VALID BUT HARMFUL: WHY CONGRESS SHOULD AMEND THE PATENT ACT TO COMPULSORY LICENSING OF DISEASE GENE PATENTS

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I. INTRODUCTION

CancerX is the sole service provider for the diagnostic test for uterine cancer. Using CancerX’s test, Lisa’s doctor diagnoses her with uterine cancer. He recommends that Lisa undergo surgery to remove her uterus and have chemotherapy to rid Lisa of the cancer. Lisa’s insurance will not cover any of the costly treatments and if she chooses to proceed with the treatment, she will be unable to bear children of her own. Because CancerX holds the patent to the only test for uterine cancer, Lisa is unable to get a second medical opinion or test for false positives before making this life-changing decision.

This is a fictional fact pattern, but the issues Lisa’s story presents are very real. After discovering the genes responsible for breast and ovarian cancer, Myriad Genetics holds the patents to the only genetic test for breast and ovarian cancer.¹ In light of recent Supreme Court cases, disease gene patents present novel questions regarding patent-eligible subject matter. This note discusses the likely effects of Association for Molecular Pathology v. Myriad (“Myriad”) on scientific progress, physicians’ ability to practice medicine, and patient access to second medical opinions. Unlike other publications in this area, this note does not recommend that disease gene patents be invalidated. After discussing patentable subject matter and analyzing the legal trend in disease gene patents, this note posits that the courts have correctly applied patent law to validate disease gene patents, but that without additional regulation, disease gene patents do more harm than good. This note recommends a new framework of compulsory licensing.

II. BACKGROUND

Article I, Section 8, Clause 8 of the United States Constitution grants Congress the authority “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;” to that end, Congress enacted the federal Patent Act codified in Section 35 of the United States Code.² A patent is a government-granted intellectual property right of an inventor “to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States” for a designated period of time in exchange for

¹ Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2112 (2013).
² U.S. CONST. art. I, § 8, cl. 8.
public disclosure of the invention. The exclusivity of patents is justified by the assumption that they foster scientific progress and technological innovation. Courts have determined that the main underlying goal of patent law is to benefit the public rather than reward the inventor for his or her efforts. Thus, in order for patents to remain justified, they must lead to higher rates of progress and innovation than their alternative.

Patents confer on their owners a limited monopoly right to exclude others from using their inventions for the benefit of society. If an inventor cannot get a patent for his invention, then his idea could simply be taken by others who wish to benefit from his invention without bearing the costs that went into its creation. Proponents of patents argue that this would likely result in fewer inventors, and thus, less progress in “science and useful arts.” The question remains, however, if this theory is accurate. Furthermore, disease gene patents may deny patients access to secondary medical opinions, which may be essential to making well-informed life-changing decisions.

A. Statutory patent-eligibility

The United States Patent and Trademark Office (“PTO”) is the administrative agency responsible for reviewing patent applications in the United States. The PTO lists three types of patents: design patents, plant patents, and utility patents. Design patents are granted for “new, original, and ornamental design[s] for an article of manufacture.” Plant patents are granted for distinctly new varieties.

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5 Quanta Computer, Inc. v. LG Elec., Inc., 553 U.S. 617, 626 (2008); see also Bilski v. Kappos, 130 S.Ct. 3218, 3252 n. 44 (2010) (Stevens, J., concurring); Edward Rothstein, Connections; Swashbuckling Anarchists Try to Take the $; Out of Cyberspace, N.Y. TIMES, June 10, 2000.
7 Quanta Computer, 553 U.S. at 626.
8 See Torrance, supra note 4, at 132.
9 Id.
11 Id.
of plants that are discovered and then asexually reproduced. Utility patents are granted for the invention or discovery of “any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof.”

Section 101 of the Patent Act states that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” In order for an invention to be patent eligible, an invention must fit within the scope of patentable subject matter codified in 35 U.S.C. § 101, as interpreted by the courts. If a patented invention fits within the scope of §101, sections 102 and 103 then require that a patented invention be novel and non-obvious to someone of ordinary skill in that area of technology. The claims contained in the patent application must also be written with enough specificity to enable one of ordinary skill in the art to duplicate the invention when the patent term expires. If a claimed invention does not fit within the scope of §101, then there is no need to inquire as to any of these other factors.

The PTO guidelines serve as a useful aid for courts deciding whether a given invention fits within the umbrella of patent-eligible subject matter of §101 of the Patent Act, but it is ultimately up to the courts to make that decision. Looking to the plain language, legislative history, and supporting case law, courts must decide what qualifies as patent-eligible under the Patent Act and the IP Clause’s mandate to “promote the Progress of the useful arts.”

