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A Crisis of Patent Law and Medical Innovation: The Category of Diagnostic Claims in the Wake of *Ariosa v. Sequenom*

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A Crisis of Patent Law and Medical Innovation: The Category of Diagnostic Claims in the Wake of *Ariosa v. Sequenom*

Alexa Johnson[†]

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Introduction

In *Ariosa v. Sequenom*, the Federal Circuit and the district courts attempted to draw the line to determine the point at which a diagnostic method so transforms a natural principle by human invention that it becomes patent-eligible subject matter.¹ Section 101 of the United States Code states that “whoever invents any new and useful process, machine, manufacture, or composition of matter . . . may obtain a patent therefore.”² However, the Supreme Court has long excluded laws of nature, abstract ideas, and physical phenomena (hereinafter collectively referred to as a “natural principle,” “natural phenomenon,” or “natural law”) from patentability under § 101.³ For example, the Supreme Court held in *Myriad* that genomic DNA itself is not patent-eligible because it is a natural phenomenon and not the product of human ingenuity, regardless of whether it had been isolated from the surrounding DNA by human means.⁴ The issue becomes more complicated, however, when the question is directed at diagnostic methods that put natural principles to use. Generally, diagnostic methods are processes used to diagnose, detect, or determine a course of treatment for a disease.⁵ Diagnostic methods and tests may incorporate natural phenomena in many ways: through the use of DNA,⁶ concentration relationships,⁷ or schedules for determining optimal vaccination times.⁸ The diagnostic methods at issue in *Ariosa* were directed to a novel use of cell-free fetal DNA (“cffDNA”). Prior to the diagnostic method patented in the *Ariosa* case, cffDNA had been discarded by medical professionals in the field as nothing more than

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1. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375 (Fed. Cir. 2015); This Note will use the encompassing term ‘natural principle’ or ‘natural phenomena’ to refer collectively to laws of nature, abstract principles, and physical phenomena as noted in *Ariosa Diagnostics, Inc.*
 2. 35 U.S.C. § 101 (2012).
 3. *Parker v. Flook*, 437 U.S. 584, 594 (1978).
 4. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2017, 2116 (2013).
 5. U.S. NAT’L LIBRARY OF MED., *DIAGNOSTIC TESTS*, <https://www.nlm.nih.gov/medlineplus/diagnostictests.html> (last updated Dec. 22 2015).
 6. *See Ariosa Diagnostics, Inc.*, 788 F.3d at 1373; *See also* *Genetic Technologies Ltd. v. Agilent Technologies, Inc.*, 24 F.Supp.3d 922, 928 (N.D.Cal. 2014).
 7. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012).
 8. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1060 (Fed. Cir. 2011).

waste matter.⁹ The new diagnostic method used cffDNA to conduct non-invasive fetal testing.¹⁰

Prior jurisprudence has held that “a process is not unpatentable simply because it contains a law of nature.”¹¹ The Supreme Court has warned against an overly broad interpretation of these exclusions, because all inventions on some level rely on natural principles.¹² The Court has held that claims directed to a process that encompasses a natural principle may be patent eligible when the process is transforming or reducing one item to a different state or different item and when there are aspects of novelty involved in the invention that go beyond the discovery of the natural principle.¹³

Though Sequenom—the company that invented the diagnostic method at issue in *Ariosa*—petitioned for its case to be reheard *en banc*, the Federal Circuit denied the petition.¹⁴ In his concurrence with the denial of Sequenom’s petition, Judge Lourie urged reconsideration of “a rule that takes inventions of this nature out of the realm of patent eligibility on grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts.”¹⁵ He further stated, “it is said that the whole category of diagnostic claims is at risk. It is also said that a crisis of patent law and medical innovation may be upon us, and there seems to be some truth in that concern.”¹⁶

The primary problem with the patent eligibility of diagnostic methods is the lack of clarity in the current patent subject-matter eligibility test employed by the United States Patent and Trademark Office (“USPTO”) and the courts. Particularly, there needs to be clarification regarding whether the discovery of a natural law is sufficient to make a combination of steps otherwise well known in the field into a patent-eligible method, or whether the steps themselves must also be novel contributions. The lack of clarity means there is confusion between the USPTO, the district courts, the Federal Circuit, and the Supreme Court about which diagnostic methods are patent-eligible uses of a natural phenomenon. This confusion leads to an excess of litigation—the USPTO grants a patent on a diagnostic test, only to have that patent invalidated by the court system when it becomes the subject of an infringement suit. A clear test for determining

9. See *Ariosa Diagnostics, Inc.*, 788 F.3d at 1373.

10. See *id.*

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

12. *Mayo Collaborative Servs.*, 132 S. Ct. at 1294.

13. *Diamond*, 450 U.S. at 185.

14. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1287 (Fed. Cir. 2015), *cert denied* (No. 2014-1139) (Lourie, J., concurring).

15. *Id.* at 1285.

16. *Id.*

whether a particular diagnostic method is eligible for patent protection would prevent the inconsistency between the standards used by the USPTO and the ones used by courts and would give companies certainty that their products are either patent protected or not. The current tests not only fail to offer guidance in the area of diagnostic tests, but also add to the confusion by using language ill-fitting the biotechnology field.¹⁷

Section I of this Note begins by providing a brief overview of what diagnostic methods are and whether or not their patent eligibility is a worthy goal. The section discusses the rationales behind patent protection in general and the arguments for and against the patenting of diagnostic methods in particular.

Section II traces the history of jurisprudence in the area, from decisions based solely on whether a claim entirely preempts a natural phenomenon, to the current *Mayo v. Prometheus* Two-Step test. This section then summarizes some of the problems with the current tests as they stand. Section III is an analysis of *Ariosa v. Sequenom* and its implications for decisions on the patent eligibility of diagnostic tests. The section outlines the facts and holding of the case and compares them with *Genetic Technologies v. Agilent* in order to highlight the confusion remaining in the field.¹⁸

Section IV explores the idea of importing language from §§ 102 and 103 of the patent code into the § 101 analysis to serve as a framework for the patent-eligibility test. This section outlines the analyses used to determine whether a patented invention is novel and non-obvious and provides an overview of jurisprudence relating to those determinations.

Section V suggests a framework for a new patent-eligibility test to be applied to claims directed to diagnostic tests. The new test proposes a three-step system that begins with an application of the Supreme Court's *Mayo* Two-Step test, and wherein the language of 35 U.S.C. §§ 102 and 103 is imported to clarify the meaning of terms as they apply to the biotechnology and medical fields. Failing the *Mayo* Two-Step creates a rebuttable presumption of unpatentability that can be overturned by the second and third steps of the proposed test. The section ends with an application of the newly proposed test to the diagnostic test at issue in *Ariosa*.

I. What are Diagnostic Methods and Why Patent Them?

Medical-technique and medical-procedure patenting is a controversial area. The Patent Office Board of Appeals has held that methods of treatment with varied likelihoods of success are not patentable due to

17. See, e.g., *Mayo Collaborative Servs.*, 132 S. Ct. at 1296-99 (problems interpreting terms such as 'inventive concept' and 'transformation').

