁶

Judge Bryson characterized the majority opinion’s deference to past precedent as adverse possession in patent law.¹⁶⁷ To counter the majority’s reliance on USPTO precedent and deference to the legislature, Judge Bryson further justified his stance based on the following: the ruling in *Chakrabarty* that rendered microorganisms patentable in the face of USPTO policy that microorganisms were not patentable, the USPTO’s lack of rule-making authority, and the Department of Justice’s Opinion on behalf of the United States.¹⁶⁸ Judge Bryson additionally cited policy arguments relating to the preemptive force of these patents resulting in a biotechnology “anticommons” as a reason against patentability.¹⁶⁹

162. *Id.* at 1367.

163. *See id.* at 1373-74 (Bryson, J., concurring in part and dissenting in part).

164. *Id.* at 1373.

165. *See id.* at 1375.

166. *See id.* at 1378 (The identity is key to its value. If it were altered in any meaningful way it could not be used for its diagnostic value).

167. *See id.* at 1381.

168. *Id.* at 1380-81.

169. *See id.* at 1379-80.

VII. WHAT NOW? LOOKING PAST THE COURT OF APPEALS DECISION

Both parties petitioned the Federal Circuit for rehearing.¹⁷⁰ The Association for Molecular Pathology moved for rehearing based on the claims to the isolated genetic sequences and an error in the determination of standing.¹⁷¹ Myriad's petition for rehearing focused only on standing and urged the Federal Circuit to dismiss the case as moot based on Dr. Ostrer's departure from N.Y.U.¹⁷² Interestingly, while Myriad asked to dismiss the case as moot, they did not ask to vacate the judgment,¹⁷³ likely because the judgment was mostly favorable to them in the assurance of the validity of genetic sequences. Additionally, Myriad did not ask for a rehearing on the diagnostic claims.¹⁷⁴ However, the Federal Circuit denied both petitions for rehearing.¹⁷⁵ While the plaintiffs have filed a petition for review in front of the Supreme Court,¹⁷⁶ even if review is granted, the outcome is uncertain for the following reasons.

A. *Standing*

By the time this case reaches a Supreme Court appeal, the parties may no longer have standing. Dr. Ostrer has left N.Y.U. and is currently at the Department of Genetics at Albert Einstein College of Medicine,¹⁷⁷ which does not have the ability to perform clinical genetic testing.¹⁷⁸ The requirement to maintain standing continues throughout the appellate process.¹⁷⁹ Dr. Ostrer no longer has the

170. See generally Plaintiffs-Appellees' Petition for Panel Rehearing, *supra* note 9; Defendants-Appellants' Petition for Panel Rehearing, *supra* note 9.

171. See Plaintiffs-Appellees' Petition for Panel Rehearing, *supra* note 9, at 1, 11.

172. See Defendants-Appellants' Petition for Panel Rehearing, *supra* note 9, at 1.

173. See *id.* at 9-11.

174. See generally *id.*

175. See *Disposition Sheet*, U.S. CT. OF APPEALS FOR THE FED. CIR. (Sept. 12, 2011), <http://www.ca9.uscourts.gov/images/stories/disposition/daily.pdf> (last visited Sept. 17, 2011).

176. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1367 (Fed. Cir. 2011), *petition for cert filed*, (U.S. Dec. 07, 2011) (No. 11-725).

177. See Faculty Profile for Harry Ostrer, M.D., ALBERT EINSTEIN C. OF MED., <http://www.einstein.yu.edu/home/faculty/profile.asp?id=12751&k> (last visited Feb. 29, 2012).

178. Letter from Gregory A. Castanias, Attorney for Defendants-Appellants, to Mr. Jan Horbaly, Clerk at the U.S. Ct. of Appeals for the Fed. Cir. 1 (July 27, 2011), *available at* <http://inventivestep.files.wordpress.com/2011/07/myriadletter1.pdf> [hereinafter Castanias Letter].

179. See *Lewis v. Cont'l Bank Corp.*, 494 U.S. 472, 477-78 (1990).

ability to immediately resume testing, which would likely extinguish his standing.¹⁸⁰

It is unlikely that the Supreme Court would apply the district court's broad finding of standing to the other plaintiffs. Judge Sweet's sweeping finding of standing was a dangerous test that does not align with patent law. Judge Lourie was correct in his reasoning that "[s]imply disagreeing with the existence of a patent or even suffering an attenuated, non-proximate, effect from the existence of a patent does not meet the Supreme Court's requirement for an adverse legal controversy or sufficient immediacy and reality to warrant the issuance of a declaratory judgment."¹⁸¹ Allowing a broad base of people, in this case patients, to litigate the validity of patents would open the floodgates of litigation. *Ex parte* re-examinations already allow third parties to question the validity of patents. Patent holders are granted a twenty-year monopoly for their investment and disclosure of their technology to the public knowledge base. A twenty-year monopoly will inevitably harm consumers of the product in some general way, but giving them standing does not create a remedy for the injury. It only serves to weaken the patent system.

B. *Composition of Matter Claims*

As evidenced by the separately written judicial opinions, the divide between both scientific and legal minds in dozens of amicus briefs,¹⁸² and disagreement even within the branches of

180. See Castanias Letter, *supra* note 177, at 2.

181. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1348 (Fed. Cir. 2011).

182. Compare, e.g., Brief for AARP as Amicus Curiae in Support of Plaintiffs-Appellees and Arguing for Affirmance at 2-4, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2011 WL 585711 (arguing that DNA and human genes are unpatentable under 35 U.S.C. §101 and the patents should be declared unenforceable, because public health necessitates their invalidation); Brief for the S. Baptist Convention as Amicus Curiae in Support of Plaintiffs-Appellees and Arguing for Affirmance at 2, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2011 WL 585712 (arguing that gene sequence patents are unpatentable subject matter and are harmful to individuals no matter what their religious beliefs); Brief of Amici Curiae E. Richard Gold et al. in Support of Appellees and Affirmance at 26, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2010 WL 5558511 (arguing that the genetic sequence contained in DNA should be considered as information, and should therefore be excluded as unpatentable abstract subject matter unless the claim has a specific function), with, e.g., Brief of Amici Curiae Rosetta Genomics, Ltd. et al. in Support of Defendants-Appellants, Supporting Reversal at 14-28, Ass'n

government,¹⁸³ reasonable people differ on how science and patent law should align. Opinions on the patentability of genes vary not so much because of the legal analysis, but because of the strong emotions behind the issue. While both the majority and concurring opinions in the Federal Circuit found that public policy fell on the side of deference to long-held property rights, Judge Bryson's dissenting opinion emphasized that his view of public policy outweighed that deference.¹⁸⁴ Therefore, the view on how patent law should be applied to science is inextricably intertwined with policy.

In *Chakrabarty*, the Supreme Court faced a similarly divisive issue.¹⁸⁵ *Chakrabarty*, like *Myriad*, presented the judiciary with a "gruesome parade of horrors" in several amicus briefs in support of the plaintiff's argument against the patentability of genetic

for *Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2010 WL 4853324 (arguing that isolated DNA is patentable subject matter, and patents stimulate innovation).