As a federal agency, the PTO’s guidelines and decisions are not per se constitutional and recent court trends have caused the PTO to reevaluate how patent examiners determine eligibility of applications that claim processes involving laws of nature and compositions of matter. On July 3 of 2012, the PTO released a thirteen-page memorandum entitled, “2012 Interim Procedure for Subject Matter

12 Id.
13 Id.
15 Id.
18 See Rose, supra note 16, at 121 (explaining that it is the role of the courts to interpret a statute’s meaning).
19 Id. at 133.
Eligibility Analysis of Process Claims Involving Laws of Nature.”\textsuperscript{20} The new PTO guidelines set forth a three-part inquiry to help examiners determine patent eligibility: (1) “Is the claimed invention directed to a process . . . or a series of acts or steps?” (2) “Does the claim focus on use of a law of nature, a natural phenomenon, or naturally occurring relation or correlation?” and (3) “Does the claim include additional elements/steps or a combination of elements/steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied, and are sufficient to ensure that the claim amounts to significantly more than the natural principle itself?”, together with “Is it more than a law of nature + the general instruction to simply ‘apply it’?”\textsuperscript{21} If a given process claim passes the first two inquiries, it must pass the third inquiry in order to be patent-eligible.\textsuperscript{22}

B. Judicially-defined exclusions to patentability

Patent categories have historically been viewed very broadly, but there are three judicially created exclusions to patentability:\textsuperscript{23} “laws of nature, physical phenomena, and abstract ideas” are ineligible for patents.\textsuperscript{24} The constitutional mandate to promote progress in the useful arts includes safeguarding the right to reasonable access to basic knowledge.\textsuperscript{25} Because laws of nature, physical phenomena, and abstract ideas are considered basic knowledge, the courts have made these absolute bars to patent-eligibility.\textsuperscript{26}

Though laws of nature are barred from patent-eligibility, products of nature and applications of laws of nature are not automatically barred from patent-eligibility. Although neither physical phenomena nor laws of nature are patentable, the Supreme Court in Diamond v. Chakrabarty held that products of nature are patent-eligible with additional human engineering making them “markedly different


\textsuperscript{21} Id. at 3.

\textsuperscript{22} Id.


\textsuperscript{24} Id.

\textsuperscript{25} See Rose, supra note 16, at 121 (examining the Constitutional mandate to promote progress).

\textsuperscript{26} Id.
compositions of nature.” 27 A mere “discovery of some of the handiwork of nature” is not patent-eligible because information that is “part of the storehouse of knowledge of all men . . . [is] . . . reserved exclusively to none.” 28 To put it differently, laws of nature are not patent-eligible, but process claims involving laws of nature may be patent-eligible.

Like physical phenomena and laws of nature, the Supreme Court in Mayo v. Prometheus held that abstract ideas that do more than simply state the idea are not automatically barred form patent eligibility. “An application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.” 29 It is not enough to simply state a law and say “now apply it,” but, “a particular, inventive application of the law” may have enough human involvement to make the matter patent-eligible. 30

There is no clearly defined test that courts must employ to determine whether a given invention is patent-eligible, and as science evolves outside the anticipated scope, it becomes increasingly more difficult for courts to distinguish between patent-eligible and patent-ineligible subject matter. Disease gene patents present such a struggle. The courts have historically relied on two major doctrinal tests for patent-eligibility—the machine-or-transformation test and the preemption test—but modern science often manages to blur the lines of patent-eligible subject matter that these tests attempt to establish.

1. The Machine-or-Transformation Test

When determining whether a given invention or process is patent eligible, the courts have long employed the machine-or-transformation test. The machine-or-transformation test states that a claim is likely patent-eligible when “(1) it is tied to a particular machine or apparatus, or (2) transforms a particular article into a different state or thing.” 31

27 Chakrabarty, 447 U.S. at 310.
29 Mayo Collaborative Serv. v. Prometheus Lab., Inc., 132 S. Ct. 1289, 1293–94 (2012) (emphasis added) (holding that the mere description of a correlation between thiopurine metabolite levels and toxicity/efficacy of thiopurine drugs was insufficient to make the application patent-eligible because it did not apply the law of nature to a known structure or process. A patent application must do more than simply state a law and say “apply it.”).
30 Id. at 1290.
Although still employed by courts today, the Supreme Court in *In re Bilski* said the machine-or-transformation test “is not the sole test for determining the patent eligibility of a process . . . but rather is a useful and important clue, an investigative tool, for determining whether some claimed inventions are patent-eligible processes.”

The Court in *In re Bilski* noted that the machine-or-transformation test had been created during the Industrial Revolution, a time in which inventions were expressly tethered to machines or other physical forms. In today’s technological age, inventions are not always tethered to a machine or physical transformation and the way in which the courts make their determinations must evolve along with the technologies with which they deal. The Court noted that the machine-or-transformation test does not work for all cases. There may be inventions that satisfy the test but are patent-ineligible, and some that do not satisfy the test but are still patent-eligible.

