Gene Patents: The Controversy and the Law in the Wake of Myriad

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I. INTRODUCTION

The topic of gene patents is as controversial as it is misunderstood, and the law surrounding these patents was not made any clearer following the United States District Court for the Southern District of New York’s decision in the Myriad patent case.\(^2\) The concept that someone might patent, and therefore own, the rights to the genes in your body has created controversy since the earliest patents on genes were issued in the early 1980s. Thirty years later, the concept remains controversial, as the courts and legislatures struggle to resolve the central issues. Can someone really own the genes in your body? And what exactly does that mean? The answers to these common questions lie at the intersection of law, science, business, and politics.

To understand the state of the law, I will begin with a discussion of the science surrounding gene patents, including the ethical, business, and policy concerns. I will then examine the history of patent law as it relates to these patents, followed by a close examination of the Myriad court decision and Myriad’s appeal. I will conclude with a discussion of possible outcomes for the case and the future of gene patents.

II. GENE PATENTS: THE SCIENCE AND THE CONTROVERSY

While a thorough discussion of genetics is beyond the scope of this paper, a cursory review of the science is necessary to understand the law and the controversy. A gene is a basic unit of heredity information that occurs

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2. The Myriad gene patent case, as it is commonly known, and as it will be referred to throughout this article, can be found at Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010). The United States Patent and Trademark Office is joined by the owners of the patents in question, Myriad Genetics and the University of Utah Research Foundation, as co-defendants. Id. at 184. The plaintiff, Association for Molecular Pathology, is joined by nineteen co-plaintiffs. Id. at 186-89. The decision has been appealed to the United States Court of Appeals for the Federal Circuit, and is pending as of the writing of this article.
naturally in all living organisms.\(^3\) It is both a molecule, in that it is an actual composition of matter, as well as a set of instructions for future cells. A gene is made up of several segments of deoxyribonucleic acid (DNA), which are comprised of several chemical units called nucleotides. One gene can have thousands of nucleotides strung together. The order of these nucleotides, and the DNA within each, form all the genes within an organism, and those genes together make up that individual organism’s genome. The genome is what determines an individual’s physical characteristics, such as sex, hair color, or height.\(^4\)

Genes can also be extracted from the cells using a variety of methods. This extracted DNA, also known as isolated DNA, can be further altered or tested to make it more useful in research. This process of analysis, commonly referred to as gene sequencing, is analogous to examining a specimen under a microscope, in that you are able to view a naturally occurring molecule that you otherwise would not be able see with the naked eye.\(^5\) By analyzing or performing diagnostic tests on the structure of isolated DNA, it is possible to locate variations or mutations which are associated with an increased risk of certain diseases such as cancer.\(^6\)

There are between 20,000 and 25,000 genes in the human body; together these make up the human genome.\(^7\) Currently over twenty percent of these genes are protected, at least in part, by a patent in the United States.\(^8\) These patents cover both the gene as they occur naturally as well as the gene in its isolated or altered form. In addition to patents on the genes themselves there are also patents on the methods, processes, and tools that are used in the isolation and diagnosis of gene sequences.

The controversy surrounding the practice of patenting genes lies mainly in negative consequences, both real and perceived, that such patents have on research and development and on consumers, particularly those without health insurance. At its core, a patent is the right to have a monopoly on an

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3. See id. at 194 (describing structure and function of DNA). For an excellent primer on the basic science of genetics, one need look no further than Judge Sweet’s opinion. See id. at 192-200. For a more in-depth understanding, see James Watson, Molecular Biology of the Gene (6th ed. 2008), on which the court relies.

4. See Molecular Pathology, 702 F. Supp. 2d at 193.

5. See id. at 199.

6. See id.

7. Estimates have varied as our understanding of gene science has evolved. At one time it was believed that there were over 100,000 genes. For an interesting discussion by the National Human Genome Research Institute (NHGRI) on the development of gene science, see How Many Genes Are in the Human Genome?, U.S. DEP’T OF ENERGY, http://www.ornl.gov/sci/techresources/Human_Genome/faq/genenumber.shtml (last updated Sept. 19, 2008).

invention.9 One who makes use of another’s patent without permission infringes on that patent and may be liable for damages to the patent holder. This is a fairly uncontroversial proposition when the subject matter is an inventor’s independent creation of a new machine that manufactures a certain item in less time and at a lower cost. A patent protects the inventor’s ingenuity and allows the inventor to profit from his investment and his vision. However, when the patent is on something that occurs within the human body, and that something could have life-saving potential, the monopoly granted by the patent abuts the public’s interest in health, safety, and societal norms.

There are numerous persuasive arguments on both sides of the debate. Those who argue against gene patents have argued that these patents are “unnecessary to promote innovation in genetic research, and violate medical and scientific ethics,”10 and that these patents are on “natural phenomena and laws of nature,”11 which “constitute part of the common heritage of humanity.”12 There is also substantial concern about the “chilling effect” gene patents may have on research.13 A recent study of laboratory directors in the United States found that sixty-seven percent believed that gene patents decrease their ability to conduct research, and fifty-three percent decided not to develop a new clinical test due to an existing gene patent or license.14

Another concern is that gene patents limit access and increase the cost to the patient. For example, in the United States, Myriad, Inc., offers a screening test for the BRCA gene that costs over $3000 per test.15 However, this same test is offered free from patent protection in Canada at a cost of $1000 per test.16 In 2008, Myriad spent $32 million providing these tests, with resulting revenues of over $222 million and a gross profit of $190 million.17 A patient who receives a patented BRCA test is also limited in their ability to get a second opinion from another doctor. Because Myriad owns the patent for BRCA, they are the only company who can offer the test; the patient, or the patient’s


11. See id. (reviewing argument of amici March of Dimes Foundation).


13. See id. at 208.

14. See Molecular Pathology, 702 F. Supp. 2d at 208 (citing studies discussing effects of gene patents on development of new clinical trials).

