
NOTES

A MYRIAD OF SOLUTIONS? A GUIDE FOR BIOTECH COMPANIES IN RESPONSE TO THE *MYRIAD* & *MAYO* DECISIONS

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I. INTRODUCTION

2013 was a major year for biotechnology (biotech) companies regarding patentable subject matter,¹ as the United States Supreme Court, in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, decided deoxyribonucleic acid (DNA) was not patentable subject matter.² While many have hailed this decision as a victory for public health and individual rights,³ others have argued this decision effectively sounded the death knell for patents on genetic-based testing and diagnostics.⁴ This Note will focus on analyzing the current law regarding patentable subject matter under section 101 of the United States Patent Act⁵ in light of the Supreme Court decisions in *Myriad*⁶ and *Mayo*⁷ in order to provide a guide for biotech companies to continue to secure intellectual property (IP) protection for their innovations.

¹ Christopher Bergin, Comment, *Take off Your Genes and Let the Doctor Have a Look: Why the Mayo and Myriad Decisions Have Invalidated Method Claims for Genetic Diagnostic Testing*, 63 AM. U. L. REV. 173, 178 (2013).

² *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, 133 S. Ct. 2107 (2013).

³ Sapna Kumar, *Life, Liberty, and the Pursuit of Genetic Information*, 65 ALA. L. REV. 625, 627 (2014).

⁴ Bergin, *supra* note 1, at 178.

⁵ 35 U.S.C. § 101 (2012).

⁶ *Ass'n for Molecular Pathology*, 569 U.S. ___, 133 S. Ct. 2107.

⁷ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. ___, 132 S. Ct. 1289 (2012).

“In 2005, it was estimated that more than 40,000 DNA-related patents had been issued by the Patent Office, . . . [but today] this number has [likely] grown.”⁸ While this data clearly reflects the Patent Office’s policy of favoring gene-based patents,⁹ it is not clear what effect, if any, the *Myriad* decision will have on existing DNA patents.¹⁰ This has left biotech companies “without any clear guidance . . . , encourag[ing them] to gamble on the prospect of [maintaining] patent protection.”¹¹ Due to the immense cost that is often associated with filing and maintaining patent protection,¹² not to mention the research and development cost of the underlying invention, this lack of clarity is not surprisingly unsettling to biotech companies.¹³ Therefore, it is imperative that biotech companies have a firm grasp on what constitutes patentable subject matter regarding gene-based technologies so that they can translate that knowledge into products that qualify for patent protection.

Part II of this article will give a brief overview of patent law and what is and is not patentable under section 101. Part III will summarize the *Myriad* and *Mayo* decisions and their impact on biotech companies. Part IV will specifically address the requirements for patentable subject matter under section 101 in light of *Myriad* and *Mayo*. Additionally, Part IV will lay out the analytical framework that a biotech company must go through when contemplating patenting DNA-based technologies. Part V will explore the gene-based technologies that are unaffected by the *Myriad* and *Mayo* decisions, in addition to providing guidelines for biotech companies seeking to patent their gene-based technology under the *Myriad* and *Mayo* rules. Additionally, Part V will address the other areas of IP law, such as trade secrets, that may provide a company with protection in the absence of a patent. Finally, Part VI will provide a summary and conclusion of the best way for biotech companies to move forward with their IP strategies. While the *Myriad* and *Mayo* decisions at first may seem insurmountable from a DNA patent standpoint, a good understanding of their applicability combined with a comprehensive IP strategy will allow biotech compa-

⁸ Jake Gipson, Note, *Patentable Subject Matter: A Myriad of Problems*, 65 ALA. L. REV. 815, 826 (2014).

⁹ Kumar, *supra* note 3, at 643.

¹⁰ Gipson, *supra* note 8, at 827.

¹¹ *Id.*

¹² Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1310–12 (2009).

¹³ See Gipson, *supra* note 8, at 827.

nies to continue to secure IP protection for their gene-based technologies.

