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Cover Page Footnote
* J.D. Candidate, 2024, Fordham University School of Law; B.A., Biological Sciences and French, 2016, Cornell University; registered U.S. patent agent. I would like to thank Professor Wendy Luftig for her thoughtful guidance and her class on Pharmaceutical Law, which inspired this Note; the editors and staff of Fordham Intellectual Property, Media & Entertainment Law Journal for their advice and diligent editing work; and my dear family, friends, and colleagues for their unwavering encouragement and support, particularly those that patiently listened to me ramble about Myriad and shared their vast legal expertise with me.

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Silly Gene Patent is Not My Lover: A Retrospective Analysis of *Myriad*

Stephanie Huang*

The U.S. Supreme Court’s decision in Association for Molecular Pathology v. Myriad Genetics, Inc. established that an isolated fragment of a gene—the basic unit of heredity—is not patent-eligible subject matter while simultaneously holding that complementary DNA (cDNA) of a gene is patent-eligible subject matter. The decision has been controversial and criticized for including two holdings that are internally inconsistent from both scientific and patent law perspectives. But are the short- and long-term criticisms overstated? A decade after Myriad, the various impacts of the case remain relevant, particularly to the biotechnology and genetic testing fields.

First, this Note examines whether Myriad was properly decided for isolated genes and cDNA, respectively, under the modern framework for patent-eligible subject matter. Then, this Note argues that the Supreme Court correctly held that isolated human genes are not patent-eligible but wrongly held that cDNA was patent-eligible merely because it is different from its naturally-occurring counterpart. Lastly, this Note explores arguments for and against gene patenting and specifically focuses on the implications of Myriad’s “no gene patenting” holding on subsequent genetic research and diagnostic testing access with the benefit of hindsight.

* J.D. Candidate, 2024, Fordham University School of Law; B.A., Biological Sciences and French, 2016, Cornell University; registered U.S. patent agent. I would like to thank Professor Wendy Luftig for her thoughtful guidance and her class on Pharmaceutical Law, which inspired this Note; the editors and staff of Fordham Intellectual Property, Media & Entertainment Law Journal for their advice and diligent editing work; and my dear family, friends, and colleagues for their unwavering encouragement and support, particularly those that patiently listened to me ramble about Myriad and shared their vast legal expertise with me.
INTRODUCTION

Both historically and in the present, gene patenting stands at the center of a heated debate due the critical importance of genes and deoxyribonucleic acid (“DNA”) to the life sciences as a whole. A gene, as coded by the unique base pairings of four DNA building blocks, generally referred to as nucleotides, is commonly considered a “basic unit of inheritance” containing information that dictates physical and biological traits in humans.\(^1\) This is because parents pass their genes to their offspring and such genes “[encode] the information for making” the proteins that “make up our cells and

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tissues.” At its core, the controversy surrounding gene patenting relates to the question of whether any individual or entity should be able to attain patent rights over a gene, a fragment thereof, or a method for its use. If the answer to that question is “yes,” then such patents would enable the patent holder to assert exclusive rights over a piece of genetic code innately present in all human beings. Nonetheless, with the rise of biotechnology in the 1970s, gene patenting became routine and such patents were regularly granted by the United States Patent and Trademark Office (“USPTO”). In the decade following, the USPTO issued the first gene patent. Since then, the USPTO and gene patent owners have faced patent law-based legal actions against these gene patents, as was the case in Association for Molecular Pathology v. Myriad Genetics, Inc. (“Myriad”). Gene-patenting critics have largely based their challenges on 35 U.S.C. § 101, which defines the four categories of patent-eligible subject matter—processes, machines, manufactures, and compositions of matter—by arguing that genes and byproducts thereof fall beyond the scope of these categories.

Myriad’s decision on gene patenting makes it one of the most controversial and significant Supreme Court cases of the twenty-first century. In that case, the Association for Molecular Pathology (“Association”) and several other medical organizations, physicians, and patients (all organized by the American Civil Liberties Union (“ACLU”)) sued the USPTO and Myriad Genetics. The action challenged the validity of several of Myriad’s patents covering isolated genes called BRCA1 (BReast CANcer gene 1), BRCA2

2 See id.
4 See id.
6 See id. at 161, 176-77.
7 See generally Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013); see also infra notes 11-22 and accompanying text.
9 See, e.g., Ass’n for Molecular Pathology v. U.S. Patent & Trademark Off. (Ass’n for Molecular Pathology II), 653 F. 3d 1329, 1373 (Fed. Cir. 2011) (Bryson, J., dissenting).
(BReast CAncer gene 2), and complementary DNA (cDNA), as well as diagnostic tests for detecting BRCA gene mutations. These isolated genes are important because they are necessary for genetic testing for certain types of breast cancer. Specifically, BRCA1 and BRCA2 are both associated with increased risks of breast and ovarian cancer when mutated. As such, the challenged patents grant Myriad “the exclusive right to isolate an individual’s BRCA1 and BRCA2 genes . . . and to synthetically create BRCA cDNA.”

The district court granted the Association’s motion for summary judgment on the basis that isolating a gene does not make it “markedly different” from genomic DNA (i.e., an isolated gene is equivalent to the naturally-occurring genomic DNA). The Federal Circuit reversed on appeal, holding that isolated genes have chemical structures distinct from genomic DNA. In 2012, the Supreme Court granted certiorari, vacating the Federal Circuit decision and remanding for further consideration in light of the recently-decided case, Mayo Collective Services v. Prometheus Laboratories. On remand, the Federal Circuit found both isolated DNA and cDNA to be patent-eligible. Granting certiorari again, the Supreme Court unanimously held that “genes and the information they encode are not patent eligible . . . simply because they have been isolated from the surrounding genetic material” but cDNA is patent eligible because it is not naturally-occurring. In doing so, the Court affirmed in part and reversed in part.

The public was divided post-Myriad. Many patent professionals objected to the decision based on its potential to stifle innovation,
reverse established precedent, and the practical impact on their livelihoods (i.e., patent prosecution and/or litigation work). However, the scientific community was elated. It argued genetic material should be part of the commons and voiced concern that over-inclusivity of patentable subject matter ties up critical knowledge and prevents patenting of other related but impactful technologies.

The issue explored in this Note is whether Myriad was properly decided for isolated genes and cDNA, respectively, under the modern framework for patent-eligible subject matter. What implications does barring the patentability of isolated genes have on genetic research and testing? This Note will proceed in four parts. Part I will explore the relevant factual background of Myriad. Part II will analyze patent-eligible subject matter and the existing exceptions in Section 101 jurisprudence. Part III will argue that the Court correctly held that isolated human genes are not patent-eligible but wrongly held that cDNA was patent-eligible solely because “it is distinct from the DNA from which it was derived.” Finally, Part IV discusses arguments for and against gene patenting and specifically focuses on the implications of Myriad’s “no gene patenting” holding on subsequent genetic research and diagnostic testing access.

