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Association of Molecular Pathology v. Myriad Genetics, Inc.: Determining the Scope of the Supreme Court's Holding for Patentable Subject Matter

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Association of Molecular Pathology

v.

Myriad Genetics, Inc.:

Determining the Scope of the Supreme Court’s Holding for Patentable Subject Matter

Ashley Winkler

INTRODUCTION

Actress Angelina Jolie, famous for her sex appeal in roles like *Tomb Raider* and *Mr. and Mrs. Smith*, sensationalized the debate surrounding diagnostic tests for “breast cancer genes” when she shocked Americans and underwent a double mastectomy following the results of her own test.² The important breast cancer genes in Jolie’s test were the subject of several patents issued to Myriad Genetics, Inc., a molecular diagnostic company that isolated the sequences in 2004 and 2005.³ The company’s unique business practices that limited access to diagnostic tests associated with the genes formed part of a heated national debate about the patentability of gene sequences, resulting in dramatic headlines like “Tell Congress: My Genes Aren’t for Sale”⁴ or “Liberate the Breast Cancer Genes.”⁵ The United States Supreme Court responded to some of these national cries in a recent decision, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.* (hereinafter *Myriad*).⁶ While the Court’s ruling comforted some observers,⁷ it also created new

¹ University of Kentucky College of Law, J.D. expected May 2015.
³ See infra Part II(b).
⁶ 133 S. Ct. 2107 (2013).
questions about the future of biotech and other industries by reversing decades of patent law in holding that the isolation of gene sequences is not patentable subject matter. In light of the Court's opinion, the scope of the holding for determining the patentability of current and future patent applications remains unclear.

This Note is a reaction to the Court's decision in Myriad and argues that the Court's holding should be narrowly interpreted. Part II of this Note outlines the necessary background information regarding the relevant science, the state of the law on patentable subject matter, and the important facts in the Myriad case. Finally, Part III argues that based on factors including the technical science, the relevant interests at play, and other agency actions external to patent law, courts should strictly interpret and assign a narrow scope to the Court's holding against patent eligibility for the information contained within isolated, human DNA gene sequences.

I. BACKGROUND

Patent law is a marriage of traditional legal policy and technical science. Consequently, in almost any question regarding patent law, in addition to studying the legal tests, there is a need to have a basic understanding of the relevant science underpinning the issue at bar. The case of Myriad is no different. The plausibility and scope of the Court's decision flows directly from the Court's application of statutory law and case law to specific biochemical facts. This section (A) outlines the legal history of the relevant issues, (B) explains the underlying invention and science, and (C) concludes with a summary of the legal decisions and early consequences of Myriad.

A. Legal Development of Gene Sequences as Patentable Subject Matter

Our current patent system has broad constitutional and statutory authority granted by Article 1, Section 8 of the United States Constitution and the Patent Act of 1952. But despite these broad grants of authority, there remain some limitations on patentability. To be patentable in the United States, an invention or

7 See Dan Munro, Supreme Court Breaks Myriad Monopoly, FORBES (June 16, 2013, 4:56 PM), http://www.forbes.com/sites/danmunro/2013/06/16/supreme-court-breaks-myriad-monopoly (quoting supporters of the Court's decision).
8 Myriad changed the law established by the Supreme Court and the United States Patent and Trademark Office. See infra Part II(a).
10 See U.S. CONST. art. I, § 8 ("The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . . ").
discovery must be eligible subject matter,\textsuperscript{12} useful,\textsuperscript{13} novel,\textsuperscript{14} non-obvious,\textsuperscript{15} and adequately supported in a United States patent application.\textsuperscript{16}

The debate regarding the patentability of gene sequences turns on the requirement for a discovery to be patentable subject matter. Today, 35 U.S.C. § 101 defines the scope of patentable subject matter, providing, "[w]hsoever 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." With broad constitutional grants for patents and similarly broad statutory authority grants, the Supreme Court has construed Congress' intent for patentable subject matter to be "anything under the sun that is made by man."\textsuperscript{17}

Despite this broad construction, the Court imposes limits on patentable subject matter for "laws of nature, natural phenomena, or abstract ideas."\textsuperscript{18} These limitations prevent minerals discovered in the earth, or even Einstein's law of\textsuperscript{19} E=mc\textsuperscript{2}, from being patentable because they are "manifestations of . . . nature, free to all men and reserved exclusively to none."\textsuperscript{20} The Court has acknowledged that it must be cautious to preclude patentability due to an invention's close relationship to nature because "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas," and "too broad an interpretation of this exclusionary principle could eviscerate patent law."\textsuperscript{21}

In \textit{Myriad}, the Federal Circuit and Supreme Court relied on language from \textit{Diamond v. Chakrabarty}, which stated that "products of nature" are not patentable subject matter.\textsuperscript{22} In \textit{Chakrabarty}, the Supreme Court found that genetic alterations in a microorganism constituted sufficient additions to nature to render the