18. *Genetic Tech. Ltd. v. Agilent Tech., Inc.*, 24 F. Supp. 3d 922, 926-933 (N.D. Cal. 2014).

their uncertainty.¹⁹ In general, medical procedures without a sufficiently certain result were not granted patent protection for fear that the public would equate a patented procedure with one that had a higher likelihood of success.²⁰ However, this decision left the door open to patenting for procedures that resulted in a sufficiently certain result, such as those used to diagnose diseases, rather than treat them.²¹

Diagnostic methods, also known as diagnostic tests or simply diagnostics, are medical tests that are used to identify a disease and track its progression.²² The term can also be used for applications such as genetic testing, where medical professionals are not identifying a particular disease but rather a series of characteristics, such as sex.²³ There are many reasons why patent protection for diagnostic tests is a desirable outcome and also many reasons to proceed with caution in establishing an overly inclusive system.

A. 35 U.S.C. § 101: Patent-eligibility Rationales

To understand why the decision in *Ariosa* is, in the words of Sequenom, “an existential threat to patent protection for an array of meritorious inventions,” one must first look to the underlying rationales for allowing patents themselves.²⁴

1. Rewarding Innovation: Why do we patent?

Article 1, Section 8 of the United States Constitution gives Congress the power “to promote the Progress of Science and the Useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”²⁵ The law incentivizes innovation by rewarding those who make a novel contribution in their art with a limited monopoly that brings with it a potential financial profit. Patent law encourages inventors to invent and to disclose those inventions to the public where they will do the most good. The law seeks to ensure that new innovations will reach the public domain, hence the

19. JOANNA T. BROUGHER, INTELLECTUAL PROPERTY AND HEALTH TECHNOLOGIES: BALANCING INNOVATION AND THE PUBLIC’S HEALTH 68 (2014); *See also* Ex Parte Brinkerhoff, 27 J. PAT. OFF. SOC’Y 793, 798 (1945).

20. *See* BROUGHER, *supra* note 19, at 68.

21. Ex parte Kettering, 35 USPQ 342, 343 (P.O.B.A. 1936).

22. Morgan Medlin, *Transformation of Diagnostic Method Patents: Why Changes in Biotechnology and the Law Make Evolution Necessary*, 23 S. CAL. INTERDISC. L. J. 627, 628 (2014).

23. *See* Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1374 (Fed. Cir. 2015).

24. Brief of Petitioner-Appellant for Rehearing En Banc at 1, Ariosa Diagnostics Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015) (No. 2014-1139).

25. U.S. CONST. art. I, § 8, cl. 8.

written disclosure requirement, the enablement requirements, and the limits on patent terms.²⁶ Furthermore, patent law requires that advances currently in the public domain remain there, hence the novelty and non-obviousness requirements codified in §§ 102 and 103.²⁷

Without the patent system, it is argued, inventors have no external motivation to bring the science and progress behind their inventions to the public domain and may instead opt to keep them secret in order to retain a monopoly over their production and use.²⁸ Instead of disclosing their invention via patent specification, inventors would opt to use trade-secret law. Unlike obtaining a patent, protecting an invention through the use of trade-secret law does not require that the inventor disclose anything about how their product is made.²⁹ Though the public would still have access to the invention itself, the science behind its production would remain a secret. This is a great detriment to the public, as it prevents others from building off of those innovations to create further public benefit. Patent law is a compromise, enticing inventors to share their secrets for the promise of a limited monopoly in order to ensure that the flow of information, human progress, and innovation is not stemmed. In order to receive a patent, inventors must submit a fully detailed description of their work, which is then published and available to all.³⁰ This system ensures that while inventors receive the direct benefit of their inventions in terms of capturing the market, the research that they have done is available to others as a resource or building block for future inventions. Without the promise of a limited monopoly, inventors would be more likely to keep the details of their inventions and research secret to monopolize the market.

In particular, the field of diagnostic tests is one in which advances are made with great frequency. Patent protection ensures that researchers have the motivation and funds to continue their work, while also ensuring that the science behind the innovations comes to the public light.

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26. See, e.g., 35 U.S.C. § 112 (2012) (the written disclosure and enablement requirements of subsection (a) require that a patent specification contain a description of the invention that is detailed enough so that a person of ordinary skill in the area of the invention would be able to make and use the invention); See also 35 U.S.C. § 154(a)(2) (2012) (the term of a patent lasts 20 years from the date the application was filed); 35 U.S.C. 154(a)(2) (the term of a patent lasts 20 years from the date the application was filed).
27. 35 U.S.C. §§ 102-103 (2012).
28. Kristen Nugent, *Patenting Medical Devices: The Economic Implications of Ethically Motivated Reform*, 17 ANNALS HEALTH L. 135, 137 (2008).
29. *Id.* at 154, 171.
30. 35 U.S.C. § 112.

2. Patent-Eligible Subject Matter and Undue Preemption

Despite these rationales—and in some cases, because of these rationales—there are still areas where courts have limited patent eligibility to prevent certain types of discoveries and inventions from receiving patent protection.³¹ Natural principles and undue preemption serve as some of the principles behind these limitations.

Patent law seeks to ensure that information that is currently in the public domain remains there. Section 101, as interpreted by the Court, deems natural phenomena, abstract ideas, and products of nature unpatentable subject matter under the theory that they already belong to the public. They are considered “part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.”³² Accordingly, the courts are loath to allow patents that claim natural principles themselves.

The historical bar on patents claiming natural principles comes from the courts’ aversion to undue preemption. Undue preemption occurs when a patent either claims a natural principle itself or claims such a broad application of the natural principle that there is no way to use the natural principle itself without infringing upon the patent.³³ Undue preemption removes a natural principle from the public domain because all other uses of the principle would infringe the preempting patent. For example, in *Diamond v. Diehr*, the invention concerned a machine that functioned by using the Arrhenius equation to determine when to open a rubber mold so that the rubber would be fully cured.³⁴ Diehr could not have patented the Arrhenius equation itself, even had he discovered it, because the equation is a natural principle; it merely describes mathematically a relationship that exists in nature. However, the Court allowed him to patent one particular use of the equation, because it did not prevent others from using the equation in a different situation.³⁵ Some preemption is inherent within the patent system and is, in fact, what the system itself is built on, but in the case of undue preemption, the detriment to the public good outweighs the benefit to the inventor.

Diagnostic testing is an area ripe for problems of undue preemption. For example, in *Mayo v. Prometheus*, the claimed method at issue was a method for calibrating the dosage of thiopurine drugs in treating

31. *Patent Law – Patentable Subject Matter – Federal Circuit Invalidates Diagnostic Method Claims as Drawn to “Abstract Mental Processes.” – Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 125 HARVARD L. REV. 658, 663 (2011).

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

33. Dan Hoang, *Prometheus Laboratories v. Mayo Clinic’s Gift to the Biotech Industry: A Study of Patent-Eligibility of Medical Treatment and Diagnostic Methods after Bilski*, 9 NW. J. TECH. & INTELL. PROP. 457, 469 (2011).

34. *Diamond v. Diehr*, 450 U.S. 175, 177 (1981).

35. *Id.* at 192-3.

autoimmune disease.³⁶ The patent claimed the actual correlation between the thiopurine-drug dosage and the amount of thiopurine metabolites in the body. This is a claim directed at the underlying natural principle itself, not a claim directed at an application of that principle. Claiming the underlying natural law, rather than a specific application of it, preempts any other uses of that natural law without first licensing the patent that claimed it. In *Mayo*, allowing a patent on the correlation between thiopurine drugs and the metabolites they create in the body would stop anyone else from using that correlation for diagnostic or research reasons.³⁷ Preemption of that magnitude would stifle the free flow of information that is necessary for the continuing advancement of the sciences.

