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AMP v. Myriad: The Future of Medicine and Patent Law

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Note

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I. INTRODUCTION

Myriad Genetics, Inc. (Myriad), a young[1] genetics company, specializes in linking human genes to diseases and establishing the likelihood of a person expressing[2] a gene developing those diseases.[3] Myriad's profitable[4] business of testing customers for diseases linked with these genes has rested upon Myriad's ability to monopolize the testing market by patenting the discovered genes and the testing process. Between 1997 and 2000, Myriad was issued seven patents related to the BRCA1 and BRCA2 genes.[5] These genes, due to Myriad's research, have been strongly linked to susceptibility to hereditary breast cancer.[6] Myriad's seven patents together

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1. Founded in May, 1991. *Myriad Genetics — About*, MYRIAD GENETICS AND LAB., http://www.myriad.com/about/ (last visited Nov. 24, 2010).

2. In biological terms, a person is said to express a gene when that gene leads to distinguishable traits in that person. SOLOMON, ET AL., BIOLOGY 261 (Nedah Rose et al. eds., 6th ed. 2002).

3. *Id.*

4. MYRIAD GENETICS, 2010 ANNUAL SHAREHOLDER REPORT 2 (Sept. 21, 2010).

5. U.S. Patent No. 5,693,473 (filed June 7, 1995); U.S. Patent No. 5,709,999 (filed June 7, 1995); U.S. Patent No. 5,710,001 (filed June 7, 1995); U.S. Patent No. 5,747,282 (filed June 7, 1995); U.S. Patent No. 5,753,441 (filed Jan. 5, 1996); U.S. Patent No. 5,837,492 (filed Apr. 29, 1996); U.S. Patent No. 6,033,857 (filed Mar. 20, 1998).

6. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad*), 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010).

give Myriad a monopoly on any research and testing related to these genes.[7] Without competition, Myriad has the ability to control the costs of all such tests, potentially driving the cost higher than some patients can afford.[8] In May 2009, a complaint against the United States Patent and Trademark Office (USPTO) and Myriad was filed in the United States District Court for the Southern District of New York by, among others, the Association for Molecular Pathology.[9] In the resulting case, *Association for Molecular Pathology v. United States Trademark Office and Myriad Genetics* ("*Myriad*"), plaintiffs attempted to invalidate Myriad's seven patents,[10] which would effectively terminate Myriad's monopoly rights on testing related to the BRCA1/BRCA2 genes. The district court agreed with plaintiffs that neither the genes nor the testing methods were patent eligible and invalidated all seven patents.[11] Myriad appealed to the Court of Appeals for the Federal Circuit on June 16, 2010.[12] The arguments in the *Myriad* case surrounding these patents have hurled genetic diagnosis to the forefront of intellectual property law and medicine.

Genetic research, treatment, and diagnostic methods are growing extraordinarily important as medicine evolves. This has led to a shift in patenting biotechnology that Congress could not have foreseen when last amending the Patent Act in 1952.[13] Without incentives to develop medical innovations, private biotech companies will likely cease much of the research that results in new diagnostic tests, treatments, and cures for diseases such as breast cancer. The extent to which patent law should incentivize this research at the expense of innovations immediately being placed in the public domain is an issue central to the *Myriad* case.

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7. *Id.* at 212–213.
8. *Id.* at 203.
9. *Id.* at 186.
10. *Id.* at 184.
11. *Id.* at 183.
12. Myriad Defendant's Notice of Appeal at 1, Ass'n for Molecular Pathology v. Myriad Genetics Inc., No. 2010-1406 (Fed. Cir. Oct. 22, 2010).
13. The Patent Act of 1952 was the last comprehensive amendment to 35 U.S.C. § 100 (1952). Since then Congress has found it necessary to update the Patent Act to keep up with the developing field of biotechnology. *E.g.* 35 U.S.C. § 103(b) (1995) (establishing special rules for determining obviousness for biotechnological process patents).

The goal of this Comment is to explain the policy concerns at issue in *Myriad* and relate them to the options available to the Court of Appeals for the Federal Circuit in light of the current state of patent law. The Background section provides information on the relevant medical, biological, and legal issues. The Case Summary section describes the facts of *Myriad* and the district court's analysis and ruling. The Analysis section critiques the district court's analysis, the analysis of the main and other interested parties, and suggests resolutions of all issues faced by the court. This Comment concludes that both genes as compositions of matter, and diagnostic testing methods utilizing those genes, are patent eligible, but that Congress must clarify patent law's stance on the issues before further controversy arises.

II. BACKGROUND

A. THE IMPACT OF CANCER

The cost of treating and researching cancer are powerful influences on our economy. In 2005, Medicare paid approximately four billion dollars to oncologists for drugs, and approximately seven hundred million dollars for chemotherapy.[14] Notwithstanding the significant investment in fighting cancer, it remains tremendously deadly, requiring continued investment. By 2007, cancer had become the second highest cause of death in the United States.[15] Further, between 1998 and 2007, total U.S. incidences of cancer had dropped by only 0.9 percent,[16] and grew by 1.9 percent in people above sixty-five between 1950 and 2007.[17] On average, the chance of

14. Letter from Laura A. Dummit, Dir., Health Care—Medicare Payment Issues to The Honorable Joe Barton, Chairman of the Comm. on Energy and Commerce, House of Representatives 12, 14 (Dec. 1, 2004) (on file with author). These figures include, presumptively, fees for drugs and oncologist visits.

15. NAT'L CANCER INST., SURVEILLANCE EPIDEMIOLOGY AND END RESULTS, SEER CANCER STATISTICS REVIEW 1975–2007: LEADING CAUSES OF DEATH IN U.S., 1975 VS. 2007 (Nov. 2009), *available at* http://seer.cancer.gov/csr/1975_2007/results_merged/topic_lead_cod.pdf.

16. NAT'L CANCER INST., SURVEILLANCE EPIDEMIOLOGY AND END RESULTS, SEER CANCER STATISTICS REVIEW 1975–2007: SEER INCIDENCE AND U.S. MORTALITY TRENDS BY PRIMARY CANCER SITE AND SEX 1 (Nov. 2009), *available at* http://seer.cancer.gov/csr/1975_2007/results_single/sect_01_table.07_2pgs.pdf.

17. NAT'L CANCER INST., SURVEILLANCE EPIDEMIOLOGY AND END RESULTS, SEER CANCER STATISTICS REVIEW 1975–2007: 58-YEAR TRENDS IN

dying younger than the average life expectancy increases by forty-four percent once cancer is contracted.[18] Estimates indicate that a person living in the United States in 2007 had a more than twenty percent risk of dying of cancer.[19]

Breast cancer makes up a large portion of cancer incidences. Malignant breast cancer alone is the second most commonly diagnosed type of cancer, and malignant and *in situ* breast cancer combined are the most frequently diagnosed.[20] More deaths result from breast cancer than any other cancer except lung cancer,[21] even though breast cancer has an 89 percent survival rate.[22] Breast cancer is the most common cancer in younger persons[23] and disproportionally affects women.[24] It is understandable that litigation concerning this disease would have an effect on a significant proportion of the United States population.

B. THE BIOLOGY OF INHERITANCE

Given the technical nature of the dispute between the

U.S. CANCER DEATH RATES 1 (Nov. 2009), *available at* http://seer.cancer.gov/csr/1975_2007/results_single/sect_01_table.02.pdf.

18. NAT'L CANCER INST., SURVEILLANCE EPIDEMIOLOGY AND END RESULTS, SEER CANCER STATISTICS REVIEW 1975–2007: AGE-ADJUSTED SEER INCIDENCE AND U.S. DEATH RATES AND 5-YEAR RELATIVE SURVIVAL (PERCENT) 1 (Nov. 2009) [hereinafter AGE-ADJUSTED SEER INCIDENCE], *available at* http://seer.cancer.gov/csr/1975_2007/results_single/sect_01_table.04_2pgs.pdf.

19. NAT'L CANCER INST., SURVEILLANCE EPIDEMIOLOGY AND END RESULTS, SEER CANCER STATISTICS REVIEW 1975–2007: LIFETIME RISK (PERCENT) OF DYING FROM CANCER BY SITE AND RACE/ETHNICITY 1 (Nov. 2009), *available at* http://seer.cancer.gov/csr/1975_2007/results_single/sect_01_table.04_2pgs.pdf.

20. NAT'L CANCER INST., SURVEILLANCE EPIDEMIOLOGY AND END RESULTS, SEER CANCER STATISTICS REVIEW 1975–2007: LIFETIME RISK (PERCENT) OF BEING DIAGNOSED WITH CANCER BY SITE AND RACE/ETHNICITY 1 (Nov. 2009) [hereinafter RISK OF BEING DIAGNOSED], *available at* http://seer.cancer.gov/csr/1975_2007/results_single/sect_01_table.14_2pgs.pdf.

21. *Id*.

22. AGE-ADJUSTED SEER INCIDENCE, *supra* note 18. These unexpected numbers illustrate the immense number of breast cancer incidences among other, deadlier cancers.

23. NAT'L CANCER INST., SURVEILLANCE EPIDEMIOLOGY AND END RESULTS, SEER CANCER STATISTICS REVIEW 1975–2007: U.S. PREVALENCE COUNTS, INVASIVE CANCERS ONLY, JANUARY 1, 2007, at 4 (Nov. 2009), *available at* http://seer.cancer.gov/csr/1975_2007/results_single/sect_01_table.21_2pgs.pdf.

24. RISK OF BEING DIAGNOSED, *supra* note 20.

parties, a basic understanding of genetic inheritance is required before analyzing the issues. Biologically, inheritance is a function of person's DNA,[25] which is handed down from previous generations.[26] DNA is composed of a long strand of sequential bases: adenine, guanine, thymine, and cytosine.[27] These bases are small, ring or figure-eight shaped molecules made up of 15 assorted carbon, nitrogen, oxygen and hydrogen atoms.[28] The specific sequence of these bases is passed down to a person from that person's parental generation; it determines development by dictating which proteins that person will produce.[29] It follows, then, that determining the sequence of bases in a person's DNA will uncover the genetic traits that person has inherited.