\textsuperscript{13} Id.
\textsuperscript{14} Id. § 102.
\textsuperscript{15} Id. § 103.
\textsuperscript{16} Id. § 112.
\textsuperscript{17} Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (citing the Committee Reports that accompany the 1952 Act establishing modern patent law, S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952)). Furthermore, the Court has stated that by "choosing such expansive terms . . . modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010) (citing Chakrabarty, 447 U.S. at 308).
\textsuperscript{19} Mayo, 132 S. Ct. at 1293 (quoting Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)).
\textsuperscript{20} Id. (quoting Diamond v. Diehr, 450 U.S. 175, 187 (1981)) ("[A] process is not unpatentable simply because it contains a law of nature or a mathematical algorithm. . . . [A]n application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.").
\textsuperscript{21} Chakrabarty, 447 U.S. at 313 ("Congress . . . recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions.").
microorganism patentable subject matter. The Court took special care to distinguish Chakrabarty from an earlier case, Funk Brothers Seed Co. v. Kalo Inoculant Co., where the Court found that a new microorganism that merely combined previously known bacteria already found in nature constituted unpatentable subject matter. Specifically, the Court emphasized in Chakrabarty that the microorganism had "markedly different characteristics from any found in nature..."

Almost immediately following Chakrabarty, the United States Patent and Trademark Office (hereinafter USPTO) demonstrated support for the Court's holding by granting patents for DNA and gene related innovations. During the subsequent three decades, the USPTO continued to issue patents to the extent that 20% of the human genome was patented by 2005. In May 2010, the director of the USPTO David Kappos summarized the historical treatment of gene sequence patents and stated the USPTO's current position on gene sequences:

The USPTO has for decades issued patents covering isolated and purified DNA on the scientific basis that an isolated snippet of DNA does not "exist" in nature in the way it is claimed in patents, because naturally occurring DNA must be isolated — that is, separated from the surrounding biological material — and purified. Your body does not contain isolated DNA. Isolated DNA simply is not found in nature.

Mr. Kappos' statement that the USPTO would continue to issue gene sequence patents reflects decades of legal support — Supreme Court findings, consistent USPTO interpretation, and Congress' repeated lack of action — that gene sequences are patent-eligible subject matter.

B. Inventions and Relevant Science

The Supreme Court's holding in Myriad was based on the question of patentability of two different types of product inventions, each related to human gene sequences. Of these two inventions, one was held not to be patentable subject

22 Id. at 309.
23 Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 132 (1948) ("[O]nce nature’s secret of the non-inhibitive quality of certain strains of the species of Rhizobium was discovered, the state of the art made the production of a mixed inoculant a simple step.... [W]e conclude that the product claims do not disclose an invention or discovery...”).
24 Chakrabarty, 447 U.S. at 310 (emphasis added). In a more recent opinion, the Court seemingly affirmed its requirement for a substantial change in the product of nature in order for the invention to be patentable. Mayo, 132 S. Ct. at 1294.
Consequently, identifying the distinctions in the two inventions is fundamental in defining the scope of the Court's decision. The following subsections explain the underlying science of the two inventions and also the unique practices of the patentee.

1. *Invention One: DNA and Isolated Gene Sequence.*—Myriad's first series of patent claims before the Supreme Court involved isolated sequences of human genes called BRCA1 and BRCA2. Modern research suggests that each human has an estimated 20,000 to 25,000 genes. These genes are the "basic units of heredity," allowing humans to transmit information to offspring. Furthermore, genes work as instructions to our cells for the production of specific molecules called proteins, which form the structure and define the function of human cells and provide for the development of our bodies.

Genes are able to give the necessary instructions to create proteins because genes are composed of a short section of deoxyribonucleic acid (DNA). Each DNA molecule is arranged from four different nucleotide bases – adenine ("A"), thymine ("T"), cytosine ("C"), and guanine ("G") – appearing in a unique, but specific, series. Generally, DNA will exist in the recognizable double helix ladder: two DNA strands that are connected through a special sugar-phosphate backbone. The backbone results from each base's attraction to a complimentary base on the opposite DNA strand, such that where A appears on the first DNA strand, T will always appear at the same location on the second DNA strand, and a particular chemical bond will form between them. Just as A and T are complimentary pairs, so are C and G. The particular order of the bases forms a DNA sequence, and each DNA sequence then codes for a sequence of amino acids which in turn make up a protein.

In humans, these gene sequences are 99.9% identical, and it is only the remaining 0.1% that codes for differences occurring in our bodies, including

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28 *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013).
31 *What is a Gene?*, supra note 29.
33 Id.
34 Id.
36 Id.
37 Id.
38 Id.; *A Brief Guide to Genomics*, supra note 29.
important mutations that could signal diseases or other health problems. The BRCA1 and BRCA2 gene sequences are the specific series of nucleotide bases that code for the BRCA1 and BRCA2 proteins, respectively. Myriad's patents include these sequences and additionally discovered mutations or deviations from BRCA1 and BRCA2. When diagnostic testing identifies a person's gene sequence is like the mutated, rather than normal, BRCA1 and BRCA2 gene sequences, it is possible to predict his or her increased chance of acquiring breast or uterine cancers.

The BRCA1 gene is just one sequence in a very long strand of DNA built of many additional sequences. When combined with proteins, DNA molecules make up complex structures called “chromosomes.” Every human body has forty-six chromosomes organized in twenty-three pairs. Although chromosomes include just one DNA molecule, because one DNA strand includes thousands of different genes, one chromosome will hold millions of sequenced nucleotide bases.

