When Myriad Genetics Prohibited a Myriad of Options: Association for Molecular Pathology v. USPTO

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WHEN MYRIAD GENETICS PROHIBITED A MYRIAD OF OPTIONS:

ASSOCIATION FOR MOLECULAR PATHOLOGY V. USPTO

"The useful properties of a gene’s sequence . . . are not ones that scientists have invented, but instead, are natural, inherent properties of the genes themselves." 2

I. INTRODUCTION

One of the “most controversial areas on patentable subject matter” arises from the issuance of patents for research or innovation directly related to biological material, such as genetic

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1. This case note is a follow up to last spring’s article in the Journal for Art, Technology, and Intellectual Property entitled “Come, Let Us Return to Reason” by Lauren M. Dunne. Ms. Dunne’s case note described and analyzed the Association of Molecular Pathology’s case against the USPTO while the case was still in its pleading phase. The note focused on the complaint and the preliminary motions and arguments made by each side. The case has since been decided in the Southern District of New York and this note now analyzes the court’s opinion.

While Ms. Dunne advocated the practice of granting patents on isolated DNA and argued for the side of the USPTO, this note instead argues for Plaintiffs, named in the case as the Association of Molecular Pathology. Ms. Dunne argued that gene patents have not inhibited research and that the arguments in support of the complaint against the USPTO and Myriad need to focus specifically more on practical matters and less on philosophical grounds. In opposition, this note uses the statutory language and the judicially created products of nature exception to patentable subject matter to support Plaintiffs’ philosophical arguments. See Lauren M. Dunne, "Come, Let Us Return to Reason": Association of Molecular Pathology v. USPTO, 20 DEPAUL J. ART TECH. & INTELL. PROP. L. 473 (2010).

material or living organisms. This controversy stems from conflicting viewpoints over the United States Patent and Trademark Office’s (USPTO) policy and practice of granting patents on human hormones, cellular proteins, and genetically engineered animals, to name a few. Since 1982, the USPTO has extended the practice and has issued patents directed to isolated DNA sequences. A particular ongoing controversy involves the pharmaceutical giant Myriad Genetics who in the 1990s obtained patents on the BRCA1 and BRCA2 gene sequences.

The BRCA1 and BRCA2 genes, collectively known as BRCA1/2, are often called the “breast cancer genes” because mutations in these genes correlate with an increased risk in breast cancer and ovarian cancer in women. Breast cancers arising from

5. U.S. Patent No. 4,652,525 (filed June 28, 1983) (Recombinant Bacterial Plasmids Containing the Coding Sequences of Insulin Genes).
9. Myriad Genetics is a healthcare company founded in May 1991 specializing in developing and marketing molecular diagnostic products to perform such tasks as assessing a person’s risk of developing a disease later in life. See Myriad Genetics – About, www.myriad.com/about (last visited Feb. 14, 2011). “Myriad is a for-profit corporation located in Salt Lake City, Utah [that does] business throughout the United States. Myriad is incorporated in Delaware. Myriad is a co-owner of patent 5,747,282, and formerly was a co-owner of several of the other patents challenged [by the Association for Molecular Pathology].” Complaint at 13, ¶28, Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 09-4515 (S.D.N.Y. filed May 12, 2009), available at http://docs.justia.com/cases/federal/district-courts/new-york/nysdce/1:2009cv04515/345544/1 [hereinafter Compl.]. At the time of the case, Myriad had an exclusive license on all of the patents challenged in the case. Id.
12. These patents are directed to isolated and purified human genes,
mutations in a person’s BRCA1 and BRCA2 genes account for between 5% and 10% of all breast cancers. The lifetime risk for ovarian cancer is about 55% for women with BRCA1 mutations and about 25% for women with BRCA2 mutations.

As the exclusive licensee of the BRCA1 and BRCA2 gene patents, Myriad Genetics’ right to commercialize the BRCA1/2 diagnostic screening test for genetic mutations ultimately gave Myriad control over all BRCA1/2 testing in the United States, for which it charged more than $3000 per test. Until the decision in Association for Molecular Pathology v. USPTO, Myriad precluded competitors from developing alternative BRCA1/2 screening tests in the United States. This exclusion prompted concerns in the genetic and breast cancer research community that Myriad’s patent rights could impede research and innovation, resulting in a complex debate over the continued practice of granting patents directed to isolated DNA and the appropriate measures to balance the reward for technological advancement with the prevention of societal harm.

mutations in those genes, and correlations between those mutations and an increased risk of breast or ovarian cancer. See U.S. Patent No. 5,747,282 (filed June 7, 1995); U.S. Patent No. 5,710,001 (filed June 7, 1995). The BRCA1 sequence is found on chromosome 17 while the BRCA2 sequence is found on chromosome 13. J A Duncan et al., BRCA1 and BRCA2 Proteins: Roles in Health and Disease, 51 J CLIN PATHOL: MOL PATHOL 237, 237–38 (1998). These genes code for proteins that are thought to be critical for DNA repair and transcription regulation. Id. Inactivation of the gene is caused through mutation, altering the protein and leading to abnormal cellular gene expression. Id.


14. Id.


16. Mildred K. Cho et al., Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services, 5 JOURNAL OF MOLECULAR DIAGNOSTICS, 3–8 (2003). Survey results indicate that 53% of laboratory directors in the United States actively decided to cease the development of new clinical tests because of a gene patent or license. Id. at 5. Sixty-seven percent of these laboratory directors believed that gene patents decreased their ability to conduct research.
The controversy surrounding the patentability of isolated DNA, such as the patents held by Myriad, is certainly not new. While patent attorneys have successfully found ways to continue obtaining patents for their clients regardless of the conflict, the complaint drafted by the American Civil Liberties Union (ACLU) against Myriad in May of 2009 contesting the validity of its patents "further polarized the already divisive issue." The ACLU sought to invalidate the USPTO practice of granting patents to isolated DNA, a practice that the USPTO adopted nearly thirty years ago.

As will be discussed in this Note, a court has now ruled for the first time that isolated DNA sequences are not patentable subject matter. While many parties had numerous reasons for supporting the invalidation of Myriad's BRCA1 and BRCA2 patents, the Southern District of New York in Association for Molecular Pathology v. USPTO avoided any comment on the societal and scientific harms of the patents and focused instead only on resolving the case on statutory grounds. This is problematic. The patenting of isolated DNA causes inexcusable and intolerable societal harm warranting its exclusion from patent protection on a deeply fundamental and equitable basis. While the above decision properly invalidated Myriad's BRCA 1/2 patents as improperly directed at non-patentable subject matter under 35 U.S.C. § 101, a rather technicality-based holding, the court practically ignored several of the equitable and policy based arguments set forth by Plaintiffs and their amici. This is not to say that it was improper for the court to apply § 101 and the "products of nature" exception to hold that isolated DNA was not patentable subject matter. Nevertheless, the court's exclusive focus on a

Id. at 7.
18. Dunne, supra note 1, at 475.
20. Id.
21. Section 101 provides: "Whoever invents or discovers any new or useful process, machines, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." 35 U.S.C. § 101 (2006).
technical resolution of the case ignores the myriad of policy arguments presented by Plaintiffs and their amici. The court subsequently failed to provide any guidance to the American patent system and the USPTO’s practices with regard to the appropriate weight to give policy and societal concerns to invalidate a patent that plainly creates more harm than good for society as a whole. Most troublingly, the court deferred any discussion or analysis of Plaintiffs’ argument that certain patents do not foster the constitutional purpose of science working for the betterment of society, leaving such an essential issue disappointingly unresolved and seemingly undervalued in the area of patent law. As a result, the court’s failure to address these issues only perpetuates the existing tension over the balance between the protection of inventors and innovation with the protection of the public from harmful patent issuances.

This article will argue that the court’s technical resolution of the case, on subject matter grounds only, could have fittingly integrated a discussion on the appropriate weight to give policy and societal concerns to invalidate a harmful patent. In particular, in the court’s application of the “products of nature” exception, the court could have reconciled Plaintiffs’ policy concerns within the context of the fundamental policy principles at the core of the “products of nature” exception, effectively giving weight to Plaintiffs’ arguments and still invalidating the BRCA1 and BRCA2 patents on § 101 grounds.

Section II of this note will first go through the legal basis for patenting a gene. This will be followed by an account of the patents that Myriad obtained on the BRCA1 and BRCA2 genes and the value of having identified these genes to the medical community’s effort to make early detections of cancer in women and men. Section III discusses the subject case of this note, Association for Molecular Pathology v. USPTO, explaining the grounds by which the court invalidated Myriad’s two patents and focusing on the court’s reasoning that strictly adhered to patent invalidation on § 101 grounds. Section IV analyzes the subject case, arguing that the court’s invalidation of the patents on § 101 grounds needlessly avoided discussion of Plaintiffs’ arguments based on policy grounds and presenting a method by which the court could have addressed the societal harms at issue in the
subject case.