However, much of a person's DNA is not translated into proteins; this DNA is termed non-coding.[30] Therefore, determining a person's genes is a more effective method of determining a person's inherited traits.[31] Genes are the portions of a person's DNA that are eventually expressed, i.e. translated into proteins.[32] The genes of a person's DNA are "read" to form RNA by a process known as transcription.[33] The type of RNA that carries information from genes is known as messenger RNA (mRNA).[34] mRNA is composed of the base sequences of a particular gene, but can itself be broken down into introns and exons.[35] Introns are noncoding sequences of mRNA; exons eventually dictate what proteins an organism will produce and thus how that organism will develop.[36] This occurs in a process called translation, during which the exons of a sequence of mRNA are "read" to determine the sequence in which to assemble amino acids to form a protein.[37] However, before this occurs, the mRNA formed in transcription must be

25. SOLOMON, *supra* note 2 at 244.
26. *Id.* at 217.
27. *Id.* at 247.
28. *Id.* at 249.
29. *Id.* at 261.
30. *Id.* at 264, 266.
31. *See id.* at 218.
32. *Id.* at 278.
33. *Id.* at 265.
34. *Id.* at 264.
35. *Id.* at 275.
36. *Id.*
37. *Id.*

processed, at which point the introns are removed.[38] The remaining exons are translated into specific proteins,[39] and those specific proteins determine how an organism will develop.[40] Therefore, by removing the regions of a person's DNA that are not genes and the introns from the remaining genes by simulating transcription and mRNA processing, one can discover, from the exons that remain, the exact proteins that person will produce. Further, by running the processed mRNA through a reaction known as reverse transcription, it is possible to produce complementary DNA (cDNA), a stable template of the exons that exhibit those proteins.[41]

If a person inherits DNA that has been changed, or mutated, that change may be reflected in that person's DNA if the mutation occurs on an exon.[42] This will change a person's physical development, which could have disastrous results.[43] Most mutations will not be expressed because they occur in the non-coding portion of a person's DNA that are either (1) not transcribed to RNA, or (2) occur in the introns, and thus are not translated into proteins.[44] However, mutations such those on the BRCA1 gene and the BRCA2 gene have effects that are not easily noticed. The BRCA1 and BRCA2 genes have been linked to susceptibility to breast cancer,[45] and therefore changes in a person's development as a result of a BRCA1 or BRCA2 mutation could significantly increase a person's likelihood of developing the disease. Furthermore, these mutations may be passed down to future generations, creating the same increased likelihood in a person's children.[46]

DNA is reproduced in an organism, but geneticists are also able to produce it in greater volume using the polymerase chain reaction (PCR).[47] In PCR, double-stranded DNA[48] is separated

38. *Id.*
39. *Id.*
40. *Id.*
41. *Id.* at 306.
42. *Id.* at 279.
43. *Id.*
44. *See id.* at 264, 266.
45. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad*), 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010).
46. *See* SOLOMON ET AL., *supra* note 2, at 217.
47. SOLOMON ET AL., *supra* note 2, at 307.
48. DNA is naturally found in a double helix form. *See id.* at 247.

into two single strands, at which point primers,[49] DNA bases, and replication enzymes[50] are added to the DNA mixture.[51] These components combine to duplicate each strand of DNA, doubling the amount of DNA in the mixture.[52] With proper enzymes and an adequate supply of components, this process can be repeated indefinitely, each time doubling the amount of DNA.[53]

It follows that, because mutations are changes in the sequences of bases in a person's DNA, a person with a mutated gene will have a different DNA sequence than a person with the "normal" or "baseline" gene. To determine the sequence of a baseline gene, geneticists perform a special method of PCR using both regular bases and dideoxynucleotides, synthetic bases that attach to a single strand of DNA just as to an ordinary base, but that stop replication once attached to the DNA strand.[54] With enough starting strands and enough bases, there will be a strand produced with the dideoxynucleotide at every position of the sequence.[55] The segments are organized from shortest to longest, and the last base of each segment length are recorded. [56] For a simplified example, if a strand had the sequence ACGT, the process would result in four groups of segments. By counting the groups of segments, it would become clear that the total segment length is four bases. Segments in the first group would be one base long (A) with the As radiated.[57] Segments in the second group would be two bases

49. A primer is a short sequence of RNA bases that attach to a strand of DNA to mark the start point of replication. They are replaced by DNA bases shortly. *See id.* at 253.

50. There are several enzymes involved in DNA replication, specific knowledge of which is not necessary here. *See generally id.* at 252–53.

51. *Id.* at 307.

52. *Id.*

53. *Id.*

54. *Id.* at 309.

55. Therefore, if the target sequence was one-hundred bases long, the result would be at least one strand produced corresponding to each of the hundred positions. *Id.*

56. Ordering by segment length and recording of terminal bases is performed using gel electrophoresis and autoradiography respectively. Gel electrophoresis and autoradiography are processes by which very small compounds can be separated and identified. No further understanding is relevant here. *Id.* at 308–09.

57. Autoradiography radiates the end bases of a strand, making the identity of the base at the end of the strand in each group easily discernable. *Id.*

long (AC) with the Cs radiated. Segments in the third group would be three bases long (ACG) with the Gs radiated, and so on. When this process is completed, the total segment length is known, the base for each position of the segment is discovered, and thus the sequence of the entire segment is known.[58]

Fortunately, PCR (and thus, dideoxynucleotide PCR) can be performed on only the target sequence to be replicated, so long as the primers (short segments at the beginning of a gene of recognized base pattern) for the sequence are known.[59] Thus, if geneticists are able to locate the gene they wish to sequence and/or replicate, they will be able to target that gene specifically for sequencing and/or replication.[60] Therefore, if the sequence of a baseline gene is known, a specific person's gene sequence can be compared to that baseline gene sequence to identify any points at which the bases differ.[61]

C. LEGAL PRECEDENT OF PATENTING GENES

The precise protection rights afforded to a holder of a patent of a human gene are hard to determine. For example, the USPTO claims that while genes are patentable, the sequences themselves and the underlying genetic information are not.[62] It is not clear what the researcher is patenting in a gene, however, if not genetic information. The USPTO's explanation of a patent holder's rights do not provide much clarification. The USPTO claims that the patent holder has the right to exclude all others from any use of that gene,[63] but also that the patent holder must promote discovery of other uses of the gene by other researchers.[64] These other uses, according to the USPTO, would be patentable by the discoverers of those uses as an improvement on an existing invention.[65] The USPTO does not explain how non-patent-holding researchers would be able to discover new uses for a gene when the patent

58. *Id.* at 309.
59. *Id.* at 307.
60. *Id.*
61. These points of differing bases would represent mutations in the person's gene.
62. U.S. PATENT & TRADEMARK OFFICE, DEP'T OF COMMERCE, RIN 0651-AB09, UTILITY EXAMINATION GUIDELINES 1093 (2001).
63. *Id.* at 1095.
64. *Id.* at 1094.
65. *Id.* at 1095.

holder has a right to ban all research on the gene.[66]

Congress has the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[67] Pursuant to these objectives, Congress passed the Patent Act of 1836, which established the USPTO as the initial deciding body for all patent determinations, established a numerical system to track patents, and established the patent eligibility criteria.[68] From that point on, "any person or persons having discovered or invented any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter . . ." could be granted patent protection.[69] In order to receive a patent, an invention or discovery must be determined to be (1) patent eligible, and (2) patentable.[70] Whether an invention is *eligible* for a patent is determined by the patent protection assigned to that type of invention.[71] Whether an invention is *patentable*, on the other hand, depends on the specific properties and history of that particular invention, not the field in which the invention falls.[72] Therefore, for an invention to be patented, it must (1) fall into a class of inventions to which patent protection can be assigned, and (2) comply with statutory provisions regarding the properties of that particular

66. It is worthy of note that § 271 of the Patent Act provides an experimental use exception which protects researchers of patented compounds, but only if they begin their research with a reasonable belief that the research, if successful, will result in information relevant to a new drug application to the Food and Drug Administration. 35 U.S.C. § 271 (2010); Merck KGAA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 208 (2005). While this exception is broad, the Court held that a research must have an intended physiological effect, and a reason to believe the research would produce that effect. General exploratory research, therefore, is not protected. *Merck*, 545 U.S. at 205–06.

67. U.S. CONST. art. I § 8, cl. 8.

68. Patent Act of 1836, 5 Stat. 117, (a), § 5–6 (1836).

69. Patent Act of 1836, 5 Stat. 117, §6 (1836); 35 U.S.C. § 100 (2006). Patent protection did not originate with the establishment of the USPTO, nor with an act of Congress. Even before the Constitution was ratified, state patent protection was available. Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 228 (1964). Additionally, some federal patent protection existed after 1790. *Id.* at 229.

70. 35 U.S.C. § 101–02 (2006).

71. *See* 35 U.S.C. § 101 (2006).

72. *See* 35 U.S.C. § 102 (2006).

invention.[73] The invention must be found by the examiner to be novel[74] and non-obvious[75] and the inventor must be able to show that he or she is the actual inventor.[76]

When the Patent Act was passed, the phrase "new and useful art" was written to refer to a method by which something was done. It now has been replaced by the phrase "new and useful process" to reflect this meaning.[77] Therefore, according to the Patent Act, an inventor can patent both a compound (a composition of matter) and the process by which that compound is made. Further, in certain biotechnical fields, a process and a composition of matter that may otherwise have been found to be too obvious to be patentable may still be patentable if, for example, the process and the composition are claimed in the same application.[78]

Patenting chemical compounds is far from a matter of first impression for the USPTO or the courts.[79] Indeed, even patenting chemical compounds that were purified but are otherwise unchanged from the compound found in nature is not a new subject.[80] Since these early patents, many patents have been issued for chemical compounds.[81] These compounds were often extractions from living organisms, whether plant or animal.[82] This eventually led to patenting the organisms themselves: in May of 1930, Congress passed the Plant Patent Act, enabling discoverers of new plants to achieve patent protection for their discoveries, provided they had asexually reproduced the plants.[83] This was a milestone for patent law,

73. *See* 35 U.S.C. §§ 101–02 (2006).