Scientists have developed several different techniques for extracting DNA from a cell and then isolating a specific gene from the DNA strand. Any of these isolation techniques require a breaking of special bonds, called covalent bonds, which are responsible for keeping each of the nucleotide bases of the DNA strand connected. Once the gene has been separated from the native DNA strand, it is called “isolated DNA” or an “isolated gene sequence.” As expected, the BRCA1 gene sequence has gone through this process of breaking covalent bonds to form a new and chemically different molecule. Scientists go through the isolation process because the resulting gene sequence is in a form that can be used for further study and other uses, like BRCA1 diagnostic testing, that are otherwise not possible when the gene is part of the long DNA strand.

2. Invention Two: cDNA Molecules.—Myriad also has patents claiming rights to complementary DNA (cDNA). The cDNA molecules in Myriad’s claims only include “exon,” not “intron,” sequences. Exons code for proteins. Introns appear

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41 See id.
45 See id. at 1328.
46 Id. at 1229–29.
47 Id. at 1341.
48 See id. at 1313–14.
among the exons in a gene sequence, but do not have a coding function.\textsuperscript{50}
Therefore, Myriad’s cDNA molecules include only the parts of the gene sequence
that are responsible for creating a specific protein. A cDNA molecule is synthesized
in a lab using messenger ribonucleic acid molecules (mRNA) as a guide for what
sequence of nucleotide bases is required.\textsuperscript{51}

An mRNA molecule results from the first step in protein creation called
transcription.\textsuperscript{52} During transcription a gene sequence is “transcribed” or copied into
ribonucleic acid (RNA). Initially, the new RNA molecule will contain both exons
and introns, but then through a process called “splicing” the introns are removed
and RNA is left only with a sequence of protein-coding exons.\textsuperscript{53} The process of
splicing creates a molecule known as mRNA.\textsuperscript{54} Because the nucleotide bases have
complementary pairs, scientists are able to match nucleotide bases in the mRNA
sequence with their pairs.\textsuperscript{55} The resulting sequence of bases opposite mRNA forms
the nucleotide sequence in cDNA.\textsuperscript{56}
cDNA technology is important to patentees, like Myriad, because by including
only the exons that code for the relevant protein, the cDNA is shorter and more
manageable for practical uses in diagnostic tests.\textsuperscript{57} The caveat, however, is that
because cDNA strands are shorter, they are easy to design around, allowing non-
patentees to practice the technology without licensing it.\textsuperscript{58} Consequently, cDNA
claims offer important protection but are less commercially productive for
patentees.

3. Patentee: Myriad Genetics, Inc.—Myriad Genetics, Inc. (“Myriad”) has
employed business practices unique in pharmaceutical research, which have
generated negative media for the company and have helped to popularize the policy
concerns weighing against gene sequence patents.\textsuperscript{59} Myriad is a twenty-year-old
molecular diagnostic company that was initially formed to raise funds to
support genome research regarding breast cancer.\textsuperscript{60} Pre-Myriad, government
encouragement and financial backing was insufficient to support the expensive

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{50} Id.
\item \textsuperscript{51} Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1313 (Fed.
Cir. 2012).
\item \textsuperscript{52} Id. at 1311.
\item \textsuperscript{53} Id.
\item \textsuperscript{54} Id.
\item \textsuperscript{55} Id. at 1313–14.
\item \textsuperscript{56} Id. at 1313.
\item \textsuperscript{57} See L. Scott Burwell et al., Gene Patents Won’t Disappear Post-Myriad, FINNEGAN (July 22,
2013), http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=b4a7795a-bee4-431a-bab2-
47ce02ea5608.
\item \textsuperscript{58} Id.
\item \textsuperscript{59} See Johanna Jacob, Comment, Should Our Genes Be Part of the Patent Bargain? Maximizing
Access to Medical Diagnostic Advances While Ensuring Research Remains Profitable, 28 SANTA
\item \textsuperscript{60} See Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 201
(S.D.N.Y. 2010).
\end{itemize}
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research. Myriad's founders relied largely on grants from the National Institutes of Health and significant funding by Eli Lilly and Company (hereinafter Eli Lilly). Importantly, Eli Lilly was encouraged to make contributions based on promises by Myriad to award licensing privileges to Eli Lilly for diagnostic kits and therapeutics products.

Myriad and associated research team members, including Eli Lilly, announced in September 1994 that they had successfully sequenced BRCA1. Further research and collaboration with a Canadian research team resulted in isolation of the BRCA2 sequence in 1995. Subsequently, the USPTO issued seven patents to Myriad regarding the BRCA1 and BRCA2 gene sequences.

Since then, Myriad has utilized the rights granted to it through these patents. The company quickly began administering cancer diagnostic tests with an initial cost of $2,400, growing to a cost of at least $3,000 per test in 2013. Furthermore, Myriad chose an "unprecedented" business model in largely refusing to license its patents and aggressively enforcing the patents by sending cease-and-desist letters to other laboratories that were using the sequences in diagnostic testing. Notably, however, the letters indicated that they were not directed to non-commercial research activities. As of 2012, despite its high diagnostic prices and monopolistic business practices, and with just three years of patent protection

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61 Id. at 200–01 (stating that “[i]n 1991, the U.S. Department of Defense created a research program devoted to breast cancer research” and that in 1990 such financial funding amounted to $90 million).