II. BACKGROUND

A. Breast Cancer and the BRCA1 and BRCA2 Genes

Breast cancer is the most frequently diagnosed cancer worldwide and is the leading type of fatal cancer in British women and the second leading type of fatal cancer in American women.22 The average American woman whose genes lack an inherited breast cancer abnormality like a BRCA1/2 mutation has about a 12% risk of developing breast cancer over a 90-year life span.23 The average American woman with an inherited mutation in BRCA1 or BRCA2 has a 60% chance of developing breast cancer, making her about five times more likely to develop breast cancer than a woman without such a mutation.24 Breast cancers arising from mutations in a person’s BRCA1 and BRCA2 genes account for between 5% and 10% of all breast cancers, or between 20,000 and 40,000 cases annually.25 The remaining 90-95% of cases are classified as sporadic cancer cases, or cases not due to hereditary causes.26 Among women with a familial history of breast cancer, 80-90% of cases are the result of DNA mutations in the BRCA1 and BRCA2 genes.27 Women with BRCA1/2 abnormalities are also at an increased

22. Ass’n for Molecular Pathology, 2010 U.S. Dist. LEXIS 35418, at *49.
24. See National Cancer Institute, BRCA1 and BRCA2: Cancer Risk and Genetic Testing, http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA (last visited Feb. 14, 2011). The names BRCA1 and BRCA2 stand for BReast CANcer susceptibility gene 1 and BReast CANcer susceptibility gene 2, respectively. Id. BRCA1 and BRCA2 genes are found in everyone and their mutations are associated with hereditary, or genetically inherited, forms of breast and ovarian cancer. Id. BRCA1 and BRCA2 are believed to be tumor suppressor genes; when they function normally, or without mutation, they suppress the growth of cancerous cells. Id.
27. Id.
risk of developing ovarian cancer. The lifetime risk is about 55% for women with BRCA1 mutations and about 25% for women with BRCA2 mutations. By comparison, about 1.8% of women without an inherited BRCA1 or BRCA2 abnormality get ovarian cancer.

The risk for certain other cancers may also be higher in individuals with BRCA1 or BRCA2 mutations. For instance, men who inherit abnormal BRCA1 or BRCA2 genes have an increased risk of approximately 6% in developing male breast cancer. That is about 80 times greater than the lifetime risk for men without BRCA1 or BRCA2 mutations. Men with mutated BRCA1 or BRCA2 genes may also be three to seven times more likely than men without the mutation to develop prostate cancer.

BRCA1 and BRCA2 mutations occur at a frequency of about 1 in 300-500 in the general population. The risk of inheriting one of these mutations is much higher in some ethnic groups. For example, certain families in the Netherlands, Iceland, and Sweden have a higher frequency of BRCA 1/2 mutations.

The United States Preventive Services Task Force recommends that women with family histories suggestive of BRCA1 or BRCA2 mutations seek appropriate genetic counseling from trained health professionals. 

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29. Id.
30. Id.
31. Id.
32. Id.
33. Id.
34. Breastcancer.org, supra note 23.
35. Id.
36. Cook-Deegan, supra note 13, at S20.
37. Id.
38. The United States Preventive Services Task Force is the independent panel convened under Agency for Healthcare Research and Quality. The panel consists of private-sector experts in prevention and primary care medicine whose members assess scientific evidence to determine the effectiveness of a broad range of clinical preventive services, including screening, counseling, and preventive medications. See U.S. Preventive Services Task Force: About the USPSTF, http://www.uspreventiveservicestaskforce.org/intro.htm (last visited Feb. 14, 2010).
care providers. For those who test positive for a mutation, there are cost-effective approaches for cancer prevention including screening and surgery, all of which result in gains in both life expectancy and quality adjusted life years relative to watchful waiting. For high-risk patients who test negative, there may be reduced anxiety about the future risks of breast or ovarian cancer.

B. Myriad and its Exclusive Licenses

Myriad has established itself as a market leader in gene discovery and diagnostics by helping to discover and patent the first genes to be associated with susceptibility for hereditary breast and ovarian cancer, the BRCA1 and BRCA2 genes. Although National Institute of Health (NIH) investigators are listed as co-inventors on some of the BRCA1/2 patents, NIH assigned administration of these patents to the University of Utah. The University of Utah subsequently granted exclusive licenses to Myriad to all the patents involved in the lawsuit, licenses that Myriad still exclusively held leading up to the lawsuit. Having a USPTO-issued patent on a human gene sequence necessarily means that the patent holders own the exclusive rights to that genetic sequence, its usage, and its chemical composition.

40. Id. at S26.
41. Id.
43. The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services, is the nation’s medical research agency. NIH is the largest source of funding for medical research in the world, funding thousands of scientists in universities and research institutions in every state across America and around the globe. See NIH – About NIH, http://www.nih.gov/about/index.html (last visited Feb. 14, 2011).
44. Cook-Deegan, supra note 13, at S20.
45. Ass'n for Molecular Pathology, 2010 U.S. Dist. LEXIS 35418, at *17.
46. Cook-Deegan, supra note 13, at S20.
47. See 35 U.S.C. § 154(a)(1) (2006). ("Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right
Therefore, gene patent holders such as Myriad had a right to prevent anyone from studying, testing, or even examining a gene as this would amount to an infringing use of the genetic sequence. Myriad's rights effectively prevented anyone else from legally developing a separate and independent BRCA1/2 screening test in the United States.48

The presence of BRCA1/2 mutations is a definitive factor in the clinical care for preventing breast, ovarian, and prostate cancer, particularly for patients deciding whether to undergo any prophylactic surgeries or more frequent cancer screenings.49 Myriad Genetics had sole control of the relevant patents for BRCA1/2 and was the sole provider of BRCA1/2 genetic testing, offering a test called BRACAnalysis to screen for mutations in both genes.50 Myriad's Comprehensive BRACAnalysis Test51 was available to patients and clinicians at a cost of over $3000 per test. Prior to the litigation, 90% of the tests Myriad performed were covered by insurance for over 90% of the test costs.52

C. Statutory Subject Matter and the Theories Behind the Products of Nature Exception

The objective of patent protection, as granted in the Constitution under Article 1, Section 8 (the “IP Clause”), has long been to “promote the progress of Science and Useful Arts, by securing for
to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.”).

48. Id.

49. Cook-Deegan, supra note 13, at S24. Surgeries include prophylactic mastectomy, prophylactic salpingo-oophorectomy, or tubal ligation. Id. at S26.

50. “BRACAnalysis is a genetic test for hereditary breast and ovarian cancer, based on full DNA sequencing of the BRCA1 and BRCA2 genes to identify deleterious mutations.” Williams-Jones, supra note 42, at 133.

51. The Comprehensive BRACAnalysis Test sequences the entire gene, instead of particular regions of the gene, looking for mutations. See id.

52. Ass'n for Molecular Pathology v. USPTO, No. 09 Civ. 4515 (RWS), 2010 U.S. Dist. LEXIS 35418, at *60 (S.D.N.Y. April 2, 2010).
limited times to authors and inventors the exclusive right to their respective writings and discoveries." 53 The issuance of a patent promotes the progress of science by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts. 54 Additionally, society benefits because inventors disclose their inventions in order to be granted a patent, fostering scientific and technical openness instead of confidenciality and secrecy. 55

Inventions are patentable if they meet the requirements of 35 U.S.C. § 101 that provides, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." 56 In evaluating whether a claimed method 57 is patentable subject matter under § 101, a patent examiner for the USPTO can analyze the invention under the "machine-or-transformation test." 58 Under the machine-or-transformation test, a claimed process can be patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a

54. See Diamond v. Chakrabarty, 447 U.S. 303, 307 (1980) (noting that patent rights encourage ingenuity). Patents provide more than recognition for an inventor’s work; patents serve as a guarantee to scientists and inventors that their financial investments and scientific findings will be protected. Mark A. Chavez, Gene Patenting: Do the Ends Justify the Means?, 7 COMP. L. REV. & TECH J. 255, 255 (2003). Scientists and investors are rewarded this guarantee in exchange for the expectation that they will advance their innovative research. Id.
57. See Gottschalk v. Benson, 409 U.S. 63, 70 (1972) (“A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.”).
different state or thing. However, the "machine-or-transformation test" is not the only means to determine whether a process is patent eligible. The process must also not be an abstract idea.

Other limitations on the scope of patentability also exist. One limitation is that a patent must serve the public good. As such, an inventor will not be issued a patent for an invention that will harm the public, or for an invention that is of no use to the public. A second limitation prevents particular subject matters that are already available to the public from coming under patent protection for a specified inventor. Generally, this limitation operates by requiring that the subject matter of the patent be novel and nonobvious. This second category of limitations encompasses the judicially created "products of nature" exception to patentable subject matter. The determination of patentability creates a threshold inquiry that precedes the inquiries into novelty, nonobviousness, and even utility.

