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Recently, the controversial interpretation of whether a patent is eligible under federal patent law protection has drawn the attention of the medical field due to its substantial significance in the adjudication of cases involving medical diagnostics.1 The Supreme Court’s application of a heightened standard of review for the patent eligibility of medical diagnostic techniques is making the acquisition of such patents nearly impossible.2 Innovators in the biotechnology field are concerned that this heightened

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1 See 35 U.S.C. § 101 (1952) (stating patent protection is available for whoever discovers a new invention). The statute states “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent.” *Id.* (providing definitions for patent law terminology). “The term ‘process’ means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.” *Id.* at 101(a). See also *Ariosa*, 809 F.3d at 1287, (finding method for detecting prenatal health of fetal baby not patent-eligible); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (Fed. Cir. 2015) (affirming previous ruling); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 19 F. Supp. 3d 9283938, 954 (N.D. Cal. 2013) (ruling prenatal testing method was based on a natural phenomenon); *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354-56 (2014) (deciding a computer implemented scheme was too abstract of an idea to be patent eligible); Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116-17 (2013) (deciding isolating a strand of DNA is not patent eligible); Mayo Collaborative Servs. V. Prometheus Labs., Inc., 132 S. Ct. 1289, 1301-02 (2012) (providing precedent eligible) regarding patentability. *Id.*

2 See *Ariosa*, 809 F.3d at 1284 (using heightened standard of review to hold medical diagnosis patent ineligible). See also *Bilinski v. Kappos*, 561 U.S. 593, 655 (2010) (Stevens, J., concurring) (reinforcing the three exceptions that deter patent eligibility); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (ruling precedent in the courts that provided three exceptions to patent eligibility). See generally *Alice*, 134 S. Ct. at 2355 (approving the application of the heightened standard of review); *Myriad*, 133 S. Ct. at 2116-7; (applying a heightened standard to the definition of invention) *Mayo*, 132 S. Ct. at 1301-02 (setting the precedent for the standard of review used in *Alice*). The governing issuance of patents excludes discoveries of laws of nature,
standard will negatively influence and substantially weaken the incentive to invest in healthcare innovation.3 The recent decision by the Federal Circuit Court in Ariosa

physical phenomena and abstract ideas because manifestations of nature are free to all men. See Bilski, 561 U.S. at 611 (describing limitations on patent eligibility); Chakrabarty, 447 U.S. at 309 (explaining that not every process is patentable).

There are two criteria for determining subject matter eligibility under 35 U.S.C. 101 and both must be satisfied ... Step 1: Is the claim directed to one of the four patent eligible subject categories: process, machine, manufacture, or composition of matter? The subject matter of the claim must be directed to one of the four subject matter categories ... Step 2: Does the claim wholly embrace a judicially recognized exception, which includes laws of nature, natural phenomena, and abstract ideas?

2106-Patent Subject Matter Eligibility, USPTO
See also Rachel L. Emsley & Linda J. Thayer, CLS Bank Further Muddies the Murky Waters of Patent Eligible Subject Matter, CIPA JOURNAL (June 2013)
http://www.finnegan.com/resoures/articles/articlesdetail.aspx?news=c22a0977-903c-4240-9b90-cadb1a96d439 (discussing the blurred line whether medical diagnostics are patent eligible)
The U.S. Supreme Court Judges agreed “the test for eligibility is not a rigid, bright-line test and must be made while evaluating the claim as a whole, on a case-by-case basis, using a flexible approach.” Id.

Diagnostics v. Sequenom, Inc. relied on the framework set out in Mayo Collaborative Servs. v. Prometheus Labs., Inc. and Alice Corp. Pty. Ltd. v. CLS Bank Int'l in determining if a method for detecting paternally inherited DNA to perform a prenatal diagnosis is eligible for patent protection. The Federal District Court and Federal Court of Appeals in Ariosa ruled that this method for prenatal diagnosis was excluded as patent-eligible subject matter because it relied too strongly on the "laws of nature," "abstract idea" exceptions, and lacked an "inventive concept."