The machine-or-transformation test ultimately tries to determine whether there is ‘inventiveness’ present in a given invention. As Chief Justice Marshall explained, if the invention results in something that is markedly different from a naturally occurring phenomenon or idea, it will likely be patent-eligible. Building upon this principle, the Court in *In re Bilski* explained that post-solution steps do not contribute to patentability because the core invention still requires inventiveness. Post-solution steps are insignificant if they do no more than recite a specific machine or a particular transformation of a specific article. An insignificant step, such as data gathering or outputting, is not sufficient to pass the test without further inventiveness.

In *Funk Bros.*, the Supreme Court said a bacteria-mixture patent was not patent-eligible because the interaction of the two species, though useful and novel, was nothing more than a naturally occurring phenomenon. In *Diamond v. Chakrabarty*, however, the Court said a patent claiming a genetically engineered bacterium was patent-eligible because the bacteria in their genetically modified state were unlike any found in nature. By inserting two plasmid coding for hydrocarbon degradation enzymes, Chakrabarty transformed the bacteria into a new composition possessing characteristics “possessed

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32 *Id.* at 3221.
33 *Id.* at 3227.
34 *Id.*
35 *Id.*
36 Davis v. Palmer, 7 F.Cas. 154 (C.C.D. Va. 1827).
37 *See* *Bilski* v. *Kappos*, 130 U.S. 3218, 3230 (2010) (explaining that post-solution steps do not contribute to patentability without inventiveness).
38 *USPTO Guidance Memo*, *supra* note 20, at 5-6.
by no naturally occurring bacteria."\textsuperscript{40} The Court found the fact that the engineered bacteria could clean up oil spills and serve a useful purpose irrelevant and relied on the fact that Chakrabarty had “produced a new bacterium with markedly different characteristics from any found in nature” to validate the biopatent.\textsuperscript{41}

\textit{Diamond v. Chakrabarty} marked the first time the Court granted a non-plant patent of a living thing.\textsuperscript{42} With the arrival of biotechnology, mankind is now able to manipulate and alter living things, resulting in markedly different products.\textsuperscript{43} Researchers can also now adequately explain their processes in enough detail for them to be replicated upon the expiration of the patent term.

Biopatents introduced a new era of patents, but their advent challenged the practicality of the machine-or-transformation test.\textsuperscript{44} Courts may still use the machine-or-transformation test as a helpful tool to determine inventiveness, but as the Supreme Court explained in \textit{Mayo v. Prometheus}, the Court’s inquiry may not stop there.\textsuperscript{45} Courts must also ask if a given invention would preempt others from employing fundamental principles that would benefit society.\textsuperscript{46}

\textbf{2. The Preemption Test}

Patent claims that may preempt ideas already in “the storehouse of knowledge of all men,” including basic tools of science and abstract ideas are not patent-eligible because they prevent future inventions.\textsuperscript{47}

\footnotesize{\textsuperscript{40} See Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980) (discussing the novel characteristics of the bacteria synthesized by Chakrabarty).}

\footnotesize{\textsuperscript{41} Id. at 310.}


\footnotesize{\textsuperscript{43} See Christopher M. Holman, \textit{Bilski: Assessing the Impact of a Newly Invigorated Patent-Eligibility Doctrine on the Pharmaceutical Industry and the Future of Personalized Medicine}, 10 CURRENT TOPICS IN MED. CHEM. 1937, 1940 (2010) (“[T]he key distinction is human intervention; products and processes arising out of active human invention are patent-eligible . . .”).}

\footnotesize{\textsuperscript{44} See Duffy, supra note 42, at 630 (explaining a weakness in only using a \textit{per se} exclusion to patentability for living inventions is that the rule could still be circumvented by claiming a living invention in conjunction with an inanimate carrier material, such as a bacteria on top of a petri dish).}

\footnotesize{\textsuperscript{45} See Mayo Collaborative Serv. v. Prometheus Lab., Inc., 132 S. Ct. 1289, 1303 (2012).}

\footnotesize{\textsuperscript{46} See John M. Golden, \textit{Patentable Subject Matter and Institutional Choice}, 89 TEX. L. REV. 1041, 1055, 1067–74 (2011) (discussing the preemption test courts employ to determine if an invention is ineligible for patent protection).}

The preemption test goes beyond the machine-or-transformation test and asks whether a patent could prohibit another inventor from employing a fundamental principle that would be necessary for scientific progress.  

Fundamental principles are necessary for other inventors to use when inventing around them would be nearly impossible. Congress has tasked the PTO and the courts to ensure that fundamental principles and basic ideas remain freely available to the public for the sake of scientific progress.

