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Stifling Scientific Progress: The District Court's Decision in Myriad

Keywords

Human Genome, DNA, gene sequencing

Stifling Scientific Progress: The District Court's Decision in *Myriad*

by Seth R. Ogden*

I. INTRODUCTION

The human genome contains approximately 23,000 protein-coding genes.¹ Approximately twenty percent of these human genes are patented, with some genes being patented as many as twenty times.² On May 12, 2009, the Association for Molecular Pathology ("AMP") and nineteen other plaintiffs, including healthcare associations and individual doctors, researchers, and patients, filed a lawsuit against the United States Patent Office ("USPTO"), Myriad Genetics ("Myriad") and ten other individual defendants in their capacity as Directors of the University of Utah Research Foundation challenging the validity of Myriad's gene patents.³ Myriad holds, through either assignment or exclusive license, a number of domestic and international patents covering isolated DNA molecules encoding the BRCA1 and BRCA2 ("BRCA1/2") mutations that cause an increased risk for the development of breast and ovarian cancer and diagnostic methods using these isolated DNA molecules to identify a patient's predisposition to the development of familial breast cancer.⁴ In its complaint, AMP alleged that the patent claims were invalid under Article 1, Section 8, clause 8 of the United States Constitution and 35 U.S.C. § 101 "[b]ecause human genes are products of nature, laws of nature and/or natural phenomena, and abstract ideas or basic human knowledge or thought."⁵ Similarly, AMP further asserted that the claims were unconstitutional under the First and Fourteenth Amendments to the United States Constitution, as they represent patents

on abstract ideas or basic human knowledge and/or thought.⁶

On March 29, 2010, Judge Robert Sweet of the United States District Court for the Southern District of New York granted the plaintiffs' motion for summary judgment, holding the patents related to *BRCA1/2* invalid.⁷ Judge Sweet's resolution of the motion was "based upon long recognized principles of molecular biology and genetics: DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature."⁸ Therefore, Judge Sweet concluded that the isolated DNA containing sequences found in nature was unpatentable subject matter under 35 U.S.C. § 101.⁹ He further concluded that the claimed comparisons of DNA involved in the diagnostic methods were simply abstract mental processes, also rendering them unpatentable under 35 U.S.C. § 101.¹⁰ Though providing no comfort for Myriad, Judge Sweet granted the USPTO's motion for summary judgment dismissing the constitutional claims, invoking the doctrine of constitutional avoidance.¹¹ Not surprisingly, Myriad filed a Notice of Appeal to the Court of Appeals for the Federal Circuit on June 16, 2010.¹² Oral arguments were heard on April 4, 2011.¹³

Although the district court's decision's applicability is limited to the patents in the instant case, if upheld by the Federal Circuit, the decision would have far-reaching implications for human gene patents currently in force and the future of the biotechnology industry, both domestically and abroad. Therefore, this paper seeks to address the legal and policy issues

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1. International Human Genome Sequencing Consortium, *Finishing the Euchromatic Sequence of the Human Genome*, 431 NATURE 931, 942 (2004).

2. Kyle Jensen and Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCI. 239, (2005).

3. Complaint at ¶ 27-29, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F.Supp.2d 181 (S.D.N.Y. May 12, 2009) (No. 09CV04515), 2009 WL 1343027 [hereinafter AMP Complaint].

4. *Id.* at ¶ 31. The challenged patents include US 5,747, 282; US 5,837,492; US 5,693,473; US 5,709,999; US 5,710,001; US 5,753,441; and US 6,033,857.

5. *Id.* at ¶ 102.

6. *Id.* at ¶ 103.

7. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 232, 237 (S.D.N.Y. Mar. 29, 2010).

8. *Id.* at 185.

9. *Id.*

10. *Id.*

11. *Id.* at 237-38.

12. Notice of Appeal to the Federal Circuit, Association for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F.Supp.2d 181 (S.D.N.Y. June 16, 2010), No. 09 Civ. 4515 (Fed. Cir. June 1, 2010).

13. U.S. Court of Appeals for the Federal Circuit, *Oral Argument Recordings*, <http://www.cafc.uscourts.gov/oral-argument-recordings/search/audio.html>.

concerning human gene patents in view of the current decision in *Association for Molecular Pathology v. United States Patent & Trademark Office* (hereinafter “Myriad”) with a view to related cases involving Myriad’s patenting of isolated DNA molecules encoding BRCA1/2 in the United States and European forums.

II. BACKGROUND

A. DNA and Genes – The Information That Life Depends On

Watson and Crick revolutionized genetic research in 1953 with their determination of the structure of deoxyribonucleic acid (“DNA”) and the elucidation of the implications for such a structure in genetic research.¹⁴ DNA exists in nature as linear sequences of nucleotides (chemical units known as adenine, thymine, guanine, and cytosine) that are packaged into chromosomes. Each chromosome contains hundreds of genes, occurring one after the other as discrete lengths of sequence within the linear DNA. The order of the nucleotide sequences within a gene determines the functioning of that gene, and the characteristics of individual genes collectively contribute to the genetic traits a person receives.

How does the nucleotide sequence determine the functioning of a gene? Crick articulated this process within the framework of what is known as the central dogma of molecular biology.¹⁵ The central dogma outlines the process by which genes are expressed; in other words, it describes the mechanism by which the genetic instructions contained in the nucleotide sequence of a gene effectuate a function within a cell. Essentially, DNA is copied repeatedly into a similar form known as mRNA (transcription), and these numerous copies of mRNA are turned into protein (translation). These proteins then interact to carry out a host of functions within the cell. A simple analogy illustrates the concept: A person reads instructions (“DNA”) for how to put a table together, and that person’s brain processes the information (“transcription”) into a signal (“mRNA”); that person’s brain then sends out that signal (“mRNA”) telling their body to carry out the processed instructions from the brain to put the table (“proteins”) together

(“translation”).