II. AN OVERVIEW OF PATENT LAW

United States patent law finds its express authorization in Article I, Section 8 of the Constitution.¹⁴ The policy rationale behind the constitutional grant of power was to incentivize invention and promote discovery in the arts and sciences.¹⁵ Congress passed the initial United States Patent Act in 1952 as a way to fulfill this policy rationale by rewarding inventors with a limited monopoly over their inventions.¹⁶ “The current patent laws provide . . . a patentee . . . [with] the exclusive right to make, use, sell, offer to sell, or import the invention for a duration of twenty years.”¹⁷ In general, to qualify for a patent an invention must meet the basic requirements of utility,¹⁸ novelty,¹⁹ nonobviousness,²⁰ and enablement.²¹ However, laws of nature, physical phenomena, and abstract ideas are not patentable subject matter.²² The basic rationale behind these exceptions “is that they are the basic tools for innovation, and their monopolization might impede rather than promote further innovation.”²³

Since the *Myriad* and *Mayo* decisions focused solely on what constitutes patentable subject matter under section 101, a deeper understanding is necessary. Section 101 sets out “the ‘threshold test’ for patentability”²⁴ by defining patentable subject matter as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”²⁵ The Supreme Court has interpreted this language as evidence of Congress’s intent to give “the patent laws . . . wide scope.”²⁶ However, this “does not mean that anything is patentable subject matter.”²⁷ As mentioned above, the

¹⁴ U.S. CONST. art. I, § 8, cl. 8.

¹⁵ Kumar, *supra* note 3, at 633.

¹⁶ ROBERT P. MERGES ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 127 (6th ed. 2012).

¹⁷ Gipson, *supra* note 8, at 816.

¹⁸ 35 U.S.C. § 101 (2012).

¹⁹ *Id.* § 102.

²⁰ *Id.* § 103.

²¹ *Id.* § 112.

²² *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

²³ Gipson, *supra* note 8, at 817.

²⁴ Bergin, *supra* note 1, at 179.

²⁵ 35 U.S.C. § 101 (2012).

²⁶ *Diamond*, 447 U.S. at 308.

²⁷ Gipson, *supra* note 8, at 817.

Court has restricted the scope of section 101 regarding laws of nature, physical phenomena, and abstract ideas.²⁸ It is important to keep these concepts in mind when discussing the *Myriad* and *Mayo* decisions.

III. *MYRIAD* AND *MAYO*: WHAT THEY MEAN AND THEIR IMPACT

In 2004, Prometheus Laboratories, Inc. (“Prometheus”) brought a patent infringement suit against the Mayo Clinic Rochester and Mayo Collaborative Services (collectively, “Mayo”) claiming Mayo had infringed on its patents covering the use of thiopurine drugs in the treatment of Crohn’s disease and ulcerative colitis.²⁹ In response, Mayo claimed that Prometheus’s patents were invalid because they “effectively claim[ed] natural laws or natural phenomena.”³⁰ The district court agreed with Mayo and held that Prometheus’s patents were invalid.³¹ The U.S. Court of Appeals for the Federal Circuit however, disagreed and reversed the district court’s decision.³² The Supreme Court granted certiorari in 2011 and held that Prometheus’s patents were invalid because they set forth laws of nature and thus were not patentable subject matter under section 101 of the Patent Act.³³

The Court in *Mayo* reasoned that Prometheus’s patent claims were nothing more than correlations between naturally occurring processes in response to the administration of thiopurine drugs to the patient.³⁴ Prometheus’s patents at issue in the case described the process for using thiopurine drugs to optimize treatment of Crohn’s disease and ulcerative colitis in patients.³⁵ In reaching its holding, the Court concluded that “[i]f a law of nature is not patentable, then neither is a process reciting a law of nature.”³⁶ However, the Court went on to state that where a “process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself,” then the process is patentable subject matter under section 101.³⁷ Relying on precedent, the Court stated that this notion of requiring “other elements or a combination

²⁸ *Diamond*, 447 U.S. at 309.

²⁹ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. ___, ___, 132 S. Ct. 1289, 1294–96 (2012).

³⁰ *Id.* at 1296.

³¹ *Id.*

³² *Id.*

³³ *Id.* at 1304–05.

³⁴ *Id.* at 1297.

³⁵ *Id.* at 1294–95.

³⁶ *Id.* at 1297.

³⁷ *Id.*

of elements” to obtain a patent on a process pertaining to a law of nature is often “referred to as an ‘inventive concept.’”³⁸ The Court heavily focused on this notion of requiring an “inventive concept” to claim a natural process in its *Myriad* decision.³⁹

Not unlike *Mayo*, the Association for Molecular Pathology (“AMP”) brought an action against Myriad Genetics (“Myriad”) claiming that Myriad’s patents covering the breast cancer genes BRCA1 and BRCA2 were invalid.⁴⁰ The district court agreed, concluding that Myriad’s patents were “invalid because they covered products of nature.”⁴¹ On appeal, the Federal Circuit disagreed and reversed the district court decision, concluding that isolating the DNA from the chromosome was an “inventive concept” that entitled Myriad to a patent.⁴² Furthermore, the Federal Circuit found that “isolating a particular strand of DNA creates a nonnaturally occurring molecule.”⁴³ The Supreme Court granted certiorari in 2013 and held that Myriad’s patents were invalid, as they pertained to DNA, because DNA was a product of nature and thus was not patentable subject matter under section 101 of the Patent Act.⁴⁴