15. See id. at 203. BRCA is a useful determinant for breast cancer and certain ovarian cancers. This gene, and Myriad’s patents on it, will be discussed fully in a later section. See infra Part IV.A.

16. See Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 203 (S.D.N.Y. 2010) (discussing funding for Myriad’s BRCA1/2 tests). In the lawsuit against Myriad, two of the co-plaintiffs’ claims were based on their inability to pay for the tests. Id. at 204.

17. See id. at 203.
physician, would only have the option to re-administer the Myriad test.\textsuperscript{18} For
this reason, the American Medical Association has spoken out against the practice of gene patents, stating “[t]he use of patents . . . or other means to limit the availability of medical procedures places significant limitation on the dissemination of medical knowledge, and is therefore unethical.”\textsuperscript{19}

There are compelling arguments for gene patents as well. Some favor allowing patents on genes on the legal ground that these patents “fall within the categories of patent-eligible subject matter because they differ in kind from naturally-occurring DNA.”\textsuperscript{20} Others have argued that these patents “promote innovation by protecting investments in the innovation process,”\textsuperscript{21} Arguments can also be raised that it is Congress, not the judicial system, who should decide what is patentable, and that existing judicial remedies are sufficient to redress grievances in light of Congress’s inaction on the subject.\textsuperscript{22} Myriad has argued that the patents significantly contribute to the field of biotechnology. To patent a gene, the patent holder must describe in detail the patented invention so that others may improve on it.\textsuperscript{23} In other words, the patent holder makes his science known to all in exchange for its patent. Myriad points out that since it patented BRCA, over 8600 research papers have been written about this gene, representing the work of over 18,000 scientists.\textsuperscript{24} These patents, Myriad claims, are “essential for obtaining capital investment in the development and commercialization of technological breakthroughs.”\textsuperscript{25} The capital investments involved are substantial. A recent survey of 150 biotechnology companies found that seventy-seven percent of those surveyed expected to spend between five and fifteen years and over $100 million developing a single commercial product.\textsuperscript{26} It is a persuasive argument, succinctly put, 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

\textsuperscript{18} See id. at 207.


\textsuperscript{20} Molecular Pathology, 702 F. Supp. 2d at 191 (internal quotation marks omitted) (noting view of Biotechnology Industry Organization).

\textsuperscript{21} See id. at 191 (discussing opinion of Boston Patent Law Association).


\textsuperscript{23} See id. at 210.

\textsuperscript{24} See id.

\textsuperscript{25} See id. at 211.

\textsuperscript{26} See Molecular Pathology, 702 F. Supp. 2d at 211. The survey, conducted by the Biotechnology Industry Organization in 2009, also found that sixty-six percent of these companies in-licensed projects at the preclinical phase, when substantial research and development expenditures would still be necessary and the company bore substantial risk that a product would never materialize. Id.
The controversy over gene patents is not limited to biotech companies and academia; the issue is also firmly in the public consciousness. In 2006, bestselling author Dr. Michael Crichton opened his novel *Next* with the phrase “Stop patenting genes”; he then penned an editorial in the *New York Times* warning readers that “[g]ene patents are now used to halt research, prevent medical testing and keep vital information from you and your doctor.”

Groups such as the American Medical Association and the American Civil Liberties Union (ACLU) have expended considerable funds pushing the issue in the courts, Congress, and in the public debate. In 2007, a patent reform bill was passed in the United States House of Representatives but failed to be considered in the Senate and as such never became law. It seems apparent to parties on both sides of the debate that a compromise must be made, one that protects and rewards investment while at the same time maximizing the opportunity for affordable lifesaving care and treatment for patients. Where to draw that line, however, will remain the subject of much debate for the foreseeable future.

III. THE LAW OF GENE PATENTS FROM CHAKRABARTY UP TO MYRIAD

The starting point for any discussion of the law of patentability is Article I, Section 8, Clause 8 of the United States Constitution, which provides that Congress shall have the power “[t]o 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.” Congress exercised this authority by passing 35 U.S.C. § 101, which provides that “[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 therefor, subject to the conditions and requirements of this title.” The scope of § 101 is to be construed broadly, as evidenced by the use of the word “any,” but this latitude is not without limits. The Supreme Court has recognized that “[t]he laws of nature, physical phenomena, and abstract ideas...
have been held not patentable,” 34 and that “manifestations of laws of nature, free to all men and reserved exclusively to none,” 35 remain in “the storehouse of knowledge of all men.” 36 This is not because these are not processes or compositions of matter—indeed they are—but rather this is because these are “not the kind of discoveries that the statute was enacted to protect.” 37