60. Bilski, 130 S. Ct. at 3227.
61. Id.; Benson, 409 U.S. at 64–67.
63. See id. (stating that absence of detriment does not warrant patent protection).
64. Mere absence of "detriment" is insufficient to warrant patent protection; there must be a credible utility put forward. Id. at 531–32. The proffered utility cannot be one of pure research. Id. In Brenner, the Court held that even if the steroid produced could be shown to have a tumor-inhibiting effect in mice, it would not be patentable unless that effect could be linked to a utility for human beings. Id.
65. See 35 U.S.C. §§ 102–103 (2006) (prohibiting patents for inventions that are, among other things, known, already in use, described in printed publications, appropriated from another person, or identical to another patent).
66. Id. § 102.
67. Id. § 103.
69. See Chakrabarty, 477 U.S. at 307 ("This case does not involve the other 'conditions and requirements' of the patent laws, such as novelty and nonobviousness." (quoting 35 U.S.C. §§ 102–103)).
The "products of nature" exception recognizes three categories of subject matter that fall outside the scope of § 101 as not patentable and includes laws of nature, physical phenomena, and abstract ideas. "Products of nature" do not constitute patentable subject matter unless the subject matter undergoes a change that results in the creation of a fundamentally new product. This change, or transformation, must somehow alter the natural properties of a material so that "a new and different article" emerges that has "a distinctive name, character, or use." One cannot obtain a patent, and the corresponding exclusive right to of its use, to a natural occurrence and its beneficial properties.

The justification for denying the patentability of a product of nature is a complex debate that involves public policy, economic interests, and even religious understandings of nature and man's limited role in its creations. Boiled down to common parlance, chemical elements are naturally occurring, and their properties...
are determined by nature alone. Thus, patent law prohibits any person from commercially controlling these naturally occurring bounties of nature. Additionally, the purification of a natural compound is insufficient to render a product of nature patentable unless the purified product possesses “markedly different characteristics” in order to satisfy the statutory requirements of § 101.77

D. Patent Law and Genomics

In 1980, the United States Supreme Court held in Diamond v. Chakrabarty that a living, genetically altered microorganism constituted patentable subject matter.78 Such a modified microorganism was not a product of nature and fell within the broadly defined concepts of manufacture and composition of matter.79 The conclusion that a living organism could constitute patentable subject matter opened the door for the potential issuance of patents on biological organisms and genes.80 In December 1980, less than a year after the Supreme Court decided Chakrabarty, the USPTO granted a patent on a recombinant DNA method.81 In 1982, the USPTO granted the University of

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76. See, id. at 642 ("If it is a natural thing then clearly, even if [the inventor] was the first to uncover it and bring it into view, he cannot have a patent for it because a patent cannot be awarded for a discovery or for a product of nature, or for a chemical element." (citing U.S. Indus. Chem. Co. v. Theroz Co., 25 F.2d 387, 391–92 (4th Cir. 1928))).

77. Ass'n for Molecular Pathology, 2010 U.S. Dist. LEXIS 35418, at *132; The American Wood-Paper Co. v. The Fiber Disintegrating Co., 90 U.S. 566 (1874) (holding that a patent claim for refined cellulose, consisting of purified pulp derived from wood and vegetable, was not patentable because it was “an extract obtained from the decomposition or disintegration of material substance”).


79. Id.


81. “The term recombinant DNA literally means the joining—or
California a patent on the gene for insulin. The allowance of the patents on recombinant DNA methods and insulin in the 1980s was a significant and controversial step in patent law and biological research.

The work done through the Human Genome Project from 1990 to 2003, a collaborative research project aimed at sequencing the entire code of human genetic material, resulted in the exponential growth rate of scientific interest and understanding of human cellular DNA. By 2000, there were more than 25,000 DNA-based patents granted worldwide. Researchers for the 2008 Congressional Research Service (CRS) Report estimated that in 2005, United States patents had claimed 20% of human genes. By the end of 2007, the CRS reported that more than 49,000 patents related to genes, including method of use, had been issued. The major funding source for biomedical research, including human genetics, is the National Institutes of Health (NIH).

recombining—of two pieces of DNA from different sources, such as from two different organisms.” BIOTECHNOLOGY INDUSTRY ORGANIZATION, GUIDE TO BIOTECHNOLOGY 2008 (2008), supra note 5, at 18. "Recombinant DNA - Artificial DNA made by splicing DNA strands from different organisms. It is used for many purposes, such as replicating DNA for research, producing important proteins, and devising gene therapies." Robert Cook-Deegan, From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns, 70 (Mary Crowley ed., Garrison, NY: The Hastings Center, 2008). The patent "laid the groundwork for using cells to produce useful proteins and turning them into valuable drugs." Id.

82. U.S. Patent No. 4,431,740 (filed June 8, 1982).


86. Williams-Jones, supra note 42, at 126.


88. Id.

89. David H. Ledbetter, Gene Patenting and licensing: the Role of Academic
The practice of granting patents directed to biological material, including genetic material and living organisms, has been one of the “two most controversial areas on patentable subject matter, the other being mathematical, computer and business related products and processes.” Though the Supreme Court has never directly addressed the question of whether isolated DNA constitutes patentable subject matter, in 1991, the Federal Circuit held that “purified and isolated” gene sequences are different from those occurring in nature. The court in Amgen, Inc. v. Chugai Pharmaceuticals Co., Ltd. found that the ingenuity involved in isolating the useful portions and removing the extraneous portions of a gene created a new composition of matter that was sufficiently different from its naturally occurring counterpart to warrant patent protection. United States patent law allowed the patenting of human genes when the full-length complementary DNA sequence was known, and in some cases where only a partial sequence was known but information on its biological function was unknown. Proposed legislation to rescind the patentability of human genes has been introduced in Congress but so far has not passed into law.

The United States Patent and Trademark Office is the administrative agency authorized to examine and grant patents. According to the 2001 Utility Guidelines published by the USPTO, DNA molecules were comparable to other chemical compounds and were eligible for patents when “isolated from their

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Researchers and Advocacy Groups, 10 GENET MED 314, 315 (2008).
90. Chisum, supra note 3, at [7].
91. Amgen, Inc. v. Chugai Pharmaceuticals Co., 927 F.2d 1200, 1204 (Fed. Cir. 1991), cert. denied, 502 U.S. 856 (validating a patent directed to a “purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin”).
92. Id.
93. Ledbetter, supra note 89, at 316.
natural state and purified or when synthesized in a laboratory from chemical starting materials. The USPTO distinguished isolated DNA from natural DNA, the former being patentable because significant changes are made. By purifying, isolating, or otherwise altering a naturally occurring product, an invention is patentable if the product is an altered form. Therefore, one could not patent a naturally occurring DNA sequence as it existed in the body, but one could patent a gene or protein that had been isolated from the body.

E. Disagreement with USPTO Policy

Much of the tension surrounding the USPTO’s policy of granting patents directed to isolated DNA arose out of debates over whether isolated DNA is still a “product of nature.” Many critics argue that if isolated DNA is a “product of nature,” then the USPTO should not grant patents directed at isolated DNA because a true product of nature cannot be patentable subject matter given that it “does not constitute a machine, composition of matter, or manufacture.”

Another point of contention for critics is that granting patents on isolated DNA creates a potential for a lack of price competition on
products controlled by few individuals.\textsuperscript{102} When a genetic testing company, such as Myriad Genetics, obtains exclusive control to a DNA sequence, the company consequently has the exclusive control over the use of the sequence necessary to develop the screening tests.\textsuperscript{103} This prevents non-patent holding researchers from identifying and providing more efficient genetic tests; indeed, with regard to the Myriad patents, this forced some international researchers to knowingly and intentionally ignore such patents in order to conduct independent testing.\textsuperscript{104} French researchers, for instance, used the patented genetic sequences and developed different genetic mutation screening strategies in their testing laboratories to keep costs down for their patients.\textsuperscript{105} The average cost per mutation detected using the Myriad approach in America was five times greater than the most cost-effective approach common to French laboratories.\textsuperscript{106} This suggests that regardless of whether isolated DNA sequences are patentable subject matter, for the sake of keeping health care costs at their lowest, exclusive licenses to patents may not be the best idea because the licensees may not care to develop the least expensive testing methods when they are the sole and exclusive provider of the genetic test.\textsuperscript{107}

In spite of these concerns, advocates for the USPTO’s policy of granting patents directed to isolated DNA argue that the policy is necessary for the maintenance of the quid pro quo nature of the patent system.\textsuperscript{108} Under the quid pro quo structure, inventors must publicize a sufficient description of the patented invention so that others may improve upon it in exchange for a limited period of

\begin{footnotesize}
\begin{enumerate}
\item\textsuperscript{102} See Cook-Deegan, supra note 13, at S29.
\item\textsuperscript{103} Gina Shaw, supra note 15, at 35.
\item\textsuperscript{104} Cook-Deegan, supra note 13, at S28.
\item\textsuperscript{105} Id.
\item\textsuperscript{106} Id.
\item\textsuperscript{107} See id.
\item\textsuperscript{108} Ass’n for Molecular Pathology, 2010 U.S. Dist. LEXIS 35418 at *80. The right of exclusion is the inventor’s “reward for inventions.” Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974) (citing Universal Oil Co. v. Globe Co., 322 U.S. 471, 484 (1944)).
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patent exclusivity. In exchange, this exclusivity then precludes competitors from profiting from the inventor’s creation and empowers the inventor to capitalize on his patent.

In Myriad’s case, the mere prospect of obtaining patents on the BRCA1/2 genes played an essential role in the initial BRCA1/2 researchers successfully securing capital investment for isolating and sequencing the genes because investors knew that patented sequences had a potential for significant profits. In the identification of the BRCA1 and BRCA2 sequences, the University of Utah researchers and Myriad needed and successfully secured private investments. In turn, investors placed heavy expectations on the fact that patent law would protect their investment. These concerns and tensions surrounding the USPTO’s gene-patenting policies were some of the major considerations underlying the following case.

