Genomics Unbound: The Bright Future of Genetic Testing and Therapy in Light of Prometheus

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I. Introduction

In ancient Greek mythos, the gods outlawed humankind from having access to the natural phenomenon of fire. Without fire, the human race was shackled to a cold and dark existence. An existence bereft of industry, arts, civilization, and ultimately, hope. Prometheus rectified this unjust monopoly over nature by stealing fire from Zeus and sharing it with all of humanity.¹ On March 20, 2012, Mayo Collaborative Services v. Prometheus Laboratories, Inc. (Prometheus) again expanded the capabilities of humankind.² However, this time the eponymous savior is a unanimous Supreme Court decision that correctly reaffirms that one cannot patent “the underlying laws of nature themselves.”³

When Congress enacted the United States Patent Act in 1952, it specified that patentable subject matter included anything “under the sun that is made by man.”⁴ Three decades ago the United States Patent and Trademark Office (USPTO) issued the first gene patent and ushered in a brave new gold rush. Some genes are associated with specific diseases, so being able to identify these sequences is an essential first step for developing genomic diagnostic tests and therapies. The problem with gene patents is that they allow modern-day prospectors to cordon off access to naturally occurring DNA

¹ The gods punished Prometheus by binding him to a rock with chains and having an eagle eat out his liver every day. As an immortal Titan, his liver regenerated every night and this torture repeated in perpetuity. Eventually, mankind repays its debt when Hercules unbinds Prometheus.
³ Prometheus, 132 S. Ct. 1289.
sequences and exclude others from conducting research or developing useful applications based on these sequences.

In 2009, a broad coalition of plaintiffs challenged sued Myriad Genetics over its breast cancer gene patents. In July 2011, the U.S. Court of Appeals for the Federal Circuit ruled 2-1 in favor of upholding Myriad’s gene patents, overturning a lower court decision in Ass'n for Molecular Pathology et al. v. U.S. Patent & Trademark Office et al (Myriad). However, on March 26, 2012, the Supreme Court vacated the Myriad decision and remanded it back to the Federal Circuit to reconsider in light of its ruling in Prometheus.

While there is a mixed consensus as to whether gene patents are dead in light of Prometheus, this article argues that properly understanding the Supreme Court’s logic should lead to no other result. Whether the “patent-friendly” Federal Circuit reaches the same conclusion is not the relevant issue for this article. The primary focus of this piece is to rebut certain vested interests in the biotechnology industry and affirm the normative claim that gene patents improperly fetter genomics research and development. First, through the lens of the Myriad case, we will recount why there was such a strong public interest movement against recognizing such patents. Specifically, we will show how this particular patent stifles research, impedes access to affordable testing, and detrimentally effects future developments in the cancer world. Second, we will briefly examine the Supreme Court’s legal reasoning in Prometheus and why it should essentially invalidate

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6 Myriad’s stock fell the day of the Prometheus decision as investors feared it meant that the Supreme Court was inclined also to rule that genes could not be patented. However, Myriad’s stock rose 56 cents to $23.34 on Monday, perhaps because the Supreme Court will now not be hearing the case itself, instead leaving it to the presumably more patent-friendly appellate court. See Id.
gene patents. Finally, we will argue why in order to advance forward, the field of genomics needs the *Prometheus* decision as much as the ancients needed fire.

II. Challenging Myriad

Since 2009, the American Civil Liberties Union (ACLU) has led the fight against Myriad Genetic Laboratories, Inc. (Myriad)\(^7\) in their strict enforcement of the BRCA1 and BRCA2 (BRCA1/2) patents.\(^8\) Almost 20 percent of human genes are patented, including those associated with Alzheimer’s disease, asthma, colon cancer, muscular dystrophy, and breast and ovarian cancer.\(^9\) The United States Patent and Trademark Office (USPTO), also a party-defendant in *Myriad*, grants these patents and gives the holders’ exclusive rights to the particular genetic sequences and their usage for 20 years.\(^10\) By controlling the sequence to BRCA 1/2, Myriad also controls exclusive rights to mutations along these genes, any methods used to locate mutations (known or not), and correlations between these mutations and breast cancer.\(^11\) In other words, Myriad has the right to prevent anyone else from testing, studying, or even looking at these genes.

The ACLU and joined co-parties contend that gene patents “undermine the free exchange of information and scientific freedom, bodily integrity, and women's health.”\(^12\) Their argument is that the contested gene patents create a dangerous monopoly that restricts health care options for women, interferes with diagnostic testing, and stifles

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\(^7\) *Ass'n for Molecular Pathology et al. v. U.S. Patent & Trademark Office et al.*, (S.D.N.Y. May 12, 2009).


\(^9\) *AMERICAN CIVIL LIBERTIES UNION*, Frequently Asked Questions: Legal Challenge to Patenting of Human Genes (Sep. 10, 2010) [hereinafter ACLU FAQ]; Available at: www.aclu.org/brca

\(^10\) ACLU FAQ, supra note 9.

\(^11\) *Id.*

research. Myriad, and its supporters in the biotechnology industry, allege that without intellectual property protection, companies will not invest the millions of dollars necessary to validate genetic tests. Myriad supporters argue that this would work contrary to the original intent of the patent system, which was designed as a way to incentivize research and reward companies’ inventions.