Importantly, alterations in the nucleotide sequences, called mutations, can occur, principally by either faulty repair of DNA damage or imperfect copying of DNA when it is passed on to new cells. Many of these mutations are silent, resulting in no perceptible consequences. However, certain specific mutations can increase a person’s risk for the development of a variety of serious diseases, including cancer.¹⁶ Accordingly, certain mutations of the “breast cancer 1, early onset” and “breast cancer 2, early onset” (*BRCA1/2*) genes lead to increased risk of breast and ovarian cancer. The average woman in the United States, without such a mutation, has about a 12% chance of developing breast cancer in her lifetime, but carriage of an abnormal *BRCA1* or *BRCA2* gene augments this to about an 80% chance.¹⁷ With regard to ovarian cancer, the average woman has an approximately 1.4% chance of developing ovarian cancer, but for a woman with a *BRCA1* or *BRCA2* mutation that risk increases to 15% to 40%.¹⁸

Because an increased risk for breast or ovarian cancer has many implications for an individual’s choice of lifestyle and preventative care, the scientific and healthcare communities have begun to intensify research into genetic testing to facilitate early identification of *BRCA1/2* mutations in patients. Genetic testing for mutations within an individual’s DNA sequence is carried out by one of a number of methodologies collectively known as gene sequencing, which allows determinations of the exact order of nucleotides within a strand of linear DNA.¹⁹ Essentially, fluorescent tags of four distinct colors corresponding to each of the four nucleotides (adenine, guanine, cytosine, and thymine)

14. See Miri Yoon, *Gene Patenting Debate: The Meaning of Myriad*, 9 J. MARSHALL REV. INT. PROP. L. 953, 954 (2010); see also James D. Watson & Francis H. Crick, *Molecular Structure of Nucleic Acid: A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737 (1953); James D. Watson & Francis H. Crick, *Genetic Implications of the Structure of Deoxyribonucleic Acid*, 171 NATURE 964 (1953).

15. See Francis Crick, *On Protein Synthesis*, SYMP. SOC. EXP. BIOL. XII 139 (1958) (presenting a new theory of how genes affect protein expression and function).

16. See Marisa Noelle Pins, *Impeding Access to Quality Patient Care and Patient Rights: How Myriad Genetics’ Gene Patents Are Unknowingly Killing Cancer Patients and How to Calm the Ripple Effect*, 17 J. INTELL. PROP. L. 377, 384 (2010) (noting that some inherited mutations may increase a “person’s risk for a variety of diseases, while others are innocuous”).

17. *Cancer Risk and Abnormal Breast Cancer Genes*, BREASTCANCER.ORG, http://www.breastcancer.org/risk/genetic/bcrisk_abnrm1_genes.jsp (last visited Oct. 22, 2010). It is important to note that hundreds of potential mutations have been identified in *BRCA1/2* genes, each one carrying with it a different level of risk of the development of breast and ovarian cancer. These percentages simply quantify overall risk for according to the frequency of each distinct mutation in the female population of the United States.

18. *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NATIONAL CANCER INSTITUTE, <http://www.cancer.gov/cancertopics/factsheet/risk/brca#r4> (last visited March 7, 2010).

19. *A Brief Guide to Genomics*, NAT’L HUMAN GENOME RESEARCH INST., <http://www.genome.gov/18016863> (last visited Oct. 22, 2010).

are allowed to bind to the DNA.²⁰ These fluorescent tags are identified by a detector, which provides the information to a computer in order to reconstruct the entire gene sequence.²¹

In order to perform gene sequencing, the specific gene to be sequenced is purified and isolated from the individual's body prior to the introduction of the fluorescent tags.²² The term "purified" implies isolation from the gene's natural state,²³ whereas the term "isolation" implies removal from the body and separation from the surrounding cellular material.²⁴ This purified and isolated DNA molecule that encodes such a gene may therefore be the same in sequence as the naturally occurring gene, albeit with an altered chemical structure due to the removal of associated cellular products that facilitate packaging of the DNA into a chromosome. Under the current USPTO policy, such a purified and isolated DNA molecule is patent eligible.²⁵

B. Patenting of Genes and Other Biological Materials in the United States

1. Development of United States Case Law

The United States Constitution gives Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to...Inventors the exclusive Right to their respective...Discoveries."²⁶ Under this authority, Congress enacted the first Patent Act in 1790²⁷ and the most recently revised Act in 1952.²⁸ 35 U.S.C. §101 describes patentable subject matter as "any new and useful process, machine, manufacture or composition of matter."²⁹ Famously, in *Diamond v.*

Chakrabarty, the Supreme Court broadly construed such statutory subject matter "to include anything under the sun that is made by man,"³⁰ but went on to hold that "laws of nature, physical phenomena, and abstract ideas" are excluded from patent-eligible subject matter.³¹

Under early cases, purified natural products were generally held to be unpatentable. It is important to note that despite its conclusions of patent-ineligibility, the Supreme Court did not appear to rely on the fact that the subject matter was a product of nature,³² but rather a lack of novelty³³ evidenced by an inability to distinguish between the natural and purified/synthetic compositions. In *American Wood-Paper Co. v. Fibre Disintegrating Co.*, the court invalidated a patent for extracted wood pulp because it found the purified product to be the same as the natural product.³⁴ Similarly, in *Cochrane v. Badische Anilin & Soda Fabrik*,³⁵ the court held that a synthetic dye was not a new composition because it had the same chemical makeup as the natural dye.³⁶

However, this line of reasoning was challenged in a line of cases holding that isolation and purification may alter a composition of matter so as to render it patent-eligible. Within the chemical context, the court in *Union Carbide Co. v. American Carbide Co.*³⁷ found that a crystalline product described in the application was different from an amorphous product found in the prior art due to physical properties that made it better suited for commercial use in gas generators.³⁸ Similarly, in *Kuehnmsted v. Farbenfabriken of Elberfeld Co.*,³⁹ the court upheld a patent for a form of aspirin (acetyl salicylic acid) purified by a process resulting in an increased therapeutic effect compared to aspirin purified by previous methods.⁴⁰ The court noted that "though the difference . . . be one

20. *Id.*

21. *Id.*

22. Pins, *supra* note 16.

23. See Pins *supra* note 16 (citing United States Patent & Trademark Office, Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001)).

24. See *id.* (citing Plaintiff's Memorandum of Law in Support of Motion for Summary Judgment at 2, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 09 Civ. 4515, 2009 WL 3269113 (S.D.N.Y. Aug. 26, 2009)).

25. See USPTO, UTILITY EXAMINATION GUIDELINES, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) [hereinafter EXAMINATION GUIDELINES] (stating that "an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.").

26. U.S. Const. art. I, § 8, cl. 8.

27. An Act to Promote the Progress of Useful Arts, 1 Stat. 109 (1790).

28. Act of 1952, 66 Stat. 792 (1952) (codified as amended at 35 U.S.C. § 101).

29. 35 U.S.C. § 101 (codification of the amended Patent Act of 1952).

30. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952) and H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)).

31. *Id.* at 309 (citing *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67, (1972); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130, (1948); *O'Reilly v. Morse*, 56 U.S. 62, 112-121, (1854); *Le Roy v. Tatham*, 55 U.S. 156, 175 (1853)).

32. See Yoon, *supra* note 14 at 962.

33. The use of the term "novelty" here refers to the inclusion of the term "new" in the 35 U.S.C. § 101 of patentable subject matter as contrasted with the statutory bar relating to novelty set out in 35 U.S.C. § 102.

34. *American Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. 566, 596 (1874); Pins, *supra* note 16 at 388.

35. 111 U.S. 293 (1884).