III. SUBJECT OPINION

In Association for Molecular Pathology v. USPTO, the court invalidated Myriad’s BRCA1 and BRCA2 patents as not patentable subject matter under 35 U.S.C. § 101. Citing the “products of nature” exception, the court found that DNA in its isolated form alters neither the fundamental property of DNA as the physical embodiment of biological information nor the information it encodes. The court also invalidated the method claims for comparing DNA sequences because the claims were directed at abstract mental processes and therefore not patentable

110. Id.
111. Id. at *80–81.
112. Id. at *81.
113. Id. “Myriad asserts that absent the promise of a period of market exclusivity provided by patents and the infusion of venture and risk capital derived therefrom, companies such as Myriad that capitalize on innovation simply would not be created and their products would not be brought to market or the clinic.” Id. at *82.
114. Id. at *5.
115. Id. at *4–5.
subject matter under § 101.116

A. Parties

1. Plaintiffs

The Association for Molecular Pathology, the named Plaintiff, is a not-for-profit scientific society dedicated to the advancement and practice of clinical molecular laboratory medicine and translational research based on the applications of genomics and proteomics.117 Additional Plaintiffs were different science laboratory organizations,118 woman’s health advocacy centers,119 individual physicians and researchers interested in working with BRCA1 and BRCA2 who were precluded from doing so because of Myriad’s patents,120 and cancer patients or at risk patients in some measure precluded from obtaining the BRCA1/2 genetic sequencing test offered exclusively by Myriad.121

116. Id. at *5.

117. Id. at *6–7; see also Association for Molecular Pathology, About AMP, http://www.amp.org/about/mission_vision.cfm (last visited Oct. 9, 2010). “Genomics is the study of all the genes of a cell, or tissue, at the DNA (genotype), mRNA (transcriptome), or protein (proteome) levels.” UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, SCIENCE POLICY COUNCIL: INTERIM POLICY ON GENOMICS 2, http://epa.gov/osa/spe/pdfs/genomics.pdf. Proteomics refers to the study of the proteome, a term first used in 1994 to describe “all the proteins in a cell, tissue, or organism.” Clinical Proteomic Technologies for Cancer, http://proteomics.cancer.gov/about/FAQs.asp#1 (last visited Oct. 9, 2010).

118. Ass’n for Molecular Pathology, 2010 U.S. Dist. LEXIS 35418, at *7–9. Plaintiffs include the American College of Medical Genetics, the American Society for Clinical Pathology, and the College of American Pathologists. Id.

119. Id. at *13–14. Plaintiffs additionally include Breast Cancer Action, a national organization that provides representation to those individuals affected by breast cancer, and Boston Women’s Health Book Collective. Id.

120. Id. at *9–13. Plaintiffs included Haig Kazazian, M.D., Anupa Ganguly, Wendy Chung, M.D., Harry Ostrer, M.D., David Ledbetter, Ph.D., Stephen T. Warren, Ph.D, Ellen Matloff, M.S., and Elsa W. Reich, M.S. Id.

121. Id. at *14–16. Plaintiffs include breast cancer patient Lisbeth Ceriani, cancer patient Runi Limary, breast cancer patients Genae Girard and Patrice Fortune, ovarian cancer patient Vicky Thomason, and at-risk breast cancer
Amici for the Plaintiffs included not-for-profit organizations representing physicians and medical students throughout the United States, not-for-profit organizations dedicated to advancing the treatment of a variety of genetic diseases, not-for-profit organizations seeking to improve the health of women, and not-for-profit organizations dedicated to assisting the public and policy makers in understanding how technology affects society.  

2. Defendants

Defendant members were neither as numerous nor as diverse as Plaintiffs. Defendant USPTO was named because it was the government organization that issued the patents to Myriad Genetics containing the claims-in-suit. Myriad was the former co-owner of several of the patents-in-suit and the exclusive licensee of all the patents-in-suit, solely providing the full sequencing of BRCA1 and BRCA2 genes in the United States on a commercial basis. Defendants additionally included the patient Kathleen Raker. Id. Ceriani was insured through MassHealth, a Medicaid insurance program for low-income people that Myriad does not accept, and was unable to afford the out-of-pocket costs for Myriad’s genetic test. Id. at *14. Limary received an inconclusive test result through Myriad and cannot pursue alternative testing options. Id. at *15. After testing positive, Girard could not obtain a second opinion because only Myriad could provide the full BRCA1/2 sequencing in America. Id. Fortune was unable to pay the full out-of-pocket cost for the BRCA1/2 genetic testing and Myriad did not accept her insurance. Id. Thomason and Raker were unable to afford the extra cost for the BRCA1/2 genetic testing. Id. at *16.


123. Id. at *16–17.

University of Utah Research Foundation. Amici for Defendants included health advocacy and diagnostic companies, patent legal professionals, and law professors.

B. Myriad’s Notices on the Infringement and the Patents’ Enforcement

Myriad actively enforced its patent claims against researchers and physicians, in several instances sending cease and desist letters to known scientists and Plaintiff party members to terminate all their infringing BRCA1/2 research or offering limited collaborative licenses. As a means to enforce its patent claims, Myriad offered Plaintiff Dr. Haig Kazazian, a physician and human genetics researcher, a limited collaborative license covering the screening for only a fraction of the known mutations for which tests exist. Dr. Kazazian’s laboratories performed BRCA1/2 analysis for research members of the Cancer Genetics Network Project (CGNP), sponsored by the National Cancer Institute. Dr. Kazazian did not accept the offer for limited screening, and Myriad eventually sent cease and desist letters to Dr. Kazazian and the University of Pennsylvania, notifying each that their actions in

125. Id. The University of Utah Research Foundation is an owner or part owner of each of the patents-in-suit. Id.
127. Id. at *21, 25. Amici include the Boston Patent Law Association and Kevin E. Noonan, Ph.D., J.D.
128. Id. at *24. Amici include Kenneth Chahine, Ph.D.
129. Id. at *61–64.
130. Ass’n for Molecular Pathology, 2010 U.S. Dist. LEXIS 35418, at *61–62. Dr. Kazazian is the Seymour Gray Professor of Molecular Medicine in Genetics in the Department of Genetics at the University of Pennsylvania School of Medicine. Id. at *9. He is also the previous chair of the Department. Id.
131. Id. at *61. The Cancer Genetics Network is a research resource for investigators conducting research on the genetic basis of human cancer susceptibility, with over 435,000 individual family members currently enrolled. See National Cancer Institute, Epidemiology and Genetics Research, http://epi.grants.cancer.gov/CGN/ (last visited Jan. 29, 2011).
the absence of a license constituted infringement.\textsuperscript{132} As a result, Dr. Kazazian and his laboratories terminated all BRCA1/2 screening both for research with other scientists and as part of its clinical practice.\textsuperscript{133}

Plaintiff Dr. Harry Ostrer, also a physician and researcher on the genetic basis of development and disease, similarly declined to enter into a limited license agreement in May 1998 with Myriad, noting that it “was too narrow to allow him to perform any meaningful BRCA1/2 testing.”\textsuperscript{134}

Myriad likewise notified Dr. Barbara Weber, a principal investigator on the CGNP sponsored by the National Cancer Institute, in September 1998 that its patents impacted her research contributions to the CGNP, consequently terminating the BRCA1/2 analysis by Dr. Kazazian on Dr. Weber’s research samples.\textsuperscript{135} In September 1999, Myriad also requested that another CGNP member, Georgetown University, cease sending genetic samples to Dr. Kazazian for BRCA1/2 analysis.\textsuperscript{136}

In December 2000, Myriad sent a cease and desist letter to the Yale DNA Diagnostic Lab concerning its BRCA1/2 genetic testing, to which the lab obliged.\textsuperscript{137} When the laboratory director sought permission from Myriad to conduct screening specifically for genetic mutations in the BRCA1/2 genes for which Myriad was not currently screening, Myriad denied her request.\textsuperscript{138}

\textsuperscript{132} \textit{Ass'n for Molecular Pathology}, 2010 U.S. Dist. LEXIS 35418, at *61–62.
\textsuperscript{133} \textit{Id.} at *62–63.
\textsuperscript{134} \textit{Id.} at *63. “Dr. Ostrer is a Professor of Pediatrics, Pathology and Medicine and Director of the Human Genetics Program in the Department of Pediatrics at New York University School of Medicine.” \textit{Id.} at *10.
\textsuperscript{135} \textit{Id.} at *63–64.
\textsuperscript{136} \textit{Id.} at *64. Georgetown University was another cancer center participating in the CGNP. \textit{Id.}
\textsuperscript{137} \textit{Id.}
\textsuperscript{138} \textit{Ass’n for Molecular Pathology}, 2010 U.S. Dist. LEXIS 35418, at *64. These mutations, not screened by Myriad, included mutations caused by large rearrangements. \textit{Id.}
C. The Complaint