The breadth of amicus briefs filed in favor of the ACLU’s position by professional medical societies, researchers, and cancer-afflicted individuals is very telling and demonstrates the outmoded and counter-normative analysis of the Court of Appeals of the Federal Circuit. Essentially, the Federal Circuit validated patents for isolated DNA claims and Myriad’s BRCA1/2 test, which vested interests within the biotechnology and pharma industries considered a victory.

The direct consequence of upholding Myriad’s patent was to “ultimately [redirect] the standard of care for breast cancer testing.” Further, this appellate decision naturally caused great concern within the diagnostic field, and those who are personally vested and impacted by the case. In the words of presiding Judge Sweet of the District Court:

The challenges to the patents-in-suit raise questions of difficult legal dimensions concerning constitutional protections over the information that serves as our genetic identities and the need to adopt policies that promote scientific innovation in biomedical research. The widespread use of gene sequence information as the foundation for biomedical research means that resolution of

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13 *Trample Civil Liberties?*, supra note 7.
14 *Id.*
16 *Id.*
17 ACLU: Declarations – DC: Shobita Parthasarathy; at pg. 12, #31.
these issues will have far-reaching implications, not only for gene-based health care and the health of millions of women facing the specter of breast cancer, but also for the future course of biomedical research.¹⁹

A. Who “Owns” Breast Cancer Genes?

I am a business owner, artist and writer and I live in Austin, Texas. I was diagnosed with breast cancer in July of 2006 at age 36 and I had a double mastectomy…. When I was confronted with this alien invasion (cancer), I decided to be as aggressive as I could to prevent the potential spread. I also decided to be diligent about getting second opinions along the treatment path. In one important area, however, I couldn't follow my second opinion treatment protocol…Because of patents on the BRCA genes, only one company out there has the ability to sequence them. I can't get a second sequencing done at a different company to validate my results. I am thinking about having my ovaries removed because of my risk for ovarian cancer. It is uncomfortable making such an important decision based on only one test.²⁰

For the 12 percent of women who develop breast cancer in their lifetime, and the 1.4 percent of women who develop ovarian cancer,²¹ prior knowledge of an inherited mutation makes the difference between life and death. BRCA1 and BRCA2 are two human genes associated with hereditary forms of breast and ovarian cancer, and while everyone has these genes, mutations sometimes occur.²² When they do, these individuals have an “elevated lifetime risk” of developing cancer.²³ In fact, studies have shown that a woman who inherits a harmful mutation in BRCA1/2 is about five times more likely to develop breast cancer than a woman who does not have such a mutation.²⁴ BRCA1/2 also associates with breast and prostate cancer in men.²⁵

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²² ACLU FAQ, supra note 9.
²³ Id.
²⁴ NATIONAL CANCER INSTITUTE, supra note 17.
²⁵ ACLU FAQ, supra note 9.
Research indicates that those individuals who test positive for the BRCA1/2 gene face an increased risk of breast cancer ranging from 40 to 85 percent, and an increased risk of ovarian cancer of 15 to 40 percent.\textsuperscript{26} Statistics from 2007 reveal the relative lifetime risk of breast cancer was 2.7 to 6.4 times greater for those with BRCA mutations, and for ovarian cancer it was 9.3 to 35.5 times greater compared with other women.\textsuperscript{27}

Myriad Genetics is a private biotechnology company based in Utah,\textsuperscript{28} whose research helped develop the BRCA1/2 patents, supported in part by National Institutes of Health (NIH) grants the National Institute of Environmental Health Sciences.\textsuperscript{29} In December of 1995, Myriad Genetics filed for patents of its Comprehensive BRACAnalysis, which consists of a full analysis of the BRCA1/2 genes and detects for 5 common mutations.\textsuperscript{30} While NIH investigators are listed as coinventors, they assign the administration of BRCA1/2 to the University of Utah with exclusive licensing to Myriad Genetics. The patents are coassigned to the University of Utah and United States Department of Health and Human Services but Myriad Genetics effectively controls the patent rights.\textsuperscript{31} Myriad’s patent rights extend to both the BRCA1/2 genes and the accompanying tests. “If Myriad had simply patented a test, then other scientists and

\begin{small}
\textsuperscript{26} Trample Civil Liberties?, supra note 12, at 12.
\textsuperscript{28} ACLU FAQ, supra note 9.
\textsuperscript{29} Impact of Gene Patenting, supra note 23, at 819-20.
\textsuperscript{31} Impact of Gene Patenting, supra note 23, at 820.
\end{small}
laboratories could offer alternative testing on these genes.”  

Instead, Myriad’s power extends to all research, testing, and future developments involving the BRCA genes. 

B. Misreading Precedent: Why Gene Sequences Fail the Patentability Test

The founder of Myriad Genetics, Dr. Mark Skolnick, has a strong belief that his company earned the patents because of the large financial investment involved in obtaining the patent. He further claims that Myriad Genetics obtained the “right” to administer this test - and they do, receiving about 350 new samples per day. Each samples analyzed uses one or both of the two tests that Myriad performs: the comprehensive BRACAnalysis test (approximately $3,000) and an additional expanded BRACAnalysis Rearrangement Test (BART), which detects large rearrangement mutations in (approximately $600). According to Dr. Skolnick, “no women would have been tested for the BRCA mutations if not for Myriad.” Further, patent protection incentives founded the reason for Myriad Genetics’s inception, “because the necessary funding would not have been made available by investors,” says Dr. Skolnick.