The Court reasoned that merely “separating [a] gene from its surrounding genetic material is not an act of invention.”⁴⁵ Furthermore, the Court concluded that Myriad’s “patent descriptions simply detail[ed] the ‘iterative process’ of discovery,” which constituted an attempt to “import [its] extensive research efforts into the section 101 patent-eligibility inquiry,” something clearly outside the scope of section 101.⁴⁶ Myriad’s patents at issue in the case claimed the DNA sequence and any fifteen base pair segment thereof for both the BRCA1 and BRCA2 genes.⁴⁷ Furthermore, Myriad’s patents claimed the cDNA sequence of both genes as well.⁴⁸ This had the effect of giving Myriad the exclusive right to conduct testing for breast cancer using an “indi-

³⁸ *Id.* at 1294.

³⁹ *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, 133 S. Ct. 2107 (2013).

⁴⁰ *Id.* at 2112.

⁴¹ *Id.* at 2114.

⁴² *Id.*

⁴³ *Id.* at 2115.

⁴⁴ *Id.* at 2120.

⁴⁵ *Id.* at 2117.

⁴⁶ *Id.* at 2118.

⁴⁷ *Id.* at 2113.

⁴⁸ *Id.*

vidual's BRCA1 and BRCA2 genes."⁴⁹ While the Court held that Myriad's claims pertaining to DNA were invalid, they specifically upheld Myriad's claims relating to cDNA.⁵⁰ In validating Myriad's cDNA claims, the Court reasoned that cDNA is manmade and not naturally occurring; thus the Court concluded cDNA was patentable subject matter under section 101.⁵¹

Both *Myriad* and *Mayo* have set the tone regarding the Court's interpretation of patentable subject matter under section 101.⁵² Going forward, DNA is no longer patentable subject matter, yet cDNA remains freely patentable.⁵³ Additionally, in order to seek patent protection for a process that harnesses a law of nature one must sufficiently alter the process such that it is possible to establish an "inventive concept."⁵⁴ While many argue this results in the "lack of a clear roadmap for determining the boundaries of patentability,"⁵⁵ it is nevertheless still possible to synthesize a rule from these cases. Thus, going forward it is important to clearly establish the rule set forth in *Myriad* and *Mayo* and how that rule shapes the analytical framework for a biotech company contemplating patenting DNA-based technologies.

IV. 35 U.S.C. § 101 AND PATENTABLE SUBJECT MATTER AFTER *MYRIAD* AND *MAYO*

Understanding the rule of law is critical in all areas of legal practice, but it becomes even more important after sweeping changes have been made. This is exactly the situation biotech companies are in as a result of the *Myriad* and *Mayo* decisions. In Part IV.A, this Note outlines the "new" rule regarding patentable subject matter under section 101. Part IV.B breaks down the guidelines set forth by the United States Patent and Trademark Office ("USPTO") in response to the *Myriad* and *Mayo* decisions. Collectively, Parts IV.A and IV.B establish an analytical framework that biotech companies can utilize when seeking to patent gene-based technologies.

⁴⁹ *Id.*

⁵⁰ *Id.* at 2119.

⁵¹ *Id.*

⁵² Bergin, *supra* note 1, at 188–99.

⁵³ *Ass'n for Molecular Pathology*, 569 U.S. at ___, 133 S. Ct. at 2107.

⁵⁴ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. ___, ___, 132 S. Ct. 1289, 1294 (2012).

⁵⁵ Gipson, *supra* note 8, at 827 (quoting Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land: Bilski's Superficial Textualism and the Missed Opportunity to Return Patent Law to Its Technology Mooring*, 63 STAN. L. REV. 1289, 1307 (2011)).

A. Myriad and Mayo: A Synthesized Rule

Through the *Myriad* and *Mayo* decisions, the Supreme Court has effectively narrowed the scope of patentable subject matter under section 101.⁵⁶ Therefore, it is important to establish the current standard as it pertains specifically to DNA-based patents. Biotech companies now must satisfy a three part test to meet the subject matter hurdle for patentability.⁵⁷ Part one requires that the end purpose of the patent must not preempt a law of nature.⁵⁸ Part two requires analysis of each step in the patented process, one at a time, to determine whether the step adds an “inventive concept” to the overall process.⁵⁹ Finally, part three requires looking at the combination of the steps and determining whether the process as a whole is transformative.⁶⁰ As discussed below, these steps provide a useful guide for biotech companies seeking patent protection for DNA-based technologies.