Prior to litigation, Sequenom was the exclusive licensee of the ‘540 patent, which is an invention that enables non-invasive prenatal testing. Ariosa possessed a similar diagnostic test and filed a declaratory relief action against Sequenom, claiming that their version of the test does not infringe or contribute to the infringement of the ‘540 patent. In response, Sequenom filed a motion for a preliminary injunction seeking to enjoin Ariosa from “making, using, selling, offering for sale, or importing . . .” the

https://www.youtube.com/watch?v=AQpaKJjEQR8 (providing differences between trademark and patents and benefits).

4 See Ariosa, 809 F.3d at 1284 (citing that Ariosa’s method fell under the exceptions from Mayo and Alice); see also Gottschalk v. Benson, 409 U.S. 63, 70 (1972) (defining a process as an act, or series of acts or steps). “A process is a mode of treatment of certain materials to produce a given result . . . performed upon the subject-matter to be transformed and reduced to a different state or thing,” Cochrane v. Deener, 94 U.S. 780, 788 (1876).

5 Ariosa, 809 F.3d at 1294 (ruling the diagnostic method was conventional and not inventive); Id. at 1286 (ruling that using blood and a conventional test was not an invention). A patent that is under the “laws of nature” category must add additional steps to the claimed process and that patent law’s objective must have significance “to the natural laws, such that those steps transform the process into an inventive application of those laws.” Id. at 1284 (citing Mayo, 132 S.Ct. at 1299). See also 35 U.S.C. §§ 102 and accompanying text cited infra note 12 (outlining what categories are patent eligible and listing the exceptions of what is not eligible).

6 See Ariosa, 19 F. Supp. 3d at 941 (N.D. Cal. 2013) (outlining the discovery of cffDNA in plasma samples produces a higher detection rate). Drs. Lo and Waincoat discovered a non-invasive prenatal diagnosis that is accurate when determining the sex of the child, blood typing and other genotyping, and detection of pre-eclampsia in the mother. Id. They accomplished this by discovering that cell free fetal DNA (“cffDNA”) was detectable in plasma samples, which increased the detection rate and suggested there was an enrichment of fetal DNA in maternal plasma. Id.

7 See id. at 941-42.
test into the United States. The U.S. District Court for the Northern District of California denied Sequenom's motion for preliminary injunction and found that Ariosa had raised a substantial question in regard to whether the '540 patent encompassed patent-eligible subject matter. Both the California Northern District Court and the Federal Circuit Court of Appeals upheld Ariosa's counterclaim alleging that the method of prenatal testing was patent ineligible. The Federal Court of Appeals held that the method merely added conventional steps to a natural phenomenon and therefore was not patent eligible. Sequenom attempted to further address the issue of patent eligibility for medical diagnostics when it filed a petition for rehearing en banc because it believed that the method to diagnose possible birth defects without using highly

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8 See id. at 942.
9 See id. at 954.
10 See generally Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013) (isolating a genetic sequence is not an act of invention); Mayo Collaborative Services, dba Mayo Med. Lab., et al. v. Prometheus Lab., Inc., 132 U.S. 1290 at 1297 (2012) (ruling a patent cannot be an instruction of a law of nature); Bilski v. Kappos, 130 S. Ct. 3220, 3231 (ruling a broad business procedure was too abstract an idea and would create a monopoly); Diamond v. Diehr, 101 S. Ct. 1048, 1060 (1981) (ruling the process of molding rubber based on a mathematical equation was patent ineligible); Parker v. Flook, 437 U.S. 584, 594 (1978) (holding a mathematical formula is not novel because it is a phenomenon); Gottschalk v. Benson, 409 U.S. 63, 68 (1972) (ruling broad mathematical claims were an abstract idea); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 129 (1948) (ruling the discovery of plants with specific bacteria were patent ineligible). The inventors discovered certain plants contained bacteria that allowed them to inoculate with seeds of other plants. Id. at 130. The Supreme Court ruled that this was merely a discovery of “the phenomena of nature” and that this was the handiwork of nature making it a discovery not an invention. Id. at 131.
11 See supra note 2 at 1378 and accompanying text. The court held that adding conventional steps to a natural phenomenon was not enough to conclude an inventive step because it was naturally occurring and the steps that amounted to a method were well understood in the art of medical diagnosis. Id. The court based their ruling on the decision in Mayo, which stated that the process of administering drugs to measure metabolites in the bloodstream was “well known in the art” and amounted to “nothing significantly more than instruction to doctors to apply the applicable laws when treating their patients.” Id. at 1376 (quoting Mayo, 132 S.Ct. at 1298-1300). Adding conventional steps to a law of nature is not enough to prove an inventive concept. Id.
intrusive means was of significant importance, novel, patent-eligible, and therefore, worthy of reevaluation.12