63 Id. ("Because large pharmaceutical companies anticipated that genetics would produce many new therapeutic products, Eli Lilly believed it was investing in research that might lead to a future development of blockbuster drugs.").


67 Gold & Carbone, supra note 62, at $42.


remaining, Myriad had still failed to recover its steep research costs and make a profit. 72

C. Legal Application and Findings in Association of Molecular Genetics v. Myriad Genetics, Inc.

1. Lower Court Decisions.—In 2009, Plaintiffs brought suit against Myriad, among others, in the Southern District of New York challenging the patentability of claims relating to BRCA1 and BRCA2 in all seven of Myriad's patents. 73 Plaintiffs included the Association of Molecular Pathology, the University of Pennsylvania together with several researchers, patient advocacy groups, and individual patients. 74 At the trial level, the court granted Plaintiffs' summary judgment motion on the merits, finding that the isolated DNA molecules were not “markedly different” from native DNAs. 75 Consequently, the fifteen challenged claims were “products of nature,” constituting claims not patentable under 35 U.S.C. § 101 because of an exception to patentable subject matter created by the Supreme Court in Chakrabarty. 76

When the case was heard by the Federal Circuit Court of Appeals, following remand to consider the recently decided Mayo Collaborative Services v. Prometheus Laboratories, Inc., 77 the appellate court unanimously upheld the patentability of Myriad’s claims regarding cDNA and split two to one in favor of finding patentable subject matter regarding the isolated gene sequence claims. 78 With regard to the cDNA claims, all three judges agreed that sufficient human contribution was made to the synthesized molecules claimed in Myriad patents, especially where the claimed molecules did not exist in nature. 79

Myriad’s patent claims over isolated BRCA1 and BRCA2 gene sequences yielded greater debate among the court, with two judges concurring that the claims were patentable subject matter and one judge dissenting. Judge Lourie, for the majority, found that when native chromosomal DNA is cleaved or synthesized into isolated DNA it becomes a distinct molecule with a chemical identity unlike native DNA. 80 The analysis particularly emphasized that covalent bonds that are broken

72 Gold & Carbone, supra note 62, at §42.
74 Id. at 1.
76 Id. at 185, 222 (citing Diamond v. Chakrabarty, 447 U.S. 303, 309–10 (1980)).
78 Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) (upholding patentability of gene sequences and cDNA as non-naturally occurring and invalidating Myriad method claims that were found to be abstract only).
79 Id. at 1337, 1348.
80 Id. at 1328.
between the isolated DNA sequence and the native DNA. Judge Lourie reasoned that this chemical change creates a molecule in the isolated DNA that is different in "name, character, and use" and thus is not a "product of nature." Judge Moore concurred regarding the patentability of isolated DNA sequences. Judge Moore recognized at least minimal chemical change in the molecule, and even added utility for some sequences at bar, but questioned the sufficiency of the chemical change. Nevertheless, Judge Moore reasoned that Congress' and the USPTO's long-term support for patentability of isolated gene sequences and purified natural substances, which have resulted in significant property rights and expectations within the biotech industry, necessitate a finding of patentability by the courts.

The final judge, Judge Bryson, dissented with regard to isolated DNA. Judge Bryson questioned the sufficiency of isolation in changing the character of DNA and emphasized the public policy concerns that necessitated a finding against patentability. Plaintiffs then petitioned for certiorari to be heard before the United States Supreme Court, and their writ for certiorari was granted.

2. Supreme Court Opinion.—In an opinion written by Justice Thomas, the Supreme Court unanimously overturned the Federal Circuit's holding regarding the patentability of BRCA1 and BRCA2 gene sequences in finding that the claimed gene sequences are not patentable subject matter. Regarding Myriad's cDNA claims, however, the Court unanimously affirmed the Federal Circuit's holding that cDNA claims are patentable subject matter. The Court held that the isolated gene sequences BRCA1 and BRCA2 are not patentable subject matter under 35 U.S.C. § 101. Notably, Justice Scalia did offer a concurrence regarding the Court's explanation and dependence on a technical understanding of the applicable science, stating that he was "unable to affirm those details on [his] own knowledge or even [his] own belief."

The Court agreed with the lower court's finding that cDNA is not a "product of nature." Like the lower court, the Court focused on the fact that cDNA does not occur in nature and must be synthesized in a laboratory. Further, the Court countered arguments that cDNA is not patentable because cDNA's sequence is dictated by nature, pointing out that cDNA is different from the DNA that it is
based on and also that "the lab technician unquestionably creates something new when cDNA is made." The Court, nevertheless, did caution that in the event a cDNA strand was short enough to contain only exons, and a DNA strand of the same length would also be composed of exons only, there may not be sufficient difference in character to support a finding of patentable subject matter.