183. See, e.g., Brief for the U.S. as Amicus Curiae in Support of Neither Party at 9-11, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2010 WL 4853320; Heidi Ledford, *Has the US Government Abandoned Gene Patents?*, NATURE.COM NEWSBLOG (Nov. 1, 2010), http://blogs.nature.com/news/2010/11/will_the_us_government_abandon.html ("[N]o lawyers from the patent office are listed on the brief – a possible sign that the position has few fans at the USPTO, which has granted thousands of gene patents over the years."); David Kappos, Under Sec'y of Commerce for Intellectual Prop., Building Bridges and Making Connections Across the IP System, Speech at the George Washington Law Symposium 3 (May 11, 2010), *in* USPTO.GOV, available at http://www.uspto.gov/news/speeches/2010/Kappos_GW_Law_Symposium.jsp.

This has a potentially enormous impact on the bio industry. The USPTO has issued more than 20,000 patents claiming isolated DNA molecules, almost 4,000 of which directly claim isolated human DNAs encoding a protein. The USPTO has also issued tens of thousands of patents on other types of isolated and purified chemicals, all of which could be put at risk by the District Court's decision. The USPTO has for decades issued patents covering isolated and purified DNA on the scientific basis that an isolated snippet of DNA does not "exist" in nature in the way it is claimed in patents, because naturally occurring DNA must be isolated—that is, separated from the surrounding biological material—and purified. Your body does not contain isolated DNA. Isolated DNA simply is not found in nature.

Id.

184. *Ass'n for Molecular Pathology*, 653 F.3d at 1373 (Bryson, J., concurring in part and dissenting in part) ("In my view, those claims are not directed to patentable subject matter, and if sustained the court's decision will likely have broad consequences, such as preempting methods for whole-genome sequencing, even through *Myriad*'s contribution to the field is not remotely consonant with such effects.")

185. See *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980).

inventions.¹⁸⁶ The court noted that “[t]hese arguments are forcefully, even passionately, presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates—that, with Hamlet, it is sometimes better ‘to bear those ills we have than fly to others that we know not of.’”¹⁸⁷ The Supreme Court strongly emphasized that Congress, and not the Court, should decide categories of statutory exclusion, especially when based on public policy:

What is more important is that we are without competence to entertain these arguments—either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.¹⁸⁸

Chakrabarty is dispositive. If a categorical statutory exclusion to genetic patents is created, dislodging long-held property rights, the decision should be made by Congress and not the judiciary. “Congress is free to amend §101 so as to exclude from patent protection” genetic sequences under the product of nature exception, “[o]r it may choose to craft a statute specifically designed” to address them.¹⁸⁹ Until Congress takes such actions, the Court must strictly construe the language of §101 as it currently exists.¹⁹⁰

In his dissent, Judge Bryson used *Chakrabarty* as an affirmation that the Supreme Court does not owe deference to past patent law policy, because the Court created a new category of patent protection in microorganisms.¹⁹¹ However, interpreting a statute as granting a

186. *Id.* at 316.

187. *Id.*

188. *Id.* at 317.

189. *Id.* at 318.

190. *Id.* at 318 (“Our task, rather, is the narrow one of determining what Congress meant by the words it used in the statute; once that is done our powers are exhausted.”).

191. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1381 (Fed. Cir. 2011) (Bryson, J., concurring in part and dissenting in part) (“Finally, prior to

property right where none existed before is much different than taking away a property right that has existed for thirty years resulting in the grant of thousands of patents without significant congressional action. Traditionally, Congress does not need to authorize the patentability of new fields of inventions, since breakthrough innovations often stretch beyond the boundaries of science.¹⁹² In contrast, an invention that has been around for decades provides Congress with ample opportunity to create legislation if they do not wish that type of invention to be a part of the patent bargain. Congress does not need to explicitly authorize inventions, but once an invention has been deemed patent eligible *and* Congress has not acted to prevent the issuance of thousands of patents over several decades, the judiciary should not arbitrarily overturn the long-standing property right.

Judge Bryson incorrectly suggested that the executive's Department of Justice brief in support of neither party indicated that the patent office has changed their stance on genetic sequence patents.¹⁹³ On May 11, 2010, the director of the USPTO, David Kappos, said in a speech to the George Washington Law Symposium:

The USPTO has for decades issued patents covering isolated and purified DNA on the scientific basis that an isolated snippet of DNA does not “exist” in nature in the way it is claimed in patents, because naturally occurring DNA must be isolated—that is, separated from the surrounding biological material—and purified. Your body does not contain isolated DNA. Isolated DNA simply is not found in nature. . . . It has been the view of the USPTO that the purified version of a naturally occurring compound—where the purified version does not exist in nature—is eligible for patent protection.¹⁹⁴

On November 1, 2010, David Kappos reaffirmed that view point even in light of the Department of Justice's brief, and told the DOW Jones news service: “The USPTO at the present time is maintaining

the Supreme Court's decision in *Chakrabarty*, the PTO had determined that microorganisms were not subject to patenting, but the Supreme Court gave no indication that it regarded that view as entitled to deference.”)

192. See *Chakrabarty*, 447 U.S. at 316 (“A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability. . . . Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable.”).

193. See *Ass'n for Molecular Pathology*, 653 F.3d at 1380-81 (Bryson, J., concurring in part and dissenting in part).

194. Kappos, *supra* note 182, at 3-4.

the status quo. We're continuing with current procedures as they are."¹⁹⁵ Clearly, the Department of Justice's brief did little to dictate USPTO policy on genetic sequences.

Accordingly, the Supreme Court should interpret 35 U.S.C. §101 through strict interpretation, apply it to the science, and rightly defer the public policy arguments to Congress. It is unlikely that the Supreme Court would declare all patents to genetic sequences as categorically unpatentable as a product of nature. It is incorrect to focus solely on the similarity between isolated DNA and native DNA as an informational carrier, rather than the differences. *Chakrabarty* clearly states that the applicable test does not focus on the similarities, but whether the non-naturally occurring composition of matter was a product of human ingenuity with "distinctive name, character [and] use."¹⁹⁶ The compositions of matter claims in fact do not claim the raw information of the genetic sequence of BRCA1 and BRCA2.¹⁹⁷ The claim is an isolated man-made DNA molecule with an amino acid sequence that carries the raw information of the genetic sequence. It is the molecule that is claimed, not the information. In other words, the molecule would not exist *but for* man's intervention.

Under a strict interpretation of §101, a composition of matter claim to an isolated genetic sequence is patent eligible because it is a product of human ingenuity, non-naturally occurring, and has a distinctive character, name and use. In this case, the claimed sequence could be used as primer and probe in the detection of genetic abnormalities, and native DNA could not. "Isolated DNA" does not exist in nature, and isolation often tips the scales to patentability.¹⁹⁸ Although larger sequences of isolated genetic sequences may not have the practicality of primer or probe, policy weighs in their favor as Judge Moore outlined in her concurring opinion,¹⁹⁹ and they are still man-made molecules with a distinct chemical composition that

195. Gene Quinn, *Conflicting Positions on Gene Patents in Obama Administration*, IP WATCHDOG (Nov. 2, 2010, 2:27 PM), <http://ipwatchdog.com/2010/11/02/conflicting-positions-on-gene-patents-in-obama-administration/id=13085/>.