PART I: PREEMPTION

Part one essentially incorporates longstanding precedent from several marquee Supreme Court decisions.⁶¹ Thus, the principle behind inquiring as to the end purpose of the patent is to ensure that laws of nature, physical phenomena, and abstract ideas do not get monopolized.⁶² In *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, the Supreme Court declared Funk Brothers’ patent was invalid because it was an attempt to patent a “phenomenon of nature.”⁶³ Similarly, in *Gottschalk v. Benson*, the Court declared Benson’s patent invalid because it was an attempt to patent an abstract idea.⁶⁴ However, the Court distinguished these cases in *Diamond v. Diehr* when it held Diehr’s patent was valid because it did not “seek to pre-empt the use of” an abstract idea.⁶⁵ In subsequent decisions, the Court has relied on the concept established in *Diehr* that, while a patent may contain elements of laws of nature, physical phenomena, and abstract ideas, as long as the patent does not preempt them, it is patentable subject matter under section 101.⁶⁶

⁵⁶ See Bergin, *supra* note 1, at 177.

⁵⁷ *Id.* at 200.

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.* at 200–01.

⁶¹ *Id.* at 201.

⁶² *Id.*

⁶³ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

⁶⁴ *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972).

⁶⁵ *Diamond v. Diehr*, 450 U.S. 175, 187 (1981).

⁶⁶ See *id.* at 185, 187.

PART 2: THE INVENTIVE CONCEPT

This step-by-step analysis of a patent's claim was utilized in *Mayo*, and the Court heavily relied on it in *Myriad*.⁶⁷ The purpose behind the analysis is to ensure that the concept from *Diehr* is fully satisfied.⁶⁸ Thus, the Court will look at each claim in the patent and determine if an "inventive concept" is present.⁶⁹ In doing so, the Court specifically looks to see if the "inventive concept" is "both (1) central to the claim and (2) results or involves a non-routine, nonobvious product or procedure."⁷⁰ If either or both of these requirements are not met, then the claim fails the test and is deemed to constitute a natural process.⁷¹ However, this does not destroy patentability under section 101.⁷² Instead, the process as a whole must be analyzed to determine if part three is satisfied.⁷³

PART 3: TRANSFORMATION

Part three acts as a failsafe to reinforce and ensure that a patentee has fully complied with part one.⁷⁴ In doing so, the Court looks at the claimed process as a whole and determines if "it is more than 'the sum of [its] parts.'"⁷⁵ This is the key to the transformative element. If the claimed process "merely 'inform[s] a relevant audience about certain laws of nature,' and only include[s] 'well-understood, routine, conventional activity already engaged in by the scientific community,'" then the process is not transformative and thus not patentable subject matter under section 101.⁷⁶ Again, the goal here is to prevent the monopolization of the basic tools for innovation, which impedes rather than promotes further innovation.⁷⁷

B. *The USPTO Response*

Not surprisingly, the USPTO recently issued a memorandum to patent examiners providing guidance on determining patentable sub-

⁶⁷ Bergin, *supra* note 1, at 201–02.

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.* at 202.

⁷¹ *See id.*

⁷² *See id.*

⁷³ *Id.* at 202.

⁷⁴ *Id.*

⁷⁵ *Id.* (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. __, __, 132 S. Ct. 1289, 1298 (2012)).

⁷⁶ *Id.* (quoting *Mayo*, 566 U.S. at __, 132 S. Ct. at 1298).

⁷⁷ Gipson, *supra* note 8, at 817.

ject matter under section 101 in light of the *Myriad* and *Mayo* decisions.⁷⁸ Interestingly, the memorandum establishes a similar three-part inquiry to the one described above.⁷⁹ Question one addresses whether “the claimed invention [is] directed to one of the four statutory patent-eligible subject matter categories.”⁸⁰ Question two addresses whether the claim “involve[s] one or more [of the] judicial exceptions,” i.e., does the claim concern “abstract ideas, laws of nature/natural principles, natural phenomena, [or] natural products?”⁸¹ Finally, question three addresses whether “the claim as a whole recite[s] something *significantly different* than the judicial exception(s).”⁸² By looking at these questions, it becomes obvious that they were drafted to specifically address the three-part analysis described in Part IV.A.

