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## Gene Patents No More? Deciphering the Meaning of Prometheus

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# Gene Patents No More? Deciphering the Meaning of *Prometheus*

Dr. Fazal Khan\* and Lindsay Kessler\*\*†

## I. INTRODUCTION

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.”<sup>1</sup> 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 sequences and exclude others from conducting research or developing useful applications based on these sequences. In 2009, a broad coalition of plaintiffs challenged 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

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Dr. Khan and Ms. Kessler would like to thank Kirk Hartley of LSP Group, LLC in Chicago, IL for his dedication, passion and inspiration for this article.

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† Dr. Khan and Ms. Kessler would like to thank Kirk Hartley of LSP Group, LLC in Chicago, IL for his dedication, passion and inspiration for this article.

1. Jonah D. Jackson, *Something Like the Sun: Why Even “Isolated and Purified” Genes Are Still Products of Nature*, 89 TEX. L. REV. 1453, 1454 (May 2011).

favor of upholding Myriad's gene patents, overturning a lower court decision.

On March 20, 2012, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*<sup>2</sup> (*Prometheus*) potentially restored sanity on the issue of whether gene sequences can be patented. While not addressing gene patents specifically, a unanimous Supreme Court correctly reaffirmed that one cannot patent "the underlying laws of nature themselves."<sup>3</sup> However, the Court explicitly linked its decision to the viability of gene patents when less than a week later it vacated the *Myriad* decision and remanded it back to the Federal Circuit to reconsider in light of its ruling in *Prometheus*.

While it is not definitively clear that gene patents are dead in light of *Prometheus*, this essay argues that properly understanding the Supreme Court's logic should lead to no other result.<sup>4</sup> Predicting whether the "patent-friendly" Federal Circuit reaches the same conclusion is not the focus of this essay.<sup>5</sup> Instead, this essay serves to rebut claims that gene patents are consonant with patent law and needed to stimulate genomics research and development.

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. Furthermore, we will briefly examine the Supreme Court's legal reasoning in *Prometheus* and why it should be read as invalidating gene patents.

## II. CHALLENGING *MYRIAD*

The ACLU and 20 others initiated the lawsuit against Myriad Genetics on May 12, 2009, officially challenging the BRCA1/2 gene patent. The joined parties comprised of researchers, genetic counselors, women patients, cancer survivors, breast cancer and women's health groups, scientific associations representing 150,000 geneticists, pathologists and laboratory professionals. Generally, the Plaintiffs pursued attacks on 4

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2. *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012).

3. *Prometheus*, 132 S. Ct. at 1305.

4. Andrew Pollack, *Justices Send Back Gene Case*, N.Y. TIMES, Mar. 26, 2012, at B1, available at <http://www.nytimes.com/2012/03/27/business/high-court-orders-new-look-at-gene-patents.html>.

5. 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.*

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.<sup>6</sup> Before issuing a final opinion, the presiding judge denied the Defendants' motion to dismiss in November of 2009, which some understood as Judge Sweet recognizing the case's importance for medical research and innovation.<sup>7</sup> Later, on March 29, 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.<sup>8</sup> Shortly after, the Defendants announced its plans to appeal the decision.<sup>9</sup>

On July 29, 2011, the appellate court found for Myriad Genetics, reversing in part the prior decision.<sup>10</sup> In the majority opinion, the court first held that isolated DNA does not stem from products of nature, and therefore is patent-eligible.<sup>11</sup> Similarly, the "growing and determining method" Myriad utilizes for screening potential cancer therapeutics was held valid.<sup>12</sup> However, the "comparing" or "analyzing" diagnostic method used on DNA sequences held not patent-eligible, because they involve abstract mental processes.<sup>13</sup> Yet the court's decision regarding the products of nature doctrine was a close one at 2-1, with a strong dissenting opinion.<sup>14</sup> The ACLU and Myriad Genetics each filed petitions for rehearings in August 2011, but both were denied.<sup>15</sup> Following this decision, the ACLU filed a writ of certiorari to the US Supreme Court,<sup>16</sup> on December 6, 2011.<sup>17</sup>

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6. Marissa Noelle Pins, *Impeding Access to Quality Patient Care and Patient Rights: How Myriad Genetics' Gene Patents are Unknowingly Killing Cancer Patients and How to Calm the Ripple Effect*, 17 J. INTELL. PROP. L. 377, 379 (Spring 2010).