B. Arguments Against Patentability

One of the main arguments against granting patents to diagnostic tests is the effect on the public's access to medical treatment.³⁸ Patents raise the costs of diagnostic tests because they create market exclusivity, allowing companies to charge whatever they would like due to the lack of competition.³⁹ Companies then pass on the increased costs to the medical industry and, by extension, to the consumers themselves. Higher prices mean that some consumers will be unable to afford necessary diagnostic treatments. Lack of patent protection would allow for a competitive market, which has the potential to lower prices, increasing access for consumers who need diagnostic treatments.

Another strong argument raised against patent protection for diagnostic tests is that they may in some ways restrict access to information.⁴⁰ In other ways, as discussed in Section I.A, patent protection may also aid in the disclosure of information. Many types of research build on the foundation of preceding tests and discoveries that came before. Over-patenting or overbroad patents themselves can create a thicket of licensing issues that exponentially raise the cost and difficulty of research. If claims directed at a diagnostic test are overly broad, they may preempt all other uses of the natural phenomenon on which the diagnostic test relies.

Furthermore, there is a public-health concern that allowing the patenting of diagnostic treatments will open the door to patent-infringement suits against doctors.⁴¹ Because patents on diagnostic tests

36. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1290 (2012).

37. *Id.* at 1294.

38. BROUGHER, *supra* note 19, at 87.

39. *Id.*

40. *Id.* at 88.

41. *Id.* at 88-9.

often claim a method for using the test itself, a doctor who utilizes a particular test to diagnose a patient may find herself suddenly being sued for patent infringement. Furthermore, doctors or medical practices unwilling or unable to afford licensing fees for particular tests may disadvantage their patients by using outdated or less-effective diagnostic tests instead of the more-effective patented ones. Any efforts to create a test that clearly defines the patent eligibility of diagnostic methods must account for these concerns.

II. Patents Claiming Applications of Natural Phenomena: The Thicket of Prior Jurisprudence

As with any legally and scientifically complicated area, the jurisprudence surrounding the patent eligibility of diagnostic tests is a quagmire. The differing decisions in recent, similarly situated cases such as *Ariosa* and *Genetic Technologies Ltd. v. Agilent Technologies, Inc.* highlight the differences in opinions regarding the patentability of diagnostic tests between the USPTO, the district courts, the Federal Circuit, and the Supreme Court.⁴² Throughout the years, courts have attempted many iterations of a test for patent eligibility of processes applying natural phenomena and will likely continue to renew and refine such tests as the area continues to expand.

A. Preemption is Not the Sole Basis for Ineligibility

In 1978, the Supreme Court limited the patent-eligibility of claims directed towards an application of a natural principle. In reversing a Federal Circuit decision, the Supreme Court held that the use of an algorithm that did not preempt all other uses of that algorithm was a patent-eligible process under *Gottschalk v. Benson*.⁴³ The Court held that whether the patent claim would prevent any other use of the natural phenomenon is not the only test for patent eligibility. Instead, the Court found the claims ineligible because their only novel feature was the natural principle itself (an abstract idea—namely, a mathematical algorithm for converting binary-coded numerals into pure binary). The Court also stated that “conventional post-solution activity” does not render the process patentable because a wily inventor could easily add some form of post-solution activity to any algorithm.⁴⁴ Conventional post-solution activity is any step already known in the field added to the process afterward to distinguish it. Adding these kinds of steps to a claim

42. See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379-80 (Fed. Cir. 2015); See also *Genetic Tech. Ltd. v. Agilent Tech., Inc.*, 24 F. Supp. 3d 922 (N.D. Cal. 2014).

43. *Parker v. Flook*, 437 U.S. 584, 587-8 (1978); *Gottschalk v. Benson*, 409 U.S. 64, 72 (1972).

44. *Parker*, 437 U.S. at 589-90.

on a natural phenomenon is not sufficient to render that claim patent eligible. For example, “the Pythagorean theorem would not have been patentable . . . because a patent application contained a final step indicating that the formula, when solved, could be usefully applied to existing surveying techniques.”⁴⁵ However, the Court gave no definition of “conventional post-solution activity” and added that a process is clearly not patent-ineligible merely because it applies a natural principle.⁴⁶

B. The Machine or Transformation Test

In 1981, the Supreme Court revisited the issue of patent eligibility of applications of natural principles in *Diamond v. Diehr*, finding that though the claimed process was an application of an algorithm, it was patent eligible because it was a specific use of that algorithm specifically tied to a machine designed for that use.⁴⁷ In determining the eligibility of the claims, the Court determined that when claims apply a natural principle in the context of a structure or process that, when viewed in totality, is “performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing),” then that process is patent eligible under § 101.⁴⁸ This test became known as the “machine or transformation test.”

In 2010, the Supreme Court revisited the “machine or transformation test” and held that it was not the sole factor in determining patentability of a process claiming application of a natural principle.⁴⁹ In *Bilski v. Kappos*, the Supreme Court held that though the Federal Circuit had reached the correct result and invalidated the patent, they had incorrectly applied the machine or transformation test as the sole test for patent-eligibility.⁵⁰ The patent at issue in *Bilski* sought to claim “both the concept of hedging risk and the application of that concept to energy markets.”⁵¹ This natural principle is an abstract idea, a mathematical formula that describes the well-known concept of hedging risk, such as by use of hedge funds. The inventors argued that because the hedging formula was designed for use by a computer, it was tied to a specific machine and thus patent eligible under the machine or transformation test. The Court held that though being tied to a specific machine or transformation of an article is a clue that a process is patentable, there is nothing in the definition of process that explicitly requires that a process be related to a

45. *Id.* at 590.

46. *Id.*

47. *Diamond v. Diehr*, 101 S.Ct. 1048 (1981).

48. *Id.*

49. *Bilski v. Kappos*, 130 S.Ct. 3218, 3227 (2010).

50. *See id.* at 3231.

51. *Id.* at 3229.

machine or transformation in order to be patentable.⁵² The process in *Bilski* was patent ineligible, not because it lacked ties to a specific machine or transformation, but rather because it was directed at an unpatentable abstract idea, the concept of risk hedging itself, and the mathematical formula describing that concept.⁵³

Patent claims directed to processes that are not directly linked to a machine or transformation of an article are not *per se* ineligible. Further examination must be undertaken to see whether, firstly, the claimed process is considered a process under § 101 and secondly, whether the process is claiming patent-ineligible subject matter.⁵⁴ In *Bilski*, the Supreme Court affirmed the Federal Circuit's holding that the claimed process was in fact claiming a natural principle but gave no exact guidance as to how it reached the conclusion that the claimed process did not qualify as a process under § 101.⁵⁵ Instead, the Court stated that it "need not define further what constitutes a patentable 'process,' beyond pointing to the definition of that term provided in § 100(b)⁵⁶ and looking to the guideposts in *Benson*, *Flook*, and *Diehr*."⁵⁷

C. *The Mayo Two-Step*

As questions of patent eligibility continued to arise, the Supreme Court realized that it was necessary to provide further guidance on the matter of whether claims were a patent-eligible application of a natural principle or whether they were claiming the underlying natural phenomenon itself and thus not patentable. In *Mayo Collaborative Services, Inc. v. Prometheus Laboratories, Inc.*, the Supreme Court again refined its test for patent eligibility, condensing it into a two-step test that has become known as the "Mayo Two-Step." The first step is a determination of whether the claims at issue are directed to patent-ineligible subject matter, such as a natural phenomenon, abstract idea, or product of nature.⁵⁸ If the answer is no, the invention is presumed to be patent eligible under § 101. If the answer to the first question is yes, the second question is whether the elements of the claim contain an inventive concept that sufficiently transforms the natural principle into patent-

52. *Id.* at 3226-27.