The Bilski Court found that certain claimed methods passed the machine-or-transformation test, but were still not patent-eligible because they encompassed fundamental principles, which, if controlled exclusively, would preempt any future innovation in the field. The processes claimed were too broad to invent around and would give patent owners exclusive control over basic ideas. Conversely, the Court in Diamond v. Diehr granted a patent for the use of a well-known mathematical formula in a process for curing synthetic rubber because the Court found no preemption issue. The patent claimed a formula that contained a fundamental principle, but the patentees “did not seek to pre-empt the use of that equation” and only sought to prevent others from using the equation in conjunction with all of the other steps described in their claim. Patent applicants can pass the preemption test by claiming a specific application of a fundamental principle accompanied by additional conditions, rather

49 See Rochelle C Dreyfuss & James P. Evans, From Bilski Back to Benson: Preemption, Inventing Around, and the Case of Genetics Diagnostics, 63 STAN. L. REV. 1349, 1352 (2011) (examining when fundamental principles are necessary to remain in the public domain).
50 See Golden, supra note 46, at 1074 (discussing the role of the PTO in ensuring progress is being pursued).
52 See Bryan Treglia, Patentable Subject Matter: Separating Abstract Ideas and Laws of Nature from Patentable Inventions, 48 JURIMETRICS J. 427, 437 (2008) (discussing how no one should have exclusive control over basic ideas).
53 See Diamond v. Diehr, 450 U.S. 175, 187 (1981) (granting a patent for the use of a well-known mathematical formula because patentees did “not seek to pre-empt the use of that equation,” and only sought to prevent others from using the equation in conjunction with all of the other steps described in their claim.).
54 Id. Unlike in Flook, where the claims to a formula for setting alarm limits were limited in scope such that they did not actually prevent the use of the formula in other applications, in Diehr, the Court said that the limitation of the scope of application was merely “post-solution activity.” Parker v. Flook, 437 U.S. 584, 590 (1978). The courts make it clear that post-solution activities without any inventive step do little to ameliorate preemption concerns.
than the fundamental principle itself.\textsuperscript{55}

III. ANALYSIS

A. The Supreme Court properly validated disease gene patents

Disease gene patents generally encompass both process claims involving laws of nature and the compositions of matter created in order to develop treatments.\textsuperscript{56} Opponents of disease gene patents typically rely on patent law to argue that disease gene patents should be invalidated as unpatentable subject matter under § 101,\textsuperscript{57} but the Supreme Court properly interpreted patent law in validating disease gene patents. The danger of disease gene patents is not the patent themselves, but rather the manner in which they are being enforced.

1. The Supreme Court properly held that process claims involving laws of nature are patent-eligible subject matter

On March 20, 2012, the Supreme Court unanimously held in \textit{Mayo v. Prometheus} that the personalized medicine dosing method invented by Prometheus Laboratories (Prometheus) was ineligible for patent protection as a law of nature.\textsuperscript{58} Prometheus is a specialty pharmaceutical and diagnostics company that researched the use of thiopurine drugs in the treatment of certain autoimmune diseases, such as Crohn’s disease and ulcerative colitis.\textsuperscript{59} Prometheus filed patents for a diagnostic test that could determine the proper dosage of thiopurine drug for any given patient.\textsuperscript{60} Every individual metabolizes drugs differently and if a dose is too high or too low, there may be adverse side effects and lower efficacy of the drug.\textsuperscript{61} When Prometheus filed for its patents, the exact correlation between metabolites and thiopurine drug efficacy was unknown, but the active metabolites responsible for thiopurine drug efficacy had already

\textsuperscript{55} See id. (explaining that the proper inquiry in preemption is whether a patent preempts the use of a natural phenomenon).


\textsuperscript{59} See id.

\textsuperscript{60} Id. at 1290-91.

\textsuperscript{61} Id.
been identified and were commonly known to researchers.62

Each of Prometheus’s claims recites an “administering” step, a “determining” step, and a “wherein” step.63 The administering step merely instructs physicians to administer the drug to the patient; the determining step tells physicians to then measure resulting metabolite in the patient’s blood; lastly, the wherein step instructs physicians to decrease or increase the dosage if the metabolites are outside the ideal range.64 The methods for making these determinations were already well known in the art before Prometheus came along, and the Court said that simply telling doctors to engage in “well-understood, routine, conventional activity previously engaged in by scientists in the field” was insufficient to make a patentable-ineligible law of nature patent-eligible.65

As previously discussed, laws of nature are patent-ineligible subject matter, but applications of laws of nature are permissible so long as there is additional human engineering giving them “markedly different characteristics from any found in nature.”66 The Supreme Court held that the correlation between thiopurine drug efficacy and the prevalence of metabolites in a person’s body is an entirely natural process, thus making Prometheus’s patents invalid for simply putting forth a natural law.67 The Court reiterated that an application of a law of nature must be limited in scope so as not to broadly preempt use of the law, and include an “inventive concept” that is significant and separate from the natural law itself.68 A mere statement of a naturally occurring correlation, despite being newly discovered, fails this inquiry.69 Additionally, “drafting efforts designed to monopolize the correlations” do not satisfy this requirement.70 The Court invalidated the Prometheus patent but held that process claims could be patent-eligible with an additional inventive step. After Mayo, disease gene patented method claims are clearly patent eligible subject matter so long as they meet this extra step. The Court correctly applied patent law to uphold process claims involving laws of nature and disease gene patents claiming processes involving laws of nature are patent-eligible.