74. In order to be novel, the process or composition of matter claimed must not be publicly known. *See* 35 U.S.C. § 102 (2006).

75. To be non-obvious, the necessary innovation from prior inventions to arrive at the new invention must not be clear to a person well versed in the field from which the invention derives. 35 U.S.C. § 103(a) (2006).

76. 35 U.S.C. § 102(f) (2006).

77. Patent Act of 1836, 5 Stat. 117, § 6 (1836); 35 U.S.C. § 101 (2006).

78. 35 U.S.C. § 103(b)(1)(A) (2006).

79. *E.g.,* U.S. Patent No. 141,072 (filed May 9, 1873).

80. *E.g.,* Parke-Davis & Co v. H.K. Mulford & Co., 196 F. 496, 496 (2d Cir. 1912) (considering whether purified adrenaline, having been previously discovered in animal suprarenal tissue, was patent eligible).

81. *See, e.g.*, U.S. Patent No. 2,200,004 (filed Nov. 12, 1988); U.S. Patent No. 2,400,006 (filed Mar. 3, 1945).

82. *See, e.g.*, Merck v. Mathieson, 253 F.2d 156, 164 (2d Cir. 1958); *Parke-Davis*, 196 F. at 496.

83. Plant Patent Act of 1930, Pub. L. No. 245 (1930).

as it allowed inventors to patent living things that may have been, in a sense, invented by nature.[84] In 1954, Congress amended the Plant Patent Act to separate the plant patent provisions from the original patent provisions and added more stringent requirements that the plants be new and distinct.[85] In 1970 Congress passed the Plant Variety Protection Act, which entrusted the Secretary of Agriculture to ensure plants are examined for protectability[86] and established a plant variety protection board to oversee appeals of an examiner's decision not to protect a plant.[87] Further, the Act extended the patent eligibility to sexually-reproducing plants, eliminating the requirement that inventors must have asexually reproduced the plant.[88]

The USPTO and Supreme Court have since extended patent eligibility to non-plant organisms, including bacteria and the process of producing bacteria.[89] However, when the "invention" for which an inventor is seeking protection is an organism or group of organisms, an exception to patent eligibility may apply, and the inventor must not simply be attempting to patent a pure product of nature.[90] To overcome this presumption, an inventor must demonstrate that the product of nature has become a new and distinctive article with new characteristics and/or a new use.[91] Further, the presumption cannot be overcome by combining different groups of organisms, unlike patents on non-natural inventions.[92] There is some suggestion that this rule applies to purifications of substances found in nature as well.[93]

84. A plant that is created artificially and is not known in nature may be eligible for patent. *See id.* However, a patented plant may still exist in nature, albeit undiscovered.

85. Pub. L. No. 775, 68 Stat. 1190 (1954).

86. Plant Variety Protection Act, Pub. L. No. 577, 84 Stat. 1542 (codified at 7 U.S.C. §§ 2321–72, 2401–504, 2531–83).

87. Pub. L. 91–577, § 7, 84 Stat. 1543 (1970) (codified at 7 U.S.C. § 2327(b)(2)).

88. Pub. L. 91–577, § 42, 84 Stat. 1547 (1970) (codified at 7 U.S.C. § 2402).

89. Diamond v. Chakrabarty, 447 U.S. 303, 310–11 (1980). It is worthy of note that the Plant Variety Protection Act specifically excluded bacteria from patent eligibility. *Id.*

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

91. Anheuser-Busch Brewing Ass'n v. United States, 207 U.S. 556, 562 (1908).

92. *Funk Bros.*, 333 U.S. at 131–32.

93. *See In re* Merz, 97 F.2d 599, 601 (C.C.P.A. 1938)

This same concept has been applied to method/process patents as well. A natural process or law of nature is patent eligible, but only if, when the process is considered as a whole, the patent is attempting to gain protection for the *application* of the law, rather than the law itself.[94] When the formula is applied to perform a function that patent law was developed to protect, the process should be given more leniency.[95] This factor has led to some confusion in differentiating between patenting the application of a law of nature and patenting a fleshed-out abstract idea.[96]

To summarize, the machine-or-transformation test required that all method/process patent eligible inventions must either be applied as some part of a machine or must be applied in a way that transforms something.[97] But the machine-or-transformation test has been rejected as the sole test to determine patent eligibility of a process; instead, the proper test is whether the process amounts to an abstract idea.[98] Unfortunately, no explicit definition or test for what constitutes an abstract idea has been provided.[99]

Yet another layer of uncertainty has recently arisen in patent law: patenting human genes. Whether human genes fall into the category of a simple product of nature[100] or something sufficiently transformed to be patent eligible[101] is unclear. In its 2001 Utility Examination Guidelines, the USPTO consistently confirmed that genes were patent eligible subject matter.[102] The USPTO suggests that a strand of DNA will be

94. Diamond v. Diehr, 450 U.S. 175, 187 (1981).

95. *Id.* at 192.

96. *Compare Diehr*, 450 U.S. at 192 (holding that an application for a mathematical formula to an end in furtherance of the purposes of patent law is patent eligible) *and* AT&T v. Excel Corp. 172 F.3d 1352, 1357 (Fed. Cir. 1999) (holding that, for patent eligibility, a mathematical formula must be applied in a manner that creates a tangible result) *with* Parker v. Flook, 437 U.S. 584, 595 n.18 (suggesting that the application of an improved method of calculation, even when supporting a specific end use, is not patent eligible).

97. *E.g., In re* Bilski, 545 F.3d 943, 956 (Fed. Cir. 2008).

98. Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010).

99. *Id.*

100. *See, e.g.*, American Fruit Growers v. Brogdex Co., 283 U.S. 1, 11–12 (1931) (finding a process not patentable because it was a simple product of nature).

101. Diamond v. Chakrabarty, 447 U.S. 303, 309–10 (1980).

102. UNITED STATES PATENT AND TRADEMARK OFFICE, DEP'T OF COMMERCE, RIN 0651-AB09, UTILITY EXAMINATION GUIDELINES *passim*

patentable when: (1) it has been isolated from its natural environment, (2) it has been purified, and (3) it meets the statutory requirements for patentability.[103] The USPTO emphasizes the nonobviousness and utility requirements of the patent statute,[104] and also clarifies that isolated genes, whether excised from a person's cells or synthesized in a lab, are patentable because they vary so greatly from their natural forms.[105]

The issue of patenting genes has also been brought to the Court of Appeals for the Federal Circuit, which has historically upheld gene patents. In 1995, the court held that a patent on a gene could not be invalidated solely because the method by which the gene was sequenced was a commonly exercised principle.[106] The court was not convinced by the fact that the method used to discover the gene sequence was "obvious to try" because one of ordinary skill in the art, when trying the method, would have very little chance of contemplating the result.[107] The court delivered a similar decision in 1993, which clarified that the obviousness of the method by which a patent holder discovered the compositions of DNA was not at issue in the case.[108] The patent holder did not claim the method of discovery, but only the compositions, and because the compositions were not at all obvious, the patent could not be invalidated on grounds of obviousness.[109] However, in 2007 the Supreme Court questioned these cases, and, in reinstating the obvious-to-try analysis, held that an invention will be considered obvious to try if "there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions."[110] The Court concluded that an invention found obvious to try can preclude patentability for § 103 purposes.[111] The Federal Circuit embraced the obvious-to-try test in the recent genetic case, *In re Kubin*, holding that a

(2001).

103. *Id.* at 1093.

104. *Id.* at 1093–95.

105. *Id.* at 1093.

106. *In re* Deuel, 51 F.3d 1552, 1557–59 (Fed. Cir. 1995).

107. *Id.*

108. *In re* Bell, 991 F.2d 781, 785 (Fed. Cir. 1993).

109. *Id.*

110. KSR Intern. Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007).

111. *See id.* (suggesting that finding a combination of elements making up an invention obvious-to-try may show that it is obvious under the statute).

finding of obvious-to-try will equal a finding of obviousness in almost all cases.[112] While the specific question with which the court is faced in *Myriad* may be one of first impression, patenting of genes and even of life is far from a new subject.

D. COMMENT PREVIEW

The purpose of this Comment is to explore the underlying issues of the suit between the Association for Molecular Pathology and Myriad Genetics, and to determine the proper course of action for the Court of Appeals for the Federal Circuit and the Supreme Court, should the case continue to that level. Analysis of such a complex issue will require an incorporation of public policy and legal issues. To that end, this Comment will first present in greater detail the disputed patents and issues of *Myriad* at its current state. The next section will examine the public policy ramifications of invalidating or validating the seven patents at issue, including a consideration of the effects on all present and potential future genetic patents. This Comment will then analyze the legal arguments and consequences of each possible decision. Finally, this Comment will conclude with a summary of the analysis section and a final suggestion on the overall best course of action.

III. CASE DESCRIPTION

In 1997, Myriad was granted a patent on a human gene, BRCA1, which directs the development of a protein in both men and women that is linked to hereditary breast cancer.[113] Between 1998 and 2000 Myriad was granted six more patents[114] relating to both the BRCA1 and BRCA2 genes and the methods of using them to diagnose hereditary breast cancer.[115] Myriad has been the sole provider offering the

112. *In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009) (holding that if an inventor merely guesses at the proper use of a large pool of prior art by "throw[ing] metaphorical darts at a board filled with prior art possibilities," or if all that was obvious to try was "to explore a new technology or general approach" and "prior art gave only general guidance," being obvious to try would not lead to a finding of obviousness. *See id.* (quoting *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)).

113. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad*), 702 F. Supp. 2d 181, 189, 201 (S.D.N.Y. 2010).