53. *Id.* at 3231.

54. *See id.* at 3229-3230.

55. *Id.* at 3230.

56. 35 U.S.C. § 100(b) (2012) ("The term "process" means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material").

57. *Bilski*, 130 S.Ct. at 3231.

58. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S.Ct. 2347, 2355 (2014) (applying the first step of the Mayo framework).

eligible material.⁵⁹ In other words, the question is whether the invention or process is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.”⁶⁰ The question remains as to what constitutes an “inventive concept” that “sufficiently transforms” the natural phenomena into “significantly more.” The Court gave some limited guidance on the issue by stating that in order to be a patent-eligible application, the transformation must be more than simply stating the natural principle and saying “apply it.”⁶¹

Currently, the Mayo Two-Step is the test used for analyzing patent claims directed at diagnostic tests. However, as shown in their recent concurrences with the Federal Circuit’s denial of Sequenom’s petition for rehearing *en banc*, both Judge Lourie and Judge Dyk take issue with the Mayo Two-Step as far as its application to diagnostic tests is concerned.⁶² Judge Lourie writes that though the claims in *Ariosa* recite novel and creative uses of a natural phenomenon, rather than claiming the phenomenon itself, “applying *Mayo*, we are unfortunately obliged to divorce the additional steps from the asserted natural phenomenon to arrive at a conclusion that they add nothing innovative to the process.”⁶³ Judge Dyk, agreeing with Judge Lourie’s opinion, stated that he

share[s] the concerns of some of [his] colleagues that a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature (reflected in some of the language in *Mayo*) may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena.⁶⁴

Though they believe that the language of the test is clear enough, neither Federal Circuit judge agrees that the *Mayo* test is the correct standard for use in the realms of diagnostic tests and the medical field. Judge Dyk further adds that he thinks the time has come for the Supreme Court to issue additional guidance on the matter.⁶⁵

D. The Ultramercial Factors

The Supreme Court specifically mentions that, had it upheld the claims in *Mayo*, it would have risked “disproportionately tying up the use

59. *Id.* at 2357 (applying the second step of the Mayo framework).

60. *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S.Ct. 1289, 1294 (2012).

61. *Id.*

62. *Ariosa Diagnostics, Inc. v. Sequenom Inc.*, 809 F.3d 1282, 1285-1287 (Fed. Cir. 2015).

63. *Id.* at 1286.

64. *Id.* at 1287 (Dyk, J., concurring).

65. *Id.* at 1293.

of their underlying natural laws.”⁶⁶ This language essentially describes the preemption test that was the Court’s original test for patent eligibility. The Court seems to be including preemption as a factor in its Mayo Two-Step, though it does not explicitly designate it as one. Its continual usage of the language of preemption, even without specifically designating preemption as a factor, reinforces the importance of preemption in the patentability analysis.

In its first decision on *Ultramercial*, wherein Ultramercial claimed a method for distributing products over the Internet using a facilitator, the Federal Circuit listed preemption among the factors to be used in determining whether a claim is meaningfully limited, therefore turning the natural principle into “significantly more.”⁶⁷ Interestingly, in the second *Ultramercial* opinion (“*Ultramercial II*”), wherein the Federal Circuit retried the case after the Supreme Court vacated the holding, preemption is no longer designated a factor for consideration.⁶⁸

Ultramercial II outlines several considerations to take into account when performing the Mayo Two-Step test.⁶⁹ After determining under the first Mayo step that a claimed process is directed to a patent-ineligible concept, one must then determine whether the limitations of the claims are sufficient to transform the natural principle into “significantly more” than a patent on only the natural principle.⁷⁰ The court in *Ultramercial* opined that in order to “sufficiently transform,” the claims must constitute more than adding routine additional steps specified at a high level of generality.⁷¹ Steps that are stated generally, such as “gather data,” do not add anything novel to the process, particularly because there is no defined method that a user must implement to gather the data. The court also cited *Bilski*, stating that restricting claims to a particular technological environment is not a sufficient transformation.⁷² The court then applied the machine or transformation test as a third factor.⁷³

As discussed, the 2014 *Ultramercial* opinion eliminates the idea of preemption as a consideration in the patent-eligibility analysis. This seems to be an odd choice in light of other opinions, which have repeatedly

66. *Mayo Collaborative Servs.*, 132 S.Ct. at 1294.

67. *See Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335, 1345-1355 (Fed. Cir. 2013), *vacated*, 134 S.Ct. 2870, *remanded*, 772 F.3d 709 (Fed. Cir. 2014).

68. *See Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 713-714 (Fed. Cir. 2014).

69. *Id.* at 715.

70. *Mayo Collaborative Servs.*, 132 S.Ct. at 1294.

71. *Ultramercial Inc.*, 772 F.3d at 716.

72. *Id.*

73. *See id.* at 716-717.

stated that preventing preemption of natural principles is a key purpose of § 101 principles.⁷⁴

E. The Problem of Diehr

Further adding to the confusion is the Supreme Court's decision in *Diamond v. Diehr*, which, despite its continued status as good law, seems to defy logic in the face of the Court's current tests. In *Diehr*, the Court held that the claimed process, which used the Arrhenius equation (a mathematical representation of a natural principle—the temperature dependence of certain reaction rates) to cure rubber, was a patent-eligible application of the equation because it was tied to a specific machine or process and did not claim the equation itself.⁷⁵

There is no mention in the opinion of whether the steps in the process were novel outside of their application to the newly discovered equation.⁷⁶ The *Mayo* opinion attempts to reconcile this difficulty by saying that the process in *Diehr* was patentable “because of the way the additional steps of the process integrated the equation into the process as a whole.”⁷⁷ The Court then distinguishes *Diehr* from *Flook* by saying that in *Flook*, the invention preempted all other uses of the natural principle *and* the other steps in the process were conventional.⁷⁸ This reasoning implies that the steps in *Diehr* must have been something other than well-known in the rubber-curing field. This is untrue, as the rubber-curing industry already knew that the Arrhenius equation could be used to model the cure time the rubber press needed.⁷⁹ The problem was that using the equation required constant recalculation, which was both difficult and time-consuming. *Diehr*'s invention solved that problem by using a computer to continuously measure the temperature inside the press and feed those temperatures into the equation, continuously recalculating the curing time.⁸⁰

In *Alice v. CLS Bank*, the Court interpreted *Diehr* differently, stating that the claims in *Diehr* were eligible because they improved a process that was already known in the art by applying the Arrhenius equation⁸¹

74. See *Prometheus Laboratories v. Mayo Collaborative*, 628 F.3d 1347, 1354 (Fed. Cir. 2010) (stating that preemption was a rationale behind the Supreme Court's decisions in *Bilski*, *Benson*, *Flook*, and *Diehr*).

75. *Diamond v. Diehr*, 450 U.S. 175, 192-93; KEITH J. LAIDLER, *CHEMICAL KINETICS* 39 (3rd ed. 1987).

76. See *Diamond*, 450 U.S. at 191.

77. *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S.Ct. 1289, 1298 (2012).

78. *Id.* at 1299.

79. *Diamond*, 450 U.S. at 177-79.