Question one essentially boils down to determining broad patentability under section 101. Is the claimed invention a “process, machine, manufacture, or composition of matter?”⁸³ This question applies across the board to anyone seeking to patent an invention and must be answered in the affirmative.⁸⁴ Questions two and three, on the other hand, directly address parts one through three discussed above. Question two squares nicely with the concept of preemption and the “inventive concept” addressed by parts one and two of the rule, respectively.⁸⁵ If the claim has elements of abstract ideas, laws of nature, natural phenomena, or natural products, then further analysis must be conducted to look for something “significantly different.”⁸⁶ Question three specifically focuses on the transformative element in the rule under part three.⁸⁷ Absent something “significantly different”—i.e., transformative—then “the claim is not patent-eligible and should be rejected under [section] 101.”⁸⁸ The remainder of the memorandum focuses specifically on what qualifies as “significantly different.”⁸⁹

⁷⁸ Memorandum from the USPTO on 2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena, and/or Natural Products to Patent Examining Corps (Mar. 4, 2014) [hereinafter USPTO] (on file with author).

⁷⁹ *Id.* at 2.

⁸⁰ *Id.*

⁸¹ *Id.* at 3.

⁸² *Id.*

⁸³ *Id.* at 2.

⁸⁴ *Id.*

⁸⁵ *Id.* at 3; Bergin, *supra* note 1, at 201–02.

⁸⁶ USPTO, *supra* note 78, at 3.

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.* at 3–18.

The memorandum provides a multifactorial analysis to determine whether the “significantly different” requirement has been met.⁹⁰ According to the memorandum, there are two ways that a significant difference can be shown: “(1) the claim includes elements or steps in addition to the judicial exception that . . . [add] significantly more to the judicial exception; and/or (2) the claim includes features or steps that demonstrate that the claimed subject matter is markedly different from what exists in nature.”⁹¹ The following is a list of the factors to be analyzed to determine if there is a “significant difference”:

Factors that weigh toward eligibility (significantly different):

- (a) Claim is a product claim reciting something that initially appears to be a natural product, but after analysis is determined to be non-naturally occurring and markedly different in structure from naturally occurring products.
- (b) Claim recites elements/steps in addition to the judicial exception(s) that impose meaningful limits on claim scope, i.e., the elements/steps narrow the scope of the claim so that others are not substantially foreclosed from using the judicial exception(s).
- (c) Claim recites elements/steps in addition to the judicial exception(s) that relate to the judicial exception in a significant way, i.e., the elements/steps are more than nominally, insignificantly, or tangentially related to the judicial exception(s).
- (d) Claim recites elements/steps in addition to the judicial exception(s) that do more than describe the judicial exception(s) with general instructions to apply or use the judicial exception(s).
- (e) Claim recites elements/steps in addition to the judicial exception(s) that include a particular machine or transformation of a particular article, where the particular machine/transformation implements one or more judicial exception(s) or integrates the judicial exception(s) into a particular practical application. . . .
- (f) Claim recites one or more elements/steps in addition to the judicial exception(s) that add a feature that is more than well-understood, purely conventional or routine in the relevant field.

Factors that weigh against eligibility (not significantly different):

- (g) Claim is a product claim reciting something that appears to be a natural product that is not markedly different in structure from naturally occurring products.
- (h) Claim recites elements/steps in addition to the judicial exception(s) at a high level of generality such that substantially all practical applications of the judicial exception(s) are covered.
- (i) Claim recites elements/steps in addition to the judicial exception(s) that must be used/taken by others to apply the judicial exception(s).

⁹⁰ *Id.* at 3–5.

⁹¹ *Id.* at 3–4.

- (j) Claim recites elements/steps in addition to the judicial exception(s) that are well-understood, purely conventional or routine in the relevant field.
- (k) Claim recites elements/steps in addition to the judicial exception(s) that are insignificant extra-solution activity, e.g., are merely appended to the judicial exception(s).
- (l) Claim recites elements/steps in addition to the judicial exception(s) that amount to nothing more than a mere field of use.⁹²

Furthermore, the memorandum states that it is the totality of the factors weighing either for or against that determines whether “the claim should be rejected.”⁹³ These factors are excellent examples of the type of information that does and does not constitute a transformative element under part three of the rule.