Plaintiffs filed a complaint in 2009 against the USPTO and Myriad, alleging violations of 35 U.S.C. § 101 of the patent statute, Article 1, Section 8, (the "IP Clause") of the United States Constitution, and the First and Fourteenth Amendments to the United States Constitution. First, Plaintiffs alleged that "human genes are products of nature, laws of nature and/or natural phenomena, and abstract ideas or basic human knowledge or thought" and therefore the issued patents were in violation of both § 101 of the patent statute and the IP Clause. Second, Plaintiffs alleged that "[a]ll the challenged claims represent[ed] patents on abstract ideas or basic human knowledge and/or thought and as such are unconstitutional under the First and Fourteenth Amendments." 139

In prior proceedings on November 1, 2009, Plaintiffs withstood Defendants’ motion to dismiss the complaint. 140 Plaintiffs’ suit challenged the patent claims “directed to (1) isolated DNA containing all or portions of the BRCA1 and BRCA2 gene sequence and (2) methods of ‘comparing’ or ‘analyzing’ BRCA1 and BRCA2 gene sequences to identify the presence of mutations correlating with a predisposition to breast or ovarian cancer.” 141

Plaintiffs asserted that Myriad’s patents and its monopolizing control of all BRCA1/2 testing hindered the ability of patients to obtain breast cancer genetic testing and precluded any research to

139. Compl. supra note 9, at 29, ¶102, 103. Plaintiffs’ statutory claim brought under the Patent Act alleged that Myriad’s patents were invalid for failing to meet the statutory requirements for patentable subject matter for the proper granting of a patent. Id. at 19, ¶52.
140. Id. at 29, ¶102.
141. Id. at 29, ¶103. The First Amendment states that “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press . . . .” U.S. CONST. amend I. The Due Process Clause of the Fourteenth Amendment prohibits state and local governments from depriving “any person of life, liberty, or property without due process of the law.” U.S. CONST. amend XIV.
143. Id. at *3.
develop improved BRCA1/2 genetic testing. Plaintiffs further asserted that other labs existed with the ability to offer not only more comprehensive testing than Myriad but also newer testing methods for improved testing quality, accuracy, and efficiency. Plaintiffs' repeated concern was that the need for the BRCA1/2 screening test was great, yet the ability for a patient to get a second confirmatory test done through another lab, the "second-opinion" patients naturally seek for numerous diagnoses, was nonexistent as a result of the patents-in-suit.

Plaintiffs' action against Myriad targeted fifteen claims contained in seven patents issued to Myriad by the USPTO. The claims-in-suit were either composition claims or method claims. The composition claims reached isolated BRCA1/2 DNA obtained from any human being. The method claims were directed to the process of determining whether an individual has inherited an altered BRCA1 or BRCA2 gene by comparing the individual's BRCA1 and BRCA2 gene sequences with the wild type, or un-mutated, BRCA1 and BRCA2 gene sequences.

Plaintiffs cited studies examining the lag time between the issuance of a patent claiming a gene sequence and the subsequent publication of papers on that gene sequence as a negative impact on knowledge of that sequence, noting that in the case of BRCA1 and BRCA2, Myriad's patents negatively impacted public awareness of the genes' identification and role in breast and...

144. Id. at *65.
145. Id. at *66.
146. Id. at *69–70.
147. These claims and patents include: claims 1, 2, 5, 6, 7, and 20 of U.S. patent 5,747,282; claims 1, 6, and 7 of U.S. patent 5,837,492; claim 1 of U.S. patent 5,693,473; claim 1 of U.S. patent 5,709,999; claim 1 of U.S. patent 5,710,001; claim 1 of U.S. patent 5,753,441; and claims 1 and 2 of U.S. patent 6,033,857. Id. at *83.
148. Ass'n for Molecular Pathology, 2010 U.S. Dist. LEXIS 35418, at *84.
149. The composition claims include: claims 1, 2, 5, 6, and 7 of U.S. patent 5,747,282; claim 1 of U.S. patent 5,693,473; claims 1, 6, and 7 of U.S. patent 5,837,492. Id. at *86–87.
150. The method claims include: claim 1 of U.S. patent 5,709,999; claim 1 of U.S. patent 5,710,001; claim 1 of U.S. patent 5,753,441; claim 20 of U.S. patent 5,747,282; and claims 1 and 2 of U.S. patent 6,033,857. Id. at *87–89.
ovarian cancers by 5-10%.\textsuperscript{151}

Myriad's cease and desist letters successfully precluded labs from performing BRCA1/2 genetic testing and researching alternative tests for screening BRCA1/2 mutations.\textsuperscript{152} The gene patents may even have impeded the development of genetic testing for other diseases; the scope of BRCA1/2 mutations was not yet confirmed as limited only to breast and ovarian cancer in women and breast and prostate cancer for men.\textsuperscript{153} Proponents for the invalidation of these patents argued that as long as these patents on gene sequences remained, no one would be able to study these genes for other disease predisposition.\textsuperscript{154}

While Myriad and its collaborators expended considerable effort and ingenuity to isolate the BRCA1/2 genes, they utilized widely understood approaches of fairly uniform isolation processes throughout the science and genetic research community.\textsuperscript{155} Plaintiffs alleged that "a number of researchers, clinicians and molecular pathologists have the personnel, equipment, and expertise to sequence and analyze genes, including the BRCA1 and BRCA2 genes, at a lower cost than Myriad's testing."\textsuperscript{156}

\textit{D. The Court's Holding and Analysis}

1. Defining "Work of Nature" and "Isolated DNA"

After a lengthy and technical description of the DNA sequencing process, the court held that the sequencing process Myriad or any other geneticists employed did not alter the information content of the original, native DNA sequence.\textsuperscript{157} The

\textsuperscript{151} Id. at *73. These are the conclusions of Dr. Fiona Murray, a researcher who studied the impact of gene patenting on scientific research and commercialization.

\textsuperscript{152} Id. at *75.


\textsuperscript{154} Ass'n for Molecular Pathology, 2010 U.S. Dist. LEXIS 35418, at *78.

\textsuperscript{155} Id. at *55.

\textsuperscript{156} Id. at *60.

\textsuperscript{157} Id. at *25–48.
court analogized the process of sequencing to examining material through a microscope, noting that both make visible something that exists in nature but is too small to be seen otherwise. Genetic mutations associated with a particular condition, like a BRCA1 or BRCA2 mutation and its association to breast and ovarian cancer, are caused by nature. The court then stated that nature dictated the significance of any person’s genetic sequence, whether wild type or mutated, and its relationship to any disease. Thus, isolated DNA is just a magnification of a person’s genetic sequence.

The court, in resolving the meaning of “isolated DNA,” accepted Myriad’s definition from the patent specifications that isolated DNA as used in the patent referred to “a segment of DNA nucleotide existing separate from other cellular components normally associated with native DNA, including proteins and other DNA sequences comprising the remainder of the genome, and includes both DNA originating from a cell as well as DNA synthesized through chemical or heterologous biological means.”

2. Composition Claims and Method Claims: Not Patentable Subject Matter

In considering whether the patents-in-suit complied with § 101, the court analyzed (1) whether the claimed invention possessed utility; and (2) whether the claimed invention constituted statutory subject matter or whether the claimed invention instead fell within the judicially created “products of nature” exception to

158. *Id.* at *45.
159. *Id.* at *45–46.
161. *Id.*
162. *Id.* at *99.
163. Section 101 provides “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.” 35 U.S.C. § 101 (2006).
Because there was no dispute that the composition and method claims possessed utility, the court’s opinion focused strictly on whether the claimed compositions and methods constituted patentable subject matter, or, in the alternative, if they fell within the judicially created “products of nature” exception, inclusive of laws of nature, physical phenomena, and abstract ideas.\(^\text{165}\)

The court determined that the composition claims directed to isolated DNA that contain naturally occurring sequences fell within the “products of nature” exception to 35 U.S.C. § 101,\(^\text{166}\) reasoning that isolated DNA does not meet the § 101 requirement of having a “new or distinctive form, quality, or property” from a product of nature.\(^\text{167}\)

The court rejected Myriad’s argument that isolated DNA molecules should be treated no differently than other chemical compounds for patent eligibility.\(^\text{168}\) The court concluded that because DNA is unique, as evidenced by the double nature of genes as chemical molecules and physical carriers of information,\(^\text{169}\) it cannot be confined to its chemical properties and treated like other objects.\(^\text{170}\) The differences cited between isolated DNA claimed in the patents and native DNA found within human cells were insufficient to “establish the subject matter patentability of isolated BRCA1/BRCA2 DNA.”\(^\text{171}\)

The court’s holding was “driven by the overriding importance of DNA’s nucleotide sequence to both its natural biological function

\(^{164}\) Ass’n for Molecular Pathology, 2010 U.S. Dist. LEXIS 35418, at *109 (citing Diamond v. Chakrabarty, 477 U.S. 303, 309 (1980)).

\(^{165}\) Id. at *109. The judicially created products of nature exception to patentable subject matter include “laws of nature, natural phenomena, and abstract ideas.” Chakrabarty, 447 U.S. at 309.

\(^{166}\) Ass’n for Molecular Pathology, 2010 U.S. Dist. LEXIS 35418, at *110.