80. *Id.*

81. *Alice Corp. Prop. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2358 (2014).

These differing interpretations of the rationale for patent eligibility in *Diehr* directly apply to the problem of determining the patentability of diagnostic methods.

If the characterization in *Mayo* is correct, then the main inquiry in the analysis of whether a diagnostic test is patentable is whether the additional steps of the process are in and of themselves novel contributions to the field of the invention. This limits patent eligibility for diagnostic tests to those tests that discover and create an entirely new method of use for a natural principle. If the characterization of *Diehr* in *Alice* is correct, the inquiry is whether the application of the natural principle to conventional steps in the art improves the process as a whole. This would allow those diagnostic tests that discover a new natural principle and apply that principle in a specific use, regardless of whether the steps of that use were conventionally known, to be patent eligible. This much-broader inquiry seems to align more with the rationales of the patent system in its entirety. In no other section in the patent code is there a requirement such as the one characterized by *Mayo*'s treatment of *Diehr*. As discussed in Section IV, other sections of the patent code allow inventions that are a newly ordered combination of steps that are already fully known in the art to be considered novel.⁸²

III. The *Ariosa* Decision

A. *Factual Background*

The claims in *Ariosa v. Sequenom* are directed to an application of cell-free fetal DNA (cffDNA) that uses the cffDNA for non-invasive fetal testing. Cell-free fetal DNA is a natural phenomenon that occurs during pregnancy wherein DNA from the fetus sheds into the mother's bloodstream.⁸³ Sequenom's first patent claim is directed to

a method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.⁸⁴

The other two independent claims contain additional or substituted steps, such as removing all nucleated or anucleated cells from the blood

82. See *Infra* Part IV.

83. See E.S. Lo et al., *Transfer of Nucleated Maternal Cells into Fetal Circulation During the Second Trimester of Pregnancy*, 100 BRIT. J. HAEMATOLOGY 605 (1998).

84. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 19 F. Supp. 3d 938, 941 (N.D. Cal. 2013), *aff'd*, 788 F.3d 1371 (Fed. Cir. 2015).

sample⁸⁵ or obtaining a non-cellular fraction of the blood sample.⁸⁶ All three independent claims stem from the discovery by two of the inventors that cffDNA is present in maternal serum and plasma and that it can be used for non-invasive fetal testing, which was not previously known.

Prior to Sequenom's invention, medical professionals were limited to more invasive prenatal diagnostic methods, such as amniocentesis or villus sampling.⁸⁷ These types of invasive tests carry a variety of risks: miscarriage, leaking amniotic fluid, needle injury to the fetus, Rh sensitization, and infection or infection transmission.⁸⁸ The test developed by Sequenom, marketed under the name MaterniT21,⁸⁹ allows non-invasive testing to determine such things as sex and blood type and to diagnose fetal abnormalities, and pre-eclampsia in the mother.⁹⁰ The test only requires a maternal blood sample.⁹¹

The district court found that the use of the natural principle, the cffDNA, was the only inventive concept in the claims, so the claims were directed to patent-ineligible subject matter and the patent was thusly invalid. The district court also held that Sequenom's patent was an attempt to preempt all other uses of the natural principle because the articles cited by Sequenom detailing other methods for detecting cffDNA, not limited to the methods disclosed in the patent, had been published after the issuance of Sequenom's patent.⁹²

B. The Federal Circuit's Decision

The Federal Circuit applied the Mayo Two-Step framework in its analysis of Sequenom's claims. Finding first that the claims were directed to a natural principle, the court then began an examination of whether the steps of the claim contained a sufficient inventive concept to transform the natural principle into patent-eligible subject matter. The court held that the steps of amplifying the cffDNA (duplicating or creating identical DNA until there is a sufficient amount to detect) and detecting the cffDNA

85. *Id.* at 942.

86. *Id.*

87. *Id.* at 941.

88. See MAYO CLINIC, RISKS OF AMNIOCENTESIS (2015); MAYO CLINIC, RISKS OF CHORIONIC VILLUS SAMPLING (2015).

89. MaterniT21, SEQUENOM LABORATORIES (2015), available at <https://laboratories.sequenom.com/providers/materniT21-plus/?gclid=CluokvXS8sgCFQ6maQodwyMKBA>.

90. See *Ariosa Diagnostics Inc.*, 19 F.Supp.3d at 941.

91. See MaterniT 21, *supra* note 89.

92. See *Ariosa Diagnostics Inc.*, 19 F.Supp.3d at 954 ("[E]ven assuming that the articles disclose alternative methods of detecting cffDNA, Sequenom has failed to show that any alternative methods existed *at the time of the invention or at the time of issuance of the patent.*" (emphasis added)).

fragments were not inventive steps that sufficiently transformed the natural principle in order to make it patent-eligible.⁹³ The steps were not inventive or transformative because steps to amplify and detect DNA were already well-known in the field of medicine and Sequenom's only addition was the application of the steps to the newly discovered cffDNA.

The Federal Circuit mentioned, but failed to fully address, the issue of preemption, stating that "in this case, Sequenom's attempt to limit the breadth of the claims by showing alternative uses of cffDNA outside the scope of the claims does not change the conclusion that the claims are directed to patent ineligible subject matter."⁹⁴ The court never addressed whether Sequenom's demonstration of alternative cffDNA uses was sufficient to show that the natural phenomena is not preempted by its claims.

C. *Comparison with the Genetic Technologies Decision*

In contrast to the decision in *Ariosa*, in *Genetic Technologies Ltd. v. Agilent Technologies, Inc.*, the Northern District of California found that amplification of genomic DNA was not an insignificant step because it was meaningfully limited under the *Ultramercial* factors.⁹⁵ The *Genetic Technologies* decision is interesting because its factual similarity to *Ariosa* highlights the problem areas in the field of patent-eligibility.

The technology in both cases is directed to a natural principle that others in the scientific community felt was unimportant. As discussed in Section IV(b) below, industry skepticism in regard to a proposed invention is a consideration to be taken into account when determining whether an invention may have been obvious under § 103.⁹⁶ In *Genetic Technologies*, the natural principle was that the non-coding regions of a DNA strand (introns) may be linked to the presence of certain alleles in the coding portions (exons).⁹⁷ The claims at issue were directed at a process for amplifying and analyzing the intron portions of the DNA strand to see what alleles presented in the exon DNA portions.⁹⁸ Applying the Federal Circuit's factors in *Ultramercial* to the Mayo Two-Step, the district court held that the addition of the amplification and analysis steps were an inventive concept that effectively transformed the natural principle into more than a claim to the natural principle itself.⁹⁹ This stands in contrast

93. See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015).

94. *Id.* at 1379.

95. See *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 714 (Fed. Cir. 2014).

96. See *infra* Part IV.B.

97. *Genetic Tech. Ltd. v. Agilent Tech., Inc.*, 24 F.Supp.3d 922, 926 (N.D.Cal. 2014).

98. See *id.*

99. *Id.* at 930; See *Ultramercial, Inc.*, 722 F.3d at 1348.

to the Federal Circuit's decision in *Ariosa*, where the steps of amplification and analysis did not sufficiently transform the natural principle using the Mayo Two-Step test.¹⁰⁰ The court in *Genetic Technologies* distinguishes its decision from *Ariosa* by stating that the amplification step in the case is limited to a specific manner of amplification using a primer pair that spans a non-coding sequence.¹⁰¹ If this is the case, and the only thing invalidating Sequenom's patent in *Ariosa* is that it did not designate a method by which the amplification should take place, then the requirement of claiming a specific method should be clearly established so that it may be taken into account during patent prosecution and subsequent examination by the USPTO.