To be eligible for a patent in the United States, the USPTO must certify that the invention meets three separate conditions: (1) novelty, (2) it utility, and (3) nonobvious. When it comes to biological material, whether genetic or not, much controversy surrounds the patent-eligibility of those “inventions” naturally occurring in humans.

When the Patent Act was enacted in 1952, it included any subject matter “under the sun

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32 ACLU FAQ, supra note 9.
33 Id.
35 Pins, supra note 30.
36 Conaboy, supra note 26.
37 Pins, supra note 30.
38 Pins, supra note 30.
that is made by man.”

Later, this assertion was modified by the product of nature doctrine, prohibiting patents based on the laws of nature, physical phenomena, and abstract ideas and mental processes. These three exceptions to patent-eligibility come from a 1980 United States Supreme Court case, *Diamond v. Chakrabarty*, which is the first and only decision directly addressing the patentability of living organisms. The Court in *Chakrabarty* upheld a patent for a laboratory-created bacterium with properties not found in nature, and two years later the USPTO granted its first human genetic material patent.

The patent system originally granted certain rights to inventors for their discoveries in order to reward and encourage human ingenuity. But like the ACLU argues, genes are not inventions but rather are natural parts of the human body. In fact, the USPTO recognizes this differentiation by maintaining the *Chakrabarty* exception, that products of nature not patentable. However, a genetic sequence may qualify if it is “isolated and purified,” through removing the gene from the human body and stripping away the “non-coding regions.” Yet the ACLU challenges the isolation and purification process when applying human genes, and argues that the process is “simple enough for any graduate student in genetics or a related field to perform.” Therefore, the ACLU analogizes the BRCA1/2 process to removing gold from a mountain and then

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40 *Something Like the Sun*, supra note 35, at XXX.
41 *Id.*
42 *Id.*
43 ACLU FAQ, supra note 9.
44 *Id.*
45 *Id.*
46 ACLU FAQ, supra note 9.
patenting the gold, therefore violating the ingenuity and nonobvious requirements for patentable material.\footnote{ACLU FAQ, supra note 9.}

Consequently, the ACLU and with 20 others initiated the lawsuit against Myriad Genetics on May 12, 2009, officially challenging the BRCA1/2 gene patent. Generally, the Plaintiffs pursued attacks on 4 patent categories: (1) patents on natural human genes, (2) patents on genes with natural mutations, (3) patents on any method of looking for mutations in natural human genes, and (4) patents over the general thought that genes are different with different effects, which correlate with an increased risk of breast and/or ovarian cancer.\footnote{Pins, supra note 30.} On March 28, 2010, the district court granted the Plaintiffs’ motion for summary judgment, effectively declaring Myriad’s patents invalid based on the theory that they contain products of nature and abstract ideas. Shortly after, the Defendants appealed.\footnote{Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al. (Fed. Cir.).}

On July 29, 2011, the appellate court found for Myriad Genetics, reversing in part the prior decision.\footnote{Id.} In the majority opinion, the court first held that isolated DNA does not stem from products of nature, and therefore is patent-eligible.\footnote{Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al.} Similarly, the “growing and determining method” Myriad utilizes for screening potential cancer therapeutics was held valid.\footnote{Id.} However, the “comparing” or “analyzing” diagnostic method used on DNA sequences held not patent-eligible, because they involve abstract mental processes.\footnote{Id.} Co-defendant Biotechnology Industry Organization (BIO)’s President/CEO, Jim Greenwood, released a statement directly following Myriad’s “win.”
Reiterating the patentability of gene processes he said, “patented DNA molecules have been put to countless uses that have benefited society… they are fundamentally different from anything that occurs in nature.”\(^{54}\) Yet the court’s decision regarding the products of nature doctrine was close at 2-1, with a strong dissent.\(^ {55}\)

The ACLU and Myriad Genetics each filed petitions for rehearings in August 2011, but both were denied.\(^ {56}\) Subsequently the ACLU’s writ of certiorari challenged the court’s ruling, specifically asking, “Did the court of appeals err in adopting a new and inflexible rule?” Even before Prometheus, many commentators predicted that the Supreme Court would reject as overly broad the scope of patent eligibility upheld by the Federal Circuit.\(^ {57}\) However the petition also makes clear that the Plaintiffs:

…are interested in not only reducing the scope of patent eligibility but in expanding the scope of declaratory judgment jurisdiction, so that members of the public affected by a patent but not threatened by suit would have standing. In many ways, this argument is much more threatening to an effective patent regime in this country, since garnering Supreme Court agreement would make the recent spate of patent litigation (that has raised so many concerns all across technology sectors) look benign (for example, if every consumer who purchases a patented product had standing to challenge the patent.\(^ {58}\)

III. The Harmful Impact of Myriad’s Gene Monopoly

*I'm a 41-year-old mother of two…Both my mother and maternal grandmother died from breast cancer. I'm worried about having a genetic predisposition for cancer but haven't been able to afford an additional test that would give me information about my

\(^{54}\) Pins, supra note 30.