36. *Id.* at 311.; see also Pins, *supra* note 16, at 388.

37. 181 F. 104 (2d Cir. 1910).

38. *Id.* at 107.

39. 179 F. 701 (7th Cir. 1910).

40. *Id.* at 705.

of purification only—strictly marking the line, however, where the one is therapeutically available and the others were therapeutically unavailable—patentability would follow.”⁴¹ This logic formed the basis for one of the most notable cases examining the patentability of biological materials, *Parke-Davis & Co. v. H. K. Mulford Co.*⁴² In that decision, Judge Learned Hand held that a patent for adrenaline was valid because the adrenaline had been isolated from nature.⁴³ Specifically, the inventor had made it available for any use by removing it from other gland tissue in which it was found, thereby transforming it for every practical purpose into a new thing, commercially and therapeutically.⁴⁴

Such decisions paved the way for the patentability of biological products in their isolated and purified form, a view that garnered further support from the Court of Customs and Patent Appeals in *Application of Bergstrom*.⁴⁵ In that case, the court held that two chemical entities of the prostaglandin family extracted from prostate glands were patentable because the compounds were not naturally occurring in their purified form.⁴⁶ The court asserted that pure materials differ from impure materials by definition,⁴⁷ and if impure materials are the only ones existing and available, consequently, the pure materials are new with respect to the impure materials.⁴⁸

Accordingly, courts have implicitly recognized the patent-eligibility of purified and isolated DNA molecules. In *Amgen, Inc. v. Chugai Pharmaceuticals Co.*,⁴⁹ the district court accepted the defendant’s assertion that the claimed invention was a purified and isolated DNA sequence encoding human erythropoietin, i.e. the cloned gene rather than the sequence listing *per se*.⁵⁰ Therefore, the claim was not directed towards a sequence that would be “a nonpatentable natural phenomenon ‘free to all men and reserved exclusively to none.’”⁵¹ The

Federal Circuit accepted the district court’s construction of the claim, specifying the subject matter as “the novel *purified and isolated* sequence which codes for EPO.”⁵²

Though the Supreme Court has not directly addressed the issue of purified and isolated gene sequences in the context of patent eligibility, an affirmative decision would be in accord with its previous decisions. With regard to biological products, the Court in *Diamond* held that a bacterium genetically engineered to carry multiple oil-degrading plasmids fell within the ambit of patentable subject matter.⁵³ The Court concluded that the claimed microorganism was a “nonnaturally occurring manufacture or composition of matter” having “markedly different characteristics from any found in nature,” contrasting it with “a new mineral discovered in the earth or a new plant found in the wild.”⁵⁴ This holding has been interpreted by at least one commentator to mean that natural things left unaltered by human intervention are unpatentable products of nature, while some natural things may be so transformed by man that they cease to be products of nature.⁵⁵ Thus, the crucial question before the Court in the instant appeal will be whether purification and isolation of a genetic sequence results in a nonnaturally occurring composition of matter with characteristics markedly different from those of DNA in its natural state sufficient to render it patentable subject matter.

2. Current Position of the USPTO

The USPTO has granted 4270 patents containing claims directed to about 4382 human genes.⁵⁶ In promulgating its Utility Examination Guidelines, the USPTO responded to a number of comments received regarding the patent-eligibility of human genes.⁵⁷ Many such comments opined that a gene is not a new composition of matter because it exists in nature, and consequently, an inventor who isolates a gene does not actually invent or discover a patentable composition.⁵⁸

41. *Id.*

42. 189 F.95 (C.C.S.D.N.Y. 1911).

43. *Id.* at 103.

44. *Id.*

45. 427 F.2d 1394 (C.C.P.A. 1970).

46. *Id.* at 1401-02.

47. *Id.* at 1401 n. 10 (“Webster’s . . . defines ‘pure’ as ‘Separate from all heterogeneous or extraneous matter; free from mixture or combination. . . .’”) (quoting Webster’s New International Dictionary, (2d ed. 1954)).

48. *Id.* at 1402.

49. No. 87-2617-Y, 1989 WL 169006, 13 U.S.P.Q.2d 1737 (D. Mass. Dec. 11, 1989) *aff’d in part, vacated in part*, 927 F.2d 1200, 1219 (Fed. Cir. 1991).

50. *Id.* at *32, 13 U.S.P.Q.2d at 1759.

51. *Id.* (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)).

52. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991) (placing emphasis upon the terms “*purified and isolated*”), *see also* *In re Kubin*, 561 F.3d 1351, 1352 (Fed. Cir. 2009) (noting that “[t]his case presents a claim to a *classic biotechnology invention—the isolation and sequencing of a human gene* that encodes a particular domain of a protein”).

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

54. *Id.* at 309-10.

55. Richard S. Gipstein, Note, *The Isolation and Purification Exception to the General Unpatentability of Products of Nature*, 4 COLUM. SCI. & TECH. L. REV. 1, 3-4 (2003).

56. Jensen & Murray, *supra* note 2, at 239.

57. See UTILITY EXAMINATION GUIDELINES, 66 Fed. Reg. 1092, 1092 (Jan. 5, 2001).

58. *Id.* at 1093.

In response, the USPTO asserted that “a patent claim directed to an *isolated and purified* DNA molecule could cover a gene excised from a natural chromosome or a synthesized DNA molecule.”⁵⁹ Relying on *Parke-Davis* and *In re Bergstrom*, the USPTO emphasized that a molecule having the same sequence as a naturally occurring gene is patent-eligible because (1) an excised gene is patent-eligible as a composition of matter because that DNA molecule does not occur in that isolated form in nature or (2) a synthetic DNA preparation is patent-eligible because its purified state is different from the naturally occurring compound.⁶⁰

3. The District Court’s Decision in *Myriad*

Myriad holds, through assignment or exclusive license, several U.S. patents on the isolated DNA molecules relating to the *BRCA1/2* sequences.⁶¹ Myriad did not enforce its patents against academic research institutions,⁶² but regularly sought enforcement against both research institutions and commercial entities providing commercial diagnostic testing through cease-and-desist letters⁶³ and litigation.⁶⁴ At least nine clinical diagnostic laboratories ceased *BRCA1/2* testing due to Myriad’s patent holdings.⁶⁵ Myriad’s enforcement actions precipitated AMP’s request for declaratory judgment that Myriad’s patents on human *BRCA1/2* are invalid under 35 U.S.C. § 101 and are unconstitutional because the granting of human gene patents by the USPTO violates Article I, section 8, clause 8 and the First Amendment of the Constitution.⁶⁶