\(^{167}\) Id. at *114–15 (quoting Am. Fruit Growers v. Brogdex Co., 283 U.S. 1, 11 (1931)).

\(^{168}\) Id. at *132–33.

\(^{169}\) Id. at *133–34. As explained by Myriad’s expert Dr. Joseph Straus, genes are multifunctional because they are chemical substances as well as physical carriers of information whose biological function as a chemical is determined by this information. Id.

\(^{170}\) Id. at *135–36.

\(^{171}\) Id. at *132.
as well as the utility associated with DNA in its isolated form. Because of DNA’s unique qualities as a “physical embodiment of information,” neither the structural nor the functional differences argued by Myriad between native BRCA1/2 DNA and the claimed isolated BRCA1/2 DNA rendered the claimed isolated DNA “markedly different.” The court relied on the preservation of this defining characteristic of DNA in both its native and isolated forms in finding that the challenged composition claims were directed to unpatentable products of nature. DNA must be isolated and absent of proteins and other nucleotide sequences through purification for it to be useful for Myriad’s claimed methods. However, this “purification of native DNA does not alter its inherent characteristics, the nucleotide sequence, that is defined by nature and central to both its biological function within the cell and its utility as a research tool in the lab.” The utility of isolated DNA for the various purposes cited by Myriad did not prove the differences between native and isolated DNA necessary to establish the subject matter patentability of what is otherwise a product of nature. While the court noted the complexity of Myriad’s discovery of the specific segments of chromosomes 17 and 13 that correlated with breast and ovarian cancer, it qualified the discovery as the “handiwork of nature” and “the natural effect of certain mutations in a particular segment of the human genome.” The court concluded its discussion on the composition claims by saying that “[b]ecause the claimed isolated DNA [was] not markedly different from native DNA as it exists in nature, it constituted unpatentable subject matter under 35 U.S.C. § 101.”

Next, the court next applied the “machine-or-transformation test” to determine whether the process or method claims were

173. Id. at *135–36.
174. Id. at *136.
175. Id.
176. Id.
177. Id. at *144–45.
179. Id. at *147.
tailored narrowly enough to encompass only a particular application of a fundamental principle rather than pre-empt the principle itself. Under the machine-or-transformation test, a claimed process is patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. Under each standard, the court held that the method claims were invalid.

The court rejected Myriad’s argument that the act of “analyzing” or “comparing” BRCA1/2 gene sequences may fulfill the requirements of the machine-or-transformation test as transformative steps. The language in these method claims, compared to the plain and ordinary meanings of the terms “analyzing” and “comparing,” established only that the method claims were directed to the abstract mental process of “analyzing” or “comparing.” While the purpose of the method claim was perhaps to “detect a germline alteration in a BRCA1 gene,” the method actually claimed was “analyzing a sequence of a BRCA1 gene.”

The court also held that the essence of the method claim for “comparing” the growth rates of cells in the presence or absence of a possible cancer therapeutic was merely the act of comparing cell
growth rates to determine that the possible therapeutic was possibly a cancer therapeutic. 186 This was not a valid method claim because it sought to patent a basic scientific principle: "that a slower rate of cell growth in the presence of a compound indicates that the compound may be a cancer therapeutic." 187 Such data-gathering steps do are not transformative and render the claimed mental process of “comparing” unpatentable under § 101. 188

3. Dismissal of all Other Claims Against the USPTO

Because the claims-in-suit were invalidated pursuant to 35 U.S.C. § 101, 189 the court applied the doctrine of constitutional avoidance that precluded it from reaching the constitutional claims against the USPTO. 190 The court left the issue of the USPTO’s policy in granting patents on isolated DNA sequences open to the Federal Circuit or the Supreme Court. 191 Until then, the court reasserted the applicability of its ruling to bind the USPTO, forcing the conformation of its examination policies to void issuing patents directed to isolated DNA or the comparison or analysis of DNA sequence. 192

IV. Analysis

Although the Southern District of New York properly invalidated the BRCA1 and BRCA2 patents on statutory grounds, the court established a sweeping rule that categorically invalidates all patents on isolated DNA. It did so without providing any guidance regarding the appropriate weight to give policy and societal concerns to invalidate a patent. The court’s technical resolution of the case should have instead integrated a discussion on the appropriate weight to give social policy concerns when

186. Id. at *159.
187. Id. at *161.
188. Ass’n for Molecular Pathology, 2010 U.S. Dist. LEXIS 35418, at *161.
189. Id. at *164.
190. Id. at *163. The doctrine of constitutional avoidance states that courts should not reach an unnecessary constitutional question. Id. at *161.
191. Id. at *163.
192. Id.
invalidating a harmful patent. The failure to do so perpetuates the tension of how to balance the protection of inventors and innovation versus the protection of the public from oppressively monopolistic patents.

The opinion certainly adhered to proper precedent in evaluating the treatment of patentable subject matter and the exceptions for products existing in nature. However, the court’s reliance on the “products of nature” exception should have also addressed Plaintiffs’ social policy arguments by analogizing them to the policy arguments at the core of the “products of nature” exception. Moreover, the court should have addressed the underlying purpose of the “products of nature” exception: meeting the United States’ Constitutional prerogative “to promote the Progress of Science and useful Arts.”

The court gave an extensive description of the harms and individual parties’ concerns with patents on isolated DNA sequences that clearly indicated its awareness of the underlying concerns surrounding the issuance of patents in this context. However, the court failed to provide any kind of legal resolution on these highly important issues. As a result, uncertainty persists as to how future courts are to effectively address concerns as to issuances of patents that prove to foster more public harm than public good. In future cases, where it may be more difficult to invalidate a patent on technical terms, courts faced with a patent that clearly serves to stifle research and create prohibitive costs on society will have little guidance on how to invalidate such a patent on more policy based grounds. Given the particular facts before it, the Southern District of New York’s approach in deciding this matter is troubling. Here, the welfare of thousands of cancer patients was threatened by Myriad’s patent protection. It is hard to fathom a riper time to address these critical issues, particularly

194. U.S. CONST., art. 1, § 8, cl. 8.
195. The court recognized the consequences of its decision, stating that the “resolution of the issues presented . . . deeply concerns breast cancer patients, medical professionals, researchers, caregivers, advocacy groups, existing gene patent holders and their investors, and those seeking to advance public health.” Ass’n for Molecular Pathology, 2010 U.S. Dist LEXIS, at *3–4.
when the legislature has failed to assist in the endeavor.

The concerns over the harms of patents are neither new nor limited to isolated DNA patents and genetic screening, and the court’s technical resolution of the matter may not be feasible to invalidate other patents that prove harmful. This case serves as further evidence that many other issues exist with the legal rights permitted by the patent system that are in need of legislative or judicial interference and final resolution.

A. The Court Missed a Golden Opportunity to Incorporate the Reasoning Behind the “Products of Nature” Exception into Its Discussion

The Southern District of New York failed to resolve Plaintiffs’ societal concerns by discussing the purpose underlying the “products of nature” exception. The need to strike a balance in today’s high paced innovative research community “between protecting inventors and not granting monopolies over procedures that others would discover by independent, creative application of general principles” is a pressing matter for the federal courts. As the United States Supreme Court noted in 2010, in its most recent

196. See Chakrabarty, 447 U.S. at 318 (Brennan, J., dissenting) (arguing that Congress, in exercising its authority under Art. I, § 8, of the constitution, never intended that an inventor could secure a monopoly on a living organism, no matter how the inventor produced or used the organism).

197. The court acknowledged and agreed that there does “exist a sharp dispute concerning the impact of patents to isolated DNA on genetic research.” Ass’n for Molecular Pathology, 2010 U.S. Dist LEXIS, at *82. However, the court went on to acknowledge the impossibility of any “resolution of these disputes” based on the motions in the suit against Myriad. Id. at *83. To that end, the court warned that its decision would not bring consolation to many of the parties’ arguments, instead leaving the topic open for future debate and resolution.

198. See Chakrabarty, 447 U.S. at 317 (Burger, J., majority) (noting that the process of invalidating an entire type of invention from patent protection “involves the balancing of competing values and interests, which in our democratic system is the business of elected officials. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts”).

patent law case *Bilski v. Kappos*, the federal courts’ refusal to “take a position on where that balance ought to be struck” is an issue that the courts cannot continue to ignore forever.\(^{200}\) In the meantime, the fundamental justification to protect society from harmful patents in the creation of the “products of nature” exception offers an effective and valuable starting point as an extension of the constitutional prerogative that the IP Clause creates for finding the balance in patents that do more harm than good.

1. The “Products of Nature” Exception is Necessary in Patent Law

The “products of nature” exception, though judicially created, is not an arbitrary creation or an instance of judicial activism in the federal courts to impose limitations on the patent system. The exception instead exists out of necessity to preclude inventors from denying the public access to something that has always been held by the public, though only recently discovered or conceptualized, such as “a new mineral discovered in the earth or a new plant found in the wild.”\(^{201}\) However, the exception’s repeated use for over a century has focused mostly on the potential inventions that are not patentable subject matter because they fall within the exception.\(^{202}\) Courts’ applications of the exception in patent case opinions to determine patentability are unaccompanied by any discussion of the reasoning behind the exception or the merits supporting its continued use.\(^{203}\) Nevertheless, the exception’s use is a reaffirmation of its goal to make certain that discoveries of purely natural phenomena remain in the public domain. The social policy concerns weighing against Myriad’s patents presented the perfect opportunity for the court to finally discuss and give weight to the goals of societal protection that lie at the foundation of the “products of nature” exception.