\(^{56}\) Conley, *supra* note 51.


\(^{58}\) Id.
genes...Since childhood I have worried about cancer. This test would give me information I need to make life-changing medical decisions. There are so many unknowns. Why did my mother and her mother die from breast cancer?...I keep thinking about the legacy of motherless children in my family. From breast cancer, my mother died when she was only 28; my grandmother, at 52. My great grandmother (maternal grandmother's mother) died from the influenza at 33. I really want to be here for my kids. It is important for me to make informed decisions about my health... If I learned that I definitely inherited a genetic link to cancer, it would significantly change how I would protect my health.59

The Myriad case attracted a large amount of media attention and the lawsuit evoked a variety of challenges. From genetic counselors to cancer patients, and researchers to corporate directors, multiple arguments developed for and against BRCA1/2. It would be impossible to encompass the breadth and depth of perspectives that take issue with human gene patenting, but it is necessary to delve into a few in order to understand the impact of the Myriad case. Some entities focus on the damaging consequences resulting from Myriad’s monopoly and patent exclusivity. Others, like the ACLU, see gene patenting as a constitutional issue that infringes upon our First Amendment Rights.60 Ultimately, many agree that the patients are the ones who are eventually harmed, as BRCA1/2 tests are expensive and insurance does not always cover the costs.

A. Gene Patents Lock Down Innovation

Myriad Genetic’s strict enforcement of its license creates a monopoly in the field. Using its patent power, Myriad has sent several cease-and-desist letters to laboratories and researchers throughout the United States, telling them to stop testing.61 Out of fear of patent infringement penalties, this resulted in a chilling effect among the various parties

60 ACLU FAQ, supra note 9.
61 Id.
who deal with diagnostic testing. Dr. Harry Ostrer, a professor of pediatrics, pathology, and medicine, and a plaintiff in the case,\textsuperscript{62} is a working example of this fear that many are experiencing. Dr. Ostrer was unable to provide patients with results of BRCA1/2 tests due to Myriad’s patent, something he desired to do, and testified he would do if the patent was invalidated.\textsuperscript{63} Dr. Ostrer displayed frustration with the BRCA1/2 patent as it currently stands:

Currently, I am recruiting hundreds of women into a new study to identify other genes associated with a risk of breast cancer...Unfortunately, once such new genes are identified, the use of this information in clinical practice could be limited because it might be viewed by Myriad Genetics as infringing on its BRCA patents.... Every day I think about how the findings of the research laboratory can be translated into new genetic tests that might benefit, not harm, people.\textsuperscript{64}

In 2010, Myriad Genetics brought in $353 million (88 percent of their total revenue) from the breast cancer test.\textsuperscript{65} However, the industry has not seen any new innovation from Myriad in the past five years, when it last introduced the most recent BRCA1/2 test.\textsuperscript{66} Executives at Myriad say they plan to prepare for technological improvements,\textsuperscript{67} in response to claims of newer DNA-sequencing techniques being faster and less expensive compared to the technology that Myriad uses, reportedly from the


\textsuperscript{63} ACLU: Declarations – DC: Harry Ostrer: Harry Osterer.pdf, at pg. 3, #4; pg. 4, #6;

\textsuperscript{64} BRCA – Plaintiff Statements, Harry Ostrer, M.D. (May 12, 2009), available at: http://www.aclu.org/free-speech_womens-rights/brca-plaintiff-statements#ostrer

\textsuperscript{65} Id.

\textsuperscript{66} ACLU – Plaintiff Statements, Harry Ostrer.

\textsuperscript{67} Pollack, \textit{supra} note 80.
Admittedly, former Myriad employee Sean Tavtigian said that the company “is trying to catch up, but it’s going kind of slow.”

In fact, Life Technologies has developed a new Proton Sequencer that can read an entire person’s genome for $1,000 - much less than Myriad charges for its two gene test. A British company, Oxford Nanopore, recently introduced the world’s first miniature DNA sequencer and will be available commercially this year for $900. But because of strict patent protection on BRCA1/2, lawyers remain unsure whether other methods, like full gene sequencing, would violate Myriad’s patents on the isolated genes. Some predict that when Myriad’s patents expire, the price of whole genome sequencing will trend as low as $100, and single-gene test methods will be moot.

B. Gene Patents Limit Access to Diagnostic Tests

Based on my personal medical history, and my family history of cancer, two genetic counselors and my oncologist all agreed that… I should have the test from a clinical standpoint… Myriad is the only provider in the country because it has patents on the BRCA genes, but it will not enter into a contract with my insurance. Myriad holds my fate and future in its administrative hands, unless of course I am able to pay $3,225 out-of-pocket. Unfortunately, as a result of my illness and treatment, I do not have an extra three grand right now.

Another compelling reason to invalidate Myriad’s patent relates to patients inability to gain access to the BRCAnalysis or BART. This occurs when patients cannot afford the price of the test, or it is not covered by insurance. Both of these administrative complexities create barriers that prevent access to the latest cancer care options.