In contrast to cDNA, the Court did not find sufficient human contribution to the patent claims relating to gene sequences that would make the claims eligible as patentable subject matter. The Court stated “[w]e... hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.” In rendering its opinion, the Court first cited to the statutory grant of patentable subject matter in 35 U.S.C. § 101, and immediately followed by listing the judicially created limitations against patentable subject matter: "laws of nature, natural phenomena, or abstract ideas." The Court framed the issue as determining whether, within the traditional patent standard of weighing the need for incentives against the need for free flow of information, "Myriad's patents claim any 'new and useful... composition of matter,' or instead claim naturally occurring phenomena." The Court then explained that isolated gene sequences are not patentable subject matter for three reasons: (1) Myriad merely discovered the BRCA1 and BRCA2 gene sequences and did not invent something new; (2) Myriad's patent, taken as a whole, was drafted reflecting the information, rather than the chemical composition, contained in the relevant gene sequences; and (3) no deference is due to the USPTO's practice of granting isolated gene sequence patents, especially where Congress has never expressly supported said practice.

First, the Court expressly stated its view that “Myriad did not create anything” in the isolated sequences BRCA1 and BRCA2. The Court characterized Myriad's claimed invention as merely "separating [a] gene from its surrounding genetic material" and unequivocally found that this act was not an invention. In its analysis, the Court concentrated on the different facts in Funk Bros. Seed Co. v. Kalo Inoculant Co., as distinguished from Diamond v. Chakrabarty. Ultimately,
the Court acknowledged that Myriad did find the location of the relevant genes, but found that this “discovery” did not alone “render the BRCA genes ‘new... composition[s] of matter’ that are patent eligible.”

Next, the Court focused its analysis on the specific language of Myriad's patents. The Court found that Myriad neither made their patent claims based on the chemical nature of the isolated gene sequences nor described chemical changes that resulted from isolation. Importantly, here, the Court emphasized Myriad’s discussion of the information within the gene sequence, rather than the chemical form, and the need for Myriad to protect the information as a way to bolster the value of their patent.

Finally, the Court responded to arguments by Myriad and Judge Moore of the lower court, finding that no deference was due to the USPTO practice of granting isolated-gene-sequence patents. The Court further supported its view against deference by pointing to an amicus curiae brief submitted to the Court by the United States wherein the government stated its opinion that Myriad's patent claims were not sufficiently patent eligible.

Despite the Court's strong opinion against the patentability of Myriad isolated gene sequence claims in BRCA1 and BRCA2, before concluding, it clearly stated several limitations on the application of its holding. First, because the processes used by Myriad to actually isolate the gene sequences were common knowledge to scientists in the field, the issue of method claims did not arise under the facts at bar, and possible patent-eligible patent claims may exist. Next, the Court supported Judge Bryson's view and pointed out that new applications of known isolated gene sequences may be possible. Finally, the Court expressed that its holding does not touch instances where scientists have altered the sequence of nucleotide bases in DNA.

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100 Id. at 2117 (internal citation omitted) (quoting 35 U.S.C. § 101 (2012)).
101 Id. at 2118 (“Nor are Myriad’s claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule. Myriad’s claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA.”).
102 Id. (“[T]he claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes. If the patents depended upon the creation of a unique molecule, then a would-be infringer could arguably avoid at least Myriad’s patent claims on entire genes (such as claims 1 and 2 of the ‘282 patent) by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair.”).
103 Id.
104 Id. at 2119.
105 Id. at 2119–20.
106 Id.
107 Id. at 2120.
108 Id.
II. THE COURT'S HOLDING SHOULD BE NARROWLY CONSTRUED

Following the dramatic reversal of thirty years of patent law practice in granting isolated gene sequence patents, it remains unclear how the Myriad holding will immediately impact patent validity. This section seeks to outline the various considerations that must be weighed by courts interpreting the Supreme Court's opinion and determining its scope. This section first presents technical problems with the Court's analysis of the technology involved; then, this section balances the various interests that were necessarily a part of the Court's opinion. Finally, this section points to considerations outside of patent law that will have an effect on the success of serving the relevant interests. In conclusion, this Note argues that, based on the foregoing factors, courts should strictly and narrowly interpret the Supreme Court's holding in Myriad to apply only to patents of isolated human gene sequences that seek to claim the information contained in that sequence. Further, courts should take the Supreme Court's lead in permitting the patent eligibility of synthesized DNA.

A. Challenges in the Court's Understanding of the Relevant Technology

Patent law is defined by the technology of an invention and the state of knowledge of that technology at the time of an inventor's innovation or discovery. In fact, one requirement for patentability, obviousness, measures what would be obvious to a person skilled in the art of that technology. Accordingly, the process of determining whether sufficient invention has occurred for patentability's sake is grounded in an analysis of the technology.

The Supreme Court began its Myriad opinion with a description of the technology involved. There are technical errors in the Supreme Court's explanation of the relevant science. Although Justice Thomas, writing for the majority, details some of the essential science behind gene sequencing, the Court

110 See Id. at 1630–31 (discussing the constitutional and statutory requirements for a patent).
113 Id. The Court's mistakes include mischaracterization of several concepts. For example, the Court misnames "complementary DNA" as "composite DNA" and also overstates the role of exons in coding for amino acids. Other associated errors and slips of terminology appear throughout the opinion. See, e.g., Maggie Koerth-Baker, Patent Life: How the Supreme Court Fell Short, BOING BOING (July 31, 2013, 7:45 AM), http://boingboing.net/2013/07/31/patent-life-how-the-supreme-court-fell-short; Ricki Lewis, Genetics Errors in Supreme Court Decision, DNA SCI. BLOG (June 13, 2013), http://blogs.plos.org/dnascience/2013/06/13/genetics-errors-in-supreme-court-decision; Steven Salzberg, Supreme Court Gets Decision Right, Science Wrong, on Gene Patents, FORBES (June 13, 2013, 3:21 PM), http://www.forbes.com/sites/stevensalzberg/2013/06/13/supreme-court-gets-decision-right-science-wrong.
indicated in oral arguments that it did not understand the science involved. In *Myriad*, Justice Scalia’s concurrence specifically refuses to adopt the Court’s description of the technical background and expressly admits his own lack of understanding of the science. The Court’s analysis of the invention at bar and its description of the science should not be used to create a limitation on patentable subject matter or on the future of diagnostic testing.