62 Id. at 1295.
63 Id. at 1290.
64 Id.
65 Id. at 1291 (citing Parker v. Flook, 437 U.S. 584, 590 (1978)).
67 See Mayo Collaborative Services, 132 S. Ct. at 1291.
68 Id. at 1292.
69 Id.
70 Id. at 1291.
The Supreme Court properly held that disease gene patent compositions of matter claims are patent-eligible subject matter

After the Supreme Court’s landmark decision on bioproduct process patents in Mayo, it addressed the patent eligibility of disease gene compositions of matter. Much of the Supreme Court’s reasoning in Mayo paved the way for Myriad. On March 20, 2012, the Supreme Court unanimously invalidated Myriad Genetics’ (“Myriad”) isolated DNA patents as products of nature, but held that Myriad’s synthetically-created DNA, known as complimentary DNA (“cDNA”), is patent-eligible because it does not naturally occur.

Unlike the patent holder in Mayo, who claimed a process involving a law of nature, Myriad claimed a process for isolating and creating cDNA and claimed the individual compositions of matter. The Federal Circuit had previously held both isolated DNA and cDNA patent-eligible, finding that isolated DNA is chemically distinct from naturally occurring DNA and cDNA is biologically and chemically distinct from its natural form. The Supreme Court—largely echoing Federal Circuit Judge Bryson’s dissent—held that isolated DNA is not patent-eligible subject matter much like “snapping a leaf from a tree” is not patentable.

Myriad discovered that mutations of BRCA1 and BRCA2 genes “can dramatically increase the risk of breast and ovarian cancer” and marketed the only genetic test for those cancers. The PTO granted Myriad patents for its isolated DNA sequences containing the BRCA1/2 mutations, the cDNA synthesized from the mutated genes for further research, and the diagnostic methods of identifying mutations in those DNA sequences. When other medical professionals began performing cheaper versions of Myriad’s genetic test, Myriad filed patent infringement suits, but the infringers counterclaimed that Myriad’s patents were invalid. After the Supreme Court vacated and remanded the case to the Federal Circuit in light of Mayo, the Federal Circuit held that Myriad’s method claims directed at “comparing” or “analyzing” DNA sequences were patent-
ineligible because they merely claimed an “abstract mental process” and contained no transformative steps; however, Myriad’s claims over the isolated DNA and cDNA were patent-eligible compositions of matter. The Supreme Court affirmed in part and reversed in part. The Supreme Court unanimously agreed that cDNA was patent eligible, but isolated DNA was not. Isolated DNA is biologically identical to naturally occurring DNA; the nucleotide sequence found in isolated DNA, which in turn codes for the proteins that make up the BRCA1/2 genes, appears identically in isolated DNA as it does in naturally occurring DNA. In order to isolate the relevant DNA sequence, Myriad breaks the chemical bonds holding the DNA sequence to the rest of a subject’s DNA. The Federal Circuit concluded that this chemical difference was sufficiently transformative to qualify isolated DNA as a composition of nature, but the Supreme disagreed. Unlike isolated DNA, cDNA is artificially synthesized through the splicing of genetic material and is both chemically and biologically different than naturally occurring DNA. The cDNA is synthesized from mRNA after transcription, in which non-coding intron sequences are naturally cut out. DNA does not naturally exist in the nucleotide sequence formed in cDNA and is thus biologically distinct from naturally occurring DNA. Additionally, the chemical bonds joining the nucleotide sequences have to be broken and remade in order to bind the new nucleotide sequence together, also making cDNA chemically distinct from naturally occurring DNA. The Court unanimously held cDNA to be patent-eligible as a composition of matter that “is not a ‘product of nature’” due to human intervention.

Unlike cDNA, isolated DNA retains the same nucleotide sequence as naturally occurring DNA. In order to isolate the DNA sequences, the chemical bonds of the DNA must be broken through human intervention, making it a chemically distinct molecule from naturally occurring DNA, but the isolated DNA retains the same biological

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79 Myriad, 133 S. Ct. at 2111.
80 Id.
81 Id. at 2116.
82 Id. at 2117.
83 Id. at 2119.
84 Id. at 2112.
85 Id. at 2119.
86 Id.
87 Id.
88 Id.
identity. The Federal Circuit held that this chemical distinction was sufficient to render isolated DNA patent-eligible because “genes are in fact materials having a chemical nature and, as such, are best described in patents by their structures rather than by their functions.” In his dissent, Judge Bryson opined that, “merely isolating the products of nature by extracting them from their natural location and making those alterations that are attendant to their extraction does not give the extractor the right to patent the products themselves.” The Supreme Court agreed with Judge Bryson’s reasoning and held isolated DNA patent-eligible. The utility of isolated DNA is its nucleotide sequence, which codes for a targeted gene, like BRCA1/2.