\(^{200}\) *Id.*


\(^{203}\) See *id.*
The purpose of the “products of nature” exception is to place limitations on the scope of patentable subject matter for inventions that are contrary to the IP Clause. This, in turn, allows all members of society the opportunity to freely utilize the “laws of nature, natural phenomena, and abstract ideas in their own creative endeavors without fear of being sued for patent infringement.”

The most noted iteration of the reasoning for the “products of nature” exception, as expressed by Supreme Court Justice Stephen Breyer in his dissent over the dismissal of certiori in Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc., joined by Justices Stevens and Souter, parallels the reasoning behind the arguments made against the USPTO practice of granting patents to isolated DNA:

[T]he justification for the principle does not lie in any claim that “laws of nature” are obvious, or that their discovery is easy, or that they are not useful. To the contrary, research into such matters may be costly and time-consuming; monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race. Rather, the reason for the exclusion is that sometimes too much patent protection can impede rather than ‘promote the Progress of Science and useful Arts.’ . . . Sometimes their presence can discourage research by impeding the free exchange of information, for example by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the cost of using the patented information, sometimes prohibitively so.

According to Justice Breyer, there are inherent and obvious dangers that arise when a patent is granted on a purported invention that is actually a "product of nature." Therefore, the negative and intolerable consequences of the USPTO's actions of granting patents on isolated DNA in violation of the "products of nature" exception were foreseeable in light of Justice Breyer's previous identification. These foreseeable dangers of patents on "products of nature" are exemplified in the latter part of the quoted material from Justice Breyer and reaffirm the understanding that the exception is one born from necessity because otherwise, these patents would effectively work against the constitutional reasoning behind the creation of the American patent system. In this regard, Plaintiffs' policy arguments warranted a closer inspection by the court. The case against the validity of Myriad's BRCA1/2 patents was a golden opportunity for the Southern District of New York to bring some resolution to Plaintiffs' concerns and guide the USPTO's future practices.

2. Foreseeable Dangers of Patents on Isolated DNA Sequences

The exclusion of "products of nature" from patentable subject matter is a workable reality that has defined the American patent system that recognizes that certain "manifestations of . . . nature, [are] free to all men and reserved exclusively to none." This premise is not arbitrary, as legitimate concerns exist to necessitate such a rule that would protect natural phenomena from removal from the public domain while maintaining a patent system that encourages and enables further research.

Continued validity of certain patents directed at isolated DNA, like the BRCA1 and BRCA2 patents, served to impede the "free exchange of information" because the patent enforcement "force[d] researchers to avoid the use of potentially patentable ideas." Plaintiffs presented substantial evidence that in the case of Myriad's patents, enforcement of the patent rights caused great harm by impeding the progress of necessary scientific research, the

207. Lab. Corp., 548 U.S. at 126-27 (Breyer, J., dissenting over the dismissal of certiori).
availability of patient care, and the development of more efficient
tests.\footnote{208}{Myriad’s patent enforcement did limit the access to the genetic test as
evidenced by Plaintiff scientists and physicians that ceased offering BRCA1 and
BRCA2 analysis in research studies for fear of patent infringement liability.\textit{Ass’n for Molecular Pathology,} 2010 U.S. Dist. LEXIS 35418, at *60–64.
Researchers have published a number of case studies and surveys on clinical
genetic testing indicating that clinical genetics testing laboratories have removed
certain tests from their available services or have chosen not to set up particular
genetic tests because of gene patent issues. Ledbetter, \textit{supra} note 89, at 314.\textit{See Mildred K. Cho et al., Effects of Patents and Licenses on the Provision of
Clinical Genetic Testing Services,} J. MOLECULAR DIAGNOSTICS 3 (2003).} For example, Myriad’s patent enforcement forcibly
precluded researchers from developing alternative screening for
the BRCA1 and BRCA2 mutations for fear of litigation.\footnote{209}{Myriad sent cease and desist letters to Dr. Kazazian, Dr. Oster, Dr.
Alternative screening could potentially be less expensive and also
more accurate than Myriad’s BRACAnalysis test. In British
Columbia, Canada, cancer agencies started providing in-house
BRCA1/2 mutation testing in 1995. In 2001, when the B.C.
Ministry of Health Services’ efforts were futile in enforcing
Myriad’s patents to stop the researchers from using the BRCA1
and BRCA2 sequences to develop their own screening tests, the
testing for BRCA1/2 mutations was performed at a third of
Myriad’s costs.\footnote{210}{Williams- Jones, \textit{supra} note 42, at 142. The Hereditary Cancer Program
at the B.C. Cancer Agency performed genetic testing at approximately C$ 1200
while the Myriad test cost C$ 3850. \textit{Id.}} Because the sequences are a product of nature, a
patent on them effectively removed the sequences from the public
domain and researchers’ use though the sequences technically had
always existed in the public domain long before Myriad filed its
patents with the USPTO.

Justice Breyer credits the “products of nature” exception as
integral in preventing researchers from forcibly having “to avoid
the use of potentially patentable ideas.” This fundamental feature
is the same one that made sure that Newton could not patent the
law of gravity and “Einstein could not patent his celebrated
E=mc\(^2\).”\footnote{211}{\textit{Diamond v. Chakrabarty,} 447 U.S. 303, 309 (1980).} The importance and necessity of having a patent
system where limits exist is essential to the proliferation of continued innovation. The impediments the BRCA1/2 patents caused on researchers, such as the inability to research certain topics when the natural sequences were taken out of the public domain, were therefore foreseeable by the justifications for the "products of nature" exception.

Further, Myriad's patents led to another negative consequence when Myriad tried to establish "complex licensing agreements" for use of the BRCA1/2 patents to the detriment of other researchers.\(^{212}\) Because the BRCA1/2 patents are directed to "products of nature," complex licensing agreements impeded the "free exchange of information"\(^{213}\) when Myriad offered only limited collaborative licensing agreements that ran the risk of underutilizing researchers' abilities and retarding the advancement of knowledge of BRCA1/2.\(^{214}\) For example, the full spectrum of cancers caused by or associated with BRCA1/2 gene mutations is unknown but suspected to stretch beyond the already identified breast, ovarian, prostate, and pancreatic cancer risks.\(^{215}\) Therefore, while Myriad enforced its patents against potentially infringing researchers, the full spectrum of the cancer risks associated with BRCA1/2 mutations remained unknown because Myriad forced the end of all research into such matters.\(^{216}\)

Finally, the patents impeded the free exchange of information where their enforcement served to raise the cost of using the patented information by disabling and in some instances prohibiting the use altogether.\(^{217}\) As the patent holder, Myriad rightfully precluded other companies from developing their own BRCA1/2 mutation-screening tests. Throughout the term of the

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213. Id.
214. Myriad also tried to establish collaborative licenses with research institutes but failed because the license terms were too limited as to the researchers' permitted use of the patents. Ass'n for Molecular Pathology, 2010 U.S. Dist LEXIS 35418, at *61–65.
216. Id.
patents, Myriad never licensed out its diagnostic tests to other laboratories; therefore, Myriad’s BRACAnalysis test was the only available option in the United States for a patient seeking to screen for mutations in his or her BRCA1 or BRCA2 sequences.\(^{218}\) As a consequence of Myriad being the sole diagnostic laboratory to analyze a person’s BRCA1/2 genetic sequence, it was impossible for a patient to obtain a second opinion independent of the Myriad test result.\(^{219}\) While in some medical settings a second opinion can be superfluous or a waste of resources, the invasive actions sometimes necessitated by a positive result for a BRCA1 or BRCA2 mutation warrant the availability of a second opinion.\(^{220}\) The Southern District of New York should have noted that these foreseeable dangers are avoidable in a patent system that adheres to the “products of nature” exception.

**B. Future Implications**

The Southern District of New York failed to align Plaintiffs’ testimony of the harms caused by Myriad’s enforcement of its patents with the justification for the “products of nature” exception. The court improperly neglected Justice Breyer’s dissent over the dismissal of *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.* that foresaw some of these exact harms. By not aligning the evidence of the social


\(^{219}\) Ass’n for Molecular Pathology, 2010 U.S. Dist. LEXIS 35418, at *15.

\(^{220}\) Cook-Deegan, *supra* note 13, at S26 (surgeries include prophylactic mastectomy, prophylactic salpingo-oophorectomy or tubal ligation). For those testing positive, a second opinion and confirmation would be desirable before embarking on cancer prevention steps that can include more frequent cancer screenings and even surgery. *Id.* Not being able to obtain a second test because an insurance provider will not pay for another $3000 Myriad screening when less expensive screening exams do exist has the potential to harm patients’ abilities to participate in informed decision-making, an important factor in deciding whether to undergo invasive prophylactic surgery to significantly decrease the chances of developing cancer from the BRCA1/2 gene mutation. *Id.*
harms caused by the patents with the justification for the "products of nature" exception, the court perpetuates the fallacy that statutory patent law is not equipped to consider social policy arguments. Making such a statement would have at least garnered some sense that the American patent law system, guiding the practices of the USPTO, was not intended to legally permit the grant of patents that so clearly caused so much harm to researchers and at-risk-patients.