The opposite holdings of the Federal Circuit Court of Appeals and the Supreme Court arguably resulted from two different interpretations of the technical field. Federal Circuit Court of Appeals Judge Lourie holds a Ph.D. in Chemistry and was the only judge with a scientific background to hear the case. Judge Lourie focused on the breaking of covalent bonds and the difference in chemical composition of the new, separate molecule when he found the invention was not naturally occurring and was patent eligible. Additionally, Judge Lourie emphasized that chemically different molecules have the possibility of sharing the same function, as in the case of Advil and ibuprofen. In contrast, the Supreme Court highlighted the similarity of the *information*, rather than the chemical composition, in the isolated molecule as compared to native DNA. The Court concluded that Myriad had focused its patents, specifically its claims, on the unpatentable discoveries of the location of the genes and the information contained in the genes.

The Court’s holding against the patentability of gene sequence isolation should be interpreted to apply only to gene sequences where the patentee attempts to claim the information in native DNA by the way it appears in the sequence. The Court’s holding can be applied as stating that the information contained in DNA is not patentable, in the same way that the location of a sequence is not patentable. The Court’s holding should not prevent a different patent claim where humans, in a new and inventive way, cause a change in chemical composition, structure, or form.

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118 *Id.* at 1330.
119 Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2120 (2013) (“We merely hold that genes and the information they encode are not patent eligible under [*35 U.S.C.*] § 101 simply because they have been isolated from the surrounding genetic material.”).
120 *Id.* at 2117–18 (“Myriad’s claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA.”).
Allowing patent monopolies is, at its heart, a policy question. In fact, in preparing to analyze the facts in *Myriad*, the Court framed the issue and standard for the case as a balancing test in stating that "patent protection strikes a delicate balance between creating ‘incentives that lead to creation, invention, and discovery’ and ‘imped[ing] the flow of information that might permit, indeed spur, invention.’" Consequently, as *Myriad* is interpreted, it should be applied in a context considering the interests that motivated the Court to reach its holding.

1. Incentives for Medical and Pharmaceutical Research.—From the time of the Founding Fathers through the modern Supreme Court, a primary motivating theory for intellectual property rights is that innovation benefits society and that the rights are necessary as incentives to encourage individuals to engage in such innovation. Certainly, advancement in medical treatment is important to society. Unfortunately, such research and innovation comes at a very large price. In fact, pharmaceutical research expenses in 2010 were reported to total a staggering $49 billion. Under the economic theory, the monopoly resulting from the grant of a patent provides the researcher with necessary incentive to engage in innovation, and also may allow the researcher to recover the high costs of innovation. Supporters of patenting genes argue that the isolation and research of genes and DNA require patents in order to provide sufficient incentives for this indispensable work and to assist research companies in regaining capital that is essential to continued innovation.

Indeed, this kind of medical innovation has proven beneficial to many Americans. In 2013, approximately 40,000 men and women died from breast cancer in the United States and another 300,000 were diagnosed with the cancer.

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121 *Id.* at 2116 (internal citation omitted) (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1305 (2012)).

122 See Burk & Lemley, *supra* note 109, at 1576 ("Patent law is our primary policy tool to promote innovation, encourage the development of new technologies, and increase the fund of human knowledge. To accomplish this end, the patent statute creates a general set of legal rules that govern a wide variety of technologies."). Empirical studies have shown that patents do prove to be successful in influencing research efforts. See Simone A. Rose, *Patent "Monopolyphobia": A Means of Extinguishing the Fountainhead?*, 49 CASE W. RES. L. REV. 509, 509-10 (1999).


125 See generally PhRMA Study, *supra* note 123, at 3-5 (discussing how intellectual property protection fosters medical innovation).

Nevertheless, improvements in early detection capabilities like BRCA tests and in treatment technologies have helped to create high survival rates. The BRCA genes, when detected, suggest the tested individual is at a higher risk of breast cancer than an individual without the genes. According to one study, where BRCA1 is detected, between 44% and 78% of women will develop breast cancer by age 70, and where BRCA2 is detected, between 31% and 56% of women will develop the disease. In fact, Eric Drogin, Chair of the ABA Section of Science and Technology Law, stated that the discovery of the two genes has “open[ed] a new chapter in the ability to individualize recommendations for a patient’s care and treatment based upon the patient’s individual genetic fingerprint.”

The BRCA genes represent just one development resulting from medical research’s growing attention to genetic diagnostic testing. Genetic testing is being researched and used to treat everything from cancer to cardiovascular diseases, central nervous system conditions, immunology, virology, and metabolic respiratory therapies.