In the seminal biotech patent case Diamond v. Chakrabarty, 38 the Court held that a living organism that did not occur in nature could be patented. The patents at issue were for both the process used to modify a naturally occurring bacterium as well as the newly created bacterium itself. 39 The Court reasoned that “the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly, it is patentable subject matter under § 101.” 40 The distinction is not “between living and inanimate things, but between products of nature . . . and human-made inventions.” 41 Contrast that with Funk Bros. Seed Co. v. Kalo Inoculant Co., 42 where the Court considered a patent on a combination of naturally occurring bacteria that, when combined, created a more useful fertilizer. The Court held that the patents were not valid because the patent holder did not create that property in the bacteria; rather those “qualities are the work of nature.” 43

An invention must have a “new or distinctive form, quality, or property” from something occurring in nature. 44 How does this affect a naturally occurring compound that has been altered or purified from its natural state? Purification is the process of taking something that occurs naturally and either isolating a certain property of it, or removing certain properties from it to render it more useful. In American Wood-Paper Co. v. Fibre Disintegrating Co., 45 the Supreme Court held that purification of a natural compound, without more, is insufficient to render a product of nature patentable. 46 The Court noted that the extract at issue was “the same, no matter from what it has been taken. A process to obtain it from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be

34. Id. at 309.
36. Id.
39. See id. at 305. The bacterium at issue was able to feed on oil, and as such was particularly useful in cleaning up oil spills. See id.
40. Id. at 310.
41. Id. at 313.
42. 333 U.S. 127 (1948).
43. Id. at 130.
44. See Am. Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11 (1931).
45. 90 U.S. 566 (1874).
46. See id. at 593-94.
called a new manufacture. 47 Even if the patentee was the first to purify a substance and bring it into view, the product is still not patentable because it is simply the discovery of a product of nature. 48 This is so because “if it possesses that quality now it is certain that it possessed it always.” 49 Following the line of cases from American Wood-Paper to Chakrabarty, it is clear that these purified compounds, without more, are not markedly different from those occurring in nature, and as such are not patentable under § 101.

IV. THE MYRIAD CASE

When the United States District Court for the Southern District of New York issued its opinion in the Myriad patent case, 50 it was immediately met with both applause and disdain. Those who oppose gene patents called it “a huge victory for women’s health and scientific freedom,” 51 and “a landmark decision that has the potential to dramatically improve patient access to genetic testing.” 52 Those opposed said the decision would “undermine U.S. global leadership and investment in the life sciences” 53 and “[i]t shows a singular ignorance of the technology and the law at the same time.” 54 The decision is currently being appealed to the United States Court of Appeals for the Federal Circuit, and the outcome is anything but certain.

We will begin our discussion of the case with an overview of the BRCA gene itself, the Myriad patents, and the facts that gave rise to the dispute. We will then dissect Judge Sweet’s 152-page opinion in the case, followed by an analysis of Myriad’s appeal and the Department of Justice’s amicus curiae brief. Finally, we will conclude this section with a restatement of the current law in light of the opinion, both in the United States and internationally.

A. Myriad and the BRCA patents

Breast cancer is among the most commonly diagnosed cancers in the world, and one of deadliest. 55 In 1990, it was discovered for the first time that a
particular gene was linked to breast cancer, though at the time the sequence of that gene was unknown. 56 Researchers later identified the location of the gene as on chromosome 17, and designated the gene Breast Cancer Susceptibility Gene 1 (BRCA1). 57 Founded in 1991, Myriad, Inc., immediately began the research necessary to sequence the BRCA. 58 In 1994, Myriad, along with the National Institute for Environmental Health Sciences (NIEHS), the University of Utah, and others, published a paper announcing that they had sequenced the BRCA1 gene at the same time that Myriad applied for a patent on it. 59 Myriad then continued their research until a second gene, BRCA2, was isolated. On December 21, 1995, Myriad filed for patents on BRCA2 and the next day they published their finding in Nature. 60

Individuals with mutations on BRCA1/2 have up to an eighty-five percent risk for developing breast cancer, and up to a forty percent risk for developing ovarian cancer. 61 For a patient, being able to identify the mutation can be critical for proper diagnosis and course of treatment options. 62 Myriad is the sole provider of BRCA testing, offering its standard testing package, BRACAnalysis, and its rearrangement package, BRACAnalysis Rearrangement Test (BART). 63 The cost to the patient for the test and diagnostic analysis is over $3000. 64 Currently, in the United States, ninety percent of tests Myriad performs are covered by insurance, which covers ninety percent or more of the cost, and Myriad does have a financial assistance program for low-income or uninsured patients who meet certain criteria that Myriad has established. 65

Myriad has vigorously enforced its BRCA patents against would-be infringers. In the late 1990s, the University of Pennsylvania began testing for BRCA1/2, using a substantially different testing method. 66 Myriad sent cease-and-desist letters and subsequently sued for infringement. 67 Myriad also sent a letter to the principal investigator for the Cancer Genetic Network Project,
sponsored by the National Cancer Institute, notifying them that Myriad’s patent position could impact their research. They subsequently ceased BRCA research. In December 2000, Myriad sent a cease-and-desist letter to the Director of Yale DNA Diagnostics Lab concerning their research on BRCA; Yale subsequently ceased all research.

B. The District Court Summary Judgment Decision

On May 12, 2009, the complaint was filed by the Association for Molecular Pathology, et al., by its attorneys, the ACLU and the Public Patent Foundation, alleging that Myriad’s patents were invalid under § 101, and further alleging a violation of Article I, Section 8, Clause 8 of the United States Constitution, and the First and Fourteenth Amendments to the Constitution. The plaintiffs moved for summary judgment asserting that the validity of the patents was a question of law. Myriad submitted a cross-motion for summary judgment under Rule 12(c) of the Federal Rules of Civil Procedure, asserting a lack of standing. The court decided against the defendants on the issue of standing, and then found all of the patent claims-in-suit to be invalid as a matter of law, dismissing the case without considering the constitutional claims. Judgment for the plaintiffs was entered on March 29, 2010.