The claims addressed by the lawsuit fall into two main categories: composition claims and method (process) claims.⁶⁷ The composition claims are directed to isolated and purified DNA molecules that encode either normal (wild-type) or mutant forms of *BRCA1/2*

proteins.⁶⁸ A representative composition claim is claim one of U.S. Patent 5,747,282, which reads, “[a]n isolated DNA coding for a *BRCA1* polypeptide, said polypeptide having the [following] amino acid sequence.”⁶⁹ The method claims are directed to diagnostic methods for assessing a patient’s predisposition to the development of breast and ovarian cancer using such isolated DNA molecules as identified in the composition claims. A representative method claim is claim twenty of U.S. Patent 5,753,441, which reads:

A method for detecting a germline alteration in a *BRCA1* gene, said alteration selected from the group consisting of the alterations set forth in [the Tables] . . . which comprise[] analyzing a sequence of the *BRCA1* gene or *BRCA1* RNA from a human sample or analyzing the sequence of *BRCA1* CDNA [sic] made from mRNA from said sample.⁷⁰

Several pre-trial motions were submitted to the court: 1) AMP moved for summary judgment, declaring that Myriad’s patents were invalid;⁷¹ 2) Myriad moved for summary judgment to dismiss AMP’s complaint for lack of subject-matter jurisdiction, characterizing the suit as consisting of a mere policy disagreement rather than a real controversy;⁷² and 3) the USPTO moved for judgment on the pleadings under the doctrine of constitutional avoidance.⁷³ The court stayed AMP’s

68. *Id.* at 211-12.

69. U.S. Patent No. 5,747,282 col. 153 ll. 56-59 (filed June 7, 1995).

70. U.S. Patent No. 5,753,441 col. 157 ll. 11-17 (filed Jan. 5, 1996). Method claims will not be discussed in detail as these claims are beyond the scope of this paper.

71. Plaintiff’s Memorandum of Law in Support of Motion for Summary Judgment, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2009 WL 3269113 (S.D.N.Y. Aug. 26, 2009).

72. Memorandum of Law in Support of Defendant’s Motion to Dismiss, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 2009 WL 3269109 (S.D.N.Y. July 13, 2009) (“This case is clearly a thinly veiled attempt to challenge the validity of patents where, other than an overall policy disagreement concerning the legitimacy of gene patents, the plaintiffs have no actual dispute with the Defendants over patent infringement.”).

73. Memorandum of Law in Support of Defendant United States Patent & Trademark Office’s Motion for Judgment on the Pleadings and in Opposition to Plaintiff’s Motion for Summary Judgment, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 2009 WL 5785024 (S.D.N.Y. Dec. 24, 2009) (“Because plaintiffs have not identified any way in which the Constitution imposes limits on patents beyond those already imposed by the patent laws, plaintiffs’ First Amendment claim merges with their statutory claims, and should therefore be

59. *Id.* (emphasis added).

60. *Id.*

61. AMP Complaint, *supra* note 3, at ¶ 31.

62. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d. 365, 379 (S.D.N.Y. 2009) (referencing letter to National Cancer Institute investigator assuring her that Myriad would not interfere with her research activities).

63. *See id.* at 378-379 (discussing letters sent to the University of Pennsylvania, Georgetown, and Yale).

64. *See id.* (discussing the litigation it was involved in with Oncormed and the University of Pennsylvania).

65. *Id.* at 380; Mildred K. Cho, et al., *Effects of Patents and License on the Provision of Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, Table 2 (2003).

66. AMP Complaint, *supra* note 3., at ¶ 102.

67. *See Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 212 (S.D.N.Y. 2010).

Motion for Summary Judgment pending its resolution of Myriad's motion to dismiss.⁷⁴ On November 2, 2009, the court denied Myriad's motion to dismiss, stating that "[t]he novel circumstances presented by this action . . . , the absence of any remedy provided in the Patent Act, and the important constitutional rights the Plaintiffs seek to vindicate establish subject matter jurisdiction over the Plaintiffs' claim."⁷⁵ Ultimately, the USPTO's motion for judgment on the pleadings was granted, dismissing the plaintiffs' claims.⁷⁶ Most significantly, on March 29, 2010, the court granted AMP's motion for summary judgment, resulting in invalidation of the challenged patent claims relating to Myriad's *BRCA1/2* composition and method claims.⁷⁷

Though the Supreme Court has never made a general statement that products of nature are patent-ineligible,⁷⁸ the district court concluded that exclusion of products of nature under 35 U.S.C. § 101 "reflects the Supreme Court's recognition that 'phenomena of nature . . . are not patentable.'"⁷⁹ Thus, the court delineated its sole task as determining "whether the claimed invention . . . falls within the judicially created 'products of nature' exception."⁸⁰ Consistent with several of the cases cited *supra*,⁸¹ the court acknowledged that a change in a product of nature resulting in the creation of a fundamentally new product would be eligible for a patent.⁸² Using the restrictive language of *Diamond* requiring that the product possess "markedly different characteristics" to establish creation of a fundamentally new product,⁸³ the court concluded that isolated and purified DNA does not possess markedly different characteristics from native DNA.⁸⁴

C. Patenting of Genes in Europe

1. European Patent Convention

dismissed.").

74. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 374 (S.D.N.Y. 2009).

75. *Id.* at 383.

76. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 238 (S.D.N.Y. 2010).

77. *Id.* at 232, 237.

78. Yoon, *supra* note 14, at 962 (citing *Am. Fruit Growers, Inc. v. Brodgeth Co.*, 283 U.S. 1, 11 (1931); *Am. Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. 566, 577-596 (1874); *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 311 (1884)).

79. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 218-19 (citing *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

80. *Id.* at 220.

81. See cases cited *supra* notes 36, 38, 43, 46, 50, 54.

82. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 222.

83. *Id.* at 229 (citing *Chakrabarty*, 447 U.S. at 310 (1980)).

84. *Id.* at 232.

The European Patent Convention ("EPC") is a multilateral treaty that instituted the European Patent Organization in order to provide an autonomous legal system by which European patents are granted. Practically, the grant of a European patent does not provide a unitary right, but rather a "group" of essentially independent patents granted on a single application, nationally-enforceable and nationally-revocable by Contracting states.⁸⁵ The EPC provides a legal framework for the granting of European patents through a single, harmonized procedure before the European Patent Office ("EPO"), a division of the European Patent Organization.⁸⁶

The EPC requires that patents be granted for "any inventions which are susceptible of industrial application."⁸⁷ Exceptions covering inventions considered "discoveries, scientific theories, and mathematical methods," among others, are codified within the treaty,⁸⁸ rather than derived from case law as in the United States. In addition, the European Union may issue directives interpreting treaties such as the EPC that require compliance by member States through harmonization of their national laws to make them consistent with the directive.⁸⁹ Notably, the European Union Biotech Directive interpreted the EPC patentable subject matter exceptions narrowly, affirming that isolated biological material is considered patentable subject matter even if previously occurring in nature.⁹⁰ The Directive further specifies that, if isolated from the human body, "the sequence or partial sequence of a gene" may constitute patentable subject matter, so long as the industrial application of that sequence is disclosed

85. Convention on the Grant of European Patents, art. 2(2), Oct. 5, 1973, 1065 U.N.T.S. 199 [hereinafter European Patent Convention]; see also Case C-539/03, *Roche Nederland BV v. Frederick Primus*, 2006 E.C.R. I-06535; Case C-4/03, *Gesellschaft für Antriebstechnik mbH & Co. KG v. Lamellen und Kupplungsbau Beteiligungs KG*, 2006 E.C.R. I-06509.