I. FACTUAL BACKGROUND

Breast cancer has long been suspected to be hereditary. Thanks to advances in gene sequencing tools, there was a scientific frenzy in the late twentieth century to identify genes responsible for causing cancer (and other diseases) which led to the discovery of a genetic source for breast cancer. Beginning in the 1970s, University of California Berkeley researcher Mary-Claire King and her team

23 See Contreras, supra note 3, at 3 (“Patent attorneys railed against the Court’s reversal of decades of established patent law and practice.”).
24 Id.
26 Myriad, 569 U.S. at 595.
27 Contreras, supra note 3, at 4.
28 Contreras, supra note 3, at 4–5.
conducted years of research to uncover the gene responsible for breast cancer. While her quest initially appeared futile because the prevailing theory at that point was that viruses caused cancer, in 1990, King’s group published evidence that the gene \textit{BRCA1} mapped to chromosome 17. Chromosome 17 is now known to rank second highest with respect to gene density among the twenty-three pairs of chromosomes in the human genome and is implicated in numerous human genetic diseases. The publication set off a race for both public and private entities to isolate and clone \textit{BRCA1}.

Following King’s publication, Mark Skolnick at the University of Utah co-founded Myriad Genetics, Inc., a private company created with the aim of developing a breast cancer genetic test based on the newly discovered \textit{BRCA1} DNA sequence. Myriad obtained funding and/or access to resources from venture capitalists and pharmaceutical companies like Eli Lilly & Co. In 1994, Myriad isolated and sequenced \textit{BRCA1} and then immediately filed a patent application covering the \textit{BRCA1} sequence. Myriad’s success was partly attributed to the university’s “access to the rich genealogical resources of Utah” and its use of and access to advanced techniques and equipment to facilitate its efforts. Research efforts continued as evidence suggested another gene (\textit{BRCA2}) was also at play, a

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30 Id.
31 Id.
33 Contreras, \textit{supra} note 3, at 6; Dreifus, \textit{supra} note 29.
34 Contreras, \textit{supra} note 3, at 7.
35 Id. at 7–8.
36 Id. at 8.
37 Id. at 8.; \textit{see} Kirk Johnson, \textit{By Accident, Utah is Proving an Ideal Genetic Laboratory}, N.Y. TIMES (July 31, 2004), https://www.nytimes.com/2004/07/31/us/by-accident-utah-is-proving-an-ideal-genetic-laboratory.html [perma.cc/HE7T-PHCW] ("With its emphasis on family records and genealogy, the Mormon church . . . created a [genetic] treasure trove of details about those people . . . . In the 1970’s, researchers at the University of Utah began melding church records with every measure of public health and mortality they could find, creating a vast database . . . that scientists can use to cross-index family trees with cancer clusters and disease patterns and death rates."
suspicion which ignited a second race.\textsuperscript{38} In December 1995, Myriad isolated BRCA2 on chromosome 13 and again, immediately filed a patent application.\textsuperscript{39} This effectively allowed the company to secure exclusive rights to the BRCA2 sequence for itself and its partners.\textsuperscript{40}

It is now known that mutations in BRCA1/2 increase cancer risk, including for breast cancer.\textsuperscript{41} All humans have BRCA1/2 genes, which are tumor suppressor genes that code for proteins that help protect against double-strand DNA damage during DNA replication.\textsuperscript{42} That is, the absence of these genes contributes to the development of tumors that may lead to breast cancer.\textsuperscript{43} Because of BRCA1/2’s role,\textsuperscript{44} any genetic test for diagnosing breast cancer necessarily involves the BRCA genes.\textsuperscript{45} Thus, Myriad found itself rigorously defending and asserting its isolated BRCA1/2 DNA patents while others fought to remove the legal barriers that prevented access to them.\textsuperscript{46} Myriad wasted no time in asserting its patent rights against commercial competitors as well as research and clinical laboratories.\textsuperscript{47} In fact, even King received a cease-and-desist letter from Myriad demanding that she stop her research on BRCA1.\textsuperscript{48} She admits to initially being “relieved when BRCA1 was cloned [because it] meant [they] could get on understanding how mutations in

\textsuperscript{38} Contreras, supra note 3, at 9.
\textsuperscript{39} Id.
\textsuperscript{40} Id.
\textsuperscript{42} See id. at 74 (“Given that BRCA1 and BRCA2 protect the genome from errors that arise during DNA replication, it is logical that cells driven to replicate would develop potentially oncogenic genetic alterations in the absence of BRCA1 and BRCA2 function.”).
\textsuperscript{43} See id.
\textsuperscript{44} Id.
\textsuperscript{45} Contreras, supra note 3, at 16 (noting that the USPTO granted Myriad “thirteen patents covering different aspects of the BRCA1 and BRCA2 genes, including their DNA sequences, the sequences of smaller DNA segments contained within the genes, the principal variants associated with increased cancer risk, methods of locating the genes, and use of the genes as diagnostic tools and screens for the development of drugs”).
\textsuperscript{47} See Cook-Deegan & Niehaus, supra note 46, at 227.
\textsuperscript{48} Dreifus, supra note 29.
it led to breast cancer.”\textsuperscript{49} But to her dismay, “Myriad demanded exclusive use of BRCA1.”\textsuperscript{50} As expected, King was thrilled by the Court’s holding in Myriad which invalidated Myriad’s patents on the gene itself.\textsuperscript{51}

However, the fight did not stop with the Myriad decision. Once the Court decided Myriad, the company’s main competitors Ambry Genetics and Gene by Gene announced they would administer BRCA tests.\textsuperscript{52} Because Myriad still had “over 500 claims in 23 patents, most of which were not challenged by the ACLU,”\textsuperscript{53} it aggressively began asserting those patent rights against competitors offering BRCA testing.\textsuperscript{54} In response, many testing facilities ceased offering the service, and most cases that were being litigated were settled.\textsuperscript{55}

II. PATENT-ELIGIBLE SUBJECT MATTER AND JUDICIAL EXEMPTIONS

35 U.S.C. § 101 defines patent-eligible subject matter, providing that: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”\textsuperscript{56} Despite the broad language of Section 101, it is “not without limit.”\textsuperscript{57} The Supreme Court has long held that certain exceptions (“judicial exceptions”) apply under Section 101; accordingly, laws of nature, natural phenomena (i.e., products of nature), and abstract ideas are not patent-eligible.\textsuperscript{58}

\begin{footnotesize}
\begin{itemize}
\item[49]\textit{Id.}
\item[50]\textit{Id.}
\item[51]\textit{Id.}
\item[52]See Cook-Deegan & Niehaus, \textit{supra} note 46, at 227.
\item[53]\textit{Id.}
\item[54]\textit{Id.}
\item[55]Contreras, \textit{supra} note 3, at 17–18.
\item[56]35 U.S.C. § 101. It is important to note that there are only four statutory categories of invention eligible for patent protection, namely processes, machines, manufactures, and compositions of matter.
\item[58]In other words, these three classes collectively referred to as “judicial exceptions” are “subject matter that the courts have found to be outside of, or exceptions to, the four
\end{itemize}
\end{footnotesize}
Patent-eligibility pursuant to Section 101 has been interpreted by the Supreme Court in several cases throughout the twentieth- and twenty-first centuries. Of particular importance were the quartet of Supreme Court decisions in the 2010s surrounding judicial exceptions and applications thereof. The issues in *Bilski v. Kappos* and *Alice Corp. v. CLS Bank International* related to abstract ideas, while those in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* related to mental steps that applied laws of nature. Here in *Myriad*, the issues involved the product of nature exception.