114. The University of Utah Research Foundation is a joint holder of these patents. *Id.* at 189–90.

115. *Id.*

diagnostic tests ever since, because its patents give it a monopoly on the underlying methods. Plaintiffs,[116] unhappy with (1) the costs of Myriad's diagnostic testing, (2) their inability to perform competitive diagnostic testing, or (3) Myriad's potential ability to prevent outside research on BRCA1 and BRCA2, brought an action against the USPTO and Myriad[117] in the United States District Court for the Southern District of New York to invalidate the patents. The district court case was heard and decided by Judge Robert Sweet.[118]

The plaintiffs moved for summary judgment, arguing that the disputed claims covered only products of nature, laws of nature/natural phenomena, and abstract ideas.[119] Myriad cross-moved for summary judgment, and the USPTO moved for judgment on the pleadings.[120] The court granted the plaintiffs' motion against Myriad, granted the USPTO's motion, and denied Myriad's cross-motion.[121]

The opinion discussed three accepted exceptions to the general patentability of new and useful inventions: the law of nature exception, the physical phenomena exception, and the abstract idea exception.[122] It then addressed the composition of matter claims and method claims in turn, citing different support for patent ineligibility for each category.[123] The opinion focused on a product of nature exception to the general patent eligible status given to compositions of matter.[124] This exception, according to the opinion, establishes that compositions of matter are not patentable if those compositions of matter are merely products of nature that have not been changed to the point of being fundamentally a new product.[125]

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116. An exhaustive list of all plaintiffs would be, appropriately, exhausting to list here. Together, there are twenty plaintiffs, encompassing four research groups, eight doctors and scientists, two health action groups, and six women diagnosed with breast cancer. *Id.* at 186–89.

117. The University of Utah Research Foundation was also listed as a defendant, as it had partial ownership of the patents-in-suit. *Id.* at 189–90.

118. *Id.* at 183.

119. *Id.* at 184.

120. *Id.* at 184–85.

121. *Id.* at 238. The claims against the USPTO were dismissed due to the doctrine of constitutional avoidance. This doctrine will not be discussed by this Comment.

122. *Id.* at 219 n. 40.

123. *Id.* at 220–37.

124. *Id.* at 222–27.

125. *Id.* at 222.

For this exception, the opinion relies on three cases:[126] *American Fruit Growers, Inc. v. Brogdex Co.*,[127] *Funk Bros. Seed Co. v. Kalo Inoculant Co.*,[128] and *Diamond v. Chakrabarty*.[129] This test establishes that an invention may defeat the product of nature exemption if the invention has been changed to such an extent as to have a "distinctive name, character, [and] use" from the product of nature.[130]

The opinion concludes that Myriad's composition of matter claims do not pass the product of nature test, as the claimed DNA is not markedly different than the natural DNA.[131] In arriving at this conclusion, it suggests that DNA should be judged differently than many chemical compounds because of the importance of the information-storing capacities of DNA.[132] That the claimed DNA does not contain non-coding regions of the strand, is not attached to other genes on a chromosome, and is not located among other components of a cell environment are irrelevant. That the information encoded remains unchanged between the claimed DNA and the natural DNA is enough to show that the claimed DNA is not markedly different from the natural DNA.[133] The opinion notes that the claimed DNA would, in fact, be worthless if the information encoded were not exactly the same as natural DNA.[134] Further, it suggests that many of Myriad's claims could be invalidated because they are broad enough to encompass natural DNA as well as synthesized DNA, which is, by definition, not markedly different from a product of nature.[135] Even the claims for cDNA, it suggests, are not markedly different from products of nature, because cells have the means to produce cDNA from native DNA, and therefore cDNA may exist in the cell.[136]

Myriad's method claims are also held to be invalid.[137] The

126. *Id.* at 222–23.
127. American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931).
128. Funk Bros. Seed Co. v. Kalo Inoculant Co. (*Funk Bros.*), 333 U.S. 127 (1948).
129. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
130. *Myriad*, 702 F. Supp. 2d at 223
131. *Id.* at 220.
132. *Id.* at 228.
133. *Id.* at 229.
134. *Id.* at 231.
135. *Id.* at 230.
136. *Id.*
137. *Id.* at 232–37.

finding is based not on any of the three discussed exceptions, but rather on the "machine or transformation" test articulated by the Federal Circuit in *In re Bilski*.[138] According to the machine or transformation test, a claim for a method is invalid if it is not connected to a machine, or does not transform an article.[139] Myriad's claims do not teach a method that is connected to a machine and the transformation argued by Myriad is insufficient.[140] The opinion states that Myriad's claims are too broad because they only use general terms such as "data gathering" and "comparing."[141] Further, drawing of a patient's blood and isolating his or her DNA sample are not transformative enough because it is simply collecting a sample and preparing it for data-gathering.[142] The transformation must be essential to the claimed process, and drawing blood and isolating the DNA are not the focus of Myriad's claimed method—the focus is in comparing the two samples.[143] Comparing the two samples is simply an application of the scientific method, which is neither transformative nor novel.[144] The court did not address whether the composition-of-matter or diagnostic-method patents were patentable under § 102 for novelty and § 103 for nonobviousness.[145]

Myriad's composition-of-matter claims were held to be patent ineligible because they were products of nature. Myriad's method claims were also held to be patent ineligible because they were not tied to a machine or transformation process. The district court opinion was filed on March 29, 2010, invalidating Myriad's patents.[146] Myriad filed a notice of appeal to the Court of Appeals for the Federal Circuit on June 16, 2010, seeking reversal of the decision.[147]

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138. *In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008), *modified,* Bilski v. Kappos, 130 S. Ct. 3218, 3226 (2010).

139. *Myriad*, 702 F. Supp. 2d at 233.

140. *Id.*

141. *Id.* at 234, 236.

142. *Id.* at 236.

143. *Id.*

144. *Id.* at 237.

145. *Id.* at 220 (noting that the sole purpose of the court was to determine whether Myriad's inventions fell under the product of nature exception).

146. *Id.* at 181.

147. Notice of Appeal for Appellant Myriad at 1, Ass'n for Molecular Pathology v. Myriad Genetics Inc., No. 2010-1406 (Fed. Cir. filed June 16, 2010). The USPTO, on the other hand, did not appeal, as the court dismissed the claims against it. *Myriad*, 702 F. Supp. 2d at 237–38.

IV. ANALYSIS

This section will present precedents of finding gene patents eligible and explain how the *Myriad* opinion improperly applied *Chakrabarty, Funk Bros.* and the now-questionable *In re Bilski* and was therefore insufficient to reverse the USPTO's decision and find that genes are patent ineligible. This section will then explain the need for gene patent eligibility from a public policy viewpoint.[148] Finally, it will explore the § 102 novelty and § 103 obviousness obstacles genetic diagnostic methods are likely to face before being granted patent status.

A. MYRIAD'S COMPOSITION-OF-MATTER CLAIMS ARE PATENT ELIGIBLE

This section will show that the court's analysis fails to invalidate Myriad's composition of matter patents. First, Myriad's composition of matter patents do not fall under the product of nature exception. Second, they are more than purifications of natural mixtures. Third, *Funk Bros.*, arguably the opinion's strongest support, does not apply to this action. Finally, deference to Congress, the USPTO, and other courts strongly supports a finding of patent eligibility.

1. The Scope of § 101

Section 101, addressing what inventions are eligible to be considered for patents, was written to apply broadly.[149] The 1793 Act is said to have been authored by Thomas Jefferson,[150] who instilled in it his belief that "ingenuity should receive a liberal encouragement."[151] Though the Act has been amended

148. This Comment approaches legal analysis first, for if patenting genes is found to be clearly foreclosed by law, public policy is moot. *See* Dir., Office of Workers' Comp. Programs v. Newport News Shipbuilding & Dry Dock Co., 514 U.S. 122, 129 (1995) (holding that, absent clear language in the statute in question, workers rights could not be brought to court by the secretary of labor even though public policy greatly favored it); Diamond v. Chakrabarty, 447 U.S. 303, 317–18 (1980) (holding that the court is neither equipped nor authorized to second-guess Congress' determinations of patent eligibility based on public policy concerns).

149. 35 U.S.C. § 101 (2006) (establishing that "*any* new and useful. . . composition of matter. . . or *any* new and useful improvement thereof" may be patented subject to other restrictions of the act) (emphasis added).

150. *Chakrabarty*, 447 U.S. at 308–09.

151. Thomas Jefferson *in* 5 WRITINGS OF THOMAS JEFFERSON 75–76 (Washington ed. 1871).

multiple times, Jefferson's broad language has never been restricted.[152] In fact, accompanying the latest amendment in the 1952 Act, Congressional committee reports explicitly state that "anything under the sun that is made by man" qualifies for patent eligibility under § 101.[153] The courts have concluded that advanced technologies that Congress would have had no way of anticipating when the act was written are not patent ineligible per se.[154] Indeed, the Supreme Court has held that it cannot read limitations into statutes that were not intended by Congress.[155] However, the Supreme Court has also cautioned that courts should use extreme prudence when "expanding" patent eligibility to those areas.[156] As guidance, the Supreme Court has established three general exceptions to the presumption of patent eligibility: laws of nature, physical phenomena, and abstract ideas.[157]

2. The Product-of-Nature Exception is Valid

The *Myriad* respondents successfully argued that human genes, when isolated from surrounding DNA and other cellular components, are not patent eligible because they fall under the product-of-nature exception.[158] Myriad argues, however, that this "product of nature' exception on which the decision relies is not one of the three exceptions described in *Chakrabarty*. *Chakrabarty* does not mention a "product of nature" exception, but only "laws of nature."[159] The *Myriad* opinion describes the "product of nature" exception as a general combination of "the law[] of nature, natural phenomenon, and abstract idea[]" exceptions cited in *Chakrabarty*,[160] and one of the examples the Court used in *Chakrabarty* to clarify the three exceptions fits Judge Sweet's definition of a product of nature.[161] Myriad

152. *Chakrabarty*, 447 U.S. at 309.

153. S. REP. NO. 82-1979 at 5 (1952). While this statement may be too overbroad to be read literally, it certainly supports a broad construction o the act.

154. *Chakrabarty*, 447 U.S. at 316.

155. United States v. Dubilier Condenser Corp. 289 U.S. 178, 199 (1933).

156. Parker v. Flook, 487 U.S. 584, 596 (1978).

157. *Chakrabarty*, 447 U.S. at 309.

158. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad*), 702 F. Supp. 2d 181, 184, 222, 228 (S.D.N.Y. 2010).

159. 447 U.S. at 309.

160. *Myriad*, 702 F. Supp. 2d at 220.