196. *Chakrabarty*, 447 U.S. at 309-10 (alteration in original) (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

197. See generally U.S. Patent No. 5,747,282 (filed June 7, 1995).

198. See *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911), *aff'd in part, rev'd in part*, 196 F. 496 (2d Cir. 1912).

199. See *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1366-67 (Fed. Cir. 2011) (Moore, J., concurring in part).

do not occur in nature.²⁰⁰ The Supreme Court should not overturn decades of recognized property rights through a categorical exclusion of genetic sequences as “products of nature”—the Court will rightly defer the policy arguments to Congress.

C. *The Diagnostic Method Claims*

Less than a year prior to the *Myriad* decision, Judge Lourie ruled on a similar diagnostic method claim in *Prometheus*.²⁰¹ The following method claim was representative of the claims at issue in *Prometheus*:

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
 - (a) *administering* a drug providing 6–thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
 - (b) *determining* the level of 6–thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6–thioguanine less than about 230 pmol per 8×10^8 red blood cells *indicates a need* to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6–thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.²⁰²

This claim essentially covers administration of a drug, a determination of a corresponding natural correlation in the human body based on that drug, and the result of that determination being compared to a predetermined amount. Judge Lourie held that the

200. See *Ass’n for Molecular Pathology*, 653 F.3d at 1351-52; Kappos, *supra* note 182, at 4 (“It has been the view of the USPTO that the purified version of a naturally occurring compound—where the purified version does not exist in nature—is eligible for patent protection.”).

201. See *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1349 (Fed. Cir. 2010), *cert. granted*, 131 S. Ct. 3027 (June 20, 2011).

202. *Id.* at 1350.

administering and determining steps were both transformative and central to the claims; therefore, Judge Lourie held the claim to be valid.²⁰³

When *Myriad* is read in correspondence with *Prometheus*, the differentiation between method claims written without a “determining” step and claims written with a “determining” step is slim.²⁰⁴ *Myriad* argued that steps of extracting a human DNA sample and sequencing the BRCA molecule from that human DNA sample necessarily preceded the comparing step, and should be read into the claim.²⁰⁵ However, Judge Lourie interpreted the claims as only comparison between two sequences “accomplished by mere inspection alone.”²⁰⁶ If the diagnostic method claims in *Myriad* had a step in which the determining of the genetic sequence was obtained through the use of an isolated genetic sequence, Judge Lourie likely would have upheld these claims as patent eligible based on his holding in *Prometheus*. Judge Lourie’s distinction between the method claims in *Prometheus* and the method claims in *Myriad* is mere semantics. If this narrow distinction is upheld, it will do little more than alter the way in which diagnostic method claims are drafted.

The Supreme Court appears to be positioning itself for a ruling on biomedical method claims in the near future. In 2006, the Supreme Court granted, and then dismissed as “improvidently granted,” review to *Labcorp v. Metabolite*.²⁰⁷ With no majority opinion, Justice Breyer, joined by Justice Stevens and Justice Souter, wrote a dissenting opinion.²⁰⁸ The claims, which were determined to be valid in the

203. *Id.* at 1357, 1359.

204. *See, e.g.*, U.S. Patent No. 5,709,999 col. 161 17-25 (filed Nov. 21, 1991).

Claim 1:

A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.

Id.

205. *See Ass’n for Molecular Pathology*, 653 F.3d at 1356.

206. *Id.* at 1357.

207. *Labcorp v. Metabolite Labs., Inc.*, 548 U.S. 124, 125 (2006) (per curiam).

208. *Id.*

lower courts, were directed to a process of measuring the level of an amino acid and human body fluid and noticing whether the level was elevated above the normal level in order to detect vitamin deficiency.²⁰⁹ Justice Breyer argued that a correlation between homocysteine and vitamin deficiency was a correlation that falls under the “natural phenomenon” exception to section 101 patentability, which cannot be avoided by an instruction to perform the process of reading numbers in light of medical knowledge.²¹⁰

The Supreme Court has granted review of *Prometheus* and will likely issue a ruling this fall.²¹¹ Based on the Supreme Court’s grant of review in *Prometheus*, Justice Breyer’s dissent in *Labcorp v. Metabolite*, and the Court of Appeals holding in *Association for Molecular Pathology*, diagnostic method claims comparing a “natural correlation” are at the forefront of the biotechnology battle. The Supreme Court’s future ruling in *Prometheus* may dictate how the Court will proceed in biotechnology cases, and will determine how the Court will proceed in *Association for Molecular Pathology* at least in regards to the method claims at issue.

Prometheus, *Labcorp*, and *Association for Molecular Pathology* highlight why patent law in biotechnology should not be bulldozed in order to attempt to address patient needs that are tangentially affected through patent law. All of these cases touch on diagnostic technologies. Of these three cases, only Myriad’s claims related to genetic diagnostics. Therefore, even if Myriad’s patents were struck down, the issues faced by the patients seeking treatment through all types of diagnostic technologies would not benefit from their invalidation. Notably, the method claims in *Myriad* were found unpatentable not because they were a natural phenomenon, but because they were an abstract mental process.²¹² This distinction will not create a bar to patenting diagnostic biotechnology tests that use natural phenomenon like metabolite correlations, genetic sequences, or chemical responses as long as they do not claim *only* an abstract mental process and satisfy *Bilski*’s “useful and important clue” of the

209. *Id.*

210. *Id.* at 134, 137.

211. See Docket for No. 10-1150, SUPREME CT. OF THE UNITED STATES, <http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/10-1150.htm> (last visited Oct. 7, 2011).

212. See *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1355 (Fed. Cir. 2011).

machine or transformation test.²¹³

Fundamentally, the issues presented in *Myriad* circulate around better patient care. Therefore, weakening patent protection at best provides an ineffective piecemeal approach of targeting limited issues in patient service. Biotechnology research is extremely expensive, and weakening patents in this sector only serves to disincentivize much needed private funding into medical technologies. Invalidation of *Myriad's* patent would be extremely limited in its scope and effect.²¹⁴ This is a broad issue, and should therefore be addressed in a manner that would actually address the needs of patients.

VIII. POLICY CONSIDERATIONS AND POSSIBLE SOLUTIONS

In April 2010, the Secretary of Health and Human Service's advisory committee on genetics, health, and society (SACGHS) wrote a report in conjunction with NIH on *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*.²¹⁵ Because it was unclear how a congressional ban on genetic sequences would affect other biotechnologies including therapeutic uses of genes, SACGHS concluded that it was prudent to narrowly tailor any solution "to improve genetic test development and patient access without affecting patent rights in other areas."²¹⁶ The Committee, therefore, did not recommend a congressional ban on genetic sequences.²¹⁷

Recently, Congress and the Executive Branch took a narrow approach to patents on genetic sequences. President Obama signed into law the America Invents Act on September 16, 2011.²¹⁸ Section

213. See *Bilski v. Kappos*, 130 S.Ct. 3218, 3227 (2010).

214. See U.S. DEPT. OF HEALTH & HUMAN SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS: REPORT OF THE SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY 92 (2010) [hereinafter SACGHS REPORT], available at http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf ("Furthermore, even if the plaintiffs prevail, this would not lead to the automatic invalidation of all existing patents on genes and associations.")