86. European Patent Convention, *supra* note 86, at art. 2(1).

87. *Id.* at art. 52 (emphasis added). Note the similarity in breadth to the language of 35 U.S.C. § 101 requiring "any new and useful process, machine, manufacture or composition of matter" for patentability. (emphasis added)

88. *Id.* at art. 52(2). Other less germane exceptions include aesthetic creations, schemes, rules and methods for performing mental acts, playing games or doing business, programs for computers, and presentations of information.

89. John Conley, *European Court Issues a Gene Patent Ruling Against Monsanto—A Myriad Connection*, GENOMICS LAW REPORT (July 28, 2010), <http://www.genomicslawreport.com/index.php/2010/07/28/european-court-issues-gene-patent-ruling-against-monsanto-a-myriad-connection/>.

90. Council Directive 98/44, art. 3, 1998 O.J. (L 213) 13-21 (EC).

in the patent application.⁹¹

A European patent is subject to revocation or narrowing by the EPO by either of two types of post-grant procedure—an opposition procedure or a limitation and revocation procedure.⁹² The opposition procedure may be initiated by any interested person from the public who believes that the patent should not have been granted.⁹³ The opposition must be based on the grounds set forth in Article 100 of the EPC,⁹⁴ which include that the invention lacks novelty, an inventive step, or industrial application, and be received within nine months of publication that the patent has been granted.⁹⁵ Once an opposition is filed, the opposition division, consisting of three experienced examiners, begins an investigation that includes examination of the patent, invitation to the parties to file any observations, and, typically, oral proceedings.⁹⁶ The final outcome is one of three possibilities: (1) revocation of the patent, (2) maintenance of the patent, or (3) maintenance of the patent in amended form.⁹⁷ Subsequent to the decision of the opposition division, the parties have the option to appeal to the independent boards of appeal.⁹⁸

2. European Patent Office's Treatment of Myriad's Patents

The EPO granted four patents to Myriad covering the *BRCA1/2* genes and related diagnostic methods,⁹⁹ one of which claimed the isolated DNA molecule encoding *BRCA1*.¹⁰⁰ Opposition to the '902 patent was filed on August 28, 2002 by organizations from eleven European countries¹⁰¹ on multiple grounds

including lack of novelty, inventive step, and/or industrial application.¹⁰² As for lack of novelty, Myriad claimed a priority date to a patent application filed in the U.S. in 1994¹⁰³ in which the *BRCA1* sequence listing contained ten errors ultimately requiring amendment on March 24, 1995 to reflect the correct sequence.¹⁰⁴ During that time, the molecule encoding *BRCA1* was isolated by other researchers and its sequence placed in scientific databases and numerous articles in the public domain.¹⁰⁵ Thus, the challengers contended that the incorrect sequence in the 1994 application could not overcome the absolute novelty bar of the European patent system.¹⁰⁶ With regard to lack of inventive step, previous work of the Breast Cancer Linkage Consortium had narrowed down the region of the chromosome containing the *BRCA1* gene considerably, so much so that one researcher felt that it was only a matter of luck as to which individual researcher would find it.¹⁰⁷ In connection with lack of industrial application, the challengers focused on Article 52(4) of the EPC, which states that “diagnostic methods practiced on the human . . . body shall not be regarded as inventions which are susceptible of industrial application.”¹⁰⁸ Though the claim was directed towards the isolated DNA molecule, the only use of that molecule supported by the specification fell within the context of a diagnostic method.

The opposition division failed to reach any conclusions regarding the assertions of the challengers regarding patentable subject matter, but instead determined that Myriad improperly extended the subject matter by amendment of claims after issuance of the patent in violation of Article 123(2).¹⁰⁹ As a result, the patent was severely limited by invalidation of claims directed towards the isolated *BRCA1* molecule; diagnostic methods; *BRCA1* protein; conceivable

91. *Id.* at art. 5.

92. EUROPEAN PATENT OFFICE, The Opposition Procedure, <http://www.epo.org/about-us/jobs/examiner/role/opposition.html> (last visited November 12, 2010).

93. *Id.*; see also Pins, *supra* note 16, at 401.

94. European Patent Convention, *supra* note 86, at art. 100.

95. The Opposition Procedure, *supra* note 94; See also European Patent Convention, *supra* note 86, at art. 100(a).

96. The Opposition Procedure, *supra* note 94. Prior to the oral proceedings, the patent holder can amend the description, claims, and drawings.

97. *Id.*

98. *Id.*

99. EPO 0699754 (issued Jan. 10, 2001); EPO 0705902 (issued Nov. 28, 2001); EPO 0705903 (issued May 23, 2001); EPO 0785216 (issued Jan. 8, 2003).

100. EPO 0705902 (entitled *17q-linked breast and ovarian cancer susceptibility gene*)

101. Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics/BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133, 138 (2004) [Hereinafter Opposition]. The eleven countries are Austria, Belgium, Czech Republic, Denmark, Finland, Germany, Greece,

Italy, the Netherlands, Switzerland, and the United Kingdom.

102. *Id.*

103. *Id.* at 142.

104. Maurice Cassier, *The Opposition Against the Patent of Myriad Genetics and Their Total or Partial Revocation in Europe: Early Conclusions*, 21(6) MÉDECINE SCIENCES (2005), available at http://www.edk.fr/reserve/revues/ms_papier/e-docs/00/00/07/91/document_article.md (translated by Google).

105. Opposition, *supra* note 102, at 142.

106. *Id.*

107. *Id.* at 143.

108. European Patent Convention, *supra* note 86, at Art. 52(4); Opposition, *supra* note 102, at 144.

109. European Patent Convention, *supra* note 86, at Art. 123(2); Jordan K. Paradise, *Lessons from the European Union: The Need for a Post-Grant Mechanism for Third-Party Challenge to U.S. Patents*, 7 MINN. J.L. SCI. & TECH. 315, 320-321 (2006) [Hereinafter Lessons].

therapeutic applications in gene therapy, drug screening, and transgenic animals; and diagnostic kits.¹¹⁰ After the opposition division's decision, the new patent issued on June 8, 2008, with only three claims directed towards a *BRCA1* DNA probe and a vector coding for said probe.¹¹¹ It appears that the EPO tacitly recognized the validity of the challengers' policy arguments in crafting its decision but specifically sought to avoid making any conclusions that might call into question the validity of European patents on isolated DNA molecules.