Consequently, Myriad is able to charge high rates for its testing, while picking and

68 Pollack, supra note 80.
69 Pollack, supra note 80.
70 http://www.ft.com/intl/cms/s/2/e3c6b7bc-3ac3-11e1-a756-00144feabdc0.html%23axzz1maUoc31U
71 http://www.ft.com/intl/cms/s/2/318a378a-5900-11e1-b118-00144feabdc0.html#axzz1oixikxkx
72 http://www.economist.com/node/15905837
choosing which insurance companies to contracts with.\textsuperscript{74} As Myriad remains the United States’ sole provider for the full BRCA1/2 DNA sequence,\textsuperscript{75} it has complete discretion regarding these important access decisions.

Myriad Genetics charges approximately $3,000 for their BRCA1/2 diagnostic test,\textsuperscript{76} and $700 for their BART test.\textsuperscript{77} The BART test was developed separately to test for genetic alterations in the BRCA1/2 genes. Instead of incorporating BART into BRCAnalysis it is offered separately. Mark Capone, president of the Myriad laboratory division, said that the company keeps BART separate because insurers would not pay for it, but the company plans to incorporate the BART test into its main product at an unspecified date.

The ACLU insists that the close relationship between price and utilization is to blame for those individuals who forgo potentially beneficial tests,\textsuperscript{78} which can be detrimental to their health. Genetic counselor Elen Matloff is similarly concerned; the BRCAnalysis costing her patients $3,400, and the supplemental BART test costing $700.\textsuperscript{79} Matloff further contends that 95 percent of patients she recommends for supplementary testing do not because of its high cost.\textsuperscript{80} Without the ability to pay for another test, Matloff worries about the potential impact it will have on patients and their relatives since many of these issues are hereditary. “[F]rom a clinician’s standpoint it is horrifying,” she says.\textsuperscript{81} Myriad counters this by providing free testing to first-degree

\textsuperscript{74} Trample Civil Liberties?, supra note 12, at 13.
\textsuperscript{75} Impact of Gene Patenting, supra note 23, at 822.
\textsuperscript{76} Trample Civil Liberties?, supra note 12, at 13.
\textsuperscript{77} Pollack, supra note 67.
\textsuperscript{78} Impact of Gene Patenting, supra note 23, at 822.
\textsuperscript{79} Amanda Wilson, ACLU Will Take Gene Patent Case to Supreme Court, INTER PRESS SERVICE, available at: http://ipsnews.net/news.asp?idnews=105472
\textsuperscript{80} Wilson, supra note 90.
\textsuperscript{81} Id.
relatives when results are ambiguous.\textsuperscript{82} However, as Matloff suggests, those affected by hereditary disease can extend from siblings and children to grandchildren, nieces and nephews.\textsuperscript{83}

\textbf{C. Lacking Competition Diminishes Quality and Efficacy of Tests}

\textit{Because of patents on the BRCA genes, only one company out there has the ability to sequence them. I can't get a second sequencing done at a different company to validate my results. I am thinking about having my ovaries removed because of my risk for ovarian cancer. It is uncomfortable making such an important decision based on only one test.}\textsuperscript{84}

One of the derivative problems stemming from Myriad’s monopoly is the inability for patients to obtain a second opinion, or verify their condition if they receive ambiguous results.\textsuperscript{85} “There are thousands of mutations along the BRCA genes and the significance of many of them is unknown. But the government allows Myriad alone to determine which mutations to test for, and to limit the study of other mutations.”\textsuperscript{86}

However, Myriad retains complete controls over the data and is under no obligation to share it with other researchers in order to fully investigate these findings. “Myriad used to share such information with a public database maintained by the National Institutes of Health, and it cooperated with academic scientists trying to analyze the mutations. But a few years ago, the company quietly stopped contributing and cooperating, in favor of building its own database.”\textsuperscript{87} This raises ethical concerns regarding Myriad’s behavior in withholding the mutation information. Not only would this information be vital for

\textsuperscript{82} Impact of Gene Patenting, supra note 23, at 830.
\textsuperscript{83} Wilson, supra note 90.
\textsuperscript{84} AMERICAN CIVIL LIBERTIES UNION, BRCA – Plaintiff Statements, Genae Girard (May 12, 2009), available at: http://www.aclu.org/free-speech_womens-rights/brca-plaintiff-statements#girard.
\textsuperscript{85} ACLU FAQ, supra note 9.
\textsuperscript{86} Id.
public health initiatives, but some question whether this extends the monopoly beyond the life of the patent itself.\textsuperscript{88}

Because Myriad does not allow anyone else to review their diagnostic procedures, women have no way of knowing whether the test was conducted properly. Similarly, there is no entity that could verify the accuracy of results or perform alternative testing without fear of patent infringement.\textsuperscript{89} This becomes an even larger issue for minority populations, who are more likely to receive test results indicating that they have a “variant of uncertain significance.”\textsuperscript{90} Therefore, African-Americans, Hispanics, and Asian-Americans are at a great disadvantage for their cancer treatment options, as they have no other way to find out if they are at a heightened risk for this disease.\textsuperscript{91} This can also lead to psychological confusion for the patients, who already face large amounts of stress given the nature of these diagnostic tests. Elsa Reich, M.S. is a genetic counselor in New York who provides insight on resulting difficulties when this situation arises:

Because there is a great burden to patients when there is no answer to the question "Why?" we as genetics professionals, go to great lengths to find those answers…When we have only one laboratory that we can use, we have no way of saying to our patients, "let's do this a different way", or "let's ask someone else."… I feel that patients deserve the opportunity to benefit from competition; the competition that brings new methods to the testing procedure; the competition that allows all comers to participate in the research and provide answers to more patients; the competition that allows for the provision of a second opinion.\textsuperscript{92}

\textsuperscript{88} Pollack, supra note 67.
\textsuperscript{89} ACLU FAQ, supra note 9.
\textsuperscript{90} Id.
\textsuperscript{91} Id.
\textsuperscript{92} BRCA – Plaintiff Statements, Elsa Reich, M.S. (May 12, 2009), available at: http://www.aclu.org/free-speech_womens-rights/brca-plaintiff-statements#reich
The common perception that Myriad’s exclusivity limits research is a large concern for many. Specifically, the Plaintiffs worry that a lack of competition does not reassure that Myriad will continue updating its test to reflect the most current scientific standards, “ultimately redirecting the standard of care for breast cancer testing.”93 Dr. Skolnick disagrees, saying the patent’s profitability actually acts as an incentive to encourage the company to solve any problems that arise.94 Further, the limited exclusivity offered by the patent encourages research, and allowed the University of Utah and Myriad Genetics to develop these tools in the first place.95 BIO agrees, adding that a restriction on gene patents would actually harm patients because the current system promotes physician and patient education, broader insurance coverage, and improved compliance in the diagnostic field.96

D. Insurance Coverage Challenges

Health insurance providers’ relationship with Myriad Genetics negatively affects patients’ ability to obtain testing. Women without insurance (nationally, 18.8 percent of women aged 19–64 are uninsured97), or with insurance that does not cover the test (one study found that 42 percent of insured women would not be covered for BRCA1/298), they might not be able to take advantage of this “potentially life-saving diagnostic tool.”99 Insurance problems can arise when Medicaid is involved, when a policy excludes genetic

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94 Pins, supra note 30.
95 Trample Civil Liberties?, supra note 12, at 12.
96 Trample Civil Liberties?, supra note 12, at 14.
97 Impact of Gene Patenting, supra note 23, at 833.
98 Id.
testing, or if the beneficiary lives in a geographic area where the insurance plan has
strong incentives to minimize utilization (as is the case in Southern California).\textsuperscript{100}

Insurance coverage of BRCA1/2 has certainly improved since 1995, when “only
4% of insurance providers…had granted coverage of BRCA testing,” but a long road lies
ahead as problems within the industry are still creating obstacles for patients and their
families. One study found that only 6 percent of decision makers for private health
insurance plans would opt to cover Myriad’s test if it were extended to all women in the
general population.\textsuperscript{101} Additionally, only 48 percent would offer it if it was restricted
only to those women with positive family history who were enrolled in an approved
research trial.\textsuperscript{102} In 2002, another study reported that only 38 percent of beneficiaries
were able to get genetic testing coverage from their insurance plan.

Myriad’s BRCAnalysis website claims that most insurance policies today cover
90 percent of the costs and reimbursement rates associated with the test and more than
2500 payers and health plans have reimbursed testing with Myriad. However a number
of insurers still do not cover BART, and Myriad has yet to secure Medicaid participating
provider status in 25 states, excluding this entire population from its services. In
response, Myriad does offer free testing via financial assistance programs and they
provide some independent non-profit institutions with free testing.\textsuperscript{103} However, some
consequences Myriad can not fix, like the 41 percent of women of women in 2002 who
chose not to file an insurance claim, despite 99 percent of those women had insurance.
Additionally, 15 percent of women in another study chose to self-pay their BRCA1/2

\textsuperscript{100} Impact of Gene Patenting, supra note 23, at 834.
\textsuperscript{101} Id.
\textsuperscript{102} Impact of Gene Patenting, supra note 23, at 833.
\textsuperscript{103} Conaboy, supra note 26.
fees. Each of these startling statistics stems from fear of insurance and employment discrimination, another reality surrounding the BRCA1/2 debate. Myriad says that only 5% of patients now self-pay, an improvement after the Genetic Information Nondiscrimination Act of 2008 (GINA) passed, which helped to reduce these fears.

Myriad’s final plea in the insurance challenge is that administration of BRCA1/2 testing is actually simplified from private insurance contracting, because it relieves patients of the hassle and associated paperwork. The company also claims that providers benefit too, as Myriad retains all legal liability for test inaccuracies. Additionally, because Myriad is a sole-source provider, they assume the sample collection, paperwork, and billing that insurance companies “might otherwise handle at their own institution through internal billing and administrative procedures.”

However, these perceived “advantages” only become available to those insurance companies and beneficiaries that have secured a contract with Myriad in the first place. Similarly, this creates an additional burden on patients who learn their condition is not covered by insurance – a result that comes from Myriad’s exclusivity and choice of insurance contracts.