The Supreme Court was correct to validate Myriad’s cDNA patents and the resulting diagnostic gene test for breast and ovarian cancer. The Supreme Court also properly refused to address the public policy harms of Myriad’s patents and narrowed their inquiry to whether the claimed inventions were patent-eligible subject matter. Disease gene patents cannot be invalidated because of their potential harms to medical consumers when existing patent law certifies their validity.

B. Disease Gene Patents are contrary to public policy because they ultimately do more harm than good

The Supreme Court correctly applied all doctrinal tests, but the “correct” holding may have profound negative consequences. As previously discussed, patent law derives from the constitutional mandate for Congress “[t]o promote the Progress of Science and useful Arts . . .” Patent law arguably only remains valid so long as it continues to promote the progress of science and useful arts. If disease gene patents do not further innovation and science and do more harm than good, then it is time for Congress to enact new legislation to remedy this result.

89 Id.
91 Id. at 1350.
92 See Rose, supra note 16, at 131–32.
93 U.S. CONST. art. I, § 8, cl. 8.
1. Disease gene patents do not further progress and innovation

Recent studies reveal that there is little evidence showing that patents do, in fact, further innovation and scientific progress and suggest that the opposite may be true. Patents slow research by “impeding others from expanding on or improving a [patented] diagnostic test.” Not only can patentees prevent laboratories and physicians from using a patent-protected test to diagnose a patient or verify result, but they may also “block development of variations” of the test. “This precludes researchers from using verification testing to identify false positives or negatives in an extant test,” or from using the patented test on alternative DNA samples. Follow-on research on patented gene patents is done to a much lesser extent than on other types of follow-on research.

Several studies attempting to analyze the correlations between innovation and patent protection have shown that in certain scenarios, patents slow down innovation rather than help speed it up. These studies generally take two forms: 1) the first relies on economic frameworks to determine if patents promote innovation, and thus increased amounts of new technologies are hitting the market; 2) the second employs mathematical models which either measure technological innovation in a single economy of interest or compare rates of technological innovation among countries offering different levels of patent protection.

In Helsinki, Finland, a group of economists using the first model of patent efficacy studies determined that, “while the effect of patents

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94 See Torrance, supra note 4, at 135.
95 Katherine L. Record, University Opposition to Unfettered Research: A New Bedfellow for Biotech?, 22 HEALTH MATRIX 139, 150 (2012).
96 Id.
97 Record, supra note 95 at 150.
99 Record, supra note 95, at 151 (quoting DEPT OF HEALTH & HUMAN SERV'S, SECY'S ADVISORY COMM. ON GENETICS, HEALTH, AND SOC'Y, GENE PATENTS & LICENSING PRACTICES & THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 4 (2010) (patent ownership “fragmentation is ... problematic for follow-on contributors to the public knowledge stream [and] ... the negative effect of patents on follow-on public knowledge production is greatest for genes closely linked to human disease”).
100 See Torrance, supra note 4, at 138.
101 Id. at 139.
is to raise the rents on and thereby the potential amount of innovations, it also tends to slow down market introduction.”

Similarly, an empirical study done at Columbia University School of Law supported the same finding. In order to test the hypothesis that patent systems promote innovation in the United States, Dr. Andrew W. Torrance and Dr. Bill Tomlinson created a program to simulate the behavior of inventors and competitors experimentally in both patent and non-patent systems. The study employed a multi-user interactive simulation of patent and non-patent systems called, “PatentSim”. Following a model of the invention process, PatentSim allowed law students to access a database of potential innovations, then patent, or open source these innovations. Users could then license, assign, buy, infringe, or enforce patents against each other. The results of the simulation suggest that a system “combining patent and open source protection for inventions (that is, similar to modern patent systems) generates significantly lower rates of innovation” than non-patent systems.

In 2003, the National Academies published one of the most comprehensive reviews of the United States patent system, entitled “Patents in the Knowledge-Based Economy”. Instead of supporting the hypothesis that patents spur invention and innovation, the National Academies concluded that “[t]here are theoretical as well as empirical reasons to question whether patent rights advance innovation in a substantial way in most industries.”

Firstly, the benefits of retaining a patent monopoly for a limited time might be outweighed by the ultimate cost of detailed disclosure that patents require. Secondly, while technological advances are, more often than not, built cumulatively upon other inventions, broad patent protection on upstream discoveries impedes subsequent innovations. In an empirical study surveying fifty-three biotechnology companies in Switzerland, a group of researchers concluded that a broad research

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103 See Torrance, *supra* note 4, at 138.

104 See generally Torrance, *supra* note 4.

105 *Id.*

106 *Id.*

107 *Id.*


109 *Id.*

110 *Id.*
exemption from patent protection, combined with compulsory licensing arrangements for DNA patents are feasible remedies for overcoming the stifling effect the current patent system can often have.\footnote{Nikolaus Thumm, Patents for Genetic Inventions: A Tool to Promote Technological Advance or a Limitation for Upstream Inventions?, 25 TECHNOVATION 1410, 1410 (2005), available at http://www.science-direct.com/science/article/pii/S0166497204001154.}

The current patent system arguably does not further progress, and, at the very least, it is questionable. If the patent system is only valid so long as it furthers progress, then it may be time for Congress to reassess whether the current patent regime is still constitutionally valid. Furthermore, any possible value patents provide must also be weighed against their potential harms. Particularly with regard to disease gene patents, limiting patients’ access to secondary medical opinions and affordable drugs and treatments may ultimately be against public policy.