The Federal Circuit Court concluded by way of en banc review that the diagnostic did not fall under a patent-eligible exception, such as a natural law, but that the claim was too broad and also expressed concern that a restrictive test could discourage health care innovation.13 The Federal Circuit applied the precedent in Mayo to determine that in order for a patent to be eligible under a law of nature, there must be

A person shall be entitled to a patent unless - the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

Arias, 809 F.3d at 1285 (providing the claims brought by the plaintiff). The first claim is “a method for detecting a paternally inherited nucleic acid of fetal origin from a pregnant female comprising amplifying a paternally inherited nucleic acid and detecting the presence of a paternally inherited nucleic acid.” Id. The twenty-first claim is a method of prenatal diagnosis by “providing a maternal blood sample, separating the sample into a cellular and non-cellular fraction, detecting the presence of a nucleic acid, and providing a diagnosis.” Id. See also Ariosa, 809 F.3d at 1288 (providing the argument by Sequenom). Sequenom argued that the claimed methods were patentable because they were novel uses of a natural phenomenon and did not preempt all uses of the cfDNA. Id.

12 See generally FED. R. CIV. P. 35(a)(2) (providing the rule when a hearing or rehearing on en banc may be ordered). Sequenom claimed the ruling should be reviewed because “the proceeding involves one a question of exceptional importance.” Id. Conditions for patentability; novelty, 35 U.S.C. §§ 102 (describing when an invention is novel).

13 See generally U.S. Const. art. 1, § 8, cl. 8 (providing the purpose of patent laws). The Constitution outlines the importance of patent law “to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” Id. Ariosa, 809 F.3d at 1284 (discussing the court's conclusions for en banc review). Judge Dyk agreed that invalidating frivolous and anticompetitive patents provided a health patent system. Id. However, Judge Dyk also stated that a too restrictive test on patent eligibility might discourage healthcare innovation and disclosure of new diagnostic and therapeutic methods in the life sciences, which rely on discovery of new natural laws and phenomena. Id. Research Funding And Support, PMC, http://www.personalizedmedicinecoalition.org/Policy/Research_Funding_and_Support (last visited Mar. 3, 2017). The challenges of developing reliable diagnostic instruments and methods can only be met with adequate funding and support from both government and private sources. Reimbursement, PMC, http://www.personalizedmedicinecoalition.org/Policy/Reimbursement (last visited Mar. 3, 2017).
an inventive concept.\textsuperscript{14} The majority opinion, however, stated that the precedent set forth in \textit{Mayo} did not take into account that a discovery of a natural law could, itself, be an inventive concept.\textsuperscript{15} The majority believed that the application of \textit{Mayo} and \textit{Alice} did not apply to the present case due to factual dissimilarities and, therefore, the patent-eligible exception of a natural law did not apply.\textsuperscript{16} Ultimately, the Court of Appeals for the Federal Circuit ruled that the precedent set by the Supreme Court bound them to rule that the method of diagnosis was patent ineligible.\textsuperscript{17}

The existence of patent law stems from the United States Constitution, which granted Congress the right to establish the first federal patent law under the Patent Act of 1790.\textsuperscript{18} The founding fathers of the Constitution believed the public would benefit from exclusive protection for inventions to promote science and innovation by incentivizing artists and inventors.\textsuperscript{19} Although the Constitution allows Congress to

\textsuperscript{14} See \textit{Mayo}, 132 S. Ct. at 1301-02 (2012) (concluding that an inventive concept cannot come from discovering something new in nature).