161. *Chakrabarty* describes a hypothetical new mineral discovered in the earth as patent ineligible under the three exceptions. 447 U.S. at 309.

argues that the products of nature test improperly limits the statute beyond congressional intent.[162] Myriad itself admits that the exceptions set out in *Chakrabarty* were meant not to limit the statute but to provide guidance for the "new and useful" determination of § 101.[163] This type of guidance is precisely the purpose of the courts.[164] Myriad also suggests that such a sweeping exception in patent law would frustrate the patent statute, but does not give support for the district court or court of appeals to overturn a holding of the Supreme Court.[165] Myriad has not established that the district court misunderstood the underlying exceptions expressed by the Supreme Court in *Chakrabarty*. Myriad's argument against the "product of nature" exception, without more, is merely semantic.

3. Myriad's Genes Do Not Fall Under the Product of Nature Exception.

Myriad's stronger argument is that which it presented to the district court: that its patented genes have been sufficiently altered so as to not fall under any of the three exceptions.[166] Even if natural DNA is generally analogous to a hypothetical—newly discovered mineral, as described in dicta as patent ineligible by *Chakrabarty*[167]—Myriad argues that its claimed DNA is not specifically analogous, because it is isolated from its cellular surroundings and is devoid of introns and any DNA associated proteins, it is purified.[168]

The *Myriad* opinion's analysis of the exceptions in *Chakrabarty* focused on whether Myriad's claimed DNA meets "[the] requirement that an invention possesses 'markedly

162. Brief for the Appellants at 1, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., No. 2010-1406 (Fed. Cir. filed June 16, 2010).

163. *Id.* at 33.

164. *Cf.* Marbury v. Madison, 5 U.S. (1 Cranch) 137, 147 (1803) (holding that the U.S. Supreme Court has jurisdiction to interpret laws passed by Congress).

165. Brief for the Appellants, *supra* note 162 at 46.

166. *Myriad*, 702 F. Supp. 2d at 224.

167. *See supra* note 161. This comment, for argument's sake, will assume that natural DNA, extracted in a pure chromosomal form, is directly analogous to the hypothetical mineral described in the Court's analysis in *Chakrabarty*.

168. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad*), 702 F. Supp. 2d 181, 224 (S.D.N.Y. 2010).

different characteristics' [than the natural analog]."[169] Myriad argues that *Chakrabarty* did not establish the "markedly different characteristics" analysis as a test.[170] Instead, Myriad suggests, the Court intended the test to be whether the claimed invention has "distinctive name, character, and use."[171] Myriad was correct that *Chakrabarty* did not establish the "markedly different characteristics" analysis as a test for determining whether a claimed invention is sufficiently altered to avoid the three exceptions. But *Chakrabarty* did not indicate that the "distinctive name, character, and use" analysis was to be the sole test; its discussion on the matter was quite specific to the facts of that case and did not establish a particular test.[172] Therefore, a proper analysis would treat the "markedly different characteristics" analysis, the "distinctive name, character, and use" analysis, and all other reasoning expressed by *Chakrabarty* equally.

When determining whether the claimed invention fits under one of the three exceptions, the *Chakrabarty* court posed the question of whether the claim is to "a hitherto unknown natural phenomenon" or a "nonnaturally occurring manufacture or composition of matter."[173] The court mentioned the following criteria as guidance: (1) whether the claim is to "a product of human ingenuity having a distinctive name, characteristic, and use,"[174] (2) whether the claim is to something "with markedly different characteristics from any found in nature and one having the potential for significant utility," and (3) whether the claim is to "nature's own handiwork or [the patentee's]."[175] While *Chakrabarty* did not establish any of these criteria as an exclusive test for patent eligibility, because Myriad's composition-of-matter claims are supported by all three characteristics, the *Chakrabarty* analysis is sufficient.

The opinion suggests that Myriad's composition claims point to natural phenomena that occur naturally absent human intervention, because both Myriad's claimed BRCA1 and

169. *Id.* at 223 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980)).

170. Brief for Appellants, *supra* note 162, at 41–42.

171. *Id.* at 42 (quoting *Chakrabarty*, 447 U.S. at 309–10).

172. *See Chakrabarty*, 447 U.S. 309–10.

173. *Id.* at 309.

174. *Id.* at 309–10 (quotation omitted).

175. *Id.* at 310.

BRCA2 genes and natural BRCA1 and BRCA2 genes have the same informational encoding capacity and purpose.[176] As Myriad notes, the court erred in focusing on such a narrow aspect of Myriad's claims,[177] because claims must be considered as a whole when determining patent eligibility.[178] Myriad essentially argues that their inventions were held patent ineligible because of general genetic concept, when they should have been held patent eligible because of the changes Myriad made to the DNA.[179] "[I]t is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis."[180] When Myriad's claims are viewed more thoroughly, they are patent eligible.

i. Myriad's Claims Are the Product of Human Ingenuity Having Distinctive Characteristics and Uses

Myriad admits that its claimed genes and the natural genes are codes for the same exact proteins.[181] This concession is not surprising, because the entire purpose of sequencing and isolating the BRCA1 and BRCA2 genes was to discover the cancer-related proteins for which they code.[182] However, this code serves different purposes in the claimed and in natural DNA. The purpose of the sequence of genes in natural DNA is to make the production of proteins possible.[183] The purpose of the sequence of genes in Myriad's claimed isolated DNA is to identify mutations in BRCA1 and BRCA2 genes.[184] The structural differences between the two types of DNA serve this

176. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad*), 702 F. Supp. 2d 181, 229 (S.D.N.Y. 2010).

177. Brief for the Appellants, *supra* note 162, at 51.

178. Diamond v. Diehr, 450 U.S. 175, 188 (1981).

179. Brief for the Appellants, *supra* note 162, at 51.

180. *Id.*

181. *Myriad,* 702 F. Supp. 2d at 231.

182. *Id.* at 201.

183. *See* SOLOMON, ET AL., *supra* note 2 at 261, 278. While Myriad's isolated DNA do not serve this purpose, some isolated DNAs could be useful for laboratory protein production. In this case, the use would still be different from that of natural DNA. Natural DNA produces only small amounts of protein for use in the body, while isolated DNA could be used to produce extremely large amounts of protein for sale or other purposes. Brief of Amici Curiae Rosetta Genomics, Ltd., et al. as Amici Curiae supporting Appellants, at 23, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 702 (No. 2010-1406) (Fed. Cir. filed June 16, 2010).

184. *Myriad*, 702 F. Supp. 2d at 203.

difference in purpose: as Myriad puts it, natural "DNA is useless for the diagnostic and detection applications for which the isolated molecules may be utilized."[185] To begin with, isolated DNA is not found in chromosomal form, and thus it is never coiled, twisted, or surrounded by proteins that make it difficult or impossible to compare the sequence of one gene with that of another.[186] That the claimed DNA is isolated suggests that it is also separated from the thousands of other genes on the chromosome, making the DNA far less unwieldy.[187] Further, isolated DNA is without extra sequences unimportant to gene comparison, such as sequences that serve to regulate cellular processes and noncoding introns.[188]

These distinctions between native and isolated DNA are not a product of nature's efforts. Indeed, the *Myriad* court admitted that the differences are a direct result of Myriad's effort and ingenuity.[189] This is necessarily so, because the human body can neither isolate DNA nor cDNA, such that neither can regularly occur in nature and both are the result of genetic manipulation.[190] The changes Myriad has made to the DNA "permit the direct yoking of natural processes for mankind's purposes."[191] Clearly, Myriad's claimed DNA is the product of human ingenuity having distinctive characteristics, uses, and (if the scientific community so chooses) names from natural DNA.[192]

ii. The Distinctions Between Myriad's DNA and Natural DNA are Marked, and Create the Potential for Significant Utility[193]

Chakrabarty gave no guidance for determining if a claimed

185. Brief for the Appellants, *supra* note 162, at 51.

186. *Myriad*, 702 F. Supp. 2d at 195–96.

187. *See* Rosetta Genomics, *supra* note 183 at 23 (describing chromosomes as large structures with numerous genes and DNA sequences).

188. *Id.* at 24.

189. *Myriad*, 702 F. Supp. 2d at 202.

190. Rosetta Genomics, *supra* note 183 at 22–23; Brief for the United States as Amicus Curiae in Support of Neither Party at 15, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., No. 2010-1406 (Fed. Cir. briefs submitted Oct. 22, 2010). The U.S. Department of Justice notes in its amicus brief that cDNAs do sometimes occur in nature, in viruses, for example, but not in humans.

191. *See* Brief for the United States, *supra* note 190, at 16.

192. *See* Rosetta Genomics, *supra* note 183, at 22–23.

193. The utility for diagnostic tests, made possible by isolated DNA is discussed in the public policy section below. *See infra* Part IV.C..

invention is "markedly different."[194] However, the way *Chakrabarty* made the determination is instructive. The patentee had invented a biologically engineered bacterium by inserting new DNA sequences into the bacterium's natural DNA.[195] The claimed bacterium, as a result of the patentee's engineering, was able to degrade oil more efficiently, and thus was useful in treating oil spills.[196] Previously, multiple bacteria were required to degrade oil, but the claimed bacterium was able to do the same work alone.[197] Therefore, in *Chakrabarty*, an organism's DNA was altered to allow it to perform a task more efficiently. The inventive difference between the invention and its natural counterpart was the change in DNA. Similarly, the inventive difference (among others) between Myriad's invention and its natural counterpart is a change in DNA.[198] While the sequences encoding the gene remain in both Myriad's invention and its natural counterpart, the amount of DNA and other substances removed cause a marked difference.[199] Further, the operative difference between the *Chakrabarty* invention and its natural counterpart is an improvement in performance.[200] However, the operative difference between Myriad's invention and its natural counterpart is an entirely new use that would have been impossible without the invention.[201] Myriad's is the only test available to diagnose hereditary breast cancer.[202] Therefore, there are marked operative differences between Myriad's DNA and natural DNA.

iii. Myriad's Claims are to Myriad's Handiwork, Not Nature's

As discussed, the new use resulting from Myriad's claimed invention developed from Myriad's ingenuity.[203] For example,

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

195. *Id.* at 305.

196. *Id.* at 305 n.2.