2. Disease gene patents inhibit physicians’ ability to practice medicine

Disease Gene patents may materially inhibit physicians’ ability to practice medicine and provide medical care to their patients. The United States, like most of the world, has long recognized the dangers of monopolies and the public harm that may arise when one company retains exclusive control of a market. These dangers are exponentially increased when they occur in medical diagnostic testing. Disease gene patents deserve special attention because of the special way they affect medicine. They not only affect the available treatments that a doctor may proscribe, but they also affect a physician’s ability to practice medicine by performing the patented tests. This trouble does not arise from the patent itself but from patent owners refusing to license their diagnostic tests.

Proponents of disease gene patents argue that without patents, such discoveries would be held as trade secrets, denying patients access to diagnostic tests indefinitely. Secrecy, however, is contrary to the goals of the entire field of sciences and “is particularly disgraceful in the health sciences.”\footnote{Jon F. Merz, Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine, 45 CLINICAL CHEMISTRY 324, 325 (1999), available at http://www.clinchem.org/content/45/3/324.long#ref-10.} Furthermore, researchers with ordinary skills in the art can typically replicate a diagnostic test once identified in its simplest terms without any further development.\footnote{Id.} Identification of
the genetic loci for a disease trait is typically enough information for one of ordinary skill in the art to develop a similar diagnostic test, and trade secret law would do little to prevent their downstream development.\footnote{Id.}

Patent holders/exclusive licensees can monopolize an entire medical service. Furthermore, disease gene patents can potentially inequitably extend the term of a gene patent. Like BRCA1/2, several genes are often responsible for a particular disease. Patent law foresees that after a gene patent’s term ends, the diagnostic test would become public domain; however, future discoveries and patents on additional genes responsible for the same disease would effectively extend the life of the patent on the diagnostic test. The ability to test for breast cancer would no longer merely require testing for the originally patented mutations in BRCA1 and BRCA2, but would essentially require testing for the additional mutation responsible for the disease. The disease gene patent would then run until the term of the latest patent expired, extending the intended period of patentability. Exclusive disease service providers will interfere with the practice of medicine because they will have the “ability to prescribe nationwide medical practices and to dictate the medical standard of care.”\footnote{Ames Dhai, Patenting Our Human Heritage: Part One, The Threats Posed by Patenting DNA, SCIENCE IN AFRICA, (Jan. 2004) http://www.scienceinafrica.co.za/2004/january/patenting.htm.} Patents restrict the types of tests physicians and clinicians may perform and the conditions for which they may be done.

\subsection*{3. Disease gene patents deny patients access to secondary medical opinions}

Disease gene patents are particularly concerning because they may deny patients access to secondary medical opinions. Courts have consistently recognized a patient’s right to a second medical opinion as a matter of public policy.\footnote{Rush Prudential HMO, Inc. v. Moran, 536 U.S. 355, 400 (2002).} There is often more than one way to approach any set of medical facts, and doctors may misdiagnose a condition.\footnote{Renee Bacher, Half of Americans Don’t Get a Second Opinion, NBCNEWS.COM, http://www.nbcnews.com/id/22829371/ns/health-health_care/t/half-americans-dont-get-second-opinion/ (last updated Feb. 4, 2008).} Most doctors and insurance plans, including Medicare, frequently require that patients receive a second medical opinion.
before having nonemergency surgeries and treatments. In *Rush Prudential HMO, Inc., v. Moran*, the Supreme Court upheld laws in 42 states that give patients a right to a second medical opinion from outside doctors if their HMOs turn them down for a medical treatment or a drug benefit. Both patients and insurers have an interest in obtaining second opinions because they help to guard against unnecessary surgeries and treatments that may be costly and life-changing. When the federal government recognized these benefits, Medicare became the first indemnity insurance plan to pay for beneficiaries to receive second medical opinions. By the mid-1980s, “second opinions were a well-established feature” of almost all other indemnity insurance programs in the United States. In 1986, the federal government considered “making second opinions mandatory for all Medicaid recipients for ten common elective surgical procedures” but the government considered second medical opinions a patient’s right, rather than a burden.

Today, patients do not seek second opinions as often as they did in the 1980’s. The current American healthcare system has moved away from indemnity insurance and fee-for-service medical care to integrated systems of coverage and care, which shift financial risk to providers; however, for procedures that insurance may not cover—i.e., expensive cancer treatments—doctors often still recommend that patients seek a second medical opinion. Even if most second

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125 See Hyman, supra note 123, at 1457.  
126 Id.  
opinions just confirm what a patient’s original physician recommended, they still play an important role because they offer patients peace of mind before they have to make life-changing decisions. In the instances in which primary physicians misdiagnose patients, second opinions can have profound economic and physical effects.