The court first addressed the issue of standing. Myriad’s primary argument was that patents have the presumption of validity under 35 U.S.C. § 282, noting the United States Patent and Trademark Office’s (USPTO) consideration and determination that gene-related patents were valid. Myriad’s brief argued that the patent claims should be held valid in light of the “carefully considered policy of the USPTO,” which is “entitled to great respect from the courts.” The court found this argument unpersuasive, reasoning that it owes no deference to the USPTO’s legal determinations. Even though Congress created the presumption of validity under 35 U.S.C. § 282, the court stated the presumption is “far from absolute,” noting that approximately forty percent of

69. Id.
70. Id.
71. Id. at 184.
72. Molecular Pathology, 702 F. Supp. 2d at 184-85; see also Fed. R. Civ. P. 12(c).
73. Molecular Pathology, 702 F. Supp. 2d at 186.
76. See Molecular Pathology, 702 F. Supp. 2d at 222 (quoting Arnold P’ship v. Dudas, 362 F.3d 1338, 1340 (Fed. Cir. 2004) (“This court reviews statutory interpretation . . . without deference.”)).
patents challenged in the courts have been found invalid. The court went on to note that the lack of congressional action to specifically prohibit gene patents does not preclude the court from taking action.

The court then addressed the plaintiffs’ claims against the patents. At issue, in particular, were fifteen claims contained in seven patents. These patent claims broadly fell into one of two categories: composition claims and method or process claims. Addressing the composition claims first, the court stated the governing standard that patentable subject matter must be “markedly different” from a product of nature, citing in support (amongst other cases) American Fruit Growers, Inc. v. Brogdex Co., Funk Bros., and Chakrabarty. Myriad, in its defense, relied heavily on Parke-Davis & Co. v. H.K. Mulford & Co., arguing that its holding established that the purification of a natural product renders it patentable. The court found this unpersuasive, arguing that Parke-Davis failed to support that conclusion and that the question before the Parke-Davis court was one of novelty, not patentable subject matter. Even if Parke-Davis did support Myriad’s assertion, the court continued, it was no longer “good law” in light of subsequent Supreme Court cases that required a claimed invention possess “markedly different characteristics.” In summation of its understanding of the “markedly different” standard, the court concluded:

[T]he clear line of Supreme Court precedent and accompanying lower court

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77. See id.
78. Id. at 221. The court referenced Bilski v. Kappos, 545 F.3d 953 (Fed. Cir. 2008), as such an instance. Molecular Pathology, 702 F. Supp. 2d at 221.
79. Molecular Pathology, 702 F. Supp. 2d at 211. In dispute were claims 1, 2, 5, 6, 7, and 20 of U.S. patent 5,747,282 (the “282 patent”); claims 1, 6, and 7 of U.S. patent 5,837,492 (the “492 patent”); claim 1 of U.S. patent 5,693,473 (the “473 patent”); claim 1 of U.S. patent 5,709,999 (the “999 patent”); claim 1 of U.S. patent 5,710,001 (the “001 patent”); claim 1 of U.S. patent 5,753,441 (the “441 patent”); and claims 1 and 2 of U.S. patent 6,033,857 (the “857 patent”). Id. at 211-12.
80. See id. at 222-23.
81. 283 U.S. 1, 11 (1931) (determining article of manufacture must “possess[,] a new or distinctive form, quality, or property” compared to naturally occurring article).
82. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (observing “[t]heir qualities are the work of nature . . . . [which] are of course not patentable,” in reference to combination of naturally occurring bacteria).
83. Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (determining work patentable because “[h]is discovery is not nature’s handiwork, but his own”).
84. 189 F. 95 (C.C.S.D.N.Y. 1911), aff’d in part, rev’d in part, 196 F. 496 (2d Cir. 1912).
86. Id. at 225. Novelty is a § 102 question, whereas patentable subject matter is within § 101. See 35 U.S.C. §§ 101-102 (2006).
87. Molecular Pathology, 702 F. Supp. 2d at 225-26. Citing Chakrabarty, the court stated that Supreme Court precedent requiring “markedly different characteristics” for a product to constitute patentable subject matter rendered Myriad’s reliance on Judge Hand’s opinion in Parke-Davis erroneous. Id. (citing Chakrabarty, 447 U.S. 303; Parke-Davis, 189 F. 95); see also Chakrabarty, 447 U.S. at 310 (requiring markedly different characteristics for derivative products to constitute patentable subject matter).
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authorities, stretching from American Wood-Paper through to Chakrabarty, establishes that purification of a product of nature, without more, cannot transform it into patentable subject matter. Rather, the purified product must possess “markedly different characteristics” in order to satisfy the requirements of § 101.88

Applying the “markedly different” standard to the claimed isolated DNA, the court found that isolated DNA did not meet the standard.89 Myriad, citing several differences between the isolated DNA claimed in the patents and the naturally-occurring DNA found within a human cell, argued that those differences were adequate to satisfy the “markedly different” standard.90 While Myriad relied heavily on the chemical nature of DNA as a physical substance or chemical compound, the court rejected this argument by citing Myriad’s own expert who testified that “[g]enes are of double nature: [o]n the one hand, they are chemical substances or molecules. On the other hand, they are physical carriers of information . . . . [t]hus, inherently genes are multifunctional.”91 The court stated “it would be erroneous to view DNA as no different than other chemicals previously the subject of patents.”92 The court continued:

In light of DNA’s unique qualities as a physical embodiment of information, none of the structural and functional differences cited by Myriad between native BRCA1/2 DNA and the isolated BRCA1/2 DNA claimed in the patents-in-suit render the claimed DNA “markedly different.” This conclusion is driven by the overriding importance of DNA’s nucleotide sequence to both its natural biological function as well as the utility associated with DNA in its isolated form. The preservation of this defining characteristic of DNA in its native and isolated forms mandates the conclusion that the challenged composition claims are directed to unpatentable products of nature.93

In concluding its argument, the court stated that the composition claims were invalid because the claimed isolated DNA is not “markedly different” from native DNA as it exists in nature, and therefore it constitutes unpatentable

88. Molecular Pathology, 702 F. Supp. 2d at 227.
89. See id. at 232.
90. See id. at 228-32 (discussing Myriad’s arguments). The court claimed Myriad’s central argument focused on the differences in “structural and functional” properties of the isolated DNA as compared to naturally occurring DNA, and on the assertion that DNA compounds should receive the equivalent treatment of chemical compounds for determining patent eligibility. Id. at 228. Rather than focus on the similarities between the two types of DNA, Myriad argued the court’s § 101 inquiry should focus solely on the differences between the two. Id. at 229.
91. Ass’n for Molecular Pathology v. U.S. Patent & Trade Office, 702 F. Supp. 2d 181, 228 (S.D.N.Y. 2010). The court argued, using Dr. Straus’s testimony, that Myriad’s focus on the chemical nature of DNA failed to acknowledge DNA’s unique characteristics that differentiate it from other chemical compounds. Id.
92. Id.
93. Id. at 229.
subject matter under 35 U.S.C. § 101.94

The court next considered and held invalid the method claims contained in the claims at issue. It is well-settled law that “an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection,”95 but “[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”96 In In re Bilski, the Federal Circuit described the “definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself.”97 This test, commonly referred to as the “machine-or-transformation test,” holds that “[a] claimed process is surely 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.”98 In other words, the “transformation must be central to the purpose of the claimed process.”99

The method claims at issue cover “analyzing” and “comparing” DNA sequences, as well as “comparing the growth rate in cells.”100 Myriad relied primarily on Prometheus Laboratories, Inc. v. Mayo Collaborative Services101 in arguing that its patent claims for analyzing and comparing DNA sequences were not merely a “mental process,” and that due to their incorporation of a “transformation step” they “therefore satisfy the transformation prong of the Bilski machine or transformation test.”102 The court distinguished the methods claims in Prometheus from those in dispute. The claims in Prometheus covered the act of determining metabolite levels, which included the extraction and measurement of metabolite concentrations;103 however, in contrast, Myriad’s claims-in-suit are directed only to the abstract processes of “comparing” or “analyzing” gene sequences.104 For example, in the 999 patent,105 the purpose of the claim is to “detect a germline alteration in a BRCA1 gene,” but the method actually claimed is “analyzing a sequence of a BRCA1 gene.”106 Myriad also argued that isolating and sequencing DNA is required for

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94. See id. at 232.
97. In re Bilski, 545 F.3d 943, 954 (Fed. Cir. 2008).
98. See id. (citing Benson, 409 U.S. at 70).
99. Id. at 962.
101. 581 F.3d 1336 (Fed. Cir. 2009), vacated and remanded, 130 S. Ct. 3543 (2010).
102. Molecular Pathology, 702 F. Supp. 2d at 233 (internal quotation marks omitted)
103. See id. at 233-34; see also Prometheus, 581 F.3d at 1347 (characterizing nature of claims).
104. Molecular Pathology, 702 F. Supp. 2d at 233-34.
105. See supra note 79.
“analyzing” or “comparing” DNA sequences, and Promethius allows for those transformative acts to be incorporated into the claim. The court rejected this argument on the ground that these “transformations” were not actually claimed by the method claims-in-suit, further reasoning that “[n]either Promethus nor any other authority supports such an expansive approach to the application of [the machine-or-transformation] test.”

In considering Myriad’s claim for “comparing” the growth rate of cells, the court concluded that the “essence of the claim, when considered in its entirety, is the act of comparing cell growth rates,” and that the claimed process was in fact the scientific method itself. The transformative steps that Myriad relies on for this comparison are merely “preparatory, data-gathering steps . . . and do not render the claimed mental process patentable under § 101.”

Finally, the court considered the plaintiffs’ constitutional claims, but dismissed them without deciding the issue on the merits because of the doctrine of constitutional avoidance. The plaintiffs addressed the doctrine in their brief arguing that it is inapplicable here as the court’s invalidation of the claims “will not necessarily invalidate the USPTO’s policy [in granting the patents].” The court rejected this logic because a decision by the Federal Circuit or the Supreme Court affirming the holding would be binding on the USPTO, current patent holders, and future patent applicants. In summary, the court stated that, “[w]ith the holding that the patents are invalid, the Plaintiffs have received the relief sought in the Complaint and the doctrine of constitutional avoidance precludes this Court from reaching the constitutional claims against the USPTO. Plaintiffs’ claims for constitutional violations against the USPTO are therefore dismissed without prejudice.”