215. See generally *id.*

216. *Id.* at 91-92.

217. *Id.*

218. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 27(a), 125 Stat. 283, 338 (2011) (to be codified in scattered sections of 35 U.S.C.), available at <http://www.gpo.gov/fdsys/pkg/PLAW-112publ29/pdf/PLAW-112publ29.pdf>. See also Press Release, The White House, President Obama Signs America Invents Act, Overhauling the

27 specifies that the “Director [of the USPTO] shall conduct a study on effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist.”²¹⁹ Notably, the study calls for research into second opinions on diagnostic tests and nothing more. The report is due no later than 9 months after the enactment of the Act.²²⁰ This is an extremely narrow provision in an act with lengthy patent reform. If Congress had wanted to create an exception to genetic sequence patentability they could have done so while passing this act.

Proponents of invalidating genetic patents cite several policy concerns in support of their contention that patent claims to genetic sequences “cause more harm than good to society and technological development.”²²¹ There are three general categories of concern: preemption of future research; quality of care and patient access; and an unearned extended patent monopoly. Most of these concerns are misplaced, and in fact, would not be well addressed by creating a broad exception to section 101 patentability.

A. Weakening Patent Rights in Biotechnology Would Both Negatively Impact Private Investment and Create Uncertainty in the Protection of Other Biotechnology Property Rights

Scientific research and development of life-saving technologies is expensive and private investment and competition significantly contributes to the efficient development of new technologies; however, investment in private research will not continue if there is no reward. In 2009, BIO (Biotechnology Industry Organization) conducted a survey of 150 biotechnology companies.²²² The survey found that half of the companies were founded on the basis of

Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs (Sept. 16, 2011), *available at* <http://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim>.

219. Leahy-Smith America Invents Act § 27(a).

220. *See* Leahy-Smith America Invents Act § 27(d).

221. *See* Mary Mitchell & Dana A. Remus, Commentary, *Interstitial Exclusivities After Association for Molecular Pathology*, 109 MICH. L. REV. FIRST IMPRESSIONS 34, 34-35 (2010), *available at* <http://www.michiganlawreview.org/assets/fi/109/mitchellremus.pdf>.

222. *See* BIO 2009 Member Survey, BIOTECHNOLOGY INDUSTRY ORGANIZATION, 1 (2009), http://www3.bio.org/ecs/bd/TechTransfer_Survey_Summary_Conclusions.pdf.

obtaining a licensing agreement and that the majority of companies with no marketed product expected to spend five to fifteen years developing the product.²²³ In the House of Representatives hearing on Gene Patents and Other Genomics, Dennis Henner from Genentech, Inc., testified that his company invests about \$400 million a year in the research and development of therapeutic products focusing on the identification of human proteins.²²⁴

The grant of a patent, in part, recognizes the investment that an individual or company assignment has spent in development of a new invention. The patent serves as a reward for the investment and risk associated with high-priced technologies, especially in the realm of biotechnology.²²⁵ Although the United States government funds most basic research (59%), the private business sector accounts for the largest share of research and development, hovering between 69-75% of total research and development funding.²²⁶

Basic research does not bring medical diagnostic technology to the market for patient care, and private industry is the largest contributor of funds to applied research and development.²²⁷ Scientists searching for gene-disease associations cannot perform the needed research without significant capital and resources.²²⁸ Funding for meaningful gene-disease associations are confirmed only when the basic research discoveries are followed by large amounts of replication and validation, which is often cost prohibitive.²²⁹ The research team that founded Myriad received \$5 million in funding in 1993 after the formation of the company.²³⁰ However, this paled in comparison to the \$10 million in private stock, along with millions in

223. *See id.*

224. *Gene Patents and Other Genomic Inventions: Hearing Before the Subcomm. on Courts & Intellectual Prop. of the H. Comm. on the Judiciary*, 106th Cong. 55 (2000) (statement of Dennis J. Henner, Ph.D., Senior Vice President, Research, Genentech, Inc.).

225. *See generally Science and Engineering Indicators 2008: Chapter 4. Research and Development: National Trends and International Linkages*, NAT'L SCI. BD. (2008), <http://www.nsf.gov/statistics/seind08/pdf/c04.pdf>.

226. *See id.* at 4-5.

227. *See Research and Development: Essential Foundation for U.S. Competitiveness in a Global Economy*, NAT'L SCI. BD. (2008), <http://www.nsf.gov/statistics/nsb0803/start.htm> (“[i]ndustrial contributions to national R&D now far outpace Federal R&D support” Most industrial contributions support applied R&D and not basic R&D.).

228. *See SACGHS REPORT*, *supra* note 213, at 23.

229. *See id.*

230. *See Gold & Carbone*, *supra* note 58, at S41.

equity from Eli Lilly, a private pharmaceutical company.²³¹ Myriad has yet to make a profit on the investment it made into the research and development of its product.²³²

On a profit-based research model, a limited patent monopoly provides the incentive to investors to take the risk in biotechnology. Investors in biotechnology believe that in order to succeed in their investment there must be strong, enforceable patents, and any perception that patent reform might weaken that patent protection will adversely impact the availability of biotechnology funding.²³³ Biotechnology companies without a successful product on the market must rely substantially on the availability of investment funding to survive.²³⁴ In 2000, when Prime Minister Tony Blair and President Bill Clinton issued a “bland” statement urging public access to raw DNA sequencing information, many biotech companies lost as much as 20% of their value.²³⁵

Private investors that are providing the funding for research and development look at patents as a protection of their investment.²³⁶ Myriad’s research into the genetic sequences associated with breast cancer was funded by Eli Lilly “in return for licensing privileges for diagnostic kits and therapeutic products for BRCA1.”²³⁷ The funding was therefore based on an exchange—the promise that Myriad would be the first to sequence the breast cancer genes in exchange for funding. The patents and licensing abilities associated with the rights of patents provide much needed capital for biotechnology companies to stay in business.

Weakening patents in the biotechnology sector risks negatively impacting investments that bring products to the market expeditiously—not only with respect to genetic sequences, but with respect to any technology that affects patient care. Congress should therefore craft legislation that addresses patient care without threatening the property rights that biotechnology companies rely on

231. *See id.*

232. *Id.* at S42.

233. *See* Christopher M. Holman, *Biotechnology’s Prescription for Patent Reform*, 5 J. MARSHALL REV. INTELL. PROP. L. 318, 327-28 (2006).

234. *See id.* at 327.

235. *See id.* at 328.

236. *See id.* at 327-28.

237. Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L.J. 123, 129 (2002).

in attracting investors.