**E. Discord with International Patent Law**

Recognition of Myriad’s patents raises disputes of how United States patents are subsequently treated abroad. Currently there are varying regulations throughout countries, which in turn, create international discrepancies in patent law, further complicating enforcement strategy in the U.S. For example, our neighbors in Canada have different public policy that permits labs to continue testing. After receiving various cease-and-desist letters from Myriad Genetics, the Canadian government issued the following statement, “it is the government’s position that predictive breast and ovarian

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104 Impact of Gene Patenting, supra note 23, at 833.
cancer tests should be available to women who require them.”\textsuperscript{105} In response, Myriad expressed its surprise that Canada would “continue to provide funding to laboratories that are directly infringing,” which resulted in a firestorm of media criticism over Myriad’s bullying tactics. Only years later did Myriad give up and redirect its efforts to building the United States Market. Today, multiple entities are able perform the BRCA1/2 test and “Canada has not altered its original position of ignoring not only Myriad’s patents but also the general issue of the interaction between the human gene patents and the public health care system.”\textsuperscript{106} Ultimately this has enabled Canadians to access to a valuable diagnostic tool without restriction and with more competitive pricing.\textsuperscript{107}

Even stricter, China has laws that explicitly opposes one type of human gene patents for embryonic stem cells, which the United States currently allows.\textsuperscript{108} Policy in China takes the same approach in challenging the validity of stem cell patents as many Plaintiffs assume for Myriad’s human gene patent: Chinese law takes into account morality considerations that U.S. patent law ignores, finding stem cell patents invalid because they are not novel nor non-obvious.\textsuperscript{109} While there are no plans today to create a universal patent system, the European Patent Office, Japan Patent Office, and USPTO recently discussed patent harmonization strategies at a November 2011 conference.\textsuperscript{110}

\textsuperscript{105} Richard Gold and Julia Carbone, \textit{Myriad Genetics: In the Eye of the Policy Storm}, 12 GENETICS IN MEDICINE 4, S39 (Supp. Apr. 2010).
\textsuperscript{106} Gold, supra note 103.
\textsuperscript{107} \textit{Trample Civil Liberties?}, supra note 12, at 12.
\textsuperscript{109} Zhu, supra note 106.
In turn, Europe strongly responded to the Myriad litigation, with numerous research institutes and genetics societies filing notices of opposition to Myriad's patents. There is also much speculation surrounding Myriad’s methods in conducting the full-sequence BRCAnalysis test, and the European Journal of Human Genetics questions whether this is the most cost-effective method. The Journal suggests that the monopoly is to blame after a Lewin Report study found BRCA1/2 to “affect development and provision of potentially more cost-effective testing strategies.”

France echoed this notion, promoting three alternative techniques to conduct BRCA1/2 diagnosis. One technique, called DDGE (denaturing gradient gel electrophoresis), would minimize the costs of diagnosis while also ensuring a comparable level of effectiveness. Also, when the Journal compared a commonly used French testing method with Myriad’s, the average cost per detected mutation was 5 times higher (this does not even including pricing strategy, it only focuses on the actual costs entailed to perform the test – supplies, equipment, personnel).

Further, the Australian government recently made developments in reviewing its own patent laws. Specifically, Australia decided to maintain genetic material and technology within the scope of its 1990 patent act, and is now reexamining the diagnostic, therapeutic and surgical treatment method. Overall, Australia hopes that this technology-neutral approach gives confidence to biotechnology research and development investments, and “ensure[s] that patients will not be denied reasonable

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111 Trample Civil Liberties?, supra note 12, at 13.
112 Impact of Gene Patenting, supra note 23, at 828.
113 Impact of Gene Patenting, supra note 23, at 828.
access to affordable treatment and essential diagnostic tests”\textsuperscript{115} that stem from inappropriate use of patent laws in Australia. This presence in the Australian community reflects upon the strength of the debate internationally, and raises the same issues being discussed here. Awaiting decision however is a 2010 bill, which would eliminate biological and genetic material patents, but Australians do not anticipate it will pass: “With the Government response…that the Patents Act should not be amended to explicitly exclude genetic materials from patentability, it is difficult to see how the Government could now support that Bill.”\textsuperscript{116}

Perhaps lawmakers in the United States should take a closer look at other countries for guidance in the Myriad case, both as a matter of public policy and to examine the realities concerning patent enforcement. Additionally, with Myriad planning to open a laboratory in Europe sometime next year, these considerations are even more timely\textsuperscript{117}

\textbf{IV. Prometheus Shapes Predicted Outcome in Myriad}

Only months after the Supreme Court granted certiorari to Myriad, the Court ruled a blood test patent developed by Prometheus invalid, reinforcing the “law of nature” doctrine. The test at issue looked at the chemical reaction after prescribing a drug, enabling a doctor to modify the dosage and make the treatment more effective or avoid unwanted side effects. In a unanimous decision, Justice Breyer wrote that inventors must do more than “recite a law of nature and then add the instruction “apply

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\textsuperscript{115} Id.  \\
\textsuperscript{116} Id.  \\
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The Court continued, noting patent monopolies might tend to impede innovation more than it would tend to promote it.  