There is still a need for the courts to decide whether to integrate the *Ulramercial* factors with the Mayo Two-Step test. Without a unified guiding standard, the patent-eligibility of diagnostic methods will remain a mystery to patent applicants, the USPTO, and the courts.

IV. The Patent Code as a Whole: Examining § 101 in Light of the Other Sections

The Supreme Court's opinion in *Mayo* states that too much reliance on later sections of the patent code may render § 101 superfluous. However, the Supreme Court "recognize[s] that, in evaluating the significance of additional steps, the § 101 patent-eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap."¹⁰² There may indeed be value in importing language from holdings in the §§ 102 and 103 areas of law to help decode the language of the § 101 inquiry. For example, the terms "inventive concept," "process," and "transformation" have all been used and defined in the jurisprudence surrounding §§ 102 and 103.

These definitions should be considered in order to aid the § 101 inquiry of patent eligibility, especially in the case of terms that are used in multiple sections, such as "inventive concept," "process," and "transformation."

A. § 102: Anticipation, the Inventive Step, and Transformation

Under the Mayo Two-Step test, in order to be patent eligible, claims directed to applications of natural principles must include an "inventive step" that "sufficiently transforms" the natural principle into patent-eligible subject matter.¹⁰³ Under this test, new combinations of steps that

100. See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015).

101. See *Genetic Tech. Ltd.*, 24 F.Supp.3d at 932.

102. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1304 (2012).

103. *Id.* at 1294.

were previously known in the art are not patent-eligible when they are directed at a natural principle. For this reason, the Federal Circuit rejected the claims in *Ariosa*, because adding the steps of amplification and detection to the natural principle of cffDNA was not considered to be an inventive step that transformed the cffDNA into eligible matter. This analysis differs from the jurisprudence that exists regarding § 102 novelty and § 103 non-obviousness.

Under 35 U.S.C. §§ 102, in order to patent a device, method, or process, it must not only be directed to patent-eligible subject matter, but it must also be novel.¹⁰⁴ In the field of patent law, practitioners say that an invention was not “anticipated” by the prior art.¹⁰⁵ For an invention to lack novelty, a single prior-art reference must disclose every element or limitation of that invention.¹⁰⁶ This means that every aspect of an invention must be described in one piece of prior art, like a single patent or research paper. The USPTO cannot combine two prior inventions to render the inventor’s patented invention ineligible.¹⁰⁷ The single reference requirement is important because it demonstrates the Court’s belief that combining previously known steps is in and of itself an inventive step.¹⁰⁸ If creating a combination of known art was not considered inventive, then there would be no reason to specify that all elements and limitations must be disclosed in a single prior reference; combinations of references would be allowed to disprove novelty.

If the court had imported this language to the analysis of § 101 to help determine whether an inventive step occurred, the claims in *Ariosa* may well have been allowed. The combination of the steps—amplifying the cffDNA and detecting the cffDNA—had not been disclosed previously by any other reference, because cffDNA was a newly discovered phenomenon.

104. See 35 U.S.C. §§ 101-102 (2012).

105. See CRAIG A. NARD, *THE LAW OF PATENTS* 264 (Rachel E. Barkow et al. eds., 4th ed. 2017).

106. *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999); See NARD, *supra* note 105, at 42 (“Prior art is knowledge—for example patents and publications—accessible to a person of ordinary skill in the art before the date of invention (pre-AIA timeframe) or before the effective filing date (post-AIA timeframe)”).

107. See U.S. PATENT & TRADE OFFICE, *2141 Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 [R-07.2015]*, Manual of Patent Examining Procedure (9th ed., 2015), available at: <https://www.uspto.gov/web/offices/pac/mpep/s2141.html>.

108. See U.S. PATENT & TRADE OFFICE, *2143 Examples of Basic Requirements of a Prima Facie Case of Obviousness [R-08.2012]*, Manual of Patent Examining Procedure (9th ed., 2015), available at: <https://www.uspto.gov/web/offices/pac/mpep/s2143.html>.

B. § 103: Non-Obviousness, Secondary Considerations, and the PHOSITA

Like the determination of patent eligibility under §101, the inquiry of non-obviousness also requires that there be an inventive step or transformation that would not have been obvious to a person of ordinary skill in the invention's field.¹⁰⁹ In *Graham v. John Deere*, the Supreme Court outlined several factors that must be used in order to establish a *prima facie* case of obviousness.¹¹⁰ However, a *prima facie* case of obviousness may be rebutted through the use of secondary considerations. Generally, secondary considerations include such factors as (1) whether the invention has been a commercial success, (2) whether there has been industry praise and unexpected results, (3) whether other companies or inventors have copied the invention, (4) whether before the invention there had been industry skepticism with respect to the idea, (5) whether customers and competitors were willing to license for the use of the inventions, and (6) whether the invention addressed some long-felt but unresolved need in the field of the invention.¹¹¹

There is value in applying these secondary considerations to the inquiry of patent-eligibility as well. Patent law seeks to reward those who bring novel and necessary innovation into the public domain. Secondary considerations are, in many ways, a measure of how much the public benefits from an invention. Large benefit to the public is a clue that an invention contains an inventive concept, because if it were not inventive, why would companies be willing to license it? Why would consumers be willing to purchase it? Why would others in the field not have discovered it already?

There may also be a patent-eligibility benefit in determining who is the person having ordinary skill in the art ("PHOSITA") for the field of art in which the invention is situated.¹¹² Patent law places great value on examining a patent from the viewpoint of a typical practitioner.¹¹³ Would a typical PHOSITA have believed that the invention was patent eligible? The PHOSITA serves as a measure of the general state of mind of those in the field regarding the invention. Due to the lack of clarity in the field of patent eligibility, this factor may be harder to use effectively, but there is still value in determining whether the average person in the art would believe that the claimed invention is patent eligible. If the typical PHOSITA

109. See 35 U.S.C. § 103 (2012).

110. See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 13-17 (1966).

111. See *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012).

112. See NARD, *supra* note 105.

113. See 2107 *Guidelines for Examination of Applications for Compliance with the Utility Requirement*[R:11.2013], U.S. PATENT & TRADE OFFICE, available at <https://www.uspto.gov/web/offices/pac/mpep/s2107.html> (last modified Nov. 4, 2015).

would not believe the claimed process is eligible, then that would be a factor against eligibility.

A court determines the PHOSITA using the relevant factors laid out in *Daiichi v. Apotex*: (1) the education level of the inventor, (2) the typical types of problems in the field and who works on those problems, (3) the inventors of any prior-art solutions to problems in the field, (4) how rapidly advancements in the field are developed, (5) the technology's sophistication, and most importantly (6) the average education level of active workers in the field of the art.¹¹⁴

In the field of diagnostic tests, the PHOSITA is typically a doctor, particularly those who specialize in the application of diagnostics, though the inventor of a diagnostic test is more likely to be a medical researcher or other academic. This distinction can be valuable when determining patentability. Would a typical doctor in the field of diagnostics find the claimed invention to be something new and non-obvious and thus deserving of a patent?