C. Myriad’s Appeal


107. See id. at 236.
108. Id.
109. Id. at 237.
110. Molecular Pathology, 702 F. Supp. 2d at 237 (describing attempt to patent scientific method under Claim 20 of ’282 patent).
111. Id. (explaining preparatory steps in process not necessarily patentable).
112. The doctrine of constitutional avoidance stands for the proposition that courts should not decide issues of constitutional law unless it is absolutely necessary to the disposition of the case. See Ass’n for Molecular Pathology v. U.S. Patent & Trade Office, 702 F. Supp. 2d 181, 238 (S.D.N.Y. 2010) (stating doctrine of constitutional avoidance precludes court from reaching plaintiffs’ constitutional claims); see also, e.g., Spector Motor Serv., Inc. v. McLaughlin, 323 U.S. 101, 105 (1944); Ashwander v. Tenn. Valley Auth., 297 U.S. 288, 347 (1936); Allstate Ins. Co. v. Serio, 261 F.3d 143, 149-50 (2d Cir. 2001).
113. Molecular Pathology, 702 F. Supp. 2d at 238.
114. Id. (citing Koninklijke Philips Elecs. N.V. v. Cardiac Sci. Operating Co., 590 F.3d 1326, 1337 (Fed. Cir. 2010)).
115. Id. (citations omitted).
Myriad made three arguments on appeal: first, that the district court lacked declaratory-judgment jurisdiction; second, that the composition claims are drawn on patent-eligible subject matter; and finally, that the method claims cover patent-eligible subject matter. We will begin with an overview of Myriad’s statement of facts and summary of its argument, followed by a consideration of each of Myriad’s arguments.

Myriad’s statement of facts began with a restatement of the applicable science, the BRCA1/2 genes, and the patents.\(^\text{117}\) Their argument then began in earnest, initially directed at the plaintiffs’ attorneys, the ACLU and the Public Patent Foundation.\(^\text{118}\) Myriad contended that the ACLU actively recruited organizations and individuals to join the case, and that the president of the Public Patent Foundation said on CNN that “[i]t is absolutely our intent that upon victory this will rend [sic] invalid patents on many other genes. We just had to pick one case as our case.”\(^\text{119}\) Myriad referred to the original complaint as “just a complaint manufactured to serve the ends of two public-advocacy groups.”\(^\text{120}\)

Myriad began their substantive argument by making three separate arguments to demonstrate that the district court lacked declaratory-judgment jurisdiction.\(^\text{121}\) To be a justiciable controversy under the Declaratory Judgment Act, there must be a “substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.”\(^\text{122}\) Myriad claimed that the plaintiffs and Myriad do not have “adverse legal interests” because “not only ha[s] Myriad not taken a concrete position adverse to [plaintiffs], but [Myriad] also ha[s] taken no affirmative actions at all related to [plaintiffs’] current product[s].’” Indeed, plaintiffs have no ‘current products’ or methods.”\(^\text{123}\) Myriad contended that the plaintiffs failed to allege an affirmative act by Myriad to establish an adverse legal interest.\(^\text{124}\) A controversy “must be based on a real and immediate injury or threat of future injury that is caused by the defendants—an objective standard that cannot be met by a purely subjective or speculative fear of future harm.”\(^\text{125}\) In this instance, the subjective harm is the plaintiffs’ assertions that,

\(^{117}\) Id. at 18-30 (highlighting appellants’ argument on appeal).
\(^{118}\) Id. at 10-12.
\(^{119}\) Id. at 12 (quoting Dan Ravicher, President and Executive Director of the Public Patent Foundation).
\(^{120}\) Brief for the Appellants, supra note 116, at 16.
\(^{121}\) Id. at 18.
\(^{123}\) Brief for the Appellants, supra note 116, at 20 (citations omitted) (quoting Prasco, LLC v. Medicis Pharm. Corp., 537 F.3d 1329, 1340 (Fed. Cir. 2008) (stating parties do not have adverse legal interests)).
\(^{124}\) See id.
\(^{125}\) See Prasco, 537 F.3d at 1339 (discussing definition of actual controversy).
but for the patents, they would have engaged in further research and testing.\footnote{126 See Brief for the Appellants, supra note 116, at 22.}

In continuing its argument against declaratory-judgment jurisdiction, Myriad also asserted that the plaintiffs failed to demonstrate a controversy of “sufficient immediacy and reality.”\footnote{127 Id. at 24.} Myriad based this argument on the fact that it had been over ten years since the communications the plaintiffs cited in establishing jurisdiction,\footnote{128 Id. at 25.} and in those instances in which Myriad did enforce its patents, none of the twenty plaintiffs was a party to the action.\footnote{129 Id. at 27.} Relying heavily on MedImmune, Inc. v. Genetech, Inc.,\footnote{130 549 U.S. 118 (2007).} Myriad also argued that the district court incorrectly applied the “all the circumstances” test by failing to apply the second prong of the test, which holds that the court should consider whether “all the circumstances . . . show that there is substantial controversy, between parties having adverse legal interest, of sufficient immediacy and reality.”\footnote{131 See id. at 30 (citing Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 240 (1937)).} Myriad concluded its declaratory arguments by stating, “[i]n sum, this is a manufactured controversy with recruited plaintiffs having no dispute with Myriad beyond a desire to assist two public-advocacy groups’ effort to use the courts to dictate public policy on DNA patents. That sort of ‘abstract’ dispute is not enough for declaratory-judgment jurisdiction.”\footnote{132 Id. at 31 (citing MedImmune, Inc. v. Genetech, Inc., 549 U.S. at 118).}