In *Mayo*, the Supreme Court established a framework for testing whether the invention seeking to be patented was directed toward a Section 101 judicial exception or a patentable application of a judicial exception. The Court in *Alice* further elaborated on the test, though the issue in *Alice* was specifically directed to software and business method claims. This analytical test is referred to as the *Mayo* or *Alice/Mayo* test and is applied irrespective of the statutory category or judicial exception of the claim(s) at issue. Before evaluating a claim for patentability, the “broadest reasonable interpretation of the claim” must be established, and the “claim as a whole” must be considered. Under the *Mayo* test, the first step is to determine whether the claims are directed toward a judicial exception. If so, then step two of the analysis requires determining whether the claim recites additional elements rendering it “significantly more”
than the judicial exception. In other words, the question at step two is whether the additional features cited in the claims are sufficient to “transform” the judicial exception into a patentable application of that exception. The Supreme Court has referred to Mayo step two as the “search for an ‘inventive concept.’”

Prior to the Court’s decisions in Myriad, Mayo, and Alice, however, the USPTO had already granted numerous DNA-based patents based on longstanding common practice. MIT researchers in 2005 claimed that approximately “20 percent of known human genes were patented.” Most of these patented human genes were those responsible for diseases like Alzheimer’s, colon cancer, cystic fibrosis, Huntington’s Disease, and Tay-Sachs. To counter the gene patenting practice, notable efforts including the Human Genome Project (a massive international initiative to map the entire human genome, sequence by sequence) and the Bermuda Principles (an international scientific effort which established rules for publicly releasing all DNA sequences generated as part of the project) arose to encourage the release of DNA into the public domain. Clearly, both sides of the gene patenting debate had been hard at work prior to and during Myriad.

III. WAS MYRIAD RIGHT?

The Myriad decision contained two related but separate holdings. First, the Court held that isolated genes are patent-ineligible. Second, the Court held that cDNA is patent-eligible. Below, I argue that the Court was correct in deciding that isolated genes are
excluded from patent eligibility but wrong in holding that cDNA is patent-eligible.

The Court found that the significance of Myriad’s isolated DNA claims was dependent on the “genetic information” of the naturally occurring gene.\textsuperscript{79} Justice Thomas wrote in the opinion for the Court, “Myriad’s principal contribution was uncovering the precise location and genetic sequence of the \textit{BRCA1} and \textit{BRCA2} genes . . . Myriad did not create or alter either the genetic information encoded in the \textit{[BRCA]} genes or the genetic structure of the DNA.”\textsuperscript{80} He further emphasized that the claims in question “focus on the genetic information encoded in the \textit{BRCA1} and \textit{BRCA2} genes,”\textsuperscript{81} and because they are unaltered, they do not satisfy the Section 101 inquiry.\textsuperscript{82}

Because Thomas does not expressly apply the \textit{Mayo} test in \textit{Myriad}, the analysis stopped there. However, if the test was applied, I analyze that the finding that a naturally occurring segment of DNA is not patent-eligible under Section 101 by virtue of being isolated from the genome in a laboratory setting would remain the same, and rightfully so. This is because under \textit{Mayo} step one, DNA, isolated or not, is a product of nature and therefore any claims directed thereto are directed to a judicial exception. Then, applying \textit{Mayo} step two, I reason that the DNA in question in \textit{Myriad} was merely isolated from the genome and completely unaltered from its natural form in a manner insufficient to transform the DNA segment into something markedly different from its natural counterpart. Thus, my straight-forward application of the \textit{Mayo} test here posits that the Court’s decision would not have changed with respect to an isolated segment of DNA.

However, in its holding regarding cDNA, the Court was incorrect to categorize cDNA differently than isolated DNA segments. Justice Thomas relied on the fact that cDNA, which is an exons-only molecule (i.e., a molecule that only comprises of coding regions),\textsuperscript{83}

\begin{quote}
\textsuperscript{79} \textit{Id.} at 577.
\textsuperscript{80} \textit{Id.}
\textsuperscript{81} \textit{Id.}
\textsuperscript{82} \textit{Id.}
\end{quote}
is not naturally occurring.\textsuperscript{84} Therefore, cDNA was “distinct from the
DNA from which it was derived.”\textsuperscript{85} Consequently, Justice Thomas
concluded that “cDNA is not a ‘product of nature’ and is patent eli-
gible under [Section] 101.”\textsuperscript{86} In fact, he even claimed that a “lab
 technician unquestionably creates something new when cDNA is
made.”\textsuperscript{87} However, it is conveniently forgotten that a mere five
pages earlier in the opinion, Justice Thomas emphasized the critical-
ity of the genetic information.\textsuperscript{88} That is, like isolated DNA, cDNA
also preserves the genetic information in unaltered form.\textsuperscript{89} Here,
Justice Thomas appears to treat cDNA as a patent-eligible chemical
compound subject to human-induced modifications as distinct from
its naturally-occurring DNA counterpart, rather than a mere carrier
of genetic information (which would make it a product of nature).\textsuperscript{90}
However, whether the removal of introns and subsequent fusing of
the isolated exons occurs through the natural processes of a cell’s
molecular machinery or by humans in a laboratory should have no
bearing on the patent-eligibility analysis in this case because the
information contained in the resultant product codes is for the same
protein(s).\textsuperscript{91}

\textsuperscript{84} Myriad, 569 U.S. at 576.
\textsuperscript{85} Id. at 595.
\textsuperscript{86} Id.
\textsuperscript{87} Id.
\textsuperscript{88} See id. at 590–91.
\textsuperscript{89} See Contreras, supra note 3, at 36. (“The same exons occur in both [genomic] DNA
and cDNA in the same order, and both will code the same protein.”).
\textsuperscript{90} For instance, Justice Thomas contends, “creation of a cDNA sequence . . . results in
an exons-only molecule that is not naturally occurring.” Myriad, 569 U.S. at 594. In doing
so, he is effectively highlighting the chemical differences between genomic DNA and
cDNA (i.e., the former is held together by covalent bonds given by “nature” and includes
introns, while the latter has human-induced covalent bonds and excludes introns) while
minimizing that the genetic information found in cDNA preserves that coded in its genomic
counterpart.
\textsuperscript{91} See Contreras, supra note 3, at 36–37. (This is a similar argument to the one Contreras
makes: “[I]f differences like covalent bonds [the breaking of which Justice Thomas holds
immaterial to the information content of the genes] and attached molecules do not make
isolated DNA markedly different from cellular DNA, then why does the absence of introns
distinguish cDNA from gDNA? After all, just like the missing covalent bonds in isolated
DNA, introns are not relevant to the coding function of a gene . . . . [The] body’s DNA
replication process nicely ignores those introns and replicates the information only from
the exons. So, if we ignore covalent bonds to reason that isolated DNA is not patentable,
then why don’t we also ignore the absence of introns in cDNA?”).
If the Mayo test was applied to cDNA, the Court’s finding that cDNA was patent-eligible under Section 101 in Myriad would have come out differently. Here, Mayo step one would similarly flag that cDNA is directed to a product of nature, and thus falls into a judicial exception, therefore channeling the analysis to step two. At step two, any additional elements distinguishing DNA from cDNA should not be enough to render cDNA markedly different from its naturally occurring counterpart. The DNA was merely isolated from the genome and subjected to routine techniques widely known by the scientific community to selectively bond coding regions of a gene to create cDNA, thereby leaving the genetic information contained in genomic and isolated DNA completely preserved. While cDNA may not be naturally occurring per se, it also does not possess markedly different characteristics from its naturally occurring counterpart because the main characteristic of DNA is the information encoded to translate into proteins—and cDNA preserves just that. Thus, cDNA should also fail the Mayo test and should not qualify as patent-eligible subject matter.