V. A Proposed Test for Patent-Eligibility of Diagnostic Methods

A. A Summary of the Current Problems with the Test for Patentability

As it stands, the Supreme Court in *Mayo* held that for an application of a natural principle—i.e., a diagnostic test—to be patent eligible, the inventive concept that transforms the natural principle must be more than an application of routine or conventional steps in the medical field. This conflicts with earlier language in the opinion wherein the Court directly quoted *Diehr* stating that “the application of a law of nature or mathematical formula to a *known structure or process* may well be deserving of patent protection”.¹¹⁵ These conflicting statements make it difficult to determine when the application of a natural principle to a known process creates a patent eligible claim.

Section 100 of the America Invents Act (“Act”) defines terms used in the context of the patent statutes.¹¹⁶ However, there are still clarifications for the court system to make regarding these terms. For example, the Act defines the term “process” as including a new use of a known process or composition of matter.¹¹⁷ It is unclear whether this definition would extend to patents that claim the application of a known process to a newly discovered natural phenomenon, such as the patent at issue in *Ariosa*.¹¹⁸

114. *Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007).

115. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293-94 (2012) (emphasis added).

116. *See* 35 U.S.C. § 100 (2012).

117. 35 U.S.C. § 100(b).

118. *See Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (Fed. Cir. 2015).

Under the language of § 100(b), *Ariosa* would appear to be a new use of a known process (applying the known process of amplifying and detecting DNA to the newly discovered natural phenomenon of cffDNA fragments), which, under the Supreme Court's language in *Bilski*, would establish strong evidence that the claimed process is patent eligible.¹¹⁹ Despite attempted clarification, the vagueness of language such as "inventive concept" and "sufficiently transforms" leave a test that is not as clear as it could be. As Judge Dyk noted in his concurrence with the denial of Sequenom's petition for rehearing *en banc*, "there is a problem with *Mayo* insofar as it concludes that inventive concept cannot come from discovering something new in nature—e.g., identification of a previously unknown natural relationship or property."¹²⁰ Diagnostic tests that rely on newly discovered laws of nature may be ill-suited to a patent-eligibility analysis that uses the *Mayo* test. The field needs a clear test for whether a diagnostic test that has its basis in a law of nature is patent eligible. To that end, I discuss suggested solutions and propose a novel test for patent eligibility of diagnostic methods.

B. Two Alternate Solutions

Some academics suggest alternate solutions for clarifying the area of diagnostic methods. The two main solutions proposed as alternatives to reshaping the *Mayo* Two-step are (1) amending § 101, and (2) creating a separate section of the United States Code applicable only to patents on diagnostic methods similar to section § 161, which applies to plant patents.¹²¹

In response to a slew of patent invalidations that followed in the wake of the *Alice Corp. Pty. v. CLS Bank* decision, attorney Robert Sachs detailed a series of proposed changes to § 101.¹²² His proposed changes include definitional changes that would fall in line with how many scientists interpret language surrounding natural phenomena and abstract ideas. Further solutions offered, some of which have already been discussed earlier in this Note, include adding a safe harbor section that creates a presumption of eligibility, determining eligibility based on a PHOSITA's viewpoint, and returning to a test of eligibility on the basis of non-preemption.¹²³

119. See *Bilski v. Kappos*, 130 S.Ct. 3218, 3222 (2010) (stating that the Court doesn't need to define a patent-eligible process beyond guiding people to § 100(b)).

120. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1289 (Fed. Cir. 2015) (Dyk, J., concurring).

121. 35 U.S.C. § 161 (2012).

122. See Robert R. Sachs, *Twenty-Two Ways Congress Can Save Section 101*, FENWICK & WEST BILSKI BLOG (Feb.12, 2015), <http://www.bilskiblog.com/blog/2015/02/twenty-two-ways-congress-can-save-section-101.html>.

123. See *id.*

Another suggested alternative is creating an entirely new statute that deals specifically with patenting inventions in the medical field. In 1930, Congress created a new statute dealing specifically with human-designed varieties of plants. This statute, 35 U.S.C. Chapter 15 §§ 161-164, has its own set of requirements distinct from those outlined for typical patents.¹²⁴ A statute created specifically for patents in the medical field could likewise have distinct requirements.

The resistance to these alternatives is often practical, rather than intellectual. They would almost certainly work, but why go through the arduous task of amending 101 or creating an entirely new statutory section to specifically encompass diagnostic tests when there is nothing in the original § 101 that excludes them? Diagnostic tests were excluded on the basis of jurisprudence, and by jurisprudence they are most effectively reinstated. Furthermore, the area of § 101 eligibility could use clarification as a whole, not merely in the medical field or the field of diagnostic tests in particular. Amending the statute or creating an entirely new statute may fix one problem area, but when new ones arise, a new test that makes certain the framework for patent eligibility is a solution that can be applied over numerous fields.

C. The Proposed Test

To provide much-needed clarity, there are several factors that should be taken into account in determining the patent eligibility of a diagnostic test. No one factor should be dispositive of patentability, but rather their impact should be balanced in order to reach a reasoned conclusion on eligibility under 35 U.S.C. § 101.

The first step in determining the patent eligibility of a diagnostic test is to apply the Supreme Court's *Mayo* test.¹²⁵ However, the application should be done using the interpretations of the "process," "inventive step," and "transformation" language imported from the jurisprudence surrounding sections § 102 and § 103, as discussed in Section IV above.¹²⁶ This means that the application of conventional steps to a newly discovered natural phenomenon should be considered an "inventive step," just as it would be under the § 102 analysis. If the claims at issue fail the application of the Mayo Two-Step, they are presumed to be patent-ineligible under 35 U.S.C. § 101. However, that presumption may be rebutted using steps two and three, as outlined below.

The second step in determining the diagnostic method's patentability is to determine whether the claimed method is sufficiently narrow in scope and whether it has been reduced to practice. Reduction to practice

124. See 35 U.S.C. §§ 161-164 (2012).

125. See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294-97 (2012).

126. See *supra* Part IV.

typically requires “the inventor to prove that the claimed invention works for its intended purpose, which typically involves the inventor constructing and testing a prototype of the invention.”¹²⁷ In his concurrence with Sequenom’s denial for rehearing *en banc*, Judge Dyk reiterates that undue preemption is the main fear behind allowing a patent on a law of nature. For that reason, Judge Dyk stated that “if the breadth of the claim is sufficiently limited to a specific application of the new law of nature discovered by the patent applicant and reduced to practice, [he] think[s] that the novelty of the discovery should be enough to supply the necessary inventive concept.”¹²⁸ The paired requirements of reduction to practice and narrowly tailored claims prevent undue preemption of the natural principle by limiting the patent to the specifically claimed application. If the patent-seeking diagnostic method is both reduced to practice and has claims that are narrowly tailored, those factors may rebut a presumption of unpatentability, especially if the third step also points to a finding of eligibility.

The third step is an analysis of secondary considerations. Secondary considerations may be used in conjunction with step two to rebut a presumption of patent ineligibility. This step has less weight than step two, meaning that multiple factors must weigh in favor of patentability for the presumption to be rebutted. The main secondary considerations include the *Transocean* factors, namely, (1) whether the invention has been a commercial success, (2) whether there has been industry praise or if the results achieved by the invention were unexpected, (3) whether other companies have copied the invention, (4) whether before the success of the invention there had been skepticism in the industry with regard to the idea, (5) whether customers and competitors were willing to license the invention, and (6) whether the invention resolved a long-felt need in the industry.¹²⁹ As explained in Section IV(B), these factors point toward a finding of eligibility because they demonstrate a very real need in the industry for the product that is being developed.¹³⁰

These considerations can rebut the presumption of patent ineligibility that occurs when a diagnostic test fails the Mayo Two-Step test. The test is particularly useful in regard to diagnostic methods that use an application of a newly discovered natural principle, as they are often rejected. Judge Dyk “worr[ies] that method claims that apply newly discovered natural laws and phenomena in somewhat conventional ways are screened out by

127. NARD, *supra* note 105, at 264.

128. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1291 (Fed. Cir. 2015) (Dyk, J., concurring).