Myriad’s second argument on appeal was that the compositions claims are drawn on patent-eligible subject matter. Myriad argued that the compositions do not fall within one of the three judicially created exceptions to § 101\footnote{133 Id. at 33-34.} and, as such, the patents are consistent with the expansive language of § 101 in that “any” composition of matter that is “new and useful” is patent-eligible.\footnote{134 Id. at 34.} They further argued that there is no blanket or judicially created exception to § 101 for “products of nature.”\footnote{135 Id. at 35-36.} They continued their composition arguments by stating that categorical exclusion of DNA molecules from § 101 would be inconsistent with longstanding USPTO practice, precedent, and Congress’s proper role in making patent law.\footnote{136 Id. at 38.} Myriad relied on the USPTO’s “Utility Examination Guidelines,” which reflect prior decisional law as well as the USPTO’s practice of allowing patents on isolated DNA molecules.\footnote{137 Id. at 37.} Myriad noted that the USPTO has assigned utility patents for plants for at least sixteen years. Most notably, Myriad pointed out that the USPTO has granted utility patents for isolated DNA molecules for over twenty-five years with no
indication by Congress or other agencies that such coverage is inconsistent with federal law.\textsuperscript{138} Moreover, Myriad asserted that the fact that Congress has not intervened demonstrates that Congress thought that isolated DNA molecules are patent-eligible.\textsuperscript{139} Myriad’s final argument for the composition patents contended that the judge erred in granting summary judgment because the question of whether isolated genes are “markedly different” than naturally occurring genes is a genuine question of material fact.\textsuperscript{140}

Myriad’s third argument on appeal was that the method claims are drawn on patent-eligible subject matter. Myriad began by asserting that these patents are eligible under the pre-	extit{Bilski} machine-or-transformation test and are certainly eligible under the “more generous approach endorsed by that decision.”\textsuperscript{141} They also contend that the machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible process.\textsuperscript{142} Citing \textit{Bilski}, they reasoned that the test may work well for the “industrial age” but is not sufficient for the “information age.”\textsuperscript{143} Myriad explained that “[w]hile the method claims are transformative, and thus patent-eligible, it bears noting that \textit{Bilski} removed any suggestion that the rigid ‘machine-or-transformation’ test provides the exclusive test for patent-eligibility, particularly as applied to ‘Information Age’ technologies like the advanced diagnostic techniques claimed in the Myriad patents.”\textsuperscript{144} Myriad also claimed that the district court erred by misreading critical elements of the claims-in-suit, elements they believe show that the claim was “transformative”\textsuperscript{145} under Supreme Court precedent.\textsuperscript{146} Myriad stated that, “[s]imply put, the patents themselves undermine the court’s conclusion that the claims are at most limited to using the DNA molecule for data-gathering steps.”\textsuperscript{147}

\textbf{D. The Department of Justice Amicus Curiae}

On October 29, 2010, the Department of Justice (DOJ) submitted an amicus curiae brief for the United States in support of neither party, pursuant to FED. R. APP. P. 29(a). The DOJ made two arguments: first, human-engineered DNA molecules are patent-eligible under § 101; and second, that isolated or
otherwise unmodified genomic DNA is not patent-eligible under § 101.\textsuperscript{148} The DOJ started by stating that § 101 “defines the subject matter that may be patented, but simultaneously defines what must remain in the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.”\textsuperscript{149} It continued:

In attempting to apply that principle here, the district court erroneously cast doubt on the patent-eligibility of a broad range of man-made compositions of matter whose value derives from the information-encoding capacity of DNA. Such compositions—e.g., cDNAs, vectors, recombinant plasmids, and chimeric proteins, as well as countless industrial products, such as vaccines and genetically modified crops, created with the aid of such molecules—are in every meaningful sense the fruits of human ingenuity and thus qualify as “human-made inventions” eligible for patent protection under section 101.\textsuperscript{150}

The DOJ further reasoned that “[t]hese molecules generally do not occur in nature, but are instead the synthetic results of scientists’ manipulation of the natural laws of genetics.”\textsuperscript{151} It then noted that the Supreme Court has stressed that the “relevant distinction” for the purposes of § 101 is not “between living and inanimate things, but between products of nature and human-made inventions.”\textsuperscript{152} The DOJ contrasted these patent-eligible “fruits of human ingenuity” with genomic DNA that has merely been isolated from the human body, without further alteration or manipulation. It argued that crossing the threshold of patentability “requires something more than identifying and isolating what has always existed in nature, no matter how difficult or useful that discovery may be.”\textsuperscript{153} It then stated that, following the district court’s judgment, the United States re-evaluated its stance and concluded that “unaltered genomic DNA is not patent-eligible subject matter under 35 U.S.C. § 101.”\textsuperscript{154} In reaching its conclusion, the DOJ reasoned that: unmodified genomic DNA is a product of nature; isolation does not transform a product of nature into a man-made invention; isolated genomic DNA is not patent-eligible merely because it is a literal composition of matter; isolated genomic DNA is not rendered patentable


\textsuperscript{149} See id. at 9-10 (citations omitted) (quoting Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010)) (internal quotation marks omitted).

\textsuperscript{150} Id. (quoting J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc., 534 U.S. 124, 130 (2001)).