The intellectual property associated with medical research and other industries additionally creates important economic factors in the balancing equation. In 2010, patients spent an estimated $5 billion on diagnostic testing, and that number is projected to increase to as much as $25 billion by 2021. Importantly, researchers across the United States and the world spend billions of dollars each year developing these technologies, and the historically robust intellectual property system of the United States encourages 31% of global spending on research and development to be brought to our country.

The broader impact of intellectual property rights on the economy has led innovation to be named “a primary driver of...”

127 Id. at 9–10 (stating that current survival rates are as high as 89% five years after diagnosis, 83% ten years after diagnosis, and 78% fifteen years after diagnosis).
128 Id. at 12 (citing Sining Chen & Giovanni Parmigiani, Meta-analysis of BRCA1 and BRCA2 Penetrance, 25 J. CLINICAL ONCOLOGY 1329, 1329-33 (2007)). Studies vary regarding the exact risk involved where BRCA1 or BRCA2 are detected, but all studies indicate that individuals with mutations of the two genes do have a higher chance of developing breast cancer. See, e.g., Breast Cancer Risk Factors You Cannot Change, AM. CANCER SOC’Y, http://www.cancer.org/cancer/breastcancer/moreinformation/breastcancerearlydetection/breast-cancer-early-detection-risk-factors-you-cannot-change (last revised Sept. 10, 2014).
130 See PhRMA STUDY, supra note 123.
131 Id.
133 See PhRMA Study, supra note 123.
134 Rod Hunter, Intellectual Property and Economic Development, TODAY’S ZAMAN (Feb. 17, 2014, 6:22 PM), http://www.todayszaman.com/news-339714-intellectual-property-and-economic-development-by-rod-hunter.html. This is in stark contrast to India, which receives a mere 2.7% of global research and development spending because it has weak intellectual property rights. Id.
U.S. economic growth and national competitiveness." In sum, there are strong interests at play in favor of encouraging reasonable intellectual property rights to exist in order to promote innovation.

2. Availability of Healthcare Processes to the General Public.—On the other side of the balancing test are the costs to society in the form of exclusion from the patented invention and the economic expense of the monopoly created by the granted patent. In the United States, the high costs of healthcare have received significant media attention and have been made a priority by the Obama administration. As a part of the healthcare battle, the high, even prohibitive, costs of genetic diagnostic testing, including the Myriad BRAC analysis test at $3,000-$4,000 per examination, received media attention. The ensuing public debate became very one-sided in the media, with over 75% of Myriad’s media coverage being negative. Many, including complainants against Myriad, argued that the large price tag was a direct result of Myriad’s monopoly and that the monopoly prevented second opinions and additional research. In sum, leading up to the Supreme Court’s holding there was incredible pressure to lower the costs of diagnostic testing by eliminating Myriad’s monopoly on the test.

3. Courts Should Narrowly Apply the Supreme Court’s Opinion.—Ultimately, the pressure to lower the cost of healthcare and the public outcry for increased availability to these diagnostic tests likely motivated the Court to find against patentability. From the late 1980s to the early 2000s when most gene sequence patents were granted, the state of molecular biology was much different than it is today, and there was an international call for incentives to map the human

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Contrastingly, today, the methods used for isolation and even for discovery that were instituted by Myriad's scientists have become commonplace and accepted in the field. Modern scientists are now charged with developing new ways of using gene sequences to better and more cost-efficiently diagnose, prevent, and treat diseases and other medical conditions. The Court's ruling promotes public interests in favor of accessible gene sequence testing, but it does not eliminate the need to offer incentives for improved use of the sequences. Therefore, courts should apply the ruling as merely foreclosing patentability of identical genetic information like that present in the Myriad patent claims.

Largely, the emphasis on public policy concerns points to the Court's role as a gatekeeper of the public interest and not an analyzer of technical science. Even the Court was careful to limit the scope of its opinion to product or composition claims where information was the target for the patent claims involved. A necessary function of patents in biotechnology is to encourage researchers to invest resources by providing a mechanism to recoup those costs and potentially make a profit. Attempts to extend the holding to limit isolation from patentability could undermine this purpose. Many areas of medicine, like antibiotics, that necessarily flow from nature are already facing decreasing research. Because of the continued need for antibiotics, an interpretation that would prevent protection of antibiotics would strip away necessary incentives. The Court's holding specifically targets identical information in product claims, and its scope should be reasonably limited with this in mind.

The Court specifically endorsed the patentability of synthesized DNA, even where the function of the synthesized DNA is the same as naturally-occurring DNA. Consequently, courts should focus on human contribution and invention in the field of molecular biology and allow claims for lab-created molecules, even in the event they act like or look like natural DNA.

4. Additional Opportunities to Balance Outlying Issues.—While it is true that the patent system flows from balancing incentives within a given technology and especially within the biotech arena, patent law and the USPTO are not the only necessary considerations. Supporters of the action brought against Myriad applauded the Court's holding and argue that it should be broadly construed and

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144 Id. (describing the failure of researchers to invest in needed antibiotics, largely because of low profitability, and suggesting that increased patent incentives are needed).
applied. However, these arguments often fail to account for resources external to the patent system that can address Myriad’s bad practices. Some problems, like Myriad’s anti-competitive attitude and aggressive enforcement tactics, arise outside the scope of patent law and should not prevent the validity of patents issued to deserving inventors who developed unique ways to test genetic material.