197. *Id.*

198. Brief for the Appellants, *supra* note 162 at 50–51. The difference between this case and *Chakrabarty* is that here DNA was removed, instead of added.

199. *See supra* notes 185–188 and accompanying text.

200. *Chakrabarty*, 447 U.S. at 305 n.2.

201. Brief for the Appellants, *supra* note 162 at 50–51.

202. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad*), 702 F. Supp. 2d 181, 206 (S.D.N.Y. 2010).

203. *Id.* at 202.

cDNA, is not found naturally in humans[204] and there is no natural method for isolation of DNA.[205] Because the differences between Myriad's invention and its natural counterpart result largely from the isolation of the DNA and its change to cDNA, the differences cannot be said to be nature's handiwork.[206] Further, because these differences are the direct causes of the usefulness of Myriad's claimed invention,[207] it follows that the invention is not nature's handiwork.

The *Myriad* opinion mentions that at least one of Myriad's claims can be read so broadly that it encompasses the DNA that it exists in the human body and that Myriad is therefore claiming nature's handiwork.[208] But this is not an appropriate reading of the claims. A patent's claims must be read in light of all other claims, the specification, and the invention as a whole.[209] Given that the clear purpose of Myriad's invention is to diagnose likelihood of hereditary breast cancer and that natural DNA is useless to that end, it is nonsensical and against patent regulations to read any of Myriad's claim in a way that would include natural DNA as it exists in humans.[210]

4. Myriad's Genes Are Not Patent Ineligible Because They Are Purifications of a Natural Substance

Amici (notably, the United States Department of Justice) argue that genes cannot be patented as compositions of matter due to the longstanding exception to § 101 that purification of something unpatentable does not result in a patent eligible invention.[211] In *Cochrane*, the patentee originally attempted to patent both a process for synthesizing a dye that was previously available only by extraction from a plant and the dye itself.[212] The synthetic dye was found not patent eligible

204. *See* United States, *supra* note 190 at 15.

205. Rosetta Genomics, *supra* note 183 at 22.

206. *See supra* notes 189–191 and accompanying text.

207. *See supra* notes 184–186 and accompanying text.

208. *Myriad*, 702 F. Supp. 2d at 230.

209. *See* 37 C.F.R. § 1.104 (2009) (establishing that examination of a patent must be a thorough study of the whole application); 35 U.S.C. § 112 (2006) (establishing that the application's specification provides context for the invention and manner of use of the invention); *supra* notes 178, 180 and accompanying text.

210. 37 C.F.R. § 1.104 (2010); *supra* notes 178, 180 and accompanying text.

211. Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 311–12 (1884).

212. *Id.*

because it was not a new article.[213] However, there is a longstanding exception to the purification exclusion: purified articles that differ from their previous counterparts not only in degree of purity but also in kind adopt a new use are patent eligible.[214] *In re Merz* invalidated a patent for a dye for the same reasons given in *Cochrane*,[215] but noted in dicta that if the dye had been so much purer that it differed in kind and was useful in a new way from the previous dye, it would have been patentable.[216]

It is undisputed that the isolation and purification of the BRCA1 and 2 genes from their natural environment has created articles different in kind from their natural counterparts.[217] While genes purified to a lesser extent than Myriad's genes may still be useful to produce proteins, they would be useless for diagnostic tests.[218] Only Myriad's genes, once purified, are useful for this application.[219] Therefore, they fall under the "different in kind" exception, and are not patent ineligible because they are purifications.

5. Myriad's Genes Are Not Patent Ineligible Under *Funk Bros.*

The *Myriad* opinion relied to a large extent on *Funk Bros.* to establish that Myriad's genes are patent ineligible under § 101.[220] *Funk Bros.* held that combining three types of bacteria into a culture that efficiently allows plants to fix nitrogen from the atmosphere did not result in a patentable invention.[221] Because it was well known that these species of bacteria allowed plants to fix nitrogen and that certain species of the bacteria inhibited the fixing effects of other species, it was a clear next step to combine only bacteria that do not inhibit each other when composing plant additives.[222] This analysis is

213. *Id.*
214. *In re* Merz, 97 F.2d 599, 601 (C.C.P.A. 1938).
215. *Id.*
216. *Id.*
217. *See supra* notes Part IV.A.3.i.
218. *See supra* notes Part IV.A.3.ii.
219. *See supra* notes Part IV.A.3.ii.
220. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad*), 702 F. Supp. 2d 181, 232 (S.D.N.Y. 2010).
221. Funk Bros. Seed Co. v. Kalo Inoculant Co. (*Funk Bros.*), 333 U.S. 127, 129–30, 131–32 (1948).
222. *Id.*

known today as the obviousness analysis from § 103.[223] However, *Funk Bros.* was decided just before the Patent Act of 1952, when the obviousness rejection from *Hotchkiss* was so named and codified under § 103.[224] Therefore, *Funk Bros.* is not applicable to modern cases of patent eligibility under § 101, but under § 103,[225] and thus Myriad's claims cannot be held to be patent ineligible under § 101 due to *Funk Bros.* Even if the obviousness standard applied to patent eligibility in this case, Myriad's claims would still not be ineligible.

6. Deference to USPTO Determination, Precedent, and Congressional Intent Support Patentability of Genes as Compositions of Matter

The Supreme Court has deferred to the longstanding judgment of the patent office in its reading of statutes governing patent eligibility.[226] Given the over 40,000 patents on genes issued by the USPTO—and the lack of any action to the contrary by Congress—a holding that genes are not patent-eligible would violate the precedent of deference to the longstanding judgment of the USPTO.[227] Further review of the precedents shows that the Federal Circuit, which, due to their expertise in the field, handles all appeals from the Board of Patent Appeals and Interferences,[228] has a history of assuming

223. 35 U.S.C § 103 (2006). *See also* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007) (explaining the test for obviousness under § 103).

224. *Funk Bros.*, 333 U.S. at 127; *KSR*, 550 U.S. at 406 (stating that the analysis and language from § 103 in the 1952 Patent Act establishing §§ 100–03 was taken from *Hotchkiss v. Greenwood*); Hotchkiss v. Greenwood, 52 U.S. (11 How.) 248, 267 (1851).

225. Brief for Alnylam Pharmaceuticals, Inc. as Amicus Curiae Supporting Petitioners at 13-14, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., No. 2010-1406 (Fed. Cir. Oct. 22, 2010).

226. *See, e.g.*, J.E.M. AG Supply v. Pioneer Hi-Bred Int'l, 534 U.S. 124, 144–45 (2001) (holding that, because the USPTO had found multiple plant inventions patent eligible under § 101, and because Congress had not expressed disapproval of such findings, a holding against the USPTO's judgment on patent eligibility would be improper).

227. Rosetta Genomics, *supra* note 183, at 14; Genomic Research and Accessibility Act, H.R. 977, 110th Cong. (2007) [hereinafter GRAA] (this bill never became law), *available at* http://www.govtrack.us/congress/billtext.xpd?bill=h110-977.

228. *Court Jurisdiction*, UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, http://www.cafc.uscourts.gov/index.php?option=com_content&view=article&id=144&Itemid=27 (last visited Nov. 22, 2010). Given the fact that this court was formed from the United States Court of Customs and Patent Appeals and

genes to be patent eligible.[229] Finally, the fact that Congress explicitly refused to bar gene patent eligibility under § 101 in the Genomic Research and Accessibility Act,[230] especially in light of growing controversy on the issue, demonstrates the congressional intent that genes remain eligible for patenting.

B. MYRIAD'S METHOD CLAIMS ARE PATENT ELIGIBLE UNDER § 101

1. The "Machine-or-Transformation" Test Is No Longer Dispositive

The *Myriad* opinion's invalidation of Myriad's method claims relied heavily on the Federal Circuit's decision in *In re Bilski*.[231] But the district court's view that Myriad's method is not tied to a particular machine or apparatus and does not perform sufficient transformation is no longer dispositive since the Supreme Court's disapproval of *In re Bilski*, on the ground that the "machine-or-transformation" test was not meant to be a binding test.[232] Instead, method patents which otherwise comply with statutory provisions are patent eligible unless they are merely abstract ideas.[233]

After the Supreme Court's *Bilski* decision, the machine-or-transformation analysis remains important as a "clue" in determining patent eligibility.[234] Myriad's method claims are made more patent eligible, rather than less, by this analysis. There are multiple steps that a court could identify as transformative; a patient's blood must first be treated and the DNA from the blood must be isolated and sequenced.[235] This is especially determinative, as the Federal Circuit has recently held similar treatment of blood to be transformative in *Prometheus Laboratories, Inc. v. Mayo Collaborative*

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the deference the Supreme Court gives to the expertise of the Board of Patent Appeals and Interferences, this court can be assumed to have some expertise in patents. *See* J.E.M. 534 U.S. at 144–45.

229. *See, e.g.*, Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1219 (Fed. Cir. 1991).

230. *See* GRAA, *supra* note 227.

231. *Supra* notes 137–144 and accompanying text.

232. Bilski v. Kappos, 130 S. Ct. 3218, 3226 (2010).

233. *See id.* at 3229–30.

234. *Id.* at 3227.

235. Brief for the Appellants, *supra* note 162 at 55.

Services.[236] The machine-or-transformation analysis, therefore, strengthens the patent eligibility of Myriad's method claims.

2. Myriad's Method Claims Are Not Abstract Ideas

The *Myriad* opinion suggests that Myriad's method claims are patent ineligible because they are related not to any particular method of analysis, but instead to the mental process of "comparing" sequences.[237] However, Myriad's method claims represent far more intricate processes than simply looking at a list of nucleotides side-by-side. To begin, isolating the correct sequences of a person's DNA requires several non-abstract steps.[238] Further, any differences between a person's DNA and Myriad's gene will need to be examined to determine whether those mutations are of any effect. Because this requires extensive analysis,[239] Myriad had to develop several tests to identify different types of mutations.[240] Myriad's tests are far from abstract ideas and are therefore patent eligible.