\textsuperscript{151} Id. at 15.

\textsuperscript{152} Id. at 15.

\textsuperscript{153} Brief for the United States, supra note 148, at 14 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 313 (1980)).

\textsuperscript{154} Id. at 11 (noting methods of identifying, isolating, and using DNA also patentable).
on the theory that it is “pure”; and isolated genomic DNA is not patent-eligible merely because it is useful or requires investment to identify.\footnote{Id. at 18-36.} The legal rationale for these arguments, and the cases cited in support thereof, closely track the district court’s analysis. The brief concluded by asserting, “the Court should reverse the district court’s invalidation of the composition claims that are limited to cDNAs and similar man-made constructs, but affirm the district court’s conclusion that the claims encompassing isolated human genomic DNA are invalid.”\footnote{Id. at 18.}

Remarkably, the DOJ acknowledged in its brief that its argument against the patentability of isolated genomic DNA conflicted with the longstanding practices of the USPTO and other governmental agencies.\footnote{See id. at 18; Andrew Pollack, U.S. Says Genes Should Not Be Eligible for Patents, N.Y. TIMES, Oct. 29, 2010, at B1, available at http://www.nytimes.com/2010/10/30/business/30drug.html.} It is significant to note that no attorneys from the USPTO were signatories of the amicus brief, leading some to speculate that the USPTO opposed the position taken in the brief.\footnote{See Andrew Pollack, Gene Patent Ruling Raises Questions for Industry, N.Y. TIMES, Nov. 1, 2010, at B1, available at http://www.nytimes.com/2010/11/02/health/02gene.html.} A USPTO spokesman later said that the office will “maintain the status quo while this matter is pending resolution by the Federal Circuit Court of Appeals” and that it would “not immediately put the policy into effect” nor would it “start denying patents on genes because of pending litigation.”\footnote{See Bryn Williams-Jones, History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing, 10 HEALTH L.J. 123, 136-37 (2002).}

V. INTERNATIONAL GENE PATENTS

It is worth considering the state of gene patents internationally, both before and after the Myriad decision. Myriad’s BRCA gene patents provide an interesting case study in international patent law primarily because Myriad in particular has aggressively pursued foreign patents and access to foreign markets. Myriad has licensed the BRCA1/2 gene, for example, in countries such as Canada, the United Kingdom, Ireland, Germany, Switzerland, Austria, and Australia, thereby subjecting the patent to the patent laws and procedures of each country.\footnote{See Bryn Williams-Jones, History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing, 10 HEALTH L.J. 123, 136-37 (2002).}

When the European Patent Office (EPO) granted Myriad a patent on BRCA1/2 in May 2001, it set in motion opposition to gene patents across Europe. The Institut Curie and other European laboratories disputed the legitimacy of Myriad’s claims, as well as the practice of gene patenting altogether, arguing that these patents constitute an “unreasonable monopoly that negatively constrains research, preventing the development of better,
A number of European nations, such as Germany, Sweden, and Belgium, voiced opposition to Myriad’s patent and their intent to continue BRCA testing in defiance of the European Union patents. In Canada, Myriad’s patents were met with similar public opposition. The first Canadian patent on BRCA1 was granted in October 2000, with the first patent for BRCA2 following in April 2001. Myriad began sending out cease-and-desist letters to public laboratories, ordering them to stop their free in-house use of BRCA tests. In Ontario, the Ministry of Health publicly refused to honor the patents, and currently, the patents are basically being ignored throughout Canada. Myriad’s patents received similar treatment in Australia where, as a result of public outcry, or perhaps as a ploy to head off copycat litigation mirroring the district court’s opinion, Myriad somewhat reluctantly offered to “gift” one of the BRCA patents to the Australian people. These countries represent only a sample of the countries in which Myriad has licensed the BRCA1/2 test, but they demonstrate the international development of the issue. It is important to note that patents are regulated not only by the law and policy of the issuing country, but are also subject to relevant international trade agreements, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the General Agreement on Trade and Tariffs (GATT), and the North American Free Trade Agreement (NAFTA).

VI. A PARTING REMARK ON THE FUTURE OF GENE PATENTS

Following the district court’s invalidation of Myriad’s gene patents, and in light of the DOJ’s amicus brief signaling significant policy changes, the future of gene patents is anything but settled, and it may remain that way for the foreseeable future. Certainly the Federal Circuit could add certainty to the law with a firm decision on the merits; however, whichever way that decision goes, it is likely to be appealed. The Federal Circuit could also find that there is a genuine question of fact underlying the district court’s assumptions and vacate the summary judgment, which would probably mean that the case would move forward into the trial phase. There is also the possibility that Congress could

161. Id. at 138-39.
162. Id.
163. Id. at 141.
164. Williams-Jones, supra note 160, at 142.
165. Cook-Deegan, supra note 30, at 71. Interestingly, Myriad has yet to file a claim for infringement, and it is not certain whether they will.
166. Id.
168. See Williams-Jones, supra note 160, at 125 (arguing international trade agreements have had significant impact on international gene patenting).
take action and pass legislation that either allows for or proscribes gene patents, but given the contentious nature of the debate, that may be easier said than done, at least politically. Finally, the USPTO, as an agency of the executive branch, could change its policy, though it has indicated that it will not do so at least until this case is settled. The future of gene patents is as unclear as the current state of the law, and it seems that both patients and patent holders could be waiting a long time for a final resolution.