3. Recent Developments in European Case Law

*Monsanto Technology LLC v. Cefetra B.V.*¹¹² is the first and only national court referral to the European Court of Justice seeking an interpretation of the EU Biotech Directive. Monsanto holds a European patent claiming modified soybean DNA molecules that confer the plant immunity to certain herbicides, also manufactured by Monsanto.¹¹³ Cefetra, in an attempt to take advantage of Monsanto's lack of an Argentinean patent covering the technology, imported soy meal containing "dead" versions of the subject DNA sequences into the Netherlands.¹¹⁴ Monsanto sued Cefetra in a Dutch court for violation of national patent law, which, similarly to that of the U.S., conveys an exclusive right on the patent holder to exclude others from importing the patented product.¹¹⁵

Cefetra asserted that the EU Biotech Directive supersedes Dutch patent law. Specifically, Article 9 provides that protection extends to "all material . . . in which the [patented] product is incorporated and in which the genetic information is contained and *performs its function*."¹¹⁶ The Dutch court referred to the European Court of Justice the question of whether absolute protection of a DNA sequence, as such, is permissible under the Directive despite the fact that the sequence did not express its function at the time of importation.¹¹⁷ The European Court of Justice determined that such

protection provided by Dutch patent law violated Article 9 of the Directive.¹¹⁸ The court stated that "a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention."¹¹⁹

Though the court's ruling does not preclude the patenting of genes, it appears to preclude absolute protection of an isolated DNA molecule *per se*. Notably, the court's language emphasizing a DNA molecule's performance of function bears an interesting connection to that of the district court in *Myriad*—it is not the chemistry of the DNA sequence that is important, but rather the function (i.e., information-delivering) of that sequence.¹²⁰ Because this decision was held to apply retroactively, it remains to be seen what effect it will have on gene patents such as those held by *Myriad*. Arguably, under a more liberal view, the isolated DNA molecules generated in the course of sequencing are not capable of performing their function, making those molecules ineligible for patent coverage in the European Union in the diagnostic context.¹²¹

III. ARGUMENTS SURROUNDING THE GENE PATENTING DEBATE

Parties on both sides of the gene patenting debate have presented a number of valid arguments to support their position. Opponents of gene patenting assert that gene patents impede access to genetic testing, hinder attempts to increase the quality of genetic testing, and create barriers to basic research on certain genetic mutations underlying development of disease. On the other hand, proponents argue that isolated and purified DNA is patentable subject matter, regardless of the policy arguments against gene patenting, and that gene patents stimulate investment in development of genetic testing and further basic research related to the genetic mutations that are the subject of such testing. In the end, because isolated and purified DNA is patentable subject matter and patents on genetic testing are crucial for obtaining much-needed research dollars, the Court of the Appeals for the Federal Circuit should overturn the district court's decision in *Myriad*.

110. Lessons, *supra* note 110, at 321.

111. Eur. Patent No. 0705902 (filed on Aug. 11, 1995).

112. Case C-428/08, *Monsanto Tech., LLC v. Cefetra B.V.*, 2010, http://curia.europa.eu/jcms/jcms/j_6/ (write case number in "Case no" box; then click "Search"; choose the "2010-07-06 Judgment").

113. *Id.*; Conley, *supra* note 90.

114. *Id.*

115. *Id.*; RIJKSOCETROOIWET [LAW ON PATENTS] art. 53 (Neth.).

116. Council and Parliament Directive 98/44, art. 9, 1998 O.J. (L 213) (EC) available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML>.

117. Case C-428/08, *Monsanto Tech., LLC v. Cefetra B.V.*, 2010; Conley, *supra* note 90.

118. *Id.*

119. Case C-428/08, *Monsanto Tech., LLC v. Cefetra B.V.*, 2010 (citing Counsel Directive, *supra* note 91 at Recital 23).

120. Conley, *supra* note 90.

121. Chris Holman, *Monsanto v. Cefetra: EU Court of Justice Limits Scope of Patent Protection Available to Gene Sequences*, HOLMAN'S BIOTECH IP BLOG, <http://holmansbiotechipblog.blogspot.com/2010/07/monsanto-v-cefetra-eu-court-of-justice.html>, (last visited Nov. 18, 2010).

A. The Arguments Against Gene Patenting¹²²

1. *Gene Patents Impede Access to Patient Testing*

As both the plaintiffs and the Secretary's Advisory Committee on Genetics, Health, and Society ("SACGHS") have recognized, the issue of limited access typically arises in the context of a sole service provider.¹²³ The basis for this argument lies in the assumption that patents associated with genetic tests limit access by raising prices above what would exist in the competitive market.¹²⁴ As a result many insurance carriers will not cover testing, requiring patients to pay for the test out-of-pocket.¹²⁵ Though the test remains available to such patients for such a premium, many patients, such as those covered under state-run Medicaid programs, may be forced to forego testing because they cannot afford it.¹²⁶ However, at least one case study demonstrated that the per-unit price of the *BRCA* test is actually comparable to a similar colon-cancer test for which the patents have been nonexclusively licensed.¹²⁷ In fact, the SACGHS concluded there is no evidence that patents have consistently led to higher prices for genetic tests.¹²⁸

Viewing this issue from another perspective, lack of patient access results from insurance industry practices, rather than from patent exclusivity. As a predictive genetic test, the *BRCA* test provides only a general estimate of patients' chances of developing breast cancer, as it fails to take into account the influence of other mutations and environmental factors, meaning many women who test positive will never develop breast cancer.¹²⁹ Such technological limitations may lead an insurance carrier to allocate its resources to forms of testing that provide more concrete information to patients. Indeed, there are a number of diagnostic tests currently available that would provide beneficial medical information to patients, whether in the context

of a sole provider or not, that insurance companies do not cover.¹³⁰ In addition, the financial gain to service providers resulting from increased market size drives active negotiation with payers in order to increase patient pools, which in turn increases access, as evidenced by Myriad's reduction of the number of self-pay patients to a single-digit percentage of its client base.¹³¹

2. *Gene Patents Result in Decreased Quality of Genetic Testing*

It has been asserted that gene patents result in decreased quality of genetic testing in two ways. First, the quality of the actual diagnostic test may remain stagnant, as market exclusivity fails to push service providers to improve testing. For example, one French study found that Myriad's *BRCA* testing procedure failed to detect ten to twenty percent of mutations.¹³² Some commentators suggest that increased competition results in improved testing regardless of whether available tests are of high quality and subject to excellent quality control procedures.¹³³ On the other hand, there are several technical advantages to centralizing genetic testing, including the consistency that results from running all tests on the same equipment using standardized protocols and reagents and the ease of maintaining regulatory oversight.¹³⁴