A common-law research exception is used in some jurisdictions to allow non-commercial research uses of patented technology without infringement. Recall that in the cease-and-desist letter Myriad sent, the research exception was referenced when the letter indicated that it did not target non-commercial research activities. However, the exception is narrow and typically only provides for de minimis use of the patented invention. Expanded adoption of this exception in more jurisdictions or statutorily by Congress could bolster the goals of patent law by encouraging additional research on patented technology while still protecting the inventor’s economic interests.

The research exception is supported by the requirement that patent applicants, in return for the possibility of a limited monopoly, are required to disclose their invention to the extent that a person skilled in the art could copy or recreate it. Patent theory suggests that such a disclosure requirement encourages invention beyond already discovered information. Realization of the goal of innovation supports the research exception because through the exception researchers are able to increase knowledge more efficiently.

146 See, e.g., Emily Bazelon, Patently Unfair, SLATE (June 13, 2013, 2:51 PM), http://www.slate.com/articles/news_and_politics/jurisprudence/2013/06/clarence_thomas_opinion_on_myriad_genetics_the_supreme_court_ruled_unanimously.html; Dan Munro, supra note 7.
147 See description of the cease-and-desist letters sent by Myriad to laboratories and other entities supra Part I(b)(3); see also Ass’n of Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 187 (S.D.N.Y. 2010).
148 See Denise W. DeFranco et al., The Experimental Use Exception: Looking Towards a Legislative Alternative, 6 J. HIGH TECH. L. 93, 94 (2006).
149 35 U.S.C. § 112(a) (2013). In the United States Patent Office, most patent applications will be published and publicly available eighteen months after filing, even if the application never results in patent protection for the applicant. § 122(b)(1).
150 See Note, The Disclosure Function of the Patent System (or Lack Thereof), 118 HARV. L. REV. 2007, 2009 (2005) ("[T]he information disclosed in the patent theoretically produces three distinct benefits for the public: helping spur further innovation, reducing wasteful duplicative research, and leading to more efficient investment in innovation.").
151 In fact, under this theory, the research exception has been largely adopted in foreign patent systems. See EVANS MISATI & KIYOSHI ADACHI, THE RESEARCH AND EXPERIMENTATION EXCEPTIONS IN PATENT LAW: JURISDICTIONAL VARIATIONS AND THE WIPO DEVELOPMENT AGENDA, (2010), available at http://unctad.org/en/Docs/ipsres_in20102_en.pdf (quoting WORLD TRADE ORG., WT/DS114/R, CANADA - PATENT PROTECTION OF PHARMACEUTICAL PRODUCTS 165, at ¶ 7.69 (2000), available at http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf) ("[A] key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public.").
without increasing their research costs, through purchasing licenses or otherwise being prohibited from pursuing their research until the twenty-year patent lapses. Patented inventors, however, are still motivated to innovate because they still receive a commercial monopoly in any patented invention they create.

Myriad's uncommon failure to license also led to an unavailability of "second opinions" because Myriad was the only company able to administer the test. A number of options external to the USPTO exist to combat this practice. While uncommon, in instances of a public health crisis, governments are able to require "compulsory licensing" of a patented technology. The United States has been willing to impose compulsory licenses in the past. Accordingly, compulsory licenses remain an option for the courts, and, in reaction to Myriad's bad practices, courts should not dramatically change validity analyses to decrease patent protections that encourage research and development throughout the United States.

Additionally, prior to the filing of Myriad, the Food and Drug Administration ("FDA") announced its intention to begin regulating diagnostic testing. The FDA is responsible for advancing public health and even tracks its origin to a close relationship with the USPTO. The FDA is poised to take on specific challenges with diagnostic testing, and to establish industry practices to support availability and reliability for United States patients.

CONCLUSION

The social contract between inventors, society, and the United States government has motivated Congress to grant limited monopolies to inventors against the public's interest in freely exercising a technology for the sake of encouraging innovation and, therefore, to benefit the public's overall breadth of knowledge. This balance became dramatic when the patent involved key cancer technology that tested a patient's own DNA, and restricted testing to just one


\[154\] See Joanna Thurston et al., Compulsory Licenses: Necessity or Threat?, CHEMISTRY WORLD (May 23, 2013), http://www.rsc.org/chemistryworld/2013/05/compulsory-licence-license-patent-drugs-debate (discussing the international agreement to limit compulsory licenses and their ability to be employed by international governments).


\[156\] See supra Part II(b)(1).


provider – the patentee. The Supreme Court balanced several interests and found that mere isolation of gene sequences is an insufficient contribution as to require the public to give up its rights to accessibility, and now courts must apply the *Myriad* opinion. Where decades of patent practice and important technical knowledge in the art are relevant, courts must additionally apply public policy and law to the pertinent science. In order to best ensure the sustainability of the biotech industry for public healthcare, the Court’s holding against the patentability of isolated, human DNA gene sequences should be narrowly construed. Lower courts should follow the Supreme Court’s indication and support the patentability of human-created gene sequences.
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