C. POLICY RAMIFICATIONS OF INVALIDATING GENE PATENTS

The *Myriad* opinion's sudden invalidation of patents on human genes, if supported by higher courts and the USPTO, will have tremendous consequences,[241] and it has already unsettled much of the patent community.[242] To begin, the

236. Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347, 1356 (2010).

237. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad*), 702 F. Supp. 2d 181, 233 (S.D.N.Y. 2010).

238. Brief for the Appellants, *supra* note 162, at 55.

239. *See Myriad*, 702 F. Supp. 2d at 195 (explaining that different types of mutations in a person's DNA will have different effects); *id.* at 195 n.5 (explaining that extensive analysis is required to determine what effect each mutation will have); *supra* notes 42–44 and accompanying text (explaining that many mutations will have no effect).

240. *Myriad*, 702 F. Supp. 2d at 203.

241. Dennis Crouch referred to the decision as "a powerful move." Dennis Crouch, *Court: Essentially All Gene Patents Are Invalid*, PATENTLY-O (Mar. 30, 2010, 7:17 AM), http://www.patentlyo.com/patent/2010/03/court-essentially-all-gene-patents-are-invalid.html. The title of this blog entry emphasizes the far-reaching potential this decision could have.

242. Paul M. Janicke, *Guest Post: An Interesting Preview of Myriad?*, PATENTLY-O (Sept. 26, 2010, 10:29 PM), http://www.patentlyo.com/patent/2010/09/guest-post-an-interesting-preview-of-myriad.html.

USPTO has granted patents to over 40,000 genes,[243] over ninety-nine percent of which have never been challenged. Moreover, only a fraction of the remaining one percent were challenged because of their patent eligibility or ineligibility.[244]

The purpose of patent law is to "promote the Progress of Science and the useful Arts."[245] The patent system promotes science by giving inventors an incentive to develop marketable inventions and technologies.[246] However, the public at large is benefitted greatly by the patent system as well for at least two reasons: (1) many useful inventions that are patented are marketed and sold to consumers, who benefit from the invention's availability; and (2) in order to get a patent, an inventor must describe (enable) the invention in the published patent application in a way that would allow another person to make and use the invention.[247] This enablement allows others to use the patent application to discover new improvements to the invention or technology, and patent law incentivizes improvements on known inventions and technology, further increasing the public's benefit from the original patent.[248]

Applying these concepts to the medical field, it follows that giving the benefits of patent protection to the inventors of medical technologies will increase the amount of benefit the public at large receives from the medical technology field.[249] However, there is some dispute as to whether the incentive to develop medical technologies such as Myriad's gene sequences and diagnostic tests is greatly increased by the benefits of patenting those technologies.[250] The research that leads to

243. Rosetta Genomics, *supra* note 183, at 14.

244. *Id.* at 29-30. *See also* Crouch, *supra* note 241 (describing Judge Sweet's *Myriad* decision as against "standard thoughts on patentability.").

245. U.S. CONST. art. 1, § 8, cl. 8.

246. *See id.* (securing, "for limited [t]imes," the patent holder's exclusive right to profit from those inventions and technologies).

247. 35 U.S.C. § 112 (2006).

248. *See* 35 U.S.C. § 101 (2006) (granting patent eligibility to improvements upon previous patented inventions).

249. *See* Brian Murphy & Daniel Murphy, Bilski*'s "Machine-or-Transformation" Test: Uncertain Prognosis for Diagnostic Methods and Personalized Medicine Patents*, 20 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 755, 760 (2010) (suggesting that the incentive provided by a broad patent eligibility test is especially important in the fields of medicine and genetic diagnostics).

250. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad*), 702 F. Supp. 2d 181, 210 (S.D.N.Y. 2010).

many of these technologies receives federal funding in the form of grants or public university research.[251] But further analysis indicates that medical technologies are not beyond the effects of patent incentivization.

1. Patent Protection Incentives Are Important to University and Private Research

Although their research is partially supported by public funds, universities are able to profit from that research,[252] and, through patents, to prevent others from competing with them.[253] Therefore, while the costs incurred by a university in developing patentable and profitable technologies may be more likely to be subsidized than those incurred by a private organization, universities' ability to reap benefits from the patent system in the same way that private organizations do suggests that they are not impervious to the incentives it provides.[254] Even assuming that university research efforts are largely unaffected by the incentives of the patent system does not defeat the importance of the patent system to their research, for, as their research is released into the public domain, private entities are free to develop improvements upon that research, creating more marketable technologies.[255] Without the incentives of the patent system, those private entities would be unable to recoup their research costs and would not improve university research in the public domain.[256]

It is true that, even absent research assistance from public universities, private entities are often given research subsidies from public funds.[257] But those funds help to research only the basic technologies of a patentable product; the cost of

251. *See, e.g.*, *id.* (revealing that research for 63% of patents on gene sequences was partially funded by the government). Also relevant, is the fact that a public university is part owner of Myriad's patents. *Id.* at 189–90.

252. *See, e.g.,* Joe Kays & Arline Phillips-Han, *Gatorade: The Idea That Launched an Industry*, EXPLORE RESEARCH AT THE UNIVERSITY OF FLORIDA (Spring 2003), http://www.research.ufl.edu/publications/explore/v08n1/gatorade.html.

253. *Property Rights: The Granting of Patents on Human Genes Has so far not Been the Disaster it Was Predicted To Be*, 458 NATURE 386, 386 (2009).

254. It is true, however, that universities may do research that is never expected to result in a patentable product, but is simply released into the public.

255. 35 U.S.C. 101 (2006).

256. *See Myriad*, 702 F. Supp. 2d at 211.

257. *See id.* at 210.

developing a commercially profitable application of that product is far greater and dwarfs the funding typically given to private research.[258] Therefore, it is likely that, without the incentives of patent protection, the research assisted by federal subsidies will stop well short of anything useful to the public, because the costs would be prohibitive.

2. The Public is Best Served by Maintaining the Incentives of Patent Protection to Medical Inventors

Advanced medical tests, especially diagnostic DNA tests, can be very expensive.[259] If the provider of a medical procedure is given a partial monopoly by patent protection, that provider will have more freedom in setting the price of the procedure.[260] Therefore, when several firms are providing a medical procedure, consumers will pay less for the procedure than if there were only one provider. Thus, if Myriad were not allowed to gain patent protection on its gene and diagnostic tests, those tests would be available to consumers at lower prices.

The benefit of allowing patents for genes and resulting diagnostic tests is not much more complicated. If Myriad had known before sequencing the BRCA1 and BRCA2 genes that it would not be granted patents on them, it would not have performed the research.[261] Retroactively taking patent protection away from a company that has already performed research and prepared the resulting genetic test will remove its monopoly of diagnostic testing and create competition to drive

258. *See id.* at 211.

259. Amy Dockser Marcus, *Obsessed With Genes (Not Jeans), This Teen Analyzes Family DNA*, WALL ST. J., Oct. 1, 2010, at A1.

260. Harold Demsetz, *Why Regulate Utilities?*, 11 J.L. & ECON. 55, 56 (1968).

261. Murphy, *supra* note 249, at 764. The costs of developing genetic tests can be hundreds of millions of dollars, while Myriad was only reported to have been given 22 million dollars in funding. *Id.* at 760–61; Ass'n for Molecular Pathology v. Myriad Genetics Inc. 09 Civ. 4515 at 49 (S.D.N.Y. 2010), *available at* http://www.aclu.org/files/assets/2010-3-29-AMPvUSPTO-Opinion.pdf. A mistake was made in the Federal Supplement version of this case, misrepresenting the amount that Myriad received in funding. The original court opinion has been cited. *Compare* Ass'n for Molecular Pathology v. Myriad Genetics Inc. 09 Civ. 4515 at 49 (S.D.N.Y. 2010), *available at* http://www.aclu.org/files/assets/2010-3-29-AMPvUSPTO-Opinion.pdf (stating that Myriad had been given 22 million dollars in funding) *with Myriad*, 702 F. Supp. 2d at 201 (stating that Myriad had been given 122 million dollars in funding).

the cost of the tests down, but may prevent the development of future genetic tests for other cancers, or improved genetic tests for breast cancer. The long-term future consequences of removing patent protection for genetic tests can be illustrated by analyzing what would have happened if patent protection had never been offered for genes. Myriad would have been less willing to spend the vast amounts of money necessary to discover the sequences BRCA1 and BRCA2 genes and develop a marketable genetic test.[262] This would prevent over 70,000 women per year from being able to receive the BRCA1 and/or BRCA2 analysis.[263] Moreover, without the patent incentive, many genes[264] with important medical implications would never have been sequenced, and thus thousands of patients would be without the benefit of decades of medical research.[265] For example, currently 250,000 Americans suffer from a hereditary genetic neurological disease known as Huntington's disease.[266] Huntington's disease causes neural degeneration, at first inhibiting an individual's fine motor skills and eventually the ability to talk, reason, and remember.[267] Huntington's disease is completely linked to the gene; if a person has the gene, he or she will develop the disease, and die within twenty or fewer years.[268] Most individuals do not develop symptoms of the disease until they are between thirty and fifty years of age—often after having children to whom they had a fifty percent chance of passing on the disease.[269] The importance of genetic testing to families with a history of Huntington's

262. *See* Rosetta Genomics, *supra* note 183, at 7 (suggesting that without patent protection, many gene based products will never reach the public).

263. Myriad charges approximately 3,000 dollars per test, and performed 220,000,000 dollars worth of tests in 2008. Therefore, Myriad performed over 70,000 tests in 2008. *See Myriad*, 702 F. Supp. 2d at 203.

264. The potential number of genes patents affected could be quite high, as 40,000 genes have been patented. *See* Editorial*: Property Rights: The Granting of Patents on Human Genes Has So Far Not Been the Disaster It Was Predicted to Be*, 458 NATURE 386, 386 (2009).

265. *See, e.g.*, Marsha L. Miller, *HD Research - Past and Future*, HUNTINGTON'S DISEASE SOCIETY OF AMERICA, http://www.hdsa.org/research/past-and-future.html (last visited June 11, 2011) (reporting that, since the discovery of the Huntington's gene in 1993, an explosion of research has been performed regarding Huntington's disease).