Therefore, the two holdings of Myriad are internally inconsistent from purely scientific and patent-law-focused perspectives. But the reality is that this space is extraordinarily complex, and the Court is trying to use Myriad as a “policy lever that toggles between encouraging two different types of research. Maintaining isolated DNA in the public domain may promote more basic research . . . [and] facilitate research insights that arise from widespread diagnostic testing.” Meanwhile, cDNA is often associated with commercial research, particularly “for commercially expressing therapeutic proteins.” Yet, the Court undervalued the potential for the significant impact that cDNA may serve. For example, scientists use cDNA to “create animal models of disease, such as fruit flies with cDNA disease genes that facilitate research on neurodegenerative

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94 Lee, supra note 25, at 1096.
95 Id. at 1098.
conditions." Unfortunately, the full impact of Myriad’s cDNA holding is difficult to gauge today partially because the decision “merely maintains the status quo.” Instead, the Court appeared to try to appease both parties by giving each side a holding to be happy about. By considering policy, the Myriad Court bent over backwards in the odd, second half of its opinion to justify why cDNA should be patentable while ignoring its rationale employed in the first half to explain why isolated DNA is not.

However, despite the Court’s insistence that cDNA is patentable subject matter under Section 101 jurisprudence, the USPTO ultimately should have rejected Myriad’s patent applications during patent prosecution. Next, I argue that while Myriad’s patent applications would not have been rejected by the Patent Office under 35 U.S.C. § 102, they certainly should have been rejected under 35 U.S.C. § 103. Section 102 elaborates on the conditions for patentability as it relates to the novelty requirement. Section 102 provides:

A person shall be entitled to a patent unless—
(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
(2) the claimed invention was described in a patent issued . . . or in an application for patent published or deemed published, . . . in which the patent or application . . . names another inventor and was effectively filed before the effective filing date of the claimed invention.

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96 Id.
97 Id.
98 For the avoidance of doubt, the Myriad Court rejects Myriad’s composition of matter claims directed to isolated DNA on the basis that they were products of nature and thus directed to patent-ineligible subject matter, but then holds that Myriad’s claims covering cDNA are valid because cDNA does not occur naturally and are thus directed to patent-eligible subject matter. See Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 590–595 (2013).
99 See id.
101 Id.
Generally, under Section 102, a patent cannot be obtained for an invention if a disclosure thereof is available to the public prior to filing a patent application for the invention.\textsuperscript{102} This is because patents are only granted if the invention is novel (per the novelty requirement embodied in Section 102) and an invention is no longer new or novel when it or knowledge of it already exists in the public domain. In Myriad’s case, because the company and its collaborators were the first to sequence \textit{BRCA1} in the world\textsuperscript{103} and \textit{BRCA2} in the United States,\textsuperscript{104} there was no prior public knowledge of the sequences in such detail. Thus, the sequences and byproducts thereof (e.g., cDNA) would be considered novel for purposes of the novelty inquiry. Thus, Myriad’s creation of cDNA would have passed the novelty requirement in the first instance.

However, despite passing the Section 102 requirement, the claims would still need to pass the Section 103 nonobviousness requirement.\textsuperscript{105} Section 103 provides that:

> A patent for a claimed invention may not be obtained . . . if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.\textsuperscript{106}

Here, Myriad’s claims directed at cDNA should have been deemed obvious because neither cDNA nor the techniques used to splice introns and merge exons into cDNA were new concepts at the time of Myriad’s first patent application filings.\textsuperscript{107} Public

\textsuperscript{102} Id.

\textsuperscript{103} See Contreras, supra note 3, at 8.

\textsuperscript{104} Id. at 9. Note that the race to sequence \textit{BRCA2} was very tight between Myriad’s team and a team lead by Michael Stratton at the Institute for Cancer Research in London. The two teams announced their respective successes in isolating the gene within a day of one another. Id.

\textsuperscript{105} 35 U.S.C. § 103.

\textsuperscript{106} Id.

\textsuperscript{107} See generally U.S. DEP’T OF ENERGY, supra note 93.
knowledge combined with “common sense” or expertise expected of a “person of ordinary skill in the art” at the time of filing the patent application in question, such as applying conventional techniques like the use of a reverse transcriptase enzyme on a messenger RNA (mRNA) molecule to make cDNA, would suffice to bar patentability. Further still, because introns are known to be non-coding regions of DNA and the human cellular machinery naturally splices them out to produce proteins, it should have been obvious to do so in the laboratory. Thus, Myriad’s claims directed to cDNA should not have been granted under the nonobviousness inquiry. Additionally, the USPTO should not allow claims directed at cDNA during prosecution based on nonobviousness moving forward.

Support for this approach is echoed in the Manual of Patent Examining Procedure (“MPEP”), a manual published by the USPTO to provide patent examiners, patent practitioners, and applicants/inventors with procedural and substantive guidance. The MPEP reminds patent examiners that Section 101 “is not the sole tool for determining patentability; [35 U.S.C. §§ 112 (indefiniteness requirement), 102, and 103] will provide additional tools for ensuring that the claim meets the conditions for patentability.” This is similarly stated by the Court in Bilski:

The § 101 patent-eligibility inquiry is only a threshold test. Even if an invention qualifies [as patent-eligible subject matter], in order to receive the Patent Act’s protection the claimed invention must also satisfy the [requirements including] that the invention

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108 See MPEP § 2141.
109 In patent law, a “person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the relevant time.” See MPEP § 2141.03 at pt. I. A number of factors are typically considered in determining what level of skill such a person would have at the time the patent application is filed, including the type of problems encountered in the art and the educational level of active workers in the field. See id.
110 See U.S. Dep’t of Energy, supra note 93, at 8 (showing that synthesis of cDNA was common knowledge at least since 1992, approximately three years prior to Myriad’s filing of the oldest of the patents at issue in Myriad).
113 See id. § 2106(1).
be novel, see § 102, nonobvious, see § 103, and fully and particularly described, see § 112.\textsuperscript{114}

As such, Section 101 was intended only to screen for patentable subject matter. Accordingly, gene-derived claims with significant scientific value should be rejected by the USPTO under Sections 102 and/or 103 with the goal of keeping such discoveries in the commons.

IV. TO BE PRO-GENE PATENTING OR NOT TO BE

A. Arguments For Gene Patents

It is worth noting that, practically speaking, the Supreme Court’s holding in \textit{Myriad} has only had a minor impact as it was specifically limited to Myriad and those patents challenged by the Association.\textsuperscript{115} Additionally, even if the patents in question were held to be valid, they would have expired in 2015, only two years after the case was decided, and many of Myriad’s other patents are not directed to isolated DNA, anyway.\textsuperscript{116} Nevertheless, this fact did not prevent mass debate following the Court’s decision and speculation about the potential impacts on research.\textsuperscript{117} Now, a decade after \textit{Myriad}, I will explore and analyze arguments from both sides.

1. Patent Law as a Balancing Act

There are many arguments for and against gene patents. However, the heart of the debate is simply based on the age-old dichotomy within patent law. The courts have consistently and repeatedly emphasized that patent law requires a fine balancing act between “creating ‘incentives that lead to creation, invention, and discovery’ and ‘imped[ing] the flow of information that might permit, indeed

\textsuperscript{115} See Lee, \textit{supra} note 25, at 1081.
\textsuperscript{116} \textit{Id.}
\textsuperscript{117} See generally \textit{Id.}
Preemption is the predominant concern. Courts seek to avoid the risk of “disproportionately tying up the use of the underlying” principles or matter that should rightfully belong to and be free for all of mankind to use. This balancing act either visibly plays out or is echoed in almost all notable cases regarding patent-eligibility.