\textsuperscript{15} \textit{Ariosa}, 809 F.3d at 1289. In \textit{Ariosa}, Judge Dyk claimed that a discovery of a law of nature could be an inventive concept based on the “creativity and novelty of the discovery of law itself.” \textit{Id.} Judge Dyk also claimed this to be especially true for medical diagnostics because this type of life science is driven by development of new diagnostic and therapeutic methods dealing with complex biological systems. \textit{Id.} The court even concluded that a future case would likely present a patent claim where the inventive concept of a natural law would be so narrowly drawn and reduced to practice that the Supreme Court would have to revisit their framework set out in \textit{Mayo} and \textit{Alice}. \textit{Id.}

\textsuperscript{16} \textit{Id.} at 1285. The methods for prenatal diagnosis in \textit{Ariosa} were not routine and conventional like the separation of genes in \textit{Mayo}. \textit{Id.} The claim in \textit{Ariosa} is not abstract because it is performing physical steps on a physical material and is a novel process, which is what patents are intended to be awarded for. \textit{Id.} at 1287.

\textsuperscript{17} \textit{Id.} at 1287 (providing reasoning for court’s decision). Judge Dyk claimed before her opinion that the precedent set forth by the Supreme Court bound the Court of Appeals for the Federal Circuit, and that any further guidance must come from the Supreme Court and not the Court of Appeals for the Federal Circuit. \textit{Id.}

\textsuperscript{18} See U.S. CONST. art. I, § 8, cl. 8. See also 35 U.S.C. § 101. See also Patent Act of 1790, ch. 7, § 1 Stat. 109-112 (1790) (current version at 35 U.S.C. § 101 (1992)) (providing the first United States patent statute). The wording of the statute almost entirely remains the same and in 1790 stated an invention or discovery can be patented if it is “any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used . . .” \textit{Id.}

\textsuperscript{19} See U.S. CONST. art. I, § 8, cl. 8 (providing the outline of intellectual property law); Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 9 (1966) (reviewing the validity of patents in light of the
To protect an author's work, the Supreme Court has the power to interpret the statutory language of patent law and determine which inventions are patentable. The Supreme Court has established precedent by applying the power of judicial review to patent law, and since 1853, has ruled that laws of nature, natural phenomena, and abstract ideas are patent-eligible exceptions.

Technological innovation and patent law exceptions began to progress simultaneously when the first patent law was enacted to cover biological materials, the Plant Patent Act of 1930 ("PPA"), which permitted the right to patent asexual species of plants. Patent law exceptions continued to expand with the Plant Variety Act of 1970 ("PVPA"), which allowed breeders to have exclusive control of new, distinct, uniform, patent-eligible exceptions.

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20 See U.S. CONST. art. III, § 1 (granting judicial power to the Supreme Court). See also Marbury v. Madison, 5 U.S. 137, 173 (1803) (announcing scope of Supreme Court's powers of judicial review).

21 See Plook, 437 U.S. at 584 (determining mathematical equations ineligible for patent protection as natural phenomena). See also Benson, 409 U.S. at 68 (identifying mathematical formula as abstract idea); Funk Bros., 333 U.S. at 130 (ruling discovery of plants as a natural phenomenon); Rubber-Tip Pencil Co. v. Howard, 87 U.S. 498, 506 (1874) (clarifying an idea by itself is not patentable); Le Roy v. Tatham, 55 U.S. 156 (1852) (ruling an abstract idea is not patentable). The court in Tatham stated "a principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right." Id. Natural Phenomena; Methods of Treatment and Diagnosis, 18 Chisum on Patents SCG-1114 (noting the difficulty associated with law of nature and medical diagnosis). A law of nature exception was created to prevent the tying up of natural law and inhibiting further discovery. Id. If the discovery falls under a law of nature, it cannot be routine or conventional steps used by researchers in the field. Id.

and stable sexually reproduced plant varieties. In 1980, this broadened view of patent law contributed to the emergence of the biotechnology industry when the Supreme Court in *Diamond v. Chakrabarty* extended patent eligibility to genetically engineered microorganisms as compositions of matter. By 1998, patent law grew even further by deeming business methods patent eligible as a process or method and not an exception as an abstract idea.