C. Congress should enact compulsory license legislation for disease gene patents

Some proponents of change call for Congress to broaden the experimental use exemption currently available to academic researchers to make gene sequences freely available to those in research, but this does not remedy all of the public harms of disease patents. While this would allow biomedical research taking place at nonprofit academic research laboratories to openly infringe gene patents, it would not allow any of those to make their way to the market to benefit consumers. Patients like Lisa would still be unable to get a second medical opinion or check for false positives.

Compulsory licensing would not undermine the intended purpose of patent protection. As previously discussed, patents grant inventors negative rights in their inventions so that they may recoup costs and profit from their development, so as to incentivize the innovation. Patentees can still recoup costs and profits if they were federally compelled to license their patented disease gene sequence in exchange for a statutory set fee. The licensing fee could be “tied to the commercial value of the product developed as a result of the licensee’s research.” Compulsory licensing of disease gene patents would ensure that available tests be improved upon and allow physicians to practice medicine by using the patented inventions to give secondary diagnoses and treatment options.

This would not be the first time Congress has acted to protect the interests of medical consumers. In 1984, Congress acted to safeguard consumer access to healthcare by enacting the "Drug Price Competition and Patent Term Restoration Act of 1984"—also known as the Hatch-Waxman Act—which established the Annotated New

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130 Id.
Drug Application process ("ANDA").\textsuperscript{131} ANDAs allow the United States Food and Drug Administration ("FDA") to speed up the timeframe in which drug manufacturers can provide to the public safe, effective, low cost alternatives to name-brand drugs.\textsuperscript{132} Similarly, compulsory licensing for disease gene patents would ensure that medical consumers could access more affordable diagnostic tests and seek secondary medical opinions. Compulsory licensing would eliminate the public harm of exclusive service providers for diagnostic tests while maintaining the current patent regime.

IV. CONCLUSION

Patent law was created to benefit the public rather than rewarding the inventor for his or her efforts. With the recent evidence suggesting that in practice, patents do not foster scientific progress and innovation, it is time for Congress to readdress whether the current patent regime is constitutional as applied. In particular, disease gene patents may deny patients access to secondary medical opinions, which may be essential to making well-informed life-changing decisions.

The Supreme Court in Myriad correctly applied the statutory and judicial tests for patent eligibility but failed to address the public policy concerns that Myriad’s patents raised. In Myriad, both the Federal Circuit and the Supreme Court refused to address whether patients suspected of having an increased risk of developing breast cancer are entitled to a second medical opinion, but that lingering question is crucial for patients facing dire medical diagnoses.\textsuperscript{133} Myriad holds the patent to the only BRCA1/2 test, which can identify an increased risk of breast and ovarian cancer. Like Lisa, women may face costly and life-changing decisions if Myriad’s test comes back positive for genetic cancer mutations. Because Myriad provides the only cancer test, patients are unable to seek a second medical opinion before accepting Myriad’s diagnosis.

The Federal Circuit and Supreme Court explicitly rejected the Petitioners’ arguments that Myriad’s gene patents limited patients’ access to care, but this issue cannot be ignored for much longer. The

\textsuperscript{132} Id
\textsuperscript{133} Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013); Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012).
Supreme Court correctly applied the law as it stands, but Congress may be forced to address whether disease gene patents violate public policy and whether they must amend present patent law.

Unlike other patents, disease gene patents enable the monopolization of testing services. Drug patents prohibit competitors from copying the patented treatment, but disease gene patents create monopolies on the testing services themselves. Monopolies of diagnostic tests inhibit physicians’ ability to practice medicine and prevent patients from attaining secondary medical opinions before undergoing costly and often life-changing treatments. Diagnostic test monopolies are fundamentally at odds with good medical practice, but the Supreme Court was correct in its application of patent law to disease gene patents. Disease gene patents can certainly constitute patent-eligible subject matter, but they ultimately do more harm to the public than good. Compulsory licensing of diagnostic gene patents is a necessary and reasonable compromise to this harm.

The Leahy-Smith America Invents Act was long overdue when it was enacted in 2011 and it only made minor changes to the present patent structure,\(^\text{134}\) so it is unlikely Congress will address patent law any time soon, but until they do, the courts may only continue to attempt to apply the law correctly. Courts cannot invalidate patents that satisfy the requirements of 35 U.S.C., even if the results are not beneficial to the public. If the underlying goal of patent law is to benefit the public rather than rewarding the inventor for his or her efforts, then Congress should consider whether disease gene patents benefit the public or cause unjustified harm. Ultimately, any change to the patent system has to come from Congress, not the courts. Until then, the courts may continue coming to the correct legal determinations but causing the wrong result, leaving people like Lisa out to dry.