B. There Is Little to No Evidence that Patents on Genetic Sequences Have Hindered Future Research Through Preemption and There Are Several Solutions Which Can Address These Concerns Without a Blanket Exception to Patentability

Although geneticists first focused on single gene associations to one disease, scientists now realize that a specific gene accounts for only a small risk of most diseases.²³⁸ Diagnostic companies are therefore shifting their focus to “multiplex tests” which scan for dozens of genes.²³⁹ The ever-lowering cost of genetic sequencing suggests that even whole-genome sequencing for diseases will soon be practical at a minimal cost.²⁴⁰ SACGHS found that patents on specific genetic sequences may hinder development of multiplex testing, parallel sequencing, and whole genome sequencing due to the large amount of licenses that would need to be gathered in order to implement the technology.²⁴¹ Proponents against the patentability of genetic sequences believe that this type of technology is negatively impacted and in some cases preempted by the gene “patent thicket” of many different private owners with unaligned interests.²⁴² Negotiating licenses to every relevant patent directed at a genetic sequence is prohibitively expensive and there is little guarantee that every patent holder would provide permission or a reasonable price.²⁴³ The “patent thicket” potentially makes it infeasible to offer a product that sequenced the genome or multiple genes due to the large number of licenses or royalty fees needed in order to avoid patent infringement.²⁴⁴

This fear is misplaced. The oft-quoted statistic that twenty percent of the genome is patented is incorrect, and many of the patents including Myriad’s would not be enforceable against the

238. Sam Kean, *The Human Genome (Patent) Project*, 331 SCI. 530, 530 (2011).

239. *Id.*

240. *Id.*

241. SACGHS REPORT, *supra* note 213, at 3.

242. *See* Kean, *supra* note 237.

243. *See* SACGHS REPORT, *supra* note 213, at 3.

244. *See* Kean, *supra* note 237, at 530-31.

technology and process used to sequence the whole genome.²⁴⁵ The study where this statistic came from did not distinguish between patent claims in which the isolated molecule is the invention and claims in which a process is using the isolated molecule.²⁴⁶ Universities and nonprofits are less likely to enforce patents aggressively and they own most patents on genes used in diagnostic tests.²⁴⁷ Additionally, many of the genetic patents expired and others have terminated for failure to pay fees.²⁴⁸ Finally, the remedy for a holder of a single gene in a microarray technology that sequenced thousands of genomes would be *de minimus*.²⁴⁹ With all of these combined factors, the threat of a “patent thicket” inhibiting whole genome sequencing or multiplex technologies is minimal.

In fact, there is no evidence that a “patent thicket” has stopped companies from developing these types of technologies.²⁵⁰ For example, Affymetrix is a company that should have experienced considerable difficulty in the creation of their technology. Affymetrix is developing a DNA chip with microarrays that might contain thousands of genetic sequences.²⁵¹ Yet, this supposed gene “patent thicket” has not hindered Affymetrix’s development.²⁵² Another example is Foundation Medicine, which is planning to offer a diagnostic test that searches for aberrations in a hundred or more genes to determine how to treat cancer.²⁵³ Originally, Foundation Medicine estimated that navigating the “patent thicket” would cost at least thirty-five million dollars.²⁵⁴ However, after fully analyzing the

245. Christopher M. Holman, *Will Gene Patents Impede Whole Genome Sequencing?: Deconstructing the Myth that 20% of the Human Genome is Patented* 1-12 (July 25, 2011), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1894715.

246. *Id.* at 2.

247. Kean, *supra* note 237, at 531.

248. Holman, *supra* note 244, at 13.

249. Whether the royalty is based on reasonable royalty, market share or lost profits, the amount of damages would likely be so minimal for a holder of one patent that targets one gene out of thousands and would not outweigh the large costs associated and years required in order to reach a verdict in trial. See SACGHS REPORT, *supra* note 213, at 53.

250. See Christopher M. Holman, *Patent Border Wars: Defining the Boundary Between Scientific Discoveries and Patentable Inventions*, 25 TRENDS IN BIOTECHNOLOGY 539, 540 (2007).

251. *Id.*

252. *Id.*

253. Kean, *supra* note 237, at 530.

254. *Id.*

patents, the company found plenty of room in which to operate.²⁵⁵ Even if there is a small genetic “patent thicket”, it can be navigated in several ways.

1. Patent Pool

A patent pool in which several patents are licensed for one price can allow companies to easily navigate through patent thickets.²⁵⁶ A patent pool gathers patents rights to multiple genetic sequences together and provides a single license that bundles all of the rights together.²⁵⁷ This would allow scientists, laboratories, and companies working on multiplex and whole genome technologies to easily gather permission from all patent holders, pay one pre-determined price, and not fear liability in patent infringement suits.

However, in technologies where patent pools are usually used, the technology is interdependent, and no single patent holder is capable of marketing their patent technology independently of others.²⁵⁸ For example, companies like Myriad can profitably market their technology without joining the pool and therefore lack incentive to join.²⁵⁹ A genetic patent pool may not operate as effectively as in other technologies. Companies and scientists holding patent on individual genes may have highly individually marketable genes that would garner little profit, and therefore would have little incentive to enter a patent pool. This would provide the same price no matter how important the sequenced gene is.²⁶⁰ Some hope that multiple holders to genetic sequences linked to the same specific condition will recognize that it is crucial that each mutation be tested simultaneously, and will therefore agree to enter a patent pool or cross-licensing agreement.²⁶¹

Despite potential difficulties in genetic patent pools, patent-licensing companies and structures have begun to emerge. For

255. *Id.* at 531.

256. SACGHS REPORT, *supra* note 213, at 55 (quoting Birgit Verbeure et al., *Patent Pools and Diagnostic Testing*, 24 TRENDS IN BIOTECHNOLOGY 115, 117 (2006)) (A patent pool is defined as an agreement “between two or more patent owners to license one or more of their patents as a package to one another, and to third parties willing to pay the associated royalties.”).

257. SACGHS REPORT, *supra* note 213, at 3.

258. *Id.*

259. *Id.* at 56.

260. *Id.*

261. *See id.*

example, MPEG LA,²⁶² the “world leader in alternative one-stop patent licenses” in April of 2011, created a genetic “supermarket” from which a “one-stop patent license” can be purchased.²⁶³ The company “announced a market-based initiative for a diagnostic genetics patent licensing facility that addresses the market’s need for nonexclusive access to patents for diagnostic genetics tests leading to personalized medical solutions that save lives and reduce healthcare costs.”²⁶⁴ If MPEG LA succeeds, the “patent thicket” in genetic patents will be a thing of the past. In another example, one biotechnology company posted a formula on their website that outlined how much the company is willing to pay for every patented gene sequenced from the thousands they sequence for every customer.²⁶⁵

2. Patent Donation

Patent donation could provide a method for companies to donate claims to isolated genetic sequences to the public; without congressional interference into their companies or subject matter limitations on patent law that might result in negative public perception and uncertainty in other types of biotechnology patents. Considering that most holders of genetic sequence patents allow basic research on the genetic sequence to continue, and liberally license genetic diagnostic testing to other facilities, a solution to the controversial issue may itself be a controversial solution—patent donation.

The genetic sequence patents could be donated to a non-practicing entity or non-profit such as the Human Genome Project. Alternatively, they could be donated to a “trust” created to hold the genetic sequences. The donation of existing patents would generate good public perception for the companies, and allow for better testing and research. Patent donation would allow the owners of the genetic sequences to generate good publicity, as opposed to the bad publicity

262. MPEG LA, <http://www.mpegla.com/main/default.aspx> (last visited Mar. 1, 2012).

263. Press Release, MPEG LA Launches Initiative to Make Gene Patents Available for Diagnostic Testing, MPEG LA (Apr. 8, 2010), <http://www.mpegla.com/Lists/MPEG%20LA%20News%20List/Attachments/230/n-10-04-08.pdf>.

