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## Discovering the Undiscoverable: Patent Eligibility of DNA and the Future of Biotechnical Patent Claims Post-*Myriad*

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DISCOVERING THE UNDISCOVERABLE:  
PATENT ELIGIBILITY OF DNA AND THE FUTURE OF  
BIOTECHNICAL PATENT CLAIMS POST-*MYRIAD*

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ABSTRACT

*In June 2013 the Supreme Court held that naturally occurring human DNA cannot be patented, but synthetically created DNA is patent-eligible. Though a major victory for patients' rights, the holding of Association for Molecular Pathology v. Myriad Genetics appears to be the latest in a series of restrictions on patents and the human body, much to the annoyance of biotechnology companies. However, this case should not be viewed as the final word in patenting "natural phenomena." Patent claims of genetic material are still viable when the claim details a new and useful improvement on the naturally occurring product or an application of the product to a process. Furthermore, the Myriad Court noted that extending the natural products rule too far would be against public policy, giving litigators room to explore the contours of this rule.*

*This Article examines the limits of the Supreme Court's decision and the avenues that potential patent seekers still have for making eligible patent claims on naturally occurring products and phenomena, as well as the processes for identifying such products and phenomena. It*

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*highlights the areas where the courts are likely to take a hard stance against patent eligibility and where opportunities still exist to claim a valid patent in three areas. First, though discovery of a natural process in its naturally-occurring state is now un-patentable, the Myriad holding signals that a variation on this natural state, no matter how slight, could make the product eligible for a patent under the “new and useful improvements” rule. Second, the “application of new processes” rule is unchanged by this case. Third, a public policy argument on the importance of protecting medical and genetic discoveries may be more relevant in light of Myriad’s broad holding.*

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INTRODUCTION

In *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court unanimously reversed the Federal Circuit Court

of Appeals' finding that human DNA was patent-eligible.<sup>1</sup> The Court instead held that naturally occurring materials, even if first "discovered" by a company, do not fall within the scope of 35 U.S.C. §101 [hereinafter "§101"] and thus cannot be patented.<sup>2</sup> In a term that saw the Court tackle gay marriage, voting rights, and affirmative action, a case concerning patents and biotechnology did not stand out as the most vital issue. However, *Myriad* proves both a major victory in the realm of patient-subject rights and a cause of concern for the biotechnology industry.

*Myriad* has a complicated procedural background and is mired in difficult science. However, the Court answered in a brief opinion that discovery of genetic material, without significant changes to the natural substance, does not satisfy the "new and useful" standard under §101. While some fear that this holding will greatly restrict the incentives to engage in scientific research, *Myriad* should be seen for the opportunities it provides potential patent holders of natural products and the gaps left unaddressed. Although discovery alone may not be enough to warrant a patent, three doctrines are at a litigator's disposal in arguing for patent eligibility of genetic material. First, the reasoning of *Myriad* and its case history suggest that the courts and the United States Patent and Trademark Office will uphold claims detailing new and useful improvements, even if they are slight. Second, application of discoveries to specific processes was upheld in *Myriad*. Third, public policy arguments against over-applying the reach of the naturally occurring exemption can provide a potential fallback argument.

## I. PROCEDURAL HISTORY AND THE SUPREME COURT'S DECISION

In order to understand the Supreme Court's straightforward holding in *Myriad*, one must first parse through complicated science and a heated series of decisions among the lower courts.

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<sup>1</sup> 133 S. Ct. 2107, 186 L. Ed. 2d 124, 2013 WL 2631062 (June 13, 2013).

<sup>2</sup> *Id.*

### A. *Myriad's Patents*

In 1994, Myriad Genetics, Inc. discovered the location and sequence of the BRCA 1 and BRCA 2 genes (pronounced brah-ka).<sup>3</sup> These genes and their mutations are strongly linked to an increased risk of developing breast and ovarian cancer.<sup>4</sup> After pinpointing the genes' locations, Myriad developed a diagnostic test to detect the presence of the BRCA mutations in an individual's DNA.<sup>5</sup> Myriad was issued the patents for BRCA 1 and the diagnostic test in 1997, and for BRCA 2 and the diagnostic test in 1998.<sup>6</sup>

Additionally, Myriad was able to extract the DNA and synthesize a strand of nucleotides referred to as complementary DNA (cDNA).<sup>7</sup> This synthetic DNA is produced by recreating the RNA transcription process but results in a DNA sequence distinguishable from the source genetic material.<sup>8</sup> As with BRCA 1 and 2 and the testing, Myriad held patents to exclusively synthesize cDNA from the BRCA genes.<sup>9</sup>