Where the arms of government continually fail to properly address the needs of society, particularly where Constitutional undertones shade the debate, courts are essential in resolving complex policy-based issues. For that matter, the USPTO has certainly failed in its own attempts to clarify this impasse. In 2001, the USPTO issued Utility Guidelines that included responses to comments made against its policy of granting patents on DNA sequences.\textsuperscript{221} While the guidelines served as a comprehensive affirmation of the USPTO practices, they did not directly address or put at ease the arguments against the practice of granting patents on sequenced genes.\textsuperscript{222} In the 2001 Utility Guidelines, the USPTO

\textsuperscript{221} 2001 USPTO Guidelines, \textit{supra} note 96, at 1092. The guidelines are to be used by the USPTO personnel in their "review of patent applications for compliance with the 'utility' requirement of 35 U.S.C. § 101." \textit{Id.} at 1092.

\textsuperscript{222} \textit{See id.} "Several comments stated that DNA should be freely available for research. Some of these comments suggested that patents are not necessary to encourage additional discovery and sequencing of genes. Some comments suggested that patenting of DNA inhibits biomedical research by allowing a single person or company to control use of the claimed DNA. Another comment expressed concern that patenting ESTs will impede complete characterization of genes and delay or restrict exploration of genetic materials for the public good." \textit{Id.} at 1095, cmt. 12. As stated in the January 2007 Congressional RS Reports, patents certainly are needed to protect innovation because the costs associated with imitating a product are extremely low compared with the inventor's costs. Cong. Research Serv., \textit{supra} note 87, at CRS-2. However, the court did not discuss how or if patents on gene-related inventions work to promote innovation by protecting investments made in the innovation process. \textit{Ass'n for Molecular Pathology}, 2010 U.S. Dist. LEXIS 35418, at *20-21. The court further did not address the argument that patent exclusivity is a requirement in the development of personalized medicine and that a wholesale abolition on patents on isolated DNA sequences is undesirable as public policy. \textit{Id.} at *22, 24.
admitted to strictly administering the laws as enacted by Congress and interpreted by the federal courts to work within the scope of subject matter that is patentable. Just as the USPTO has failed to address the policy concerns brought up against the practice of granting patents on isolated DNA, so has the Southern District of New York in Association for Molecular Pathology v. USPTO.

Plaintiffs’ arguments that isolated DNA falls under the “products of nature” exception to patentable subject matter were the same rejected arguments that littered the 2001 Utility Guidelines. These arguments previously had little effect on altering the USPTO’s course of action as evidenced in the responses to the comments presented in the 2001 Utility Guidelines. This inconsistency rightfully leaves one to wonder exactly what value can such policy arguments hold in future cases. As noted in the decision, the USPTO granted these patents pursuant to a formal written policy that permitted the patenting of isolated and purified DNA encoding human genes. The written policy described the USPTO’s policy to only allow claims to DNA that had been isolated or purified. Similar to the Association for Molecular Pathology decision, this written formal policy of granting patents on DNA sequences like the patents on the BRCA1 and BRCA2 sequences held by Myriad never formally addressed the history or justifications for the “products of nature” exception to patentable subject matter. If, however, the “products of nature” exception were to be framed as a rule rooted in constitutional necessity for the protection and betterment of society, the task of incorporating policy arguments in patent case decisions and USPTO guidelines would become much more

223. 2001 USPTO Guidelines supra note 96, at 1095 response to cmt. 12 (“Congress creates the law and the Federal judiciary interprets the law. The USPTO must administer the laws as Congress has enacted them and as the Federal courts have interpreted them.”).

224. See id.

225. Ass’n for Molecular Pathology, 2010 U.S. Dist LEXIS 35418, at *83, n.25. The policy permits the issuance of patents on DNA sequences and the correlations created by nature between natural elements of the body and a predisposition to disease. Id.

226. 2001 USPTO Guidelines, supra note 96, cmt. 2 at 1093.

227. Id. at 1095, response to cmt. 12.
feasible.

C. Possible Actions Through Appeals and Licensing Changes

By leaving these policy issues unaddressed, the court makes it impossible to judge whether any weight ought to be given to policy arguments or whether such arguments should instead be flatly rejected and ignored in future cases. This opinion perpetuates the continuation of a long history of judicial precedent that has failed to strike a proper balance in what Justice Kennedy identified in *Bilski* between protecting inventors and preventing monopolies.228

If this case is appealed, it may be that the reviewing court will similarly find that the BRCA1 and BRCA2 genes are products of nature on the same grounds as the Southern District of New York, upholding the decision and again never discussing the policy arguments and alleviating the societal concerns raised by Plaintiffs. Even if on appeal a court finds that isolated DNA is instead not a product of nature, as Myriad argues, and reverses the invalidation on § 101 grounds for subject matter, addressing the societal harms can still work to give bite to the IP Clause. The gene patents can be declared unconstitutional, as Plaintiffs argue, under the IP Clause on the grounds that “the patent claims in this case can be held as a matter of law to impede rather than promote the progress of science.”229 As with the policy reasons behind the “products of nature” exception discussed above, an assessment under the IP Clause would be a long overdue opportunity for a

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228. *Bilski v. Kappos*, 130 S. Ct. 3218, 3228 (2010). "With ever more people trying to innovate and thus seeking patent protections for their inventions, the patent law faces a great challenge in striking the balance between protecting inventors and not granting monopolies over procedures that others would discover by independent, creative application of general principles. Nothing in this opinion should be read to take a position on where that balance ought to be struck.” *Id.*

court to strike a balance and determine just how much impediment to the progress of science is enough to invalidate a patent.

In the meantime, this ruling could even encourage Congress to step in and say that while patents on isolated DNA are valid, their use must be reformed. For instance, the National Institute of Health and the Association of University Technology Managers strongly encourage nonexclusive licensing strategies except in cases where this model will not lead to successful commercialization.230 In the cases of genetic testing, nonexclusive licensing strategies have the significant advantages of encouraging multiple laboratories to make the test readily available.231 This encourages test improvement and creates cost-competition, addressing two of the arguments made by those against patents on isolated DNA.232

Investigators at academic institutions could instead be forced to adopt a policy that allows multiple clinical laboratories to offer genetic testing on any new genes discovered and patented.233 The success of such a compromise, however, is uncertain as the American College of Medical Genetics has an official position against genetic patenting.234

The large reach of this decision is vulnerable to a significant number of challenges from patent holders, wanting a return on any time, money, and resources invested and intent on maintaining their patents as a means to further profit off their work. The 2008 CRS Report published that as of the end of fiscal year 2007, the USPTO had issued more than 49,000 patents related to genes, including method of use.235 The status of these patents on isolated DNA is at most uncertain after the invalidation of Myriad’s BRCA1 and BRCA2 patents. However, to hand down such a definitive ruling to invalidate all patents direct to isolated DNA, the court should have addressed the societal concerns in line with the policy justification for the products of nature exception to give

230. See Ledbetter, supra note 89, at 316, 318.
231. Id. at 317.
232. Id. at 315.
233. Id.
234. Id. at 314.
A discussion of how the social harms weighed in the decision against Myriad may never happen. In an amicus brief filed by the United States Department of Justice in support of neither party of this case, the support to invalidate the BRCA1 and BRCA2 patents was again limited to only a statutory discussion on patentable subject matter. This brief’s potential influence in the case’s appeal will likely maintain the opinion’s resolution through technical means and leave out any discussion of the social harms, ultimately perpetuating the notion that patent law is too inflexible to account for the prevention of such harms. The Southern District of New York’s opinion would in due course be just another application of the “products of nature” exception having missed the opportunity to incorporate the evidence of societal harm to invalidate a patent.

V. Conclusion

The Southern District of New York’s opinion in Association for Molecular Pathology v. USPTO thoroughly described the societal harms associated with the patents granted on the BRCA1 and BRCA2 genetic sequences. The court’s holding does prevent additional societal harm: researchers now have legal access to the BRCA1 and BRCA2 gene sequences as a means to develop more accurate, efficient, and affordable screening tests to ensure adequate access for high-risk cancer patients. The court’s ability to achieve this goal, however, did not justify the lack of discussion of how these societal concerns influenced the bright line rule to invalidate all patent claims directed at isolated DNA sequences.

The court’s decision to create a bright line rule, invalidating all isolated DNA patents on 35 U.S.C § 101 grounds, lends itself to appeal proceedings and leaves vulnerable significant and valid arguments made by Plaintiffs against patents on 2 sequences that ultimately did more harm than good. The absence of such

discussion by the court leaves one to wonder how valid these other arguments focusing on the harm caused by patents really are and how future courts will handle these other arguments. The judiciary is not powerless, having itself created the “products of nature” exception that has continued to hold up in patent law. As such, it should not find itself now powerless to apply the policies that necessitated the creation of the exception to invalidate patents. Until appeals or additional cases are heard, the legitimacy of Myriad’s patents is still debatable along with the future of all previously valid isolated DNA patents.

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