129. *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012).

130. See *supra* Part IV.B.

the *Mayo* test.”¹³¹ Rather than disregard those contributions entirely, they should serve as a means to rebut the *Mayo* Two-Step.

The novelty of the test comes from the three pieces added to the current *Mayo* Two-Step analysis: importing definitions from the jurisprudence surrounding §§ 102 and 103, the step of determining reduction to practice and sufficiently limited claim scope, and finally, the step of applying secondary considerations. The test improves the existing *Mayo* standard by adding the ability to rebut the initial finding of patent ineligibility using the narrowed language of the claim and actual reduction to practice. These additions are an improvement because they widen the scope of the test, allowing diagnostic tests that are an application of a newly discovered natural principle to be patent eligible, even if the steps applied to that principle are not themselves novel. The addition of the third step, allowing secondary considerations to be taken into account to rebut a presumption of unpatentability, hearkens back to the purpose of patent law itself. At its heart, patent law is about bringing innovative and new inventions to the public. Secondary considerations take into account the effect the invention has had on its given field. Factors such as whether the invention has been copied illustrate that there is a need in the field for the invention. An invention that is a needed improvement to its field is the exact feature that patent law seeks to reward.

Some of the potential objections to the test have been addressed in Section V(B) above. Most notably, the limitations on patent eligibility of diagnostic tests were created through jurisprudence, and altering that jurisprudence is the path to most easily remedying them.

D. Applying the Proposed Test to Ariosa

Applying this Note’s proposed test to the technology at issue in *Ariosa*, it becomes evident that the determination of patent-eligibility as it regards the process of non-invasive fetal testing using cffDNA would be different than the Federal Circuit’s decision.

First, we must apply the *Mayo* Two-Step test to the technology at issue. In the Federal Circuit’s 2015 *Ariosa* decision, the court first found that the claims at issue were based on a natural phenomenon.¹³² It then addressed the second step of the framework in order to determine if the use of the cffDNA described in the claims sufficiently transformed the natural principle of cffDNA into a patent-eligible method. The Federal Circuit held that the steps of cffDNA amplification and detection did not sufficiently transform the cffDNA to render the method patent eligible.¹³³ However, under the proposed test, one would import the language regarding transformation from § 102, which considers a new combination

131. *Ariosa Diagnostics, Inc.*, 809 F.3d at 1289.

132. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015).

133. *See id.* at 1376-77.

of steps previously known in the art to be an inventive step. The application of previously known steps such as amplification and detection to the newly discovered phenomenon of cffDNA would be a sufficient transformation of the natural principle for that method to become patent eligible because it is an application of known steps to a previously unknown phenomenon, thus creating a new combination. However, if the Courts found that the claims at issue in *Ariosa* still did not reach the level of patent eligibility after applying the *Mayo* test, the following two steps of the proposed test could rebut that finding of unpatentability.

In order to determine whether the presumption of unpatentability could be rebutted, a court would have to determine whether the claims at issue were narrowly tailored and whether the invention itself had been reduced to practice. In *Ariosa*, the claims at issue were limited to a particular use of the cffDNA. Through amplification and detection, medical practitioners could use the cffDNA fragments as a non-invasive fetal diagnostic test. This is a narrow application of the natural phenomenon of cffDNA; it does not prevent cffDNA from being used in other applications unrelated to fetal testing or in fetal testing applications that do not use the steps of both amplification and detection. Furthermore, the testing method has been fully reduced to practice. Sequenom has already marketed its method under the name Maternit21, which demonstrates that it is a fully realized invention that works for its intended purpose.¹³⁴ The combination of the narrowly tailored claim and the reduction to practice demonstrates that Sequenom's invention does not seek to preempt all other uses of the natural principle of cffDNA. These factors support a finding that the technology at issue should be patent eligible.

Finally, if the above considerations were still found to be insufficient, secondary considerations should also be applied to the invention in *Ariosa*. This would allow a court to see whether there is a need in the medical field that outweighs a preliminary finding of patent ineligibility. With regard to commercial success and industry praise, the Maternit21 test has wide market application and has seen high levels of success.¹³⁵ With regard to previous industry skepticism and unexpected results, prior to Sequenom's discovery, medical practitioners regarded the maternal plasma or serum that contains the cffDNA as waste material and discarded it,¹³⁶ implying that the material is worthless. Since the industry regarded the material as waste, the fact that Sequenom created a worthwhile and beneficial test from that waste material, one that solves a huge problem of high-risk prenatal tests, should be heralded as an unexpected result.

In considering whether the invention addressed some long-felt need in the medical field, one must only look to the previous methods for fetal

134. See Maternit21, *supra* note 89.

135. See *id.*

136. *Ariosa Diagnostics, Inc.*, 788 F.3d at 1373.

testing and the inherent risks in those procedures. Amniocentesis and chorionic-villus sampling carry risks as severe as miscarriage.¹³⁷ A non-invasive fetal test like Sequenom's is an improvement over the prior tests and addresses the need for a safe and reliable method of fetal diagnostic testing. With regard to copying and licensing the invention, as shown by the infringement suit at issue in *Ariosa v. Sequenom*, companies such as Ariosa began producing tests identical to Sequenom's as soon as Sequenom's test hit the market. Overall, the analysis of the secondary considerations points favorably toward patent eligibility for Sequenom's claims.

Under the proposed test, it is likely that Sequenom's claimed method for using cffDNA would be a patent-eligible use of a natural phenomenon.

Conclusion

In adopting of the Mayo Two-Step test, the Supreme Court sought to set forth a test for determining whether an invention or method that claims a use of a natural principle is patent-eligible under 35 U.S.C. § 101. In particular, the Court sought to meaningfully limit the scope of patent eligibility to exclude those inventors who would wish to overstep their bounds, claiming patent rights on the laws of nature themselves or applications of those laws so broad as to be indistinguishable from the former. For these reasons, the test limited patent eligibility of natural principles to those inventions that contained additional steps that sufficiently transform the phenomenon into a limited and useful application. However, the Court did nothing to clarify the meaning of such terms as "sufficiently transform" or "inventive concept." These terms are of particular importance in the field of diagnostic tests and are often the crucial factor between a determination of eligibility and a determination of non-eligibility. Requirements such as transformation are difficult to quantify, particularly in the medical field. For this reason, it is necessary to create a test that helps distinguish when a diagnostic test should be eligible for patent protection.

The proposed test clarifies these terms and facilitates the determination of eligibility. Furthermore, the test takes into account factors such as preemption, incentives for research, and benefit to the public. By adopting a test such as this one, courts would be taking steps to clarify which uses of natural principles are acceptable and which overstep their bounds into areas of undue preemption. Courts would be returning patent law to its roots in rewarding the creation of innovative technologies for the benefit of the public.

137. See MAYO CLINIC, RISKS OF AMNIOCENTESIS (2015); MAYO CLINIC, RISKS OF CHORIONIC VILLUS SAMPLING (2015);