Looking ahead, by combining the guidance set forth in the USPTO memorandum with the synthesized rule from the *Myriad* and *Mayo* decisions, a biotech company has a much clearer path regarding patentability of DNA-based technologies under section 101. Companies that put this guidance to use are likely to find that there still exists ample opportunity to seek patent protection for gene-based innovations within the confines of the new rule. The part that follows will address how to work within those confines and the areas of DNA-based technologies that are unaffected by the *Myriad* and *Mayo* decisions. Additionally, this part will address other solutions in the area of IP law that a biotech company can rely on in the absence of patent protection.

V. THINKING AHEAD: SECURING IP PROTECTION IN SPITE OF *MYRIAD* AND *MAYO*

While the *Myriad* and *Mayo* decisions have deemed DNA alone is not patentable subject matter, the Court left open other avenues for patenting DNA-based technologies.⁹⁴ Biotech companies may not be able to vigorously pursue patents on DNA-based technologies, as they once could, for fear of ultimately having their patent invalidated in court,⁹⁵ but biotech companies can utilize the guidelines established above to generate patent worthy gene-based technologies. Part V.A will address the areas of genetic research that appear to be unaffected

⁹² *Id.* at 4–5.

⁹³ *Id.* at 4.

⁹⁴ *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, ___, 133 S. Ct. 2107, 2119–20 (2013).

⁹⁵ *See* Gipson, *supra* note 8, at 827.

by the *Myriad* and *Mayo* decisions. Part V.B examines a hypothetical new DNA-based product and assess its patentability under the guidelines established in Part IV. Finally, Part V.C will address how biotech companies can use trade secrets to protect their innovations in the absence of patent protection.

A. *What Is Not Affected by Myriad and Mayo?*

At the end of its opinion in *Myriad*, the Court made it quite clear that “innovative method[s] of manipulating genes,” novel “applications of knowledge” about DNA, and naturally occurring DNA that has been altered (i.e., genetic mutations) were all still patentable subject matter.⁹⁶ Additionally, the Court specifically stated that manmade cDNA was patentable subject matter.⁹⁷ Looking outside the Court’s opinion, there are other areas of patentable genetic material that fall outside the scope of the *Myriad* decision. Gene therapy products “that involve synthesized, nonnaturally occurring genetic sequences,” as well as “[the] process to administer [the] genetic therapy” still qualify as patentable subject matter.⁹⁸ Additionally, DNA sequences that have been “artificially integrated (or vectored) into existing DNA or cells . . . [to] express new sequences or proteins” also likely qualify as patentable subject matter.⁹⁹ Furthermore, variations within the non-coding intron regions of a gene have been considered patentable subject matter.¹⁰⁰

In assessing why these examples fall outside the scope of the *Myriad* decision it is important to think about them in terms of the analysis in Part IV. The key in gene therapy products is that they use manmade sequences.¹⁰¹ These products easily pass step one, determining whether the product preempts a law of nature, as the resulting gene therapy does not exist in nature.¹⁰² Furthermore, the delivery and use of the gene therapy satisfies both the “innovative concept” and transformative element requirements, as the therapy itself is central to the

⁹⁶ *Ass’n for Molecular Pathology*, 569 U.S. at ___, 133 S. Ct. at 2119–20.

⁹⁷ *Id.* at 2119.

⁹⁸ David S. Olson, *Patent Protection for Genetic Innovation: Monsanto and Myriad*, 2013 CATO SUP. CT. REV. 283, 298.

⁹⁹ Dan Liu, *Owning the Code: The U.S. Supreme Court’s Decision in Myriad Genetics Distinguishes Between DNA and cDNA*, L.A. LAW., Dec. 2013, at 20, 26.

¹⁰⁰ *Genetic Techs. Ltd. v. Agilent Techs., Inc.*, No. CV 12–01616 RS, 2014 WL 941354, at *2 (N.D. Cal. Mar. 7, 2014).

¹⁰¹ Olson, *supra* note 98, at 298.