Pro-gene-patenting advocates articulate many reasons for why the Court should have followed precedent and USPTO common practice by continuing to allow patents on human genes. First, some argue that overall, fewer patenting efforts in this area may impact scientific advancement negatively. They assert that patent law is not concerned with promoting equitable access to genetic tests and so the patent system should not be held responsible for such downstream effects. The patent system does, however, concern itself with the primary purposes of protecting and rewarding inventors who have made patent-eligible findings with exclusive rights in exchange for detailed disclosure of the invention to the public. Without the patent incentive, many fear that individual researchers or institutions would be inclined to keep both big and small discoveries to themselves as trade secrets.

Footnotes:
119 See, e.g., Bilski, 561 U.S. at 611–12 (holding that upholding the patent in question “would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea”).
120 Mayo, 566 U.S. at 77 (2012); see also Gottschalk v. Benson, 409 U.S. 63, 67 (1971) (“Phenomena of nature, . . . mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”).
121 See, e.g., Myriad, 569 U.S. at 590; Bilski, 561 U.S. at 648; Mayo, 566 U.S. at 71–72.
122 See Contreras, supra note 3, at 10 (“Representatives of the biotech industry . . . argued that patents on genes should be encouraged because they could foster new businesses and fuel the discovery of drugs and diagnostic tests.”).
123 Lee, supra note 25, at 1079.
124 See, e.g., 35 U.S.C. § 112(a) (“The specification . . . shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.”)
125 Lee, supra note 25, at 1097 (“[P]atents on inputs to scientific experimentation may contribute to a culture of secrecy within academia . . . ”).
126 Id. at 1088.
Further, 35 U.S.C. § 112(a) codifies the best mode requirement, which mandates that the specification of the patent application “set forth the best mode contemplated by the inventor . . . of carrying out the invention.” This statutory requirement safeguards against the human desire to “obtain patent protection without making a full disclosure as required by the statute. The requirement does not permit inventors to disclose only what they know to be their second-best embodiment, while retaining the best for themselves.” While scientists may still release their gene discoveries in journals or at conferences, for example, such forms of disclosure by themselves are not within the purview of patent law because engaging in them would not advance a scientist’s goal to obtain a patent. The fact that patent law does not extend to such forums of invention sharing could motivate researchers to share only their second- or third-best embodiments. This is considered to be detrimental to the advancement of science.

Second, advocates of gene patents maintain that there is evidence that patents do not actually inhibit research as much as scientists fear. For one, a “de facto experimental use exception operates whereby patentees rarely sue basic researchers—especially university scientists—for patent infringement . . . [because of the] absence of significant monetary damages, fear of undermining potential licensing relationships, and concerns about harming public relations all dissuade patentees from suing universities.” Patents also do not impose as great of an inhibitory force on research as expected because researchers consciously choose to ignore them. This way of working based on a “norm of ignoring patents” helps scientists to work around potential inhibitory effects of existing patents. However, it is worth noting that companies like Myriad still have a

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127 35 U.S.C. § 112(a); MPEP § 2165.
128 MPEP § 2165. An example of a case where the best-mode requirement was not satisfied is Dana Corp. v. IPC Ltd. P’ship, 860 F.2d 415 (Fed. Cir. 1988), where “the inventor failed to disclose whether to use a specific surface treatment that he knew was necessary to the satisfactory performance of his invention, even though how to perform the treatment itself was known in the art.” MPEP § 2165.04 (II).
129 See Lee, supra note 25, at 1091–94.
130 See Lee, supra note 25, at 1091.
131 See Lee, supra note 25, at 1092.
132 See Lee, supra note 25, at 1092
number of enforceable patents on hand, i.e., patents which could be used to bring an infringement suit. After all, it is clear that opting not to assert one’s patent rights does not mean such exclusive rights cannot and will not be asserted at a later date if things were to go awry.

2. (Patent) Money Talks

Rather than inhibiting research, maintaining isolated DNA as patent-eligible subject matter arguably “would actually lead to a net increase in scientific research,” because the financial benefits that come directly or indirectly from patent protection can be substantial. The general biotechnology industry stance is that gene patenting should be allowed, and in fact encouraged, to “foster new businesses and fuel the discovery of drugs and diagnostic tests” as well as new gene sequences. To start, patents in biotechnology and downstream fields serve to draw in capital investments from, and/or partnership opportunities with, other companies and institutions. For instance, “companies have invested heavily in developing the clinical evidence base for diagnostics to exploit a strong IP position based on exclusive licenses to DNA patents” because possession of granted patents can influence significant investments

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133 See id. at 1081 (noting that about three-fourths of Myriad’s BRCA-related patent portfolio was directed to cDNA, probes, and methods that were left untouched by the Myriad decision—meaning these patents were still valid and therefore could be used against others, unless invalided by subsequent litigation.).

134 See id. at 1082 (“Myriad has long maintained that it allows ‘research’ . . . uses of its patents to proceed.”). But see id. at 1088 (In “diagnostics, . . . patentees (like Myriad Genetics itself) have aggressively asserted exclusive rights.”). The contrast in Myriad’s approach for academic/non-commercial use of its BRCA-related patents with commercial use thereof illustrates that patent enforcement is a choice by the patent holder.

135 Id. at 1095.

136 See id. at 1095–96.

137 Contreras, supra note 3, at 10.

138 See Lee, supra note 25, at 1096.

139 See Cook-Deegan & Niehaus, supra note 46, at 224.

140 See Contreras, supra note 3, at 7–8 (Myriad “benefitted from access to high-throughput sequencing equipment acquired by its partner Eli Lilly,” a pharmaceutical giant that also financially supported Myriad in exchange for “Myriad stock and the exclusive right to commercialize Myriad’s discoveries in the area of breast cancer therapeutics.”).

141 Michael M. Hopkins & Stuart Hogarth, Biomarker Patents for Diagnostics: Problem or Solution?, 30 NATURE BIOTECH. 498, 499 (2012); see also Lee, supra note 25, at 1096.
from other entities. In most cases, the gene-related discoveries that occur are “based on publicly funded research conducted at hospitals, non-profit research institutes, or academic health centers.” Patents may also be licensed to other entities in exchange for royalty fees, and companies with such licenses may use the patented inventions to further develop commercial products and services. All such revenue can fund more research, both basic and commercial.

In addition, emerging fields, such as molecular diagnostics, could benefit from additional protections and the monetary incentives imparted by patents. The U.S. Food and Drug Administration (“FDA”) requires molecular diagnostics to undergo strict clearance approvals (a process that could cost a company millions of dollars), which could effectively deter smaller laboratories or startup companies from seeking FDA approval for their tests. The patent incentive may help to “spur more targeted research by parties who are incentivized by exclusive rights to discover new gene sequences and perform applied research to translate them into commercial diagnostic tests.” Maintaining at least the possibility of obtaining exclusive rights through patents could thus motivate researchers to both embark and continue on the journey that could eventually lead to commercially available tests accessible to both testing providers and patients alike. Thus, the main takeaway here is that patents are capable of drawing in significant resources for the patent owner, such as royalty fees and public and/or private investments, which can then help to fund further research initiatives. Conversely, a lack

142 Contreras, supra note 3, at 14 (“External investors—venture capitalists and, at a later stage, investors in public markets—would provide the capital necessary to fund the commercial growth of the company.”).
143 Cook-Deegan & Niehaus, supra note 46, at 224.
144 See id.
146 See id. (For example, “[i]t may cost up to $20 million to get pre-market approval for a molecular-based companion diagnostic.”).
147 Lee, supra note 25, at 1096.
of patent protection on isolated genes post-Myriad could decrease research opportunities in this area.