Though after 1980 it seemed patent eligibility would continue to expand its reach, the decision in *Bilski v. Kappos* in 2010 slowed the pace of this expansion by ruling a business process ineligible as an abstract idea. The Supreme Court began to apply a

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24 See *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980) (holding that a genetically engineered micro-organism is patentable). The court in *Chakrabarty* draws the distinction between finding a mineral in the ground or Einstein's law E=mc^2, which is not patentable but a natural occurrence in nature, and discovering a plant by using a unique cultivation that cannot be imitated by nature. *Id.* at 309, 313. Using expansive terms such as "composition of matter" means that Congress intended patent law to have a wide scope. *Id.* at 308. A composition of matter has been defined as "all compositions of two or more substances and ... all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids." Shell Dev. Co. v. Watson, 149 F.Supp. 279, 280 (D.C. 1957) (defining composition of matter). See also Douglas Robinson & Nina Medlock, *Diamond v. Chakrabarty: A Retrospective on 25 Years of Biotech Patents*, 17 INTELL. PROP. & TECH. L. J. 12, 13 (2005) (discussing the aftermath of Chakrabarty and the success of biotechnology). In the last 25 years since Chakrabarty, the biotechnology industry has exploded from revenues of $8 billion in 1992 to $39.2 billion in 2003. *Id.* In 2003, the United States biotechnology industry spent $17.9 billion on research and development alone. *Id.* The value of 314 publicly held biotechnology companies rose from $45 billion in 1994 to $311 billion as of mid-March 2004. *Id.* The number of patents granted within the field of biotechnology rose from 2,160 in 1989 to 7,732 in 2002 and has granted on average over 7,000 patents a year since 1998. *Id.*

25 See *State St. Bank & Trust Co. v. Signature Fin. Grp.*, 149 F.3d 1368, 1375 (Fed. Cir. 1998) (ruling a mathematical algorithm for business methods can survive section 101 analysis). The court in *State St. Bank* states that since the 1952 Patent Act, business methods have and should be patentable as a process or method. *Id.* See *infra* note 1 (defining a process or method). Whether the business method is too broad or lacks novelty is not decided under § 101, but under § 102, § 103 and § 112. *Id.* at 1377. See *also infra* note 30 (defining novelty, non-obviousness, and specification).

26 See *Bilski v. Kappos*, 561 U.S. 593, 611 (2010) (ruling process to protect buyers and sellers in energy market from price change not patentable). In *Bilski*, the first claim involved hedging, which is a fundamental economic practice and the fourth claim reduced the concept of hedging
heightened standard of review to patent-eligible subject matter because it believed the rule was becoming over-inclusive and interfered with competition by monopolizing natural laws. In 2011, the Supreme Court in Myriad determined that isolating genes from surrounding genetic material were merely well-known steps applied to a natural law. This standard of review was reinforced in Mayo and Alice and required any discovery or invention that included a patent-eligible exception to also have an "inventive concept" that amounts to more than adding conventional steps to the exception. The issue that often arises in current courts is whether this heightened standard of review that incorporates novelty, non-obviousness, and specification is too restrictive.

27 See Bilski, 561 U.S. 593, 648 (stating that monopolies may stifle competition and deter advancement in the science and arts). The court in Bilski states that providing patents on a law of nature, natural phenomena, or abstract idea would hinder competition by providing exclusive rights to basic tools of science and technology and thus restrain the advancement of science and technology. Id. at 653. See also Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 146 (1989) (stating the Constitution's intent to balance competition). The court in Bonito Boats states in reference to the patent clause of the Constitution that there is a "balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'" Id.

28 See Myriad, 133 S. Ct. at 2119-20 (ruling that new applications of knowledge to a law of nature are not patent-eligible).