By 1996, the University of Pennsylvania's Genetic Diagnostic Laboratory (GDL) began providing, for a fee, BRCA 1 and 2 diagnostic tests, while other labs sent patient samples to GDL for separate BRCA tests.<sup>10</sup> Myriad responded with letters advising GDL researchers that it would enforce its patents, and early litigation was resolved with agreements that the labs would discontinue activity that potentially infringed on Myriad's patents.<sup>11</sup>

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<sup>3</sup> *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1313 (Fed. Cir. 2012). This is the appellate decision that the Supreme Court overruled. Due to its more detailed and extensive discussion of the facts and science, it will be cited for most of the case background.

<sup>4</sup> *Id.*

<sup>5</sup> *BRCA Analysis*, MYRIAD GENETICS, <http://www.myriad.com/products-services/hereditary-cancers/braanalysis/> (last visited Aug. 25, 2014).

<sup>6</sup> *Ass'n for Molecular Pathology*, 689 F.3d at 1313 n.5.

<sup>7</sup> *Id.* at 1313–14.

<sup>8</sup> *Id.* at 1313.

<sup>9</sup> *Id.* at 1309.

<sup>10</sup> *Id.* at 1313.

<sup>11</sup> *Id.* at 1315–16.

*B. Road to the Supreme Court*

Myriad's warning letters were merely the beginning of what would become a drawn out legal battle. After GDL's agreement, a variety of clinical laboratories, medical societies, individual researchers, health-advocacy groups, and individual breast cancer patients challenged Myriad's patents.<sup>12</sup> Their suit commenced in May 2009 in the District Court for the Southern District of New York.<sup>13</sup> The complaint alleged violations of 35 U.S.C. §101 (patentable inventions), the Copyright Clause,<sup>14</sup> and the First and Fourteenth Amendments.<sup>15</sup>

The district court quickly dismissed the constitutional claims via the avoidance doctrine, and instead focused on the scope of 35 U.S.C. §101.<sup>16</sup> Examining the patents for the isolated BRCA genes and cDNA, the court held that a product of nature is not patentable unless the patent holder transforms the original product to the point that the new product possesses "markedly different characteristics."<sup>17</sup> The court found that Myriad failed to show the BRCA genes, in isolated form, were significantly different from their natural state.<sup>18</sup> Even the patents for the cDNA were determined to be naturally occurring products, as they were essentially the result of a natural splicing process of pre-mRNA to mature mRNA.<sup>19</sup>

In regard to the "method" claims of Myriad, the court again implemented a strict reading of §101, holding that a process claim is patent-eligible only if: "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different

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<sup>12</sup> Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 186–90 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011).

<sup>13</sup> *Id.* at 186.

<sup>14</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>15</sup> 702 F. Supp. 2d at 184.

<sup>16</sup> *Id.* at 232.

<sup>17</sup> *Id.* at 228.

<sup>18</sup> *Id.*

<sup>19</sup> *Id.* at 230.

state or thing.”<sup>20</sup> The court dismissed Myriad’s argument that the “analyzing” and “comparing” functions of the isolated DNA amounted to a transformation from its natural state, instead finding this process to be comparable to mere “data-gathering.”<sup>21</sup> Additionally, the patent Myriad held on a process to compare the growth of cancer cells in the presence of different therapeutic substances was determined to merely involve the measuring of a basic scientific principle and was also deemed un-patentable. As such, both Myriad’s DNA and method claims were held invalid.<sup>22</sup>

Upon review, the Federal Circuit reversed the district court’s invalidation of the isolated DNA patents, affirmed the holding as to the method claim for comparing isolated gene sequences, and reversed on the process to compare growth of cancer cells claim.<sup>23</sup> Upon a grant of certiorari, the Supreme Court vacated the order and remanded to the Federal Circuit in light of its recent decision, *Mayo Collaborative Services v. Prometheus Laboratories Inc.*,<sup>24</sup> a case which, as discussed below, foreshadowed the final Supreme Court decision in *Myriad*.<sup>25</sup>

On its second hearing of the case, the Federal Circuit ultimately maintained its original position, holding the DNA claims and cancer-growth process patent-eligible but the methodology for observing the gene sequences patent-ineligible.<sup>26</sup> Finding both the isolated BRCA genes and the cDNA to have a different chemical structure from their original source DNA, the court determined these compositional claims fell within the scope of §101.<sup>27</sup> The court found that the products-of-nature exemption used by the lower court was too broad, as any product can be

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<sup>20</sup> *Id.* at 233 (quoting *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008)).