¹⁰² *Id.*

claimed process and involves a novel procedure.¹⁰³ Similarly, DNA sequences that have been engineered into another DNA sequence or cell type are nonnaturally occurring and produce novel sequences or proteins.¹⁰⁴ The central feature in both of these products is that the DNA being used is a manmade variant much like cDNA, which the Court held was patentable subject matter.¹⁰⁵

On the other hand, variations within the non-coding intron regions of a gene poses a slightly different question. Introns are naturally occurring DNA sequences;¹⁰⁶ thus a patent involving intronic DNA would seem to fall squarely within the scope of the *Myriad* decision.¹⁰⁷ However, in a recent case decided in March of 2014 this year, the United States District Court for the Northern District of California refused to extend *Myriad's* holding to invalidate a patent for detecting variations within intronic DNA.¹⁰⁸ In reaching its decision, the court applied a multifactorial analysis much like the process described in the memorandum issued by the USPTO.¹⁰⁹ The court focused on whether the patent claims preempted a law of nature, contained minor pre- or post-isolation modifications, were “overly-generalized,” and were transformative.¹¹⁰ Ultimately the court held that while the patent claims addressed laws of nature, the patent as a whole was sufficiently innovative to “transform the unpatentable natural law into a patentable application of that law.”¹¹¹ This case serves as an excellent example of how a DNA patent can meet the criteria set forth in Part IV.

B. *Assessing Patentability: A Hypothetical*

As is clear from Part V.A, there are several areas where biotech companies can still obtain patent protection for DNA-based technologies. Furthermore, the USPTO has continued to issue patents for

¹⁰³ See USPTO, *supra* note 78, at 3.

¹⁰⁴ Liu, *supra* note 99, at 26.

¹⁰⁵ See Marylee Jenkins & Kristi Nicholes Burton, *Isolated DNA Compositions Are Not Patent Eligible*: Ass’n for Molecular Pathology v. Myriad Genetics, 6 LANDSLIDE, no. 2, 2013, at 24, 27.

¹⁰⁶ *Id.* at 25.

¹⁰⁷ See Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. ___, ___, 133 S. Ct. 2107, 2120 (2013).

¹⁰⁸ Genetic Techs. Ltd. v. Agilent Techs., Inc., No. CV 12–01616 RS, 2014 WL 941354 (N.D. Cal. Mar. 7, 2014).

¹⁰⁹ *Id.* at *5.

¹¹⁰ *Id.*

¹¹¹ *Id.* at *8.

DNA-based technologies after the decisions in *Myriad* and *Mayo*.¹¹² In general, the recently issued patents can be broken into three categories: (1) patents that have added “extra steps to their core method claim;” (2) patents that “incorporate physical biological structures in their claims;” and (3) patents that incorporate a “method claim inside a compositional claim.”¹¹³ These categories provide an excellent framework for biotech companies seeking patent protection on a gene-based therapy. However, by digging a little deeper and looking at a hypothetical DNA-based patent claim, one can gain a better understanding of what is necessary for patentability.

Suppose a biotech company sought to patent a new set of primers for amplifying a novel DNA sequence for a specific disease.¹¹⁴ In its patent it would likely claim the sequence of its primers and the process of amplifying the target DNA sequence. On submission to the patent office, the patent examiner would then apply the process described in Part IV.B to the patent claims. In this case, both the primers and the process of amplifying the target DNA sequence encompass a product of nature; thus each claim must be analyzed individually to determine if the claim adds something significantly different to the natural products. Examining the factors to determine whether a claim adds something significantly different, the claim for the primers fails factor (a) and satisfies factor (g) because the primers are essentially copies of the natural sequence and thus are naturally occurring and not markedly different in structure.¹¹⁵ The remaining factors (b)-(f) and (h)-(l) are not applicable because nothing other than the naturally occurring DNA is claimed.¹¹⁶ Therefore, the claim on the primer sequences would be invalid as nonpatentable subject matter under section 101.

On the other hand, the claim for the process of amplifying the target DNA sequence has a different analysis. In this case factors (b), (c), (d), (h), (i), (k), and (l) all weigh in favor of the claim adding something significantly different because the claimed process is limited in scope, lacks generality, and contains transformative elements.¹¹⁷ Factors (a) and (g) are not relevant in this case because a process, not

¹¹² See Bergin, *supra* note 1, at 209.

¹¹³ *Id.*

¹¹⁴ This hypothetical is modified from example E in Part III in USPTO, *supra* note 78, 11-13.

¹¹⁵ See USPTO, *supra* note 78, at 4.

¹¹⁶ See *id.* at 4-5.

¹¹⁷ *Id.*

a product, is claimed.¹¹⁸ Thus, the only factors weighing against the claim being found to add something significantly different are factors (e), (f), and (j) because portions of the process may be well understood within the field.¹¹⁹ Therefore, the totality of the factors weighs in favor of the claim being found to add something significantly different, and the claimed process of amplifying the target DNA sequence would be valid subject matter under section 101.