7. See Association for Molecular Pathology v. United States Patent and Trademark Office, 669 F. Supp. 2d 365 (S.D.N.Y. Nov. 1, 2009) [hereinafter Order to Deny Defendants' Motion to Dismiss].

8. Association for Molecular Pathology v. United States Patent and Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

9. Pins, *supra* note 6, at 382.

10. Association for Molecular Pathology v. United States Patent and Trademark Office, 653 F.3d 1329, 1333 (Fed. Cir. 2011).

11. *Id.* at 1350.

12. See *id.* at 1357.

13. *Id.*

14. John Conley, *ACLU and Myriad Both Seek Further Federal Circuit Review*, GENOMICS LAW REPORT (Sep. 2, 2011), <http://www.genomicslawreport.com/index.php/2011/09/02/aclu-and-myriad-both-seek-further-federal-circuit-review/>.

15. *Id.*

16. Allison Dobson, *Classen: Has the Federal Circuit Lost Interest in Patentable Subject Matter?*, GENOMICS LAW REPORT (Sep. 14, 2011), <http://www.genomicslawreport.com/index.php/2011/09/14/classen-has-the-federal-circuit-lost-interest-in-patentable-subject-matter/>.



Additionally, the USPTO scheduled two hearings “on independent second opinion genetic testing where patents and exclusive licenses exist that cover primarily genetic diagnostic tests,” for February 16 and March 9, 2012.<sup>18</sup> As we now know, these hearings are moot following *Prometheus*.

### III. LEGAL ARGUMENTS

To be eligible for a patent in the United States, the USPTO must certify that the invention meets three separate conditions: (1) it must be novel, (2) it must have utility, and (3) it must be nonobvious.<sup>19</sup> 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 that is made by man.”<sup>20</sup> Later, this assertion was modified when patents were prohibited on the laws of nature, physical phenomena, and abstract ideas and mental processes, otherwise known as the product of nature doctrine.<sup>21</sup> 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.<sup>22</sup> 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.<sup>23</sup>

The patent system was originally designed to grant certain rights to inventors for their inventions in order to reward and encourage human ingenuity.<sup>24</sup> 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.<sup>25</sup> However, a genetic sequence may qualify if it is

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17. Kevin Noonan, *Plaintiffs File Petition for Certiorari in AMP v. USPTO*, PATENT DOCS (Dec. 8, 2011), [http://www.patentdocs.org/2011/12/plaintiffs-file-petition-for-certiorari-in-amp-vuspto.html?utm\\_source=feedburner&utm\\_medium=email&utm\\_campaign=Feed%3A+PatentDocs+%28Patent+Docs%29](http://www.patentdocs.org/2011/12/plaintiffs-file-petition-for-certiorari-in-amp-vuspto.html?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+PatentDocs+%28Patent+Docs%29).

18. Donald Zuhn, *USPTO to Hold Hearing on Genetic Diagnostic Testing*, PATENT DOCS (Feb. 15, 2012), [http://www.patentdocs.org/2012/02/uspto-to-hold-hearing-on-genetic-diagnostic-testing.html?utm\\_source=feedburner&utm\\_medium=email&utm\\_campaign=Feed%3A+PatentDocs+%28Patent+Docs%29](http://www.patentdocs.org/2012/02/uspto-to-hold-hearing-on-genetic-diagnostic-testing.html?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+PatentDocs+%28Patent+Docs%29).