<sup>21</sup> *Id.* at 236.

<sup>22</sup> *Id.* at 238.

<sup>23</sup> *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1357 (Fed. Cir. 2011).

<sup>24</sup> 132 S. Ct. 1289 (2012).

<sup>25</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012).

<sup>26</sup> *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1336 (Fed. Cir. 2012).

<sup>27</sup> *Id.* at 1332–33.

traced back to a naturally occurring source.<sup>28</sup>

In regard to the cancer-growth process, the court noted that because the method included the “growing of host cells *transformed*” by an altered BRCA 1 gene or a cancer therapeutic, the claim on this process was patent-eligible under §101.<sup>29</sup> The transformative element distinguished this process from a mere comparison and analysis of cells.<sup>30</sup> Again, the court found no transformative process in the analysis of the BRCA sequences.<sup>31</sup> This claim, the court held, merely involved an abstract mental process, which could be accomplished by a simple inspection of the DNA.<sup>32</sup>

### C. The Supreme Court’s Decision

Following the Federal Circuit’s opinion, the Supreme Court granted certiorari in November 2012 and prepared to hear the case on the merits. The Supreme Court issued its decision in June 2013. Justice Thomas, authoring the unanimous decision, did away with much of the complex scientific background and theories of §101, instead asking simply whether Myriad’s patents assert a “new and useful . . . composition of matter” or merely a “naturally occurring phenomena.”<sup>33</sup>

Rejecting the Federal Circuit’s liberal application of transformation in the isolation of DNA, the Supreme Court found no significant change between the isolated BRCA genes and the genes in their original state.<sup>34</sup> The Court held that the discovery of an important and useful gene, no matter how groundbreaking or innovative, does not satisfy §101’s new compositions requirement.<sup>35</sup>

In contrast, the Court held cDNA is not naturally occurring and

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<sup>28</sup> *Id.* at 1331.

<sup>29</sup> *Id.* at 1335 (emphasis added).

<sup>30</sup> *Id.* at 1336.

<sup>31</sup> *Id.* at 1334.

<sup>32</sup> *Id.* at 1335.

<sup>33</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (June 13, 2013).

<sup>34</sup> *Id.* at 2117.

<sup>35</sup> *Id.*



is therefore patent-eligible.<sup>36</sup> Despite the cDNA strand containing the exons of its original source, the Court determined that this synthesized strand does not occur as a natural phenomenon. It is only producible in a lab setting.<sup>37</sup>

Finally, unlike in the previous decisions, the Court did not analyze the method claims. It did, however, suggest that had Myriad created an innovative way to manipulate an individual's genes in its search for the BRCA genes, a method patent could have been valid.<sup>38</sup> Here, since the processes for isolating the genes "were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach," the Court found no such novel claim.<sup>39</sup>

Subsequent cases have generally followed the holding of *Myriad* closely, declining to explore the questions that remain.<sup>40</sup> This lack of exploration also means that the questions on the limits of naturally occurring product and method claims have not been completely answered. These unanswered questions provide a viable option for patent seekers: arguing that a once naturally occurring product exists only through man-made manipulation, even to the slightest extent, is enough to establish patentability.

## II. AN EXAMINATION OF THE "NATURALLY OCCURRING PRODUCT" REQUIREMENT AS INTERPRETED BY THE SUPREME COURT

Though §101 appears on its face to be a straightforward rule, a deeper examination of its application reveals the statute's limitations that may still be exploited to a patent seeker's benefit. Justice Thomas relied heavily on the plain language of §101 in *Myriad*. However, as in *Mayo*, the Court again refused to define the contours of this section and when a product is no longer

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<sup>36</sup> *Id.* at 2119.

<sup>37</sup> *Id.*

<sup>38</sup> *Id.* at 2119–20.

<sup>39</sup> *Id.*

<sup>40</sup> See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, No. C11-06391 SI, 2013 WL 5863022 (N.D. Cal. Oct. 30, 2013); *Oleksy v. General Elec. Co.*, No. 06 C 01245, 2013 WL 3233259 (N.D. Ill. June 26, 2013).

considered “naturally occurring.” This section will introduce the challenges and shortcomings within the statute itself and the court-created limitations.