Second, in the sole provider context, confirmatory testing from an independent laboratory remains unavailable.¹³⁵ Therefore, it is difficult to assess whether concerns about testing quality are well-founded.¹³⁶ Further, patients who receive inconclusive test results lack additional options for determining their predisposition to the development of disease. However, Myriad has never received a single request from a patient or healthcare provider to conduct a second test at another lab.¹³⁷ At least in the case of Myriad,

122. See *supra* Section II(B)(3).

123. AMP Complaint, *supra* note 3, at ¶¶ 84–95; see also Office of Biotechnology Activities, Report of the Secretary's Advisory Committee on Genetics, Health, and Society, Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests 39–45 (Dep't of Health & Human Services, Apr. 2010) [hereinafter SACGHS], available at http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_patents_report_2010.pdf (collecting case studies examining limitations on clinical and patient access imposed by gene patents).

124. SACGHS, *supra* note 124, at 38.

125. *Id.* at 3.

126. *Id.*

127. *Id.* at 38.

128. *Id.* at 39.

129. *Opposition*, *supra* note 102, at 147.

130. See generally SACGHS, *supra* note 124 (discussing insurance carriers' refusal to cover genetic testing for long-QT syndrome, hearing loss, and spinocerebellar ataxia).

131. R. Cook-Deegan et al., *Impact of patents and licensing practices on access to genetic testing for inherited susceptibility to cancer: comparing breast and ovarian cancers to colon cancers*, 12 GENETICS IN MEDICINE S30 (2010) (noting that Myriad's testing is presently covered by over 300 providers).

132. Steve Benowitz, *French Challenge to BRCA1 Patent Underlies European Discontent*, 94 J. NAT'L. CANCER INST. 80 (2002).

133. SACGHS, *supra* note 124, at 47.

134. *Id.* at 47–48.

135. *Id.* at 3.

136. *Id.* at 46.

137. Defendants' Memorandum of Law (1) in Support of Their Motion for Summary Judgment and (2) in Opposition to Plaintiffs' Motion for Summary Judgment, Association for

such quality concerns, in addition to recent scientific developments, led the company to develop a second, more robust test (the BART test), which is offered at no cost when indicated.¹³⁸

3. Gene Patents Create Barriers to Research

A common argument against the patenting of isolated human DNA molecules is that such patents impede research. In the instant case, the plaintiffs allege that several scientists, due to potential liability for their research activities, discontinued their research on *BRCA* genes after Myriad secured its patents.¹³⁹ Though Myriad is not currently targeting non-commercial researchers with its enforcement activities,¹⁴⁰ there is no exemption for these researchers, meaning that it would be possible for Myriad to seek an injunction or institute a patent infringement action against these researchers. However, there is little evidence that gene patents held by Myriad or any other entity have a negative impact on basic or clinical research. For example, an empirical study conducted at the University of Illinois examining 125 academic researchers demonstrated little to no negative impact on research productivity.¹⁴¹ Another study by the German government found that DNA patents created no barrier to entry into fields of research where isolated DNAs had been patented.¹⁴² Though the prospect of receiving a patent is “not the major force motivating scientists,” that is not a justifiable reason to preclude genes as patentable subject matter, as patents are important for commercialization of genetic tests.¹⁴³

There is one valid argument that pervades the issue of gene patents as an impediment to research—there are possible negative effects on the future of genetic testing due to its dependence on the growing capacity to analyze multiple genes simultaneously.¹⁴⁴

Molecular Pathology v. U.S. Patent & Trademark Office, No. 09 Civ. 4515, 2009 WL 5785008, at 49 (S.D.N.Y. Dec. 23, 2009) [hereinafter Myriad’s Memo].

138. *Myriad Introduces Enhanced BRCA Analysis Test for Exceptionally High-Risk Cancer Patients* (Aug. 1, 2006), <http://investor.myriad.com/releasedetail.cfm?ReleaseID=325803>. An example of such an indication would be inconclusive *BRCA1* test results.

139. Plaintiffs’ Rule 56.1 Statement of Material Facts at 3-5, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 09 Civ. 4515 (S.D.N.Y. Aug. 26, 2009) [hereinafter Plaintiffs’ Statement].

140. *Association for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d. 365, 379 (S.D.N.Y. Nov. 2, 2009).

141. Myriad’s Memo, *supra* note 136, at 45.

142. *Id.*

143. SACGHS, *supra* note 124, at 1-2.

144. *Id.* at 3.

Because approximately twenty percent of genes have been patented, development of multiplex tests and parallel sequencing will be dependent on acquisition of rights to multiple gene patents.¹⁴⁵ Similarly, whole-genome sequencing would require acquisition of rights to most, if not all, existing gene patents.¹⁴⁶ The cumulative costs of multiple licenses, the associated costs of negotiations, and the right of a patent holder to refuse to license his invention could prevent such products from ever reaching the market.¹⁴⁷

B. The Arguments for Gene Patenting

1. Purified and Isolated DNA Is Patentable Subject Matter

From the beginning, the district court appeared to view Myriad’s assertion of the isolation and purification of DNA as transforming it into something distinctly different in character with hostility, framing such practice as a “lawyer’s trick” that circumvents the prohibitions on the direct patenting of the DNA in our bodies.”¹⁴⁸ However, the district court’s assertion that DNA’s unique characteristics differentiate it from other chemical compounds¹⁴⁹ seems to rely on philosophical underpinnings in lieu of the scientific analysis that provides the basis for this so-called “lawyer’s trick.” Such philosophical justifications are evident in the court’s statement that “DNA represents the physical embodiment of biologic information” and “DNA’s existence in isolated form alters neither this fundamental quality of DNA as it exists in neither the body nor the information it encodes.”¹⁵⁰

The difference in the structural and functional properties of isolated DNA when compared to those of native DNA is critically important to the utility and function of such claimed isolated DNA molecules.¹⁵¹ Native DNA is protected in the cell because it remains surrounded by proteins and stably embedded in chromosomes.¹⁵² Removal of associated cellular products that facilitate packaging of the DNA into a chromosome by isolation and purification fundamentally alters the chemical structure of DNA. Such isolation renders DNA molecules useful as physical probes and primers for the identification of mutations in patients, thereby

145. *Id.*

146. *Id.*

147. *Id.*

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

149. *Id.* at 228.

150. *Id.* at 185.