3. A Myriad of Genetic Tests on the Market

Finally, many believe that foreclosing gene patenting encourages competition, which then “pushes down test pricing to unsustainable levels.”\textsuperscript{148} If this were the case, the diagnostic testing market would then be saturated with an excess of testing options.\textsuperscript{149} In 1996, a complete BRCA1/2 sequence test from Myriad cost $4,040.\textsuperscript{150} After Myriad, the prices of comparable tests, for instance, were $3,350 from Ambry Genetics (as of June 13, 2014), $2,200 from the University of Washington (as of June 14, 2014), and $2,895 from LabCorp (as of December 2, 2013), while institutional offerings may have cost even less.\textsuperscript{151} If genetic testing becomes too unprofitable, companies may be reluctant to invest further (or at all) in developing new genetic tests and improvements thereof. Potential negative effects of this reluctance are decreased quality of available genetic tests and the number of providers offering testing services. However, the concept of the “Iron Triangle” in healthcare (i.e., that access, price, and quality cannot all be simultaneously improved) dictates that access will be improved as costs, and potentially quality, decrease.\textsuperscript{152} Consequently, patients could have greater access to tests when more competitors make and/or offer genetic tests and would be more likely to afford associated costs of testing when increased competition in the genetic testing market drives prices down. However, the quality of the tests themselves might be inferior

\textsuperscript{148} O’Connor, supra note 145.

\textsuperscript{149} See id. (“The breadth of new entrants into the omics and molecular diagnostics space since the Supreme Court decisions created competition that has driven down costs and made substitute tests available. To continue to differentiate offerings, labs developed next-generation sequencing tests and launched larger panels, providing increased access to new people.”).

\textsuperscript{150} Cook-Deegan & Niehaus, supra note 46, at 228 tbl.1.

\textsuperscript{151} Id. at 229–39 tbl.1.

because a company making less profit on a product is also less likely to invest that profit back into improving its quality.\textsuperscript{153}

\textbf{B. Arguments Against Gene Patents}

1. This Gene is Your Gene, and This Gene is My Gene

Of the arguments against gene patenting, the most prevalent is that overly broad patent claims preempt future research because scientific progress is cumulative.\textsuperscript{154} The Association and \textit{Myriad amici} (including the National Research Council, the American Medical Association, the National Women’s Health Network, and leading physicians and geneticists) arguing against gene patenting encourage the release of all human DNA sequences for public use.\textsuperscript{155} In their view, genetic information belongs to all and should not be owned by any individual or institution.\textsuperscript{156} They argue that DNA is part of the “common heritage” of humans.\textsuperscript{157} They praise \textit{Myriad} for “ensur[ing] that direct research on isolated DNA can proceed without a license.”\textsuperscript{158} Specifically, all researchers could freely study the \textit{BRCA1/2} genes without worrying about potential patent infringement of the claims at issue in \textit{Myriad}. When its gene patents were in force, Myriad’s cease-and-desist letters forced many laboratories or providers to pivot or completely discontinue any \textit{BRCA} testing services.\textsuperscript{159} Thus, gene patents are rightfully foreclosed to ensure public access to human genes.

\begin{flushleft}
\textsuperscript{153} See id. (For quality, “you generally get what you pay for and high quality is generally expensive.”).
\textsuperscript{154} See Lee, supra note 25, at 1088.
\textsuperscript{155} See id. at 1079; Contreras, supra note 3, at 10.
\textsuperscript{158} Lee, supra note 25, at 1086.
\textsuperscript{159} Contreras, supra note 3, at 18.
\end{flushleft}
2. A-Thicket, A-Tasket

An additional argument against gene patenting relates to the phenomenon known as patent thickets, which are “dense web[s] of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology,” typically by obtaining licenses from one or more patent owners. A patent thicket in the industry often involves a strategy of filing numerous patent applications (often continuation applications) for essentially the same invention with minor improvements or modifications to extend the duration of patent protection for a product.

In the case of Myriad’s patent thicket, the company obtained thirteen patents:

[C]overing different aspects of the BRCA1 and BRCA2 genes, including their DNA sequences, the sequences of smaller DNA segments contained within the genes, the principal variants associated with increased cancer risk, methods of locating the genes, and use of the genes as diagnostic tools and screens for the development of drugs.

The Myriad decision helps to discourage stagnating research and development efforts that would have otherwise occurred because competitors can now actively research BRCA in the absence of exclusive patents locking it up. Additionally, foreclosing human genes as patent-eligible subject matter definitively deprives entities of the ability to create patent thickets around human genes, which

160 Carl Shapiro, Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting, 1 INNOVATION POL’Y & ECON. 119, 120 (2001); Lee, supra note 25, at 1089 (defining patent thickets as a phenomenon wherein “multiple overlapping patents cover a single technology.”).


162 Contreras, supra note 3, at 16.

163 See Cook-Deegan & Niehaus, supra note 46, at 224 (“The recent court rulings thus clear the path for unfettered pursuit of whole-genome analysis and multi-gene methods.”).

164 This is simply a logical extension of the fact that genes are patent-ineligible subject matter. It is much more difficult, if not near impossible, to build a patent thicket around a human gene when the building blocks of such a patent thicket (i.e., a gene patent) are unobtainable.
has the effect of forcing additional creativity and innovation on the part of researchers from all sides to arrive at patent-eligible inventions. Patent thickets are problematic because it is always easier for an entity to file another patent application and prosecute it than to make another groundbreaking discovery or develop another blockbuster product.\footnote{See, e.g., Jonathan Gardner, A Three-Decade Monopoly: How Amgen Built a Patent Thicket Around Its Top-Selling Drug, BIOPHARMA DIVE (Nov. 1, 2021), https://www.biopharmadive.com/news/amgen-enbrel-patent-thicket-monopoly-biosimilar/609042/ [perma.cc/LWW4-GSMU]. Matthew Lane, executive director of the Coalition Against Patent Abuse, for example, has said that it is “easier to keep the monopoly [through patent protection] on an old one than it is to find a new blockbuster drug . . . . The cost to pay patent attorneys to file applications is a drop in the bucket” compared to the money and time that research and development would have to invest. \textit{Id}. \footnote{See Cook-Deegan & Niehaus, supra note 46, at 224; see also Lee, \textit{supra} note 24, at 1093.}}

Thus, the \textit{Myriad} decision against gene patenting may actually stimulate and encourage research and innovation because the holding discourages patent holders from becoming complacent with the intellectual property protection that they currently have on an invention.