This hypothetical provides an example of how a biotech company must analyze its DNA-based technologies when seeking patent protection. By focusing on the transformative elements of its process and avoiding purely naturally occurring DNA claims, a company is more likely to overcome the subject matter hurdle of section 101. But what if a biotech company's gene-based product is unable to meet the requirements under section 101? Is all hope of securing IP protection lost? The simple answer is no. As discussed in Part V.C below, other areas of IP law can be utilized in the absence of patent protection.

C. Utilizing Trade Secret Protection

When patent protection is unavailable because a biotech company's "invention" falls squarely within the scope of the *Myriad* decision, the company can pursue other forms of IP protection such as trade secrets. Trade secrets have a distinct advantage over patents in that they have few requirements and apply to a wide variety of subject matter.¹²⁰ In order to qualify for trade secret protection, the information must "(i) derive independent economic value, actual or potential, from not being generally known . . . [or] readily ascertainable by proper means . . . , and (ii) [be] the subject of . . . reasonable [efforts] . . . to maintain its secrecy."¹²¹ Therefore, the only information that does not qualify for trade secret protection is information that is generally known or readily ascertainable.¹²² As long as a biotech company

¹¹⁸ *Id.* at 4.

¹¹⁹ *Id.* at 4–5.

¹²⁰ See Andrew Beckerman-Rodau, *The Choice Between Patent Protection and Trade Secret Protection: A Legal and Business Decision*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 371, 379 (2002).

¹²¹ UNIF. TRADE SECRETS ACT § 1(4) (amended 1985), 14 U.L.A. 538 (2005).

¹²² ELIZABETH A. ROWE & SHARON K. SANDEEN, CASES AND MATERIALS ON TRADE SECRET LAW 40–41 (2012).

keeps its DNA sequence a secret, it would qualify for trade secret protection.¹²³

On the other hand, there are two ways whereby genetic material is vulnerable to trade secret protection. The first is discovery by independent invention.¹²⁴ Should a competitor invent a competing product based on the same genetic sequence, the original trade secret holder would lose protection for its product.¹²⁵ The second is discovery by reverse engineering.¹²⁶ This poses a significant threat in today's world where it is fairly easy to determine the DNA sequence of something.¹²⁷ Nevertheless, "[t]rade secret protection may be the only viable form of IP protection available for [DNA] sequences."¹²⁸ Additionally, biotech companies should seek to utilize trade secrets in combination with patents, giving them a more robust IP strategy.¹²⁹ For example, a biotech company could file for patent protection on a DNA-based diagnostic kit, while keeping the actual DNA sequence and underlying know-how a trade secret.¹³⁰ This circumvents the patent subject matter issues of the DNA sequence and helps to build a stronger IP portfolio.

VI. CONCLUSION

As the Director of the National Institutes of Health, Dr. Francis S. Collins, said in his recent book, "[w]e are on the leading edge of a true revolution in medicine, one that promises to transform the traditional 'one size fits all' approach into a much more powerful strategy that considers each individual as unique and as having special characteristics that should guide an approach to staying healthy."¹³¹ Myriad, by and large was a part of that revolution by creating a diagnostic product capable of detecting an individual's susceptibility to breast cancer.¹³²

¹²³ M. Scott McBride, *Bioinformatics and Intellectual Property Protection*, 17 BERKELEY TECH. L.J. 1331, 1354 (2002).

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ Karl F. Jorda, *Patent and Trade Secret Complementariness: An Unsuspected Synergy*, 48 WASHBURN L.J. 1, 1 (2008).

¹³⁰ *See id.* at 13.

¹³¹ Tiana Leia Russell, *Unlocking the Genome: The Legal Case Against Genetic Diagnostic Patents*, 16 MARQ. INTELL. PROP. L. REV. 81, 81 (quoting FRANCIS S. COLLINS, *THE LANGUAGE OF LIFE: DNA AND THE REVOLUTION IN PERSONALIZED MEDICINE* xxiii–xxiv (2010)).

¹³² *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, __ U.S. __, __, 133 S. Ct. 2107, 2112 (2013).

Arguably, the Supreme Court's decision to invalidate Myriad's patents has somewhat hindered the revolution in personalized medicine. While some have hailed this decision as a victory for individual rights,¹³³ others have viewed this decision as the death sentence for patents on genetic-based testing and diagnostics.¹³⁴ In the end, the biotech companies that apply the guidelines discussed throughout this article and take advantage of all the IP strategies at their disposal will continue to carry forward the revolution in individualized medicine.

¹³³ Kumar, *supra* note 3, at 627.

¹³⁴ Bergin, *supra* note 1, at 178.