151. Myriad’s Memo, *supra* note 136, at 31.

152. *Id.* at 30.

allowing diagnosis of increased cancer susceptibility.¹⁵³ Thus, the utility of such molecules is based on their ability to target and interact with other DNA molecules, not just the biological information contained within. Such a function is dependent on an isolated DNA molecule's unique structure and chemistry,¹⁵⁴ a structure and chemistry that, importantly, is lacking in native DNA molecules. As the court acknowledged, purified DNA can be used as a tool for biotechnological applications for which native DNA cannot be used.¹⁵⁵

The uncontradicted scientific evidence demonstrates that the isolation and purification of a DNA molecule results in a new and useful composition of matter in satisfaction of the requirements of 35 U.S.C. § 101 or an invention in the field of biotechnology in satisfaction of Art. 52 of the EPC.¹⁵⁶ This composition of matter is not a law of nature, physical phenomenon, or abstract idea, and so it does not fall within the exceptions to § 101 established by case law.¹⁵⁷ Similarly, it does not fall within the EPC exceptions of a discovery, scientific theory, or mathematical method.¹⁵⁸ In determining patent eligibility, isolated DNA molecules should be treated no differently from other chemical compounds, and the courts' misplaced focus on the information-containing or information-delivering qualities of DNA should not be used to justify such differential treatment.

2. Gene Patents Stimulate Investment

Though individual scientists may not be motivated by the prospect of receiving a patent, "meaningful gene-disease associations are confirmed only if the initial discoveries are followed by large scale replication and validation studies using multiple sample sets, the costs of which are prohibitive for many research groups."¹⁵⁹ Congress's enactment of the Bayh-Dole Act, which established a uniform policy among federal agencies that academic institutions may patent inventions arising from federally supported research and license them to companies, is a direct acknowledgment of this

economic reality.¹⁶⁰ It was premised on the belief that absent exclusive patent rights from licenses, companies will not invest resources to develop an invention into a product because free-riders could copy the finished product.¹⁶¹ Indeed, the strength of a company's intellectual property strategy and position is one of the top three questions posed by investors.¹⁶² Thus, due to the enormous sums of money required to discover, develop, test, and approve genetic tests, notwithstanding the time it takes to develop such tests, protection of the related intellectual property is critical.¹⁶³

Had it not been for the exclusive patent rights it obtained regarding *BRCA1/2* and the infusion of capital that follows from such exclusivity, Myriad would never have been created, and its *BRCA1/2* tests would never have been brought to the market, resulting in a true barrier to patient access.¹⁶⁴ For example, Eli Lilly agreed to fund Myriad's ongoing research efforts in return for licensing privileges on diagnostic kits and therapeutic products related to *BRCA1*.¹⁶⁵ Similarly, the prospect of gene patents has also been critical to funding the development of genetic testing for other diseases, including hereditary hemochromatosis (Mercator Genetics), spinal diseases (Axial Biotech), diseases that predominantly affect women (Juneau Biosciences), spinal muscular atrophy (Claire Altman Heine Foundation), and muscular dystrophy (Boston Children's Hospital).¹⁶⁶ Though the federal government remains the major funder of basic genetic research,¹⁶⁷ private investment is necessary to translate basic research from the lab bench to the patient's bedside.

3. Gene Patents Stimulate Research

While it is evident that gene patents stimulate the translational research needed to drive genetic testing innovation from the lab to market, it is also clear that gene patents stimulate basic research and discovery. Since Myriad's public disclosure of the *BRCA1* gene in 1994 and *BRCA2* gene in 1996, more than 18,000 scientists

153. *Id.* at 32; *See, e.g.*, U.S. Patent No. 5,693,473 (filed June 7, 1995).

154. *Id.* at 33.

155. 702 F. Supp.2d at 196.

156. 35 U.S.C. § 101; European Patent Convention, *supra* note 86, at art. 52(1).

157. *Diamond v. Chakrabarty*, 447 U.S. at 309 (setting forth the exceptions of laws of nature, physical phenomena, and abstract ideas).

158. European Patent Convention, *supra* note 86, at art. 52(2).

159. SACGHS, *supra* note 123, at 23.

160. *Id.* at 28.

161. *Id.* at 29.

162. Lisa A. Haile, *IP Position Critical to Biotech Investment*, 30(7) WALL STREET BIOBEAT (April 1, 2010), <http://www.genengnews.com/gen-articles/ip-position-critical-to-biotech-investment/3235/> One investment banker stated that "[w]e know that if the IP position is not strong, it is unlikely that we will pursue the opportunity further." SACGHS, *supra* note 124, at 29.

163. Haile, *supra* note 16; SACGHS, *supra* note 124, at 29.

164. Myriad's Memo, *supra* note 136, at 47.

165. SACGHS, *supra* note 124, at 23.

166. *Id.* at 24-26.

167. *Id.* at 25.

have researched the genes, leading to the publication of over 5,600 papers on *BRCA1* and over 3,000 papers on *BRCA2*.¹⁶⁸ Interestingly, the individual plaintiffs and their declarants in the instant case published forty-eight peer-reviewed research papers on the *BRCA1/2* genes without any interference from Myriad.¹⁶⁹ Apparently, Myriad's gene patents did nothing to impede their research. Furthermore, Myriad has found it in its own best interest to freely allow academic scientists to conduct research studies on the *BRCA1/2* genes, provide direct assistance to such researchers, and publish and actively disseminate its own research into the public domain.¹⁷⁰ Such stimulation of research is not unique to the field of breast cancer. Human Genome Sciences provided collaborators at Johns Hopkins University access to the company's proprietary database of DNA sequences coding for receptor proteins, resulting in the discovery of the *MLH1* gene involved in colon cancer.¹⁷¹ Though opponents of gene patenting may see the biotech industry as capitalistic and self-serving, such characteristics have resulted in an increased recognition by biotech entities of the mutual benefits that flow from collaborations with independent groups engaged in basic research.

IV. CONCLUSION

The United States Court of Appeals for the Federal Circuit should overturn the district court's decision in *Myriad*. First and foremost, isolated DNA molecules fit within the definition of patentable subject matter as defined by statute and developed through case law. In addition, though there are valid arguments against the patenting of such molecules, including the creation of barriers to patient access, research, and improvement of test quality, when weighed against arguments in support of this type of patenting, namely stimulation of research and investment, it becomes clear that patenting of isolated DNA molecules will have the most benefit to the public as a whole. The intellectual property position of biotech companies is one of the most important factors potential investors consider, and, without significant capital investment, research groups would lack the considerable resources required to translate these technologies into reliable, effective diagnostic tests and treatments. The future of genetic medicine looks promising, offering a number of innovations for

identifying and curing heritable disorders—a future that will never happen without patent protection.

168. Myriad's Memo, *supra* note 136, at 46.

169. *Id.*

170. *Id.* at 47.

171. SACGHS, *supra* note 124, at 25; R. Cook-Deegan et al., *supra* note 130 at S29.