266. *What is HD*, HUNTINGTON'S DISEASE SOCIETY OF AMERICA, http://www.hdsa.org/about/our-mission/what-is-hd.html (last visited June 11, 2011).

267. *Id.*

268. *Id.*

269. *Id.*

disease is clear, but without gene patent eligibility, the testing would likely not be available today.[270]

Applying this illustration to future research elucidates the effects that stripping patent eligibility from genes may hinder genetic research and slow the development of medical innovation. This result would be devastating to future generations suffering from currently incurable genetic diseases or genetically linked diseases that cannot currently be diagnosed because the genes are undiscovered. Without patent protection, further research on both unidentified and identified genes and their effects would not be incentivized, potentially foreclosing treatments and cures for currently untreatable or incurable diseases such as breast cancer and Huntington's disease.[271]

On the other hand, it has been suggested that allowing patent protection for genes will allow patent holders to prevent further research on those genes, thus stunting genetic research more than a lack of incentive would.[272] In reality this is highly unlikely; patent law is specifically designed to encourage improvements and innovations of currently patented inventions and technology.[273] While some scientists may believe that gene patents would restrict their research,[274] those scientists appear to be over-cautious because scientists being blocked from research is a nonissue.[275] Even Myriad's patents, the controversy of which is made clear by the existence of this case, has left research open to the public and has had almost no effect on BRCA1 and BRCA2 research.[276] Indeed, since Myriad's patents were granted, over 18,000 scientists have

270. Rosetta Genomics, *supra* note 183, at 7.

271. *Id.*; *see also* Murphy & Murphy, *supra* note 249, at 764.

272. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad*), 702 F. Supp. 2d 181, 208 (S.D.N.Y. 2010)..

273. 35 U.S.C. § 101 (2006) (establishing that discoverers of improvements on previous inventions may patent those improvements). *But see* 35 U.S.C. § 271 (2006) (establishing that patent holders can prevent the making, using or selling of their inventions).

274. *Myriad,* F. Supp. 2d at 208.

275. *See* Editorial, *supra* note 264, at 386. The editorial suggests that, even in cases where a scientist's research could be hindered, legal workarounds are quite simple.

276. DEP'T OF HEALTH & HUMAN SERVS., 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 at 75 (2010).

conducted research on the BRCA1 and BRCA2 patents, resulting in over 7000 papers.[277] It appears, then, that hindrance of future genetic research is not a reasonable policy argument against patenting genes.

D. MYRIAD'S METHOD CLAIMS MAY NOT BE VALID UNDER §102 OR §103

Though it is clear public policy favors patenting of genes and the diagnostic tests based on those genes, and even if Myriad's method claims are held to be patent eligible under § 101, affirming the district court's invalidation of the claims on different grounds could be proper for novelty's or nonobviousness' sake.[278]

1. Myriad's Diagnostic Methods May Be Considered Not Novel

As the *Myriad* opinion notes, all methods employed by Myriad in its diagnostic claims have been in the public domain for some time[279] and are known and performed by scientists every day.[280] Further, the processes used in Myriad's diagnostic tests (isolating and sequencing DNA) are the same processes performed when locating and sequencing a gene, the necessary steps for patenting a gene. Therefore, these steps have been well known since at least 1990, the start of the Human Genome Project.[281] Given that Myriad's first patent application was not until 1994,[282] this creates a large novelty obstacle to holding Myriad's method claims valid.[283] That these particular diagnostic procedures have never been performed before with

277. Rosetta Genomics, *supra* note 183, at 15. Of particular interest is the fact that several of the plaintiffs complaining that gene patents block genetic research have themselves published over 48 papers on the very genes Myriad has patented. *Id.*

278. 35 U.S.C. §§ 102–03 (2006). If Myriad's process claims are found invalid, a further argument could be made against the composition of matter claims: without any way to prosper from the genes, the genes would not be useful aside from their benefits to the public domain. As usefulness is a condition of patent eligibility, this may create a bar to the composition of matter claims. 35 U.S.C. § 101 (2006). This line of reasoning is beyond the scope of this comment, though could be addressed in further publications.

279. *Myriad*, 702 F. Supp. 2d at 200.

280. *Id.*

281. *Id.* at 193.

282. *Id.* at 212 n.26.

283. *See* 35 U.S.C. § 102 (establishing that any procedure that was in use by the public more than one year before the patent's application date is not novel).

this particular gene may influence the reviewing court, especially given the public policy interests and the deference to USPTO determinations.[284] Whatever the court's determination on the issue, an opinion validating or invalidating Myriad's method claims should address this issue.

2. Myriad's Diagnostic Methods and Compositions of Matter May Be Considered Obvious

Even if a court does not invalidate Myriad's diagnostic methods for novelty reasons, the obstacle of obviousness will remain for both the diagnostic methods and the compositions of matter. Arguments are strong for both a finding of obviousness and nonobviousness. Under § 103, an invention is obvious when a person of ordinary skill in the art would have known how to produce and patent the article under scrutiny as of the date of the invention.[285] The determination of whether an invention is obvious may involve consideration of the commercial success of the patented article, "[the] long felt but unsolved needs, failure of others, etc."[286] Because the processes used in Myriad's diagnostic tests are used by scientists every day,[287] it is reasonable that they would be obvious to someone "of ordinary skill in the [field]."[288]

However, it is also reasonable that if the diagnostic methods escape the novelty rejection because the methods had never been applied to this particular gene, the court may also overlook an obviousness rejection based on the same argument. This is especially true because the knowledge that makes it obvious to apply the method to this gene is the gene's sequence, which was not known by those of ordinary skill in the art until the patent application was published. Patent law indeed holds an obviousness exception when a biotechnology method, as here, is applied to a composition of matter patented at the same time, but the methods listed in the statute do not seem to encompass diagnostic testing.[289]

This leads to Myriad's composition of matter claims.

284. *Supra* notes 259–268 and accompanying text; *supra* notes 226–227 and accompanying text.

285. *See* Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966).

286. *Id.*

287. *Myriad*, 702 F. Supp. 2d at 200.

288. 35 U.S.C. § 103 (2006).

289. 35 U.S.C. § 103(b).

Because Myriad's claims resulted in an invention with great commercial success, [290] and because many others attempted but failed to develop the same invention,[291] there some merit to the argument that Myriad's invention was not obvious.[292] However, many of ordinary skill in Myriad's field realized the need for the invention[293] and there are only so many possible sequences the BRCA1 and BRCA2 genes could have expressed, therefore the composition of matter patents may be found obvious to try.[294] On the other hand, while there is a finite number of possible sequences for the BRCA1 and BRCA2 genes, one who is trying to discover a gene can assume that it is thousands of base pairs long,[295] and because each position could be held one of four nucleotides, the number of possible sequences for any one gene is enormous.[296] Therefore, a court could also find that, though the prior art gives guidance as to the form of the invention, the only way to discover the invention is to throw darts at a board composed of all possibilities, and therefore being obvious to try would not give rise to obviousness.[297]

The Federal Circuit considered this argument in *Kubin*, and found that determining a gene sequence was indeed obvious because it was obvious to try.[298] However, in that case, the applicant started off knowing the sequence of the one protein for which the gene encoded, from which they could work backwards to determine the sequence of the gene.[299] Being able to work backwards from an expressed gene product to the gene would be a far more predictable, and profoundly less similar to throwing darts at a board of composition of matter possibilities

290. *Myriad*, 702 F. Supp. 2d at 203 (stating that Myriad made over 200 million dollars in revenue from their diagnostic tests in 2008).

291. *Id.* at 201–02 (stating that multiple other groups were attempting to develop the claimed invention at issue, but that they did not succeed before Myriad).

292. *See* Graham v. John Deere Co., 383 U.S. 1, 17–18 (1966) (suggesting that the long-felt need for an intention and the failed attempts of others may be useful in the determination of obviousness).

293. *See Myriad*, 702 F. Supp. 2d at 201 (describing the funds and efforts that several research teams across the world put into being the first to discover the sequence of the BRCA1 gene).

294. *Supra* notes 110–111 and accompanying text.

295. *See Myriad*, 702 F. Supp. 2d at 194 (stating that a typical gene is thousands of nucleotides long).

296. *Supra* note 27 and accompanying text.

297. *In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009).

298. *Id.* at 1361.

299. *Id.* at 1360.

than would sequencing a gene from scratch.[300] Therefore, it appears that the obviousness of *Myriad's* composition of matter claim could be resolved in either direction.

V. CONCLUSION

It is unwise to blithely remove patent eligibility from fields in which incentives for innovation have a dramatically positive effect on the population as a whole. Patent law was established to incentivize inventions that are useful to the public, while still allowing fair access to innovations. Because the public benefit resulting from incentivizing gene patents far outweighs the potential for public loss, it is in the country's best interest to structure and interpret patent law to find genes and methods employing them patent eligible.

Unfortunately, patenting genes is a controversial issue right now, and the courts cannot decide patent eligibility on the basis of public policy alone. Patent law does allow for an interpretation that would find genes and the methods employing them patent eligible, but those methods are likely to encounter novelty and obviousness rejections that they may be unable to overcome. Currently, patent law does not provide a clear solution.

This Comment suggests that the Court of Appeals for the Federal Circuit should reverse the district court's decision in *Myriad* on all counts. However, it is the stance of this Comment that patent law does not provide enough clarity for gene patents, especially where methods are concerned. Therefore, any decision made by this court and the Supreme Court on gene patent eligibility should include an appeal to Congress to amend the current patent laws to provide more and clearer protection to gene patents in terms of patent eligibility, novelty, and obviousness.

The Association for Molecular Pathology, and other research organizations should also appeal to Congress. Although Congress has shown unwillingness to outlaw gene patents, researchers may be placated by a compromise that would protect their interests. Mandatory licensing of all gene patents to not-for-profit researchers, for example, would allow

300. *See id.* (suggesting that those skilled in the art would consider working backwards from a known protein sequence to determine the gene coding for it to be "profoundly predictable.").

public research into genes, while protecting the genetic diagnosis industry. Whatever the result in the *Myriad* appeal, the continuing market for patents in genes and genetic diagnostic tests, and the medical advances that could follow will depend on a system of patent law more appropriate for the advancing field of genetics.