264. *Id.*

265. Kean, *supra* note 237, at 531.

storm generated by Myriad's business practices.²⁶⁶ Additionally, patent donation could provide the companies a tax break for the donation of these patents. Congress could enact legislation providing a strong tax incentive to companies willing to donate their patents on genetic sequences and other basic research tools to the public. A tax break and the good public opinion generated by recognizing the public need for access to genetic disease research, testing and advancement might encourage companies to donate their genetic sequence patents.

One issue with this method of encouraging companies to donate genetic sequences to the public domain is that tax incentives do not equal a mandate. A company like Myriad generates revenue by holding a 20 year exclusionary property right on a diagnostic test that affects a large amount of the national population. A tax incentive would not measure up to the potential revenue generated by the patent, especially for a company that has invested money in research and development, lawyers, patent prosecution, patent maintenance fees and possible litigation.

However, companies fearing increased negative perception and possible court decisions negating genetic subject matter as patentable may be better served in donating their patents on sequences while maintaining their other patents. This allows the companies to quell any dissatisfaction with the patenting of biological matter, while still maintaining patents on genetic diagnostics (which are speculated to be so broad as to not actually need a claim on the sequence itself). This will ease any uncertainty that investors have in continued biotech research, and it will ease public dissatisfaction and the risk of the courts etching out sections of the biotech sector as unpatentable.

In conclusion, there is little evidence that the genetic "patent thicket" exists, and even if there is a small thicket the effect has been minimal. Potential solutions include patent pools, cross licensing, or donation to the public. Companies have already started to implement these services. Clearly, current patents on genetic sequences are not significantly preempting research and do not justify a broad ruling that all genetic sequences are unpatentable.

266. See *supra* Part III.B.

*C. Better Patient Treatment Will Not Be Achieved Through
Invalidation of Patentable Subject Matter*

Patient access to better quality care permeated the complaint in *Myriad*.²⁶⁷ When patents create a sole provider of a genetic test, like the *Myriad* test for BRCA1/BRCA2, patients' access to that test is limited based on price, the companies processing capacity, and health insurance coverage. When there is only one provider, patients are unable to receive a second opinion from an independent laboratory. Quality control of a sole provider's diagnostic test and improvements in the methods is often set back, since no other independent lab is available to process the sample and verify the results. Additionally, insurance companies may not always deem it necessary for a patient to receive the test or may not have an agreement with the company providing the test. While these are significant issues, the invalidation of a patent would not address these concerns. Invalidation of genetic sequence patents would not guarantee that other companies would offer the diagnostic test, accept medical insurance, provide a lower rate, or provide quality assurance. These issues are not patent law issues. Other, more narrowly tailored solutions that actually address these concerns are outlined below.

1. Quality Control Through FDA Regulation

The quality and accuracy of diagnostic tests could easily be monitored within existing regulatory framework. Several government agencies are already involved in the oversight of genetic testing.²⁶⁸ The Center for Medicare and Medicaid Services (CMS) regulates laboratory compliance under the Clinical Laboratory Improvement Amendment of 1988.²⁶⁹ The Federal Trade Commission oversees the advertising of diagnostic tests.²⁷⁰ The Food and Drug Administration currently regulates "diagnostic devices" which are manufactured by one company and then sold as a kit to another laboratory for genetic testing.²⁷¹ The FDA, however, does not regulate diagnostic tests that

267. See generally Complaint, *supra* note 59.

268. See *Genetic Testing*, NAT'L HUMAN GENOME RESEARCH INST., <http://www.genome.gov/10002335> (last visited Sept. 22, 2011).

269. *Id.*

270. *Id.*

271. *Id.*

are both manufactured and performed by the same laboratory—like the Myriad test.²⁷² The Myriad test for BRCA is currently marketed directly to the medical community and the public, without any FDA regulation or oversight.²⁷³ The FDA has held public meetings on whether they should oversee these types of tests.²⁷⁴ The FDA has indicated that they believe that these types of tests should fall under their oversight.²⁷⁵ Greater FDA oversight will come with greater costs in the research and development phase of a product, which only strengthens the argument that patent protection is needed in order to encourage investment in the industry.²⁷⁶

2. Quality Control Through Broader Experimental Use Exception and Limited Liability Rule

A broader experimental use exception would also allow quality assurance to take place in independent laboratories, without that laboratory incurring liability. Many industrialized countries recognize a much stronger experimental use exception to patent infringement liability than the United States currently allows.²⁷⁷ There are several strong policy arguments for a broader research exemption. Foremost, the words in a patent often fail to fully explain the complete nature of a biological invention.²⁷⁸ Additional reasons include: determining how the patent works; whether it works as taught; how to improve it and how to work around it.²⁷⁹ A more expansive research exemption

272. *Id.*

273. *Id.*

274. See generally *FDA/CDRH Public Meeting: Oversight of Laboratory Developed Tests (LDTs)*, Date July 19-20, 2010, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm212830.htm> (last visited Sept. 22, 2011).

275. See Dan Vorhaus, *DTC Genetic Testing and the FDA: Is There an End in Sight to the Regulatory Uncertainty?*, GENOMICS LAW REPORT (June 16, 2011), <http://www.genomicslawreport.com/index.php/2011/06/16/dtc-genetic-testing-and-the-fda-is-there-an-end-in-sight-to-the-regulatory-uncertainty/>.

276. See Kirell Lakhman, *FDA Tells Lame-Duck SACGHS of LDT 'Loophole,' But New Regs Could Beget More*, GENOMEWEB (Oct. 5, 2010), <http://www.genomeweb.com/blog/fda-tells-lame-duck-sacghs-ldt-loophole-new-regs-could-beget-more>; Kirell Lakhman, *What Labs Should Expect – and Demand – from FDA's New LDT Strategy*, GENOMEWEB (July 19, 2010), <http://www.genomeweb.com/node/945450>.

277. Janice Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 5 (2001).

278. See Merz & Cho, *supra* note 56, at 203.

279. *Id.* at 207.

is especially necessary in basic scientific research, where the success of an experiment is largely regarded as reproducibility of results and minimization of statistical error. It makes little sense to wait until the expiration of a patent term to learn if the research actually works.

One option is to allow the development of new therapies and diagnostics through the non-consensual use of the genetic sequences, even if ultimately used for commercial purpose, by enforcing a “liability rule.”²⁸⁰ The liability rule would compensate the patent owner appropriately through an *ex post* royalty based on the marketplace value of any new products developed through use of the tool.²⁸¹ This *ex post* royalty would allow the owner of a gene sequence patent to be rewarded only when a profitable expansion of his intellectual property had been discovered, while increasing the public’s knowledge and furthering scientific process. It would also have the added benefit of developing different types of diagnostic tests that potentially could serve to increase precision of the tests that are developed, while still returning profits to the owner of the patent for their investment in sequencing the gene. Therefore, only successfully marketed products would incur liability.

3. Safe Harbor for Second Opinions

In an amendment to the 2011 Patent Reform Act, the House of Representatives introduced a “safe harbor for second opinions” provision. The proposal created a new section 287(d) under the Patent Act to establish a safe harbor for second opinion genetic diagnostic testing providers,²⁸² much like the safe harbor that already exists at section 287(c) for medical practitioner performance of medical activities.²⁸³ Although second opinions were one of the issues that the ACLU identified in the patent suit against Myriad, they vehemently

280. Mueller, *supra* note 276, at 9-10.

281. *Id.* at 9-10.