19. Pins, *supra* note 6, at 385.

20. Jackson, *supra* note 1, at 1454.

21. *Id.*

22. *Id.*

23. *Id.*

24. AMERICAN CIVIL LIBERTIES UNION, *Frequently Asked Questions: Legal Challenge to Patenting of Human Genes* (Sep. 10, 2010), available at [http://www.aclu.org/files/assets/legal\\_faq\\_brca.pdf](http://www.aclu.org/files/assets/legal_faq_brca.pdf) [hereinafter ACLU FAQ].

25. *Id.*

“isolated and purified,” through removing the gene from the human body and stripping away the “non-coding regions.”<sup>26</sup> Yet the ACLU challenges the isolation and purification process as applied to human genes, and argues that the process is “simple enough for any graduate student in genetics or a related field to perform.”<sup>27</sup> Therefore, the ACLU analogizes the BRCA1/2 process to removing gold from a mountain and then patenting the gold, therefore violating the ingenuity and non-obvious requirements for patentable material.<sup>28</sup>

#### IV. WHY PROMETHEUS SHOULD BE READ AS INVALIDATING GENE PATENTS

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.<sup>29</sup> 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.<sup>30</sup> In a unanimous decision, Justice Breyer wrote that inventors must do more than “recite a law of nature and then add the instruction “apply the law.”<sup>31</sup> As discussed below, the concerns raised by the Court in *Prometheus* are directly applicable to Myriad’s gene patents.

Myriad Genetics’ strict enforcement of its license created a monopoly in the field of BRCA 1/2 testing. 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.<sup>32</sup> Out of fear of patent infringement penalties, this has resulted in a chilling effect among the various parties who deal with diagnostic testing. Dr. Harry Ostrer, a professor of pediatrics, pathology, and medicine, and a plaintiff in the case,<sup>33</sup> 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

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26. *Id.*

27. *Id.*

28. *Id.*

29. Pollack, *supra* note 4.

30. *Id.*

31. *Id.*

32. AMERICAN CIVIL LIBERTIES UNION, *Legal Challenge to Human Gene Patents*, 2, 6 (June 27, 2009), [http://www.aclu.org/files/pdfs/freespeech/brca\\_qanda.pdf](http://www.aclu.org/files/pdfs/freespeech/brca_qanda.pdf) [hereinafter *Legal Challenge to Human Gene Patents*].

33. Plaintiff statement from Harry Ostrer, M.D., AMERICAN CIVIL LIBERTIES UNION, *BRCA-Plaintiff Statements*, (May 12, 2009), [http://www.aclu.org/free-speech\\_womens-rights/brca-plaintiff-statements#ostrer](http://www.aclu.org/free-speech_womens-rights/brca-plaintiff-statements#ostrer) [hereinafter Ostrer].

the patent was invalidated.<sup>34</sup> 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. False 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.<sup>35</sup>

In 2010, Myriad Genetics brought in \$353 million (88 percent of their total revenue) from the breast cancer test.<sup>36</sup> 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.<sup>37</sup> Executives at Myriad say they plan to prepare for technological improvements, in response to claims of newer DNA-sequencing techniques being faster and less expensive compared to the technology that Myriad uses, reportedly from the 1990s.<sup>38</sup> Admittedly, former Myriad employee Sean Tavtigian said that the company “is trying to catch up, but it’s going kind of slow.”<sup>39</sup>

In fact, Life Technologies has developed a new Proton Sequencer that can read an entire person’s genome for \$1,000<sup>40</sup> - less than Myriad charges for just two genes. A British company, Oxford Nanopore, has followed suit and recently introduced the world’s first miniature DNA sequencer and will be available commercially this year for \$900.<sup>41</sup> 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.<sup>42</sup> Some predict that when Myriad’s patents expire, the price of whole genome sequencing will trend as low as \$100, and single-gene test

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34. *Id.*

35. Declaration of Harry Ostrer, M.D., *available at* <http://docs.justia.com/cases/federal/district-courts/new-york/nysdce/1:2009cv04515/345544/47/0.pdf?ts=1251485192>.