#### A. *Statutory Shortcomings*

The statute in question, 35 U.S.C. §101, does not provide specific guidance on the limits of patent-eligibility. Rather, the statute reads, “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”<sup>41</sup> Based on only the statute’s plain language, the *Myriad* opinion is troubling since *Myriad* did *discover* a new and useful process. Yet the discovery did not satisfy the statutory standard. Additionally, *Myriad* isolated the BRCA genes for testing, but again this was not a valid “new or useful improvement.” Thus, on the face of the case, *Myriad* appeared to have satisfied the discovery requirement. The Supreme Court’s decision reveals, however, that a patent seeker cannot rely on the plain language of §101 alone. As guidance through the Court’s interpretation, the patent seeker must also consider the common law exceptions to the statute.

#### B. *Interpreting the Statute’s Court-Created Limits*

Recognizing that certain items and phenomena cannot truly be “created” for the purposes of patents, the Supreme Court gradually identified three subjects over time that are not patentable under §101: (1) laws of nature; (2) natural phenomena; and (3) abstract ideas.<sup>42</sup> However, the Court has also realized that these exceptions cannot be overly broad. Since nearly every invention or theory will rely on either a law of nature, natural phenomenon, or abstract idea, the possibility of “eviscerating” patent law must constantly be kept in mind.<sup>43</sup> At some point the creative manipulation of a law of

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<sup>41</sup> 35 U.S.C. § 101 (1952).

<sup>42</sup> *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

<sup>43</sup> *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S. Ct. 1289, 1293 (2012).

nature, natural phenomena, or abstract idea will need to be protected under patent law. The Court declined to specify where the line is drawn between the exceptions to §101 and the eviscerating, overly-broad interpretations. The *Myriad* opinion, however, hints at when a patented natural product falls within the realm of patentability.

### III. CREATING VIABLE PATENT CLAIMS POST-*MYRIAD*

Despite the Supreme Court issuing a very blunt and fairly straightforward decision in *Myriad*, the Court alluded to the contours of the Court-created limits of §101 as well as unaffected arguments. In the case, *Myriad*'s arguments about the usefulness of its discovery and difficulty in isolating the BRCA genes were not enough to satisfy §101. The opinion appears on its face to be so broad and insensitive to the nuances of *Myriad*'s claims that it created a sweeping bar against patenting any natural materials. However, an analysis of the cDNA claims, application rules, and policy concerns reveals that the Court left room for arguments to circumvent the basic natural products rule, which the careful attorney can utilize in drafting, defending, or challenging patent claims.

#### A. *Deciphering the Limits of New and Useful Improvements through cDNA*

As noted above, §101 poses a difficult dilemma for patent seekers. Natural products cannot be patented, but since everything comes from a natural product, what constitutes enough manipulation of the natural state to qualify as a patentable product under §101? The Court's short analysis of cDNA suggests that the required transformation from natural to unnatural may in fact be minimal.

Immediately following *Myriad*, the United States Patent and Trademark Office issued a memorandum to its staff directing examiners to reject product claims "drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or

not . . . .”<sup>44</sup> However, the Office recognized that claims demonstrating that the naturally occurring matter has been altered (“e.g., a man-made variant sequence”) are eligible.<sup>45</sup> The Office later issued additional guidance to the Patent Examining Corps, directing that all claims that recite or involve a law of nature, natural phenomenon, or natural product be rejected unless the claims also recite something “significantly different” than the judicial exception.<sup>46</sup> The Office suggested two general ways in which a significant difference can manifest: (1) the claim adds elements or steps to the judicial exception that “practically apply the judicial exception in a significant way” or (2) the claim states some features or steps demonstrating the claimed subject matter is “markedly different” from the natural product or phenomena.<sup>47</sup> Additionally, the Office listed six factors that suggest a claim is eligible and six that suggest it is ineligible. Two of these factors are of particular relevance to patent claims involving genetic material: “factor (a),” where the claim is a product that appears to be merely a natural product but demonstrates that it is non-naturally occurring and markedly different from the natural product (weighing in favor of eligibility), or “factor (g),” where the claim recites a natural product or something that resembles a natural product but is not markedly different.<sup>48</sup> Thus, in applying for a patent, the most significant step an applicant can take is stressing the variation that has occurred to the natural product. However, these guidance memos do little to clarify what constitutes a marked or significant difference in the claimed product.