3. A Myriad of Incentives?

Next, some argue that the incentive aspect of patents is exaggerated.\footnote{Cook-Deegan & Niehaus, \textit{supra} note 46, at 224} Some note that the “patent incentive is relatively weak as a ‘pull’ for initial discovery” of genes.\footnote{Diamond v. Chakrabarty, 447 U.S. 303, 318 (1980) (The Court in \textit{Chakrabarty} held that human-made bacteria was patent-eligible subject matter under Section 101 because it constituted a “manufacture” or “composition of matter.”).} In fact, in 1980, the Supreme Court in \textit{Diamond v. Chakrabarty} quelled unfounded fears at the time that the lack of patent incentive would stymie research in the relevant field:

\begin{quote}
The grant or denial of patents . . . is not likely to put an end to genetic research or its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter
\end{quote}
the scientific mind from probing into the unknown any more than Canute could command the tides.\textsuperscript{169}

The Advisory Committee for Genetics Health and Society has also concluded that patent rights are “neither necessary nor sufficient conditions” for the development of genetic tests.\textsuperscript{170} Moreover, most empirical research shows that there is “little to no inhibitory effect” of DNA patents on later scientific research efforts.\textsuperscript{171} Further still, patents are not the only incentive system in place. For academic science, where substantial amounts of genetic discoveries are made, “public funding, professional rewards, and scientific norms of discovery already provide robust incentives for invention, thus undermining the justification for exclusive rights.”\textsuperscript{172} Thus, the \textit{Myriad} holding that genes are patent-ineligible subject matter should not impede gene discovery efforts or development of genetic tests because patents were not a major driving force in the field to start.

A post-\textit{Myriad} case to be considered is the 2014 Federal Circuit decision in \textit{In re Roslin Institute (Edinburgh)}.\textsuperscript{173} The invention at issue in \textit{Roslin Institute} was a breakthrough somatic method of cloning mammals\textsuperscript{174} famous for successfully producing Dolly the Sheep, the first mammal ever cloned from adult somatic cells in 1996.\textsuperscript{175} By definition, a clone is an “identical genetic copy of a cell, cell part, or organism.”\textsuperscript{176} While acknowledging the significance of the discovery, the Federal Circuit held, however, that the method was not

\textsuperscript{169} Id. at 317.


\textsuperscript{171} Lee, supra note 25, at 1088. \textit{But see} id. at 1088–89 (noting the specific situation where “a patent on an indispensable resource for where there are no substitutes may impede biomedical research. For example, the Wisconsin Alumni Research Foundation’s patents on extracted and purified human embryonic stem cells . . . as there is no scientifically adequate substitute for this biological entity.”).

\textsuperscript{172} Id. at 1096.

\textsuperscript{173} In re Roslin Inst. (Edinburgh), 750 F.3d 1333, 1333 (Fed. Cir. 2014).

\textsuperscript{174} Id. at 1334; see U.S. Patent No. 7,514,258.

\textsuperscript{175} In re Roslin Inst. (Edinburgh), 750 F.3d at 1334.

\textsuperscript{176} Id.
It is unclear why the Federal Circuit considered the routine process of breaking and forming covalent bonds to create cDNA enough to render the otherwise unaltered genetic material patent-eligible subject matter a mere two years earlier, but not a complex somatic method of cloning. Myriad illustrates the difficulty in drawing a clear distinction between patent-eligible technologies and patent-ineligible products of nature. Therefore, some speculate that the Court’s attempt to keep the distinction flexible may invite future challenges to other patents.

Roslin Institute also begs the question of whether the court’s decision has any implications on biomedical substitutes for human organs (i.e., artificial organs) created from human cells and tissue because, in theory, the resultant organs must be essentially identical to their naturally occurring counterparts to resist transplant rejection. Since the cloning of whole sheep has been deemed patent-ineligible, are inventions like laboratory-engineered livers and hearts as well? Based on the Supreme Court’s decision in Myriad, the answer is no: an “artificial but otherwise-found-in-nature” invention is not patentable. But would such a prospect stymie biomedical research in this area? The answer is also thought to be no. Societal needs, such as those for new diagnostic tests or bio-compatible artificial organs, will dictate where the demand for

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177 Id. at 1337.
178 Ass’n for Molecular Pathology v. U.S. Patent & Trademark Off., 689 F.3d at 1329.
179 In re Roslin Inst. (Edinburgh), 750 F.3d at 1337.
180 Lee, supra note 254, at 1108.
181 See Contreras, supra note 3, at 32.
182 See generally In re Roslin Inst. (Edinburgh), 750 F.3d 1333.
183 Contreras, supra note 3, at 32. The Federal Circuit also affirmed this rationale in cases following Myriad. See id.; In re BRCA1–& BRCA2–Based Hereditary Cancer Test Patent Litig., 774 F.3d 755, 760 (Fed Cir. 2014) (holding that synthetic DNA primers are not patent-eligible subject matter because they are “structurally identical to the naturally occurring compositions”).
184 See Contreras, supra note 3, at 33 (“[B]ecause of market demand, manufacturers have continued ample market incentives to keep developing even better methods of production, whether these are superior in terms of speed, cost, sustainability, worker safety, or anything else.”). Similar to market demand reasoning, I think the need for new and improved diagnostic tests will counter potential disincentivizing effects from the patent system.
research is and innovation, therefore, should organically follow irrespective of the possibility of obtaining patents.

Now, it could be argued that while genes themselves are patent-ineligible, the decision does not discourage patenting or prevent applicants from submitting creative patent applications on cDNA and/or potentially “sufficiently transformed” versions of isolated DNA. Pursuant to 35 U.S.C. § 122(b)(1)(A), patent applications are automatically published into the public domain eighteen months after filing\(^\text{186}\) unless exempted under 35 U.S.C. § 122(b)(2).\(^\text{187}\) Thus, inventors who attempt to patent their inventions are still required to publicly disclose, for example, their best mode of use in compliance with the aforementioned Section 112 best mode requirement,\(^\text{188}\) thereby perpetuating one of the primary purposes of the U.S. patent system.

It is also worth noting that a portion of applications are filed defensively, not offensively.\(^\text{189}\) Defensive patenting involves filing patent applications for the sake of providing the applicant protection from others operating in the same technical field, rather than being intended for active use to sue competitors for infringement.\(^\text{190}\) Even if the USPTO ultimately does not grant a defensive patent application, the publication requirement embodied in 35 U.S.C. § 122(b)(1)(A) is enough to prevent competitors from obtaining later-filed patents on the same or a similar invention under Sections 102 and/or 103.\(^\text{191}\) Therefore, *Myriad* should not generally impede the filing of patent applications as some applications are filed defensively anyway.

\(^{186}\) 35 U.S.C. § 122(b)(1)(A) (“[E]ach application for a patent shall be published, in accordance with procedures determined by the Director, promptly after the expiration of a period of 18 months from the earliest filing date.”).


\(^{188}\) 35 U.S.C. § 112(a); see also discussion *supra* Part IV.A.


\(^{190}\) *Id.*

\(^{191}\) 35 U.S.C. §§ 102–03; see also discussion *supra* Part III.
4. The Myriad Impacts of *Myriad* on Genetic Testing

This Section examines the impact of the *Myriad* decision on genetic testing. The decision in *Myriad*, in conjunction with *Mayo*, encourages competition and innovation in molecular diagnostics and omics by removing “gene patents as a legal barrier to large-scale sequencing.” Critics against gene patenting argue that the foreclosure of gene patenting opens the door for substitute testing options from competitors, thereby driving down the costs to patients and medical providers. According to them, an increase in testing will also help to “reveal more genetic variants and provide insights into their biological significance” thanks to the resulting increase in sample size and corresponding data. This could reveal new information to be shared on ClinVar, a public database funded by the National Institutes of Health (“NIH”). Currently, however, Myriad and its patent licensees have exclusive access to Myriad’s proprietary database containing valuable data on *BRCA* mutations, which in 2015 contained at least 300,000 cases and is protected by the company as a trade secret. The wider scientific community could substantially benefit from access to Myriad’s “most valuable asset” to collaborate on the “cataloging and interpreting” of

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192 *Omic*, MIT BIOLOGICAL ENG’G, https://be.mit.edu/research-areas/omics [https://perma.cc/R8FP-6MLY] (last visited Oct. 30, 2023) (Omics refers to “the field of research analyzing and [integrating] studies of many different -omes, including the genome, proteome, and metabolome, generally using bioinformatics and computational biology.”).