36. Andrew Pollack, *Despite Gene Patent Victory, Myriad Genetics Faces Challenges*, N.Y. TIMES, Aug. 24, 2011, at B1, *available at* <http://www.nytimes.com/2011/08/25/business/despite-gene-patent-victory-myriad-genetics-faces-challenges.html?pagewanted=all> [hereinafter *Myriad Genetics Faces Challenges*].

37. Ostrer, *supra* note 35.

38. Myriad Genetics Faces Challenges, *supra* note 38.

39. *Id.*

40. Clive Cookson, *Machine to read individual’s DNA for \$1,000*, FINANCIAL TIMES (Jan. 10, 2012), <http://www.ft.com/intl/cms/s/2/e3c6b7bc-3ac3-11e1-a756-00144feabdc0.html%23axzz1maUoc31U>

41. Clive Cookson, *Oxford Nanopore unveils mini-DNA reader*, FINANCIAL TIMES (Feb. 17, 2012), <http://www.ft.com/intl/cms/s/2/318a378a-5900-11e1-b118-00144feabdc0.html#axzz1oixikxkx> [hereinafter *Oxford Nanopore*].

42. Myriad Genetics Faces Challenges, *supra* note 38.

methods will be moot.<sup>43</sup>

In other words, the exact concerns raised by the Supreme Court in *Prometheus* directly support 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."<sup>44</sup> 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.<sup>45</sup> 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 non-obviousness requirements.

## V. CONCLUSION

Before *Prometheus*, gene patent opponents faced an uphill battle. With almost thirty years of patent law affirming the patentability of genes<sup>46</sup> 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,<sup>47</sup> *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.<sup>48</sup> 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,"<sup>49</sup> this can make an incredible difference. The possibilities are endless if Myriad's

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43. THE ECONOMIST, *More harm than good? Patenting genes is bad for diagnosis*, Apr. 15, 2010, available at [http://www.economist.com/node/15905837?story\\_id=15905837](http://www.economist.com/node/15905837?story_id=15905837).

44. *Prometheus*, 132 S. Ct. at 1302.

45. *Id.*

46. Jackson, *supra* note 1, at 1487.

47. *Id.*

48. Miri Yoon, *Gene Patenting Debate: The Meaning of Myriad*, 9 J. MARSHALL REV. INTELL. PROP. L. 953, 973-74 (Spring 2010).

49. Plaintiff statement from Vicky Thomason. AMERICAN CIVIL LIBERTIES UNION, *BRCA-Plaintiff Statements*, (May, 12, 2009) [http://www.aclu.org/free-speech\\_womens-rights/brca-plaintiff-statements#thomason](http://www.aclu.org/free-speech_womens-rights/brca-plaintiff-statements#thomason).

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.<sup>50</sup>

Arguably, the Supreme Court granted certiorari in *Myriad* for the limited purpose of vacating and remanding the case for consideration in light of *Prometheus*.<sup>51</sup> *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.<sup>52</sup> "It then comes down to whether Myriad added anything non-routine or non-conventional, beyond that law of nature, to make it patentable."<sup>53</sup> 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.<sup>54</sup> 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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50. Ann Weibaecher, *Can Patent Protections Trample Civil Liberties? The ACLU Challenges the Patentability of Breast Cancer Genes*, 15 PUB. INT. L. REP. 10, 17 (2009).

51. John Conley & Dan Vorhaus, *Myriad Finally Reaches the Supreme Court (But Only For a Moment)*, GENOMICS LAW REPORT (Mar. 27, 2012), <http://www.genomicslawreport.com/index.php/2012/03/27/myriad-finally-reaches-the-supreme-court-but-only-for-a-moment/>.

52. See Christine Livoti, *Myriad's gene patents case may still end up at Supreme Court*, FINANCIAL TIMES (Apr. 3, 2012), <http://www.ft.com/intl/cms/s/2/ebad0c7a-7dca-11e1-9adc-00144feab49a.html#axzz1rg2V5HoW>.

53. *Id.*

54. See *id.*