Rather, a determination of the degree necessary to satisfy this

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<sup>44</sup> Memorandum from Andrew H. Hirshfeld, Deputy Comm’r for Patent Examination Policy, U.S. Patent and Trademark Office, to the Patent Examining Corps (June 13, 2013), *available at* [http://www.uspto.gov/patents/law/exam/myriad\\_20130613.pdf](http://www.uspto.gov/patents/law/exam/myriad_20130613.pdf).

<sup>45</sup> *Id.*

<sup>46</sup> Memorandum from Andrew H. Hirshfeld, Deputy Comm’r for Patent Examination Policy, U.S. Patent and Trademark Office, to the Patent Examining Corps (Mar. 14, 2014), *available at* [http://www.uspto.gov/patents/law/exam/myriad-mayo\\_guidance.pdf](http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf).

<sup>47</sup> *Id.* at 3–4.

<sup>48</sup> *Id.* at 4.

“significantly different” standard is best clarified by the *Myriad* decision and previous natural product cases. Central to the Court’s rejection of Myriad’s BRCA patents was the idea that the company had not made any new or useful improvements to the original gene sequence.<sup>49</sup> The BRCA genes isolated from the individual’s DNA were structurally the same product as the genes in their natural state. Conversely, the Court in *Diamond v. Chakrabarty* found that when scientists added plasmids to a bacterium, which broke down various components of a bacterium, the resulting bacterium was patentable.<sup>50</sup> The process of breaking down the bacterium was not the claim in dispute, but the resulting product was.<sup>51</sup> The Court found that the final bacterium was the result of “human ingenuity,” having “a distinctive name, character [and] use.”<sup>52</sup> Thus, *Chakrabarty* indicates that the final product resulting from the natural reaction between two other natural products meets the patentability standard.

While the extent of the change has not been defined, the *Myriad* Court’s examination of the cDNA claims provides insight on how little the change really needs to be. The Court found that cDNA easily meets the threshold for §101, despite the petitioner’s arguments that the basic structure of cDNA is “dictated by nature, not by the lab technician.”<sup>53</sup> Since the exon-only sequence does not occur in nature, the Court found the cDNA patents to be valid.<sup>54</sup> The holdings of *Myriad* and *Chakrabarty* suggest that all that is required to meet the new and useful improvement standard for natural products is a change that could not occur but for the patent seeker’s intervention or process.

Without any firm measurement by the Court, even the slightest variation could meet the standard under §101 as long as the change does not occur as a natural process. Litigators defending or challenging future patent claims on similar grounds should seize

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<sup>49</sup> Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (June 13, 2013).

<sup>50</sup> 447 U.S. 303, 309–10 (1980).

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> 133 S. Ct. at 2119.

<sup>54</sup> *Id.*

upon this ambiguity, stressing the uniqueness of the holder's claims, or lack thereof. In particular, focus should be drawn to the differences between the naturally occurring state and the processed result.

While Myriad relied heavily on its discovery of the BRCA genes, the Court's decision and the Patent Office's subsequent guidance documents may result in a shift away from the discovery arguments. Discovery, no matter how groundbreaking, is merely a noteworthy accomplishment that affords little legal protection post-*Myriad*. Instead of attempting to protect their discovery, patent seekers will likely find more success arguing the validity of the resulting product. Patent seekers might even forgo method claims, especially those involving well-known scientific processes, and stress the new and useful improvements on a naturally occurring product in their patent requests.

*B. "Application of New Processes" Patents Remain Valid*

Patent seekers should also not ignore the importance of making application claims, an opportunity the Supreme Court and Federal Circuit each believed Myriad had squandered.<sup>55</sup> The Supreme Court suggested that Myriad was in an advantageous position to claim new applications of its knowledge about BRCA 1 and 2.<sup>56</sup> The Federal Circuit noted that Myriad could claim application of the BRCA discoveries especially in its fight against breast cancer.<sup>57</sup> However, to a future patent seeker, an application claim will be easier said than done. The claim will have to state a specific application of the discovery, but such a statement does not guarantee that the discovery, process, or modified product will be protected by patent law.<sup>58</sup> Practitioners should keep in mind that

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<sup>55</sup> *Id.* at 2120; Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1349 (Fed. Cir. 2012).

<sup>56</sup> 133 S. Ct. at 2120 (quoting 689 F.3d at 1349).