The laws of nature involved here are the “relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm.” The legal question then becomes, “do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws?” For all nine members of the Court, the answer was a clear no.

Most importantly, Prometheus offers a clinical rationale directly supporting the ACLU in its fight against Myriad. The Court argued that Prometheus’ blood test patent directs a treating physician towards a particular course of action, imposing on the sanctity of the doctor-patient relationship. Explicitly the Court recognizes that these patents “tie up the doctor’s subsequent treatment” and “threaten to inhibit the development of more refined treatment recommendations.” Further, Prometheus’ patent encourages physicians to discard crucial treatment factors such as individual patient characteristics and physician’s own medical inferences in favor of a metabolic blood test. In the world of patent eligibility, Prometheus forces applicants and courts to reconsider the law of nature prohibition, as opposed to the equally controversial novelty, and nonobviousness requirements.

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119 Prometheus, 132 S. Ct. 1289.
121 Prometheus, 132 S. Ct. 1289.
122 Id.
V. Conclusion

When I was diagnosed with breast cancer, I was only 28. Because I am younger than most breast cancer patients and because the case was so aggressive, my doctor recommended that I take the BRCA genetic test to see if I was at higher risk for a second breast cancer or ovarian cancer. I took the test but my results were ambiguous. They showed that my BRCA genes had a "variant of uncertain significance," indicating that I have a mutation that may or may not mean a higher risk of cancer...I will have to make a decision about whether or not to have an oophorectomy (removal of the ovaries). I'm only 32 and don't have children. I want to be able to make an educated decision before I undergo such a serious and life changing surgery.123

Before Prometheus, gene patent opponents faced an uphill battle. With almost thirty years of patent law affirming the patentability of genes124 and a struggling economy, companies like Myriad Genetics have found a source of revenue they will fight to protect. While some earlier predicted that the USPTO is not ready to change its standards,125 Prometheus has changed the analytical framework regarding human gene patents.

Myriad Genetics cautioned about the negative repercussions that would result in finding for the Plaintiffs, claiming that the entire foundation of the biotechnology industry would unravel if human gene patents were invalidated.126 This facile argument overlooks the advantages that could result if other companies are allowed to compete. Most importantly, the cancer patients who need access to the BRCA1/2 test would have more affordable insurance options because more laboratories would offer the test.

For individuals like Vicky Thomason who are unable to pay for BRCA1/2, and “get up every day not knowing if [they] have a mutation,”127 this can make an incredible

123 ACLU – Plaintiff Statement: Runi Limary.
124 Jackson, supra note 10, at 1487.
125 Jackson, supra note 10, at 1487.
127 ACLU – Plaintiff Statements: Vicky Thomason.
difference. But instead of focusing on these objectives, Dr. Skolnick defends his company against ACLU and the Plaintiffs by saying:

“[T]he reason for the bilious attacks against us is that in the past various academic groups competed with each other on the one hand and various commercial groups competed with each other on the other hand. There had never previously been competition between a company and more than a dozen academic groups. If research stays in academia, the same groups which make the discoveries control the funding. When important research migrates to biotechnology and genomics companies in particular, the funding is generated outside of academia, and they lose control.”

The possibilities are endless if Myriad’s gene exclusivity ends: researchers would gain access to valuable data, more efficient testing methods could be developed, and future developments on the BRCA1/2 gene would not be seen as patent infringement. For the first time in patent history, the ACLU is questioning a human gene patent on constitutional grounds:

“The patenting of human genes undermines the free exchange of information and scientific freedom, bodily integrity, and women’s health. In granting exclusive rights to gene patent holders, the U.S. government in essence gives patent holders complete control over those genes and the information contained within them. This interferes with a person’s right to know about his or her own genetic makeup and scientists’ rights to study the human genome and develop new genetic tests. Granting a monopoly on fundamental pieces of knowledge infringes on First Amendment rights, which protect the freedom of scientific inquiry and the free exchange of knowledge and ideas.”

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129 Trample Civil Liberties?, supra note 12, at 17.
130 ACLU FAQ, supra note 4; see also Trample Civil Liberties? supra note 7, at 17.
Arguably, the Supreme Court granted certiorari in *Myriad* for the limited purpose of vacating and remanding the case for consideration in light of *Prometheus*. Here, the Court reinforced the notion that “laws of nature, natural phenomena, and abstract ideas” are not patentable, thus fueling the fire against Myriad. *Prometheus* directly contradicts the appellate court’s decision to uphold Myriad’s patents. With the case on remand, hopefully the court will follow *Prometheus*’ lead and set new precedent for human gene patent litigation in the future. Once the natural phenomena component of Myriad’s claims are stripped away, the court will consider the Myriad’s contribution to the BRCA1/2 test. “It then comes down to whether Myriad added anything non-routine or non-conventional, beyond that law of nature, to make it patentable.”

More crucial to the Court is the concern that scientists are unable to do research without infringing on the BRCA1/2 patent - not only does Myriad’s exclusivity stifle innovation and cancer research, but also it intrudes on the practice of medicine as a profession. After *Prometheus*, there is now real hope that gene patents will not impede the progress of researchers and medical professionals seeking to help patients through a better understanding and application of nature’s laws.

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