282. Amendment to H.R. 1249, H.AMDT.491, 112th Cong. § 27 (June 23, 2011), available at <http://www.genomicslawreport.com/wp-content/uploads/2011/06/HR-1249-Managers-Amendments.pdf>; See also Dan Vorhaus, *Update: Proposed Second Opinion Safe Harbor for Genetic Diagnostic Testing Withdrawn*, GENOMICS LAW REPORT (June 16, 2011), <http://www.genomicslawreport.com/index.php/2011/06/16/update-proposed-second-opinion-safe-harbor-for-genetic-diagnostic-testing-withdrawn/>.

283. Amendment to H.R. 1249, H.AMDT.491, 112th Cong. § 27 (June 23, 2011); 35 U.S.C. § 287(c) (2006).

opposed this amendment.²⁸⁴ The ACLU noted that “[t]he proposed language would fail to block all patent holder objections to such testing, fails to address the many other limitations on scientific research arising out of the issuance of such patents, and risks allowing gene patent holders to argue that Congress implicitly endorses the validity of such patents.”²⁸⁵ Following this letter, the safe harbor provision was removed.²⁸⁶ While this amendment failed, Congress clearly does have the ability to create a second opinion safe harbor that could apply to all diagnostic tests, but more importantly would provide farther-reaching patient care reform than patent invalidation.

4. Second Opinions and Increased Access Through Congressional Legislation:

Instead of throwing thousands of genetic patents into question and fundamentally altering the national outlook on patentable subject matter, Congress should consider narrower approaches in dealing with the issue, such as excluding genetic diagnostic methods from the patent protection while not completely excluding patents on genetic sequences.²⁸⁷ Europe allows the patenting of isolated genes while preventing the patenting of the diagnostic process such as comparing genes to find mutations.²⁸⁸ The European patent statute reads, “European patents shall not be granted in respect of . . . methods for treatment of the human or animal body by surgery or therapy and *diagnostic methods practi[c]ed on the human or animal body.*”²⁸⁹ This would allow for the concerns of sick individuals to be addressed (the need for second opinions, better diagnostics, lower prices, insurance coverage and access) while still rewarding biotechnology companies for their investment in research.

In 2002, Representative Lynn Rivers introduced the Genomic

284. See, e.g., Letter from ACLU to Chairman Dreier, Chairman Smith, Ranking Member Slaughter, and Ranking Member Conyers (June 15, 2011), available at http://www.aclu.org/files/assets/final_itr_re_opposing_wasserma_schultz_amendment_with_coalition_letter.pdf; Vorhaus, *supra* note 281.

285. Letter from ACLU, *supra* note 283.

286. Vorhaus, *supra* note 281.

287. See Olga Bogard, Comment, *Patenting the Human Body: The Constitutionality of Gene Patents and Suggested Remedies for Reform*, 63 SMU L. Rev. 1319, 1333-1334 (2010).

288. *Id.* at 1333.

289. *Id.* (quoting Convention on the Grant of European Patents, art. 53(c), Oct. 5, 1973, 13 I.L.M. 270 (as amended by Revision Act of Nov. 29, 2000) available at <http://www.epo.org/law-practice/legal-texts/epc.html>).

Research and Diagnostic Accessibility Act (GRDAA).²⁹⁰ GRDAA did not affect the patentability of sequenced genes, but would have provided limited exemptions from patent infringement liability for certain uses of patented genetic sequences and information in the context of basic research and diagnostic testing.²⁹¹ The exemption would have been very narrow, and may have had little practical effect since pure non-commercial research is very rare, but it would have provided an exemption from the remedies of a patent infringement suit in the performance of genetic diagnostic testing.²⁹² There is some precedent for this type of exemption, since a medical practitioner is exempted from liability for performing a medical or surgical procedure.²⁹³ If genetic testing is considered to be a medical procedure, then the exemption may still apply, but the person providing the kit to conduct the test could still be held liable. The narrow exceptions in GRDAA would have provided modest reforms while addressing the primary concerns of genetic sequence patenting by allowing broader access for genetic testing while still enforcing the patent holders' rights in all other circumstances.²⁹⁴

Compulsory licensing of human gene patents is another option that may balance the competing interests of the need to encourage companies to continue to pursue cutting edge research, protecting fundamental scientific principles, and providing maximum access to medical breakthroughs. Examples of compulsory licensing that could be utilized include: "march-in" rights under the Bayh-Doyle Act, refusal of injunctive relief under 35 U.S.C. §154(a)(1), and mandatory licensing under the Clean Air Act.²⁹⁵

Congress could enact a type of compulsory license through "march-in rights" similar to the rights the federal government maintains under the Bayh-Doyle Act. March-in rights, like those

290. Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002), available at <http://www.gpo.gov/fdsys/pkg/BILLS-107hr3967ih/pdf/BILLS-107hr3967ih.pdf>; Christopher M. Holman, *Recent Legislative Proposals Aimed at the Perceived Problem of Gene Patents*, SCITECH E-MERGING NEWS, 2 (2008), http://www.abanet.org/scitech/biotech/pdfs/recent_legislative_chris_holman.pdf.

291. Holman, *supra* note 289.

292. *Id.*

293. *Id.* at 2-3.

294. *Id.* at 3.

295. Miri Yoon, *Gene Patenting Debate: The Meaning of Myriad*, 9 J. MARSHALL REV. INTELL. PROP. L. 953, 969 (2010).

under the Bayh-Doyle Act, allow commercialization and public availability on federally funded inventions, which allows the government to “march in” and require a recipient of funds to license the invention under limited circumstances.²⁹⁶ The limited circumstances include underutilized technologies that have been developed through federally funded research.²⁹⁷ Since most basic research is aided by federal funds,²⁹⁸ some genetic sequence patents may already qualify for this type of protection. Expanding the government’s “march-in” rights to genetic sequence patents could solve several of the issues that patients currently face—lack of insurance coverage, prohibitive cost of the test, inability to obtain a second opinion, and quality control. This approach is not ideal because it lends itself to discretionary abuse. If enacted, the “march-in rights” provision would have to be narrowly tailored and carefully implemented in order to avoid abuse of discretion and overuse.²⁹⁹

If the government enacts “march-in” rights, the patent owner would still need to be assured of reasonable compensation when those rights are exercised.³⁰⁰ One model of compulsory licensing through “reasonable compensation” is the Clean Air Act, which was enacted in the 1970s, and provided compulsory licenses for technologies related to air pollution prevention and control.³⁰¹ A Clean Air Act compulsory license required that a patent that is critical to control air pollution must be compulsory licensed if the attorney general determines that the invention is not reasonably available, that there are no reasonable alternatives, and that the unavailability of the invention may result in a substantial problem of competition that would create a monopoly in the technology area.³⁰² The application of a Clean Air Act like compulsory license would require the attorney general, or some other designated government entity, to determine if there was another way for the disease to be diagnosed, if the

296. *Id.* at 970.