<sup>57</sup> 689 F.3d at 1349.

<sup>58</sup> See Memorandum from Andrew H. Hirshfeld, Deputy Comm'r for Patent Examination Policy, U.S. Patent and Trademark Office, to the Patent Examining Corps (Mar. 14, 2014), available at [http://www.uspto.gov/patents/law/exam/myriad-mayo\\_guidance.pdf](http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf) (stating that a natural product claim can be analyzed with only factors (a) and (g) while other claims, including

the Court separated the application claims from the product claim.<sup>59</sup>

For example, in *Myriad*, while the BRCA genes could never have been patentable, the patent claim would be acceptable had it made a new or useful application claim. Conversely, one could make a valid patentable product claim, but the claim for the application of the product, if relying upon well-known processes, would not be eligible. Thus the patent seekers should recognize that product and application claims are not necessarily bound together and that a claim for application may still protect discovery even if the product claim is deemed ineligible.

### *C. Limits of the Exceptions: How Far Is Too Far?*

If significant changes to a product of nature are impractical or impossible and an application claim is futile, a policy argument still remains a powerful tool in defending a patent. Though the Supreme Court raised the issue of whether an overly broad reading of §101 will detrimentally impact future patent claims, the line is yet to be definitively drawn. Though such arguments have no place in applications for patents, this issue will continue to be an important argument for the courtroom.

One important aspect of the policy argument is the difficulty of discovery. Even the Supreme Court missed the opportunity to distinguish between easily made discoveries of natural products, phenomenon, or abstract ideas and discoveries that involve a far more nuanced approach. The strict adherence to the plain language of §101 does not allow for such distinctions. In *Mayo*, decided shortly before the final *Myriad* decision, the Court equated (at least in terms of patent eligibility) medical discoveries to discoveries based on basic observations, noting that “a new plant found in the wild is not patentable subject matter.”<sup>60</sup> Unlike a person who stumbles upon a plant and discovers it has medicinal purposes through mere chance, genetics is a very deliberate and expensive

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application claims, should be analyzed with the remaining factors).

<sup>59</sup> 133 S. Ct. at 2119.

<sup>60</sup> *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S. Ct. 1289, 1293 (2012).

science. Individuals do not merely come across genes in the course of their day. Trained scientists with advanced equipment and funding make concentrated efforts to seek out such phenomena. Yet the Court refused to make such a distinction and essentially held the geneticist's discovery to the same standard as the lucky individual who discovers the plant.

Another issue is the potential chilling effect on the biotech industry. The basic principles of patent law are that patent law needs first to seek to "foster and reward" inventor and second to promote disclosure of inventors' ideas to stimulate further innovations.<sup>61</sup> As the field of genetics continues to grow, the courts will have to continue to keep these principles in mind. While patient rights will always remain a valid concern, the fostering of scientific discovery should not be ignored. In light of the broad holding of *Myriad*, this public policy argument against stifling discovery may carry increasing weight and, as such, courts may be reticent to remove protections for innovative discoveries.

#### CONCLUSION

Given the relatively recent publication of *Myriad*, application of the case has been slow in lower courts. Nonetheless, the importance and profitability of scientific, and specifically genetic, research requires that the courts draw a line so as to not completely stifle the field. However, this need must be balanced with patient rights. The *Myriad* decision offers insights into both these arguments. As long as a claim attempts to patent genetic material in its natural state, the courts will invalidate the patent for the foreseeable future. However, the validation of the cDNA patents suggests that even the slightest changes to the natural state can suffice for patentability under §101. Additionally, *Myriad* does not appear to have had an effect on method or application claims. Thus, practitioners are still left with the ability to patent genetic materials as long as the claim places emphasis on variations on the product, method, or unique application of a process. Finally, the

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<sup>61</sup> Robert A. Matthews Jr., 1 Annotated Patent Digest §1:2: Purposes of the patent system (updated July 2014).



public policy argument against overly broad interpretations of §101 can continue to be argued with attention to the necessity for protection and promotion of discovery.

#### PRACTICE POINTERS

- Keep in mind policy arguments about the overreach of the law and argue the necessity of protecting and promoting innovation.
- When drafting a patent application, stress that the new product cannot occur in nature and only exists through the process rendered by the patent seeker.
- Put additional emphasis on the description of utility and the transformative elements of the inventive method or composition as an application of a natural law.
- Avoid claims that only have “comparing” or “determining” elements associated with a natural correlation.