193 O’Connor, supra note 145.

194 Id.; see also supra notes 148–49 and accompanying text.

195 Lee, supra note 25, at 1087.


197 Lee, supra note 25, at 1087.

198 Id. at 1110.

199 Id.
mutation variants. Together, these concerted efforts could help advance understanding in this area at a much faster speed than would otherwise be possible. There have been calls from leading medical organizations to have Myriad and other labs share their variant classification data, however, Myriad has yet to do so on ClinVar.

With respect to the pro-gene patenting argument that an experimental use exception for academic research exists (i.e., that patent owners may opt out of enforcing their patents against academic researchers conducting basic scientific research), there is no such equivalent for genetic testing. Using Myriad’s cease-and-desist crusade discussed in Part I as an example, patent owners tend to aggressively enforce their patent rights against both commercial competitors and academic researchers alike in the genetic testing space. This has had a detrimental impact on commercial testing activity. To avoid any potential trouble, a testing facility would most likely discontinue offering such services upon receiving a cease-and-desist letter because “diagnostics produce relatively low profits.” In fact, one study found that “twenty-five percent of clinical laboratories stopped performing a clinical genetic test because of patent concerns, and fifty-three percent did not develop a new test because of such concerns.” Because genetic testing in clinical settings also generates data from which “fundamental biological knowledge” may be gleaned, such inhibitory effects of gene patents on testing do in fact impact scientific progress.

Further, critics against gene patents argue that such patents, when given to a single company or multiple companies, for instance, could prevent competitors from offering substitute tests and/or testing services. Under this view, exclusive rights obtained through patents can lead to increased “cost[s] of testing, hampered

200  Id. at 1087.
201  Marcus, supra note 196.
202  See Lee, supra note 25, at 1092 (“[C]ommercial diagnostic testing . . . is not subject to the de facto experimental use exception.”).
203  See discussion supra Part I.
204  See Lee, supra note 25, at 1092.
205  Id. at 1094.
206  Id.
207  Id. at 1095.
208  Id. at 1079.
verification of test results,” and fewer substitute tests commercially available to consumers. At such a crossroads, it appears that competing entities attempting to enter the testing market must conduct a cost-benefit analysis of whether they wish to negotiate (i.e., pay) for patent licenses, which could be costly, or stay out of the market altogether. Because “diagnostics produce relatively low profits,” the latter is more likely to occur. Here, the lack of competition, or even the existence of a monopoly, could increase pricing for tests due to the absence of substitute options on the market. In other words, companies could charge more for each test simply because they can; there is no incentive for them to make their products more affordable in the absence of competition. Then, the “Iron Triangle” predicts that an increase in price will decrease overall patient access to tests. This could further impact the quality of the available test either positively or negatively: quality could improve because companies with patent protection are given such a monopoly of the market that they can further invest funds into the research and development of better diagnostics; conversely, quality could decrease if the companies become complacent due to their exclusive market position and decide to cut corners in producing the tests. Overall, under this view, the consequence is that a lack of active competition due to excessive protection granted by isolated DNA patents could increase costs, which would likely reduce the number of patients able to afford genetic testing, and thereby decrease access to tests.

5. I Gotta Myriad of Feelings

Lastly, from a purely moral perspective, the human instinct is to argue that patenting a gene is wrong because it feels wrong. It also feels wrong when researchers, like King, whose life work is directed to a judicial exception and thereby statutorily barred from obtaining patent protection, are later threatened or prevented from continuing their research projects by downstream entities that benefited from the researchers’ discoveries. Myriad would not have gotten to where it was without King’s contributions in the first place, so one’s

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209 Id.
210 Id. at 1094.
211 Lewis, supra note 152.
212 See discussion supra Part II.
gut instinct is to say that it is wrong to reward entities like Myriad, especially when that reward comes at the expense of other equally, if not more, deserving researchers.

**CONCLUSION**

Nearly ten years after the Supreme Court decided *Myriad*, the holding that isolated DNA segments are not patent-eligible subject matter under the Section 101 inquiry remains controversial. But time has demonstrated that foreclosure of gene patenting by the Court has yet to negatively impact research and innovation in a manner that calls for societal concern. In general, it appears that the fears and objections voiced by advocates of gene patenting are overblown, including the arguments that less patenting efforts in this field will impede scientific progress and that absence of patent protection encourages competition and inferior products will saturate the market. It seems crystal clear to me that the Court correctly decided that isolated genes are not patentable. Post-*Myriad*, all researchers and entities have access to not just *BRCA1/2*, but *all* human genes. For the scientific community, this is a tremendous win. Use and access to human genes should be free and available to all.

Despite the Court’s *Myriad* holding effectively preventing the USPTO from granting new gene-related patents, cDNA is still considered patent-eligible subject matter. The Court should have extended the “genetic information”-focused rationale applied to isolated DNA segments to cDNA and/or properly applied the *Mayo* test to cDNA. Under either approach, cDNA should not have been deemed patent-eligible. Despite cDNA’s active use in both basic and commercial research, the Court failed to see the value in placing cDNA in the commons for all researchers and entities to use as tools to uncover more of nature’s mysteries. However, as of today, patent claims directed toward cDNA are still allowable and the impact of potentially foreclosing cDNA as patent-eligible subject matter can neither be accurately gauged nor speculated on since it merely maintains the status quo. Perhaps as the research community finds broader, more routine applications of cDNA in research efforts, thereby suggesting an increasing detriment to scientific advancement if cDNA were to continuously be afforded patent protection,
then another legal challenge like that brought in *Myriad* may occur for cDNA. Patent law is meant to be dynamic and evolving, particularly as scientific understanding becomes increasingly advanced and precedent is now seemingly a mere legal fiction to which the Court can choose to adhere to or distinguish how it sees fit. Until then, however, cDNA patents remain valid and enforceable.

Finally, one must still consider the plethora of granted gene patents prior to the decision. Existing patents “are not automatically invalidated by the *Mayo, Alice*, and *Myriad* decisions. Each patent must be treated on its own . . . [and] a company that has an existing patent can sue a potentially infringing party and try to enforce it.”213 Additionally, unless invalidated by courts, existing patents are typically enforceable by their owners for a substantial length of time: seventeen years from grant if filed before June 8, 1995, or twenty years from the filing date if filed after.214 Thus, interest groups must bring separate invalidity challenges against each of the existing patent owners one by one, an endeavor that is undoubtedly time-consuming, costly, and impractical.215 Furthermore, this Note only explores patentability under Section 101. It is interesting that “plaintiffs and their counsel [in *Myriad*] deliberately chose patentable subject matter, rather than other doctrinal grounds [like novelty or non-obviousness], as the sole vehicle for challenging *Myriad*’s patents,”216 but perhaps future challengers to patentable subject matter looking to invalidate specific patents may consider use of those other requirements, especially those in Sections 102 and 103. But for the time being, the effects of prior patents directed toward human genes still linger in the scientific community and general industry like clouds on an otherwise sunny day.

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213 O’Connor, *supra* note 145.
214 See MPEP § 2701.