297. Eric W. Gutttag, *Foaming at the Mouth II: My Alternative to the New But Inane Becerra Bill*, IP WATCHDOG (Apr. 15, 2010, 3:11 PM), <http://ipwatchdog.com/2010/04/15/foaming-at-the-mouth-ii-my-alternative-to-the-new-but-inane-becerra-bill/id=10104/>.

298. *See generally Science and Engineering Indicators 2008*, *supra* note 224.

299. Gutttag, *supra* note 296.

300. *Id.*

301. *Id.*

302. Yoon, *supra* note 294, at 970.

unavailability of another diagnosis creates a significant problem to the public health, and the reasonableness of other alternatives. Additionally, a reasonable royalty would be set and distributed to any company found to qualify under this analysis. The threat of a compulsory license or “march-in” rights would influence companies to be more flexible in the licensing and access to their patents on genetic sequences, and would rarely need to be invoked considering most companies already provide reasonable access to genetic sequence patents.

Court-implemented compulsory licenses could be enacted through a refusal by the court system to provide injunctive relief when infringement of a genetic sequence is found. Refusal to provide injunctive relief under 35 U.S.C. §154(a)(1) allows a court to order compulsory licensing if injunctive relief is improper when infringement is found.³⁰³ This method of compulsory licensing presents a problem because it is not a hard-line rule, so researchers and the public will not know when a court will deem the facts of their case to qualify for a compulsory license over injunctive relief. Injunctive relief bypasses a ruling that genes are unpatentable by taking the sting out of an infringement suit.

5. Health Care Reform to Address Patient Access and Health Insurance Issues

The government at a state and federal level can institute insurance reform mandates that could require coverage of diagnostics tests.³⁰⁴ One of the key allegations in the ACLU’s complaint was that patients cannot get tested because they were either uninsured or their insurance would not cover the Myriad tests.³⁰⁵ A federal or state mandate requiring insurance coverage for genetic diagnostic tests

303. *Id.*

304. *See, e.g.*, Victoria Craig Bunce & J.P. Wieske, *Health Insurance Mandates in the States 2010*, COUNCIL FOR AFFORDABLE HEALTH INS. (Oct. 20, 2010), http://www.cahi.org/cahi_contents/resources/pdf/MandatesintheStates2010ExecSummary.pdf (summary of state mandate health insurance initiatives); *id.* at 8 (Summary of federal mandates in 2010). *See generally* The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), available at <http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>.

305. Complaint, *supra* note 59, at 2 (“Many women at risk cannot even be tested because they are uninsured and/or cannot afford the test offered by Myriad”); *see also id.* at 10 (“Myriad will not accept the MassHealth Coverage”); *see also id.* at 12 (“Myriad would not accept her insurance”).

when a doctor recommends the test would better solve this complaint than invalidation of genetic patents. Additionally, personal insurance mandates, as in Massachusetts, could require that every individual have health insurance, which would prevent uncovered individuals from accessing the technology. However, requiring insurance to cover the test or requiring an individual to carry health insurance would not ensure that a sole provider would accept that health insurance provider. In order to solve this issue, Congress would need to implement a requirement that health insurance cover diagnostic tests. Although this is an imperfect solution, it would have greater benefit than the invalidation of a patent, because even if there are two or more providers of a diagnostic test—it does not guarantee that *any* of the providers will accept all health insurance or that *any* of the health insurance providers will cover the test.

Additionally, Congress, independent health care community regulators or the FDA could implement national standards that would address the manner in which the test is administered, the way in which the test is marketed, and the method in which the patient receives counseling after negative or positive results are received.

In summary, there are several options to addressing patient access to diagnostic technologies. Patent invalidation will not broadly address all diagnostic technologies, which, regardless of subject matter, carry the same access and quality issues. In fact, patent invalidation will not guarantee that any of the access or care issues are addressed. Therefore, these issues should not be addressed through patent law, but through regulatory agencies and congressional legislation with the ability and foresight to craft much needed reforms in health care.

D. Myriad Should Not Have Unfair Access to Medical Samples Based on Their Patents

Some proponents of invalidating Myriad's patent assert that Myriad's patent allows the company "to collect annotated DNA samples that would give it an unfair advantage over potential competitors in discovering cures."³⁰⁶ It could also give Myriad an unfair advantage in discovering other BRCA mutations, due to the large exclusive DNA sample size the company had immediate access

306. Gold & Carbone, *supra* note 58, at S45.

to.³⁰⁷ Effectively, this argument postulates that Myriad has a competitive advantage in the patenting of other BRCA mutations which could extend their monopoly.

However, Myriad contends that they never intended to create a “private mutation database” and the company has extensively contributed new mutations to the Breast Cancer Information Core Mutation Database.³⁰⁸ There is some indication that they have already stopped contributing to the database and publishing articles,³⁰⁹ but this, like patient care and oversight of genetic testing, is not a patent issue. A patient’s tissue sample should not be placed into a “mutation bank” without informed consent. A patient’s autonomy necessitates that the conflicting interest of a company providing a medical test and the researcher trying to patent the next big invention should not cross.³¹⁰

First, to be placed in any type of “genetic mutation bank” a patient would first need to fully consent to sharing their medical information and tissue sample.³¹¹ An oversight committee could require all genetic tissue banks to secure patient consent before releasing information for research use, and that all information would then go into a nationally recognized database and not a privately held database. While a patent grants a negative right to a company to exclude others from practicing their invention, it does not provide a property right in an individual’s tissue sample. Legislation in genetic confidentiality, patient autonomy, and health care records is not a new area for Congress. Therefore, congressional legislation could easily extend to the creation and implementation of a national genetic database. Interestingly, if genetic sequences were ruled ineligible for patent protection, the likelihood of shared data might decrease due to the absence of a patent’s incentive to publicly disclose the research.

307. John Conley & Dan Vorhaus, *How Will Myriad Respond to the Next Generation of BRCA Testing?*, GENOMICS LAW REPORT (Mar. 1, 2011), <http://www.genomicslawreport.com/index.php/2011/03/01/how-will-myriad-respond-to-the-next-generation-of-brca-testing/>.

308. Gold & Carbone, *supra* note 58, at S45.

309. Conley & Vorhaus, *supra* note 306.

310. David Resnik, *Are DNA Patents Bad For Medicine?*, 65 HEALTH POL’Y 181, 192 (2002).

311. *Id.* at 191.

IX. CONCLUSION

The patentability of genetic sequence is an interesting patent law query precisely because the arguments are strong on both sides. Patents are fundamental in the United States in order to further scientific research. Without the patent race, the expansive biotechnology sector would suffer. If patents on genetic sequences are held unpatentable, investors in biotechnology and medical diagnostics may worry that other types of biomedical patents will be excluded from the patent bargain in the future. Uncertainty in the biotechnology sector will have a negative impact on investments in research and development. Fundamentally, quality of patient care and access to diagnostic tests is a health care issue and patent law is not the solution. Myriad's business practices essentially dictated how medical tests were distributed and regulated, how doctors were trained, how patients received results, patient access, and patient counseling. These are not issues for a private company or for patent law. Congress must ensure that patients are not treated at the whim of a company, but in a consistent and effectual manner that ensures quality access to healthcare and counseling afterwards.