29 See Alice, 134 S. Ct. at 2355 (stating the requirement of an inventive concept in step two of the analysis); Mayo, 132 S. Ct. at 1299 (citing Flook, 437 U.S. at 594) (ruling there was no inventive concept in the application of a logarithm). The court in Mayo describes an inventive concept as a natural lawcontaining other elements or a combination of elements sufficient to ensure the patent relies on more than the natural law itself. Id. The combination of elements cannot merely apply "well-understood, routine, conventional activity previously engaged in by researchers in the field" to a natural law. Id at 1294.

30 See Ariosa, 809 F.3d at 1284 (stating when a patent is considered inventive and new). The claimed invention cannot be "described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention" or a published patent, however there are also exceptions to this rule. 35 U.S.C. § 102. See also Conditions for patentability; non-obvious subject matter, 35 U.S.C. § 103 (stating an invention cannot be obvious) The conditions for patentability include:
The Supreme Court’s reasoning in Mayo applied a strict analysis to determine the patent eligibility of a medical diagnostic that provides instructions to physicians on how to administer a drug, advises the doctor to measure the metabolite levels in patients’ blood, and reads those levels to determine harmful side effects in order to increase or decrease patient drug dosages.\(^{31}\) The Supreme Court ruled that the discovery of these relationships, although not a natural law, was not sufficient enough to transform them from a routine conventional activity, but merely an attempt to monopolize the process.\(^{32}\) The Supreme Court established further precedent by utilizing this standard in Alice, applying the idea of an “inventive concept” to a computer system that configured a method to exchange financial obligations.\(^{33}\) The Supreme Court in Alice ultimately ruled that the computer system was purely conventional and did not add any substance to the underlying abstract idea.\(^{34}\)

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.

\(^{31}\) See Mayo, 132 S. Ct. at 1290-91 (explaining how Prometheus’s patent uses thiopurine drugs to treat autoimmune diseases). The methods for making these determinations were conventional, routine, and a well-known art for doctors to engage in and lacked the inventive concept the Supreme Court was looking for to be patent eligible. \(^{32}\) See id. at 1291 (holding Prometheus is not patentable).

\(^{33}\) See Alice, 134 S. Ct. at 2349-50 (finding computer system to be drawn to abstract idea and thus, not patentable). The computer system claim was too general and applied a method to a previously known and “well-known art” of the industry and therefore, was not inventive enough. \(^{34}\) See id. at 2350 (merely adding steps to a well-known method does not establish the “inventive concept”). The computer system did not “improve the functioning of the computer itself or effect an improvement in any other technology or technical field.” \(^{35}\) Id. at 2351. An instruction to apply an abstract idea is not enough to transform that abstract idea into patent eligible subject matter. \(^{36}\)
The Federal Court of Appeals in *Ariosa* ruled that the court is bound by the Supreme Court's decisions in *Mayo* and *Alice* even though it disagreed with the application of the Court's heightened standard of review.\(^{35}\) The majority opinion expressed concern that this standard of review could reduce funding for medical diagnostics and require companies to secure funding by other means.\(^{36}\) In the concurring opinion, Circuit Judges Lourie and Moore concluded that the claim was too broad and not patent ineligible due to an intrusion on a law of nature or abstract idea.\(^{37}\)

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\(^{35}\)See *Ariosa*, 809 F.3d at 1286 and 1288 (applying previous standard of review in *Mayo* and *Alice*); *Mayo*, 132 S. Ct. at 1299 (determining claims must be more than just conventional steps to laws of nature). The court in *Mayo* found that a claimed process that involves a law of nature has to be more inventive than applying "well understood, routine, conventional activity previously engaged in by researchers in the field" to a law of nature. *Id.* at 1294. *Mayo* also states that upholding such conventional patents would tie up the use of natural laws and inhibit their use and deter new discoveries. *Id.* *Mayo* stated and *Alice* recited that a claim containing an exception must include additional features to ensure "that the [claim] is more than a drafting effort designed to monopolize the [law of nature, natural phenomena, or abstract idea]." *Id.* at 1297. *Alice*, 134 S. Ct. at 2355 (applying two-prong analysis in *Mayo* and focusing on step two proving inventive steps). First, the court determined whether the claims are patent ineligible in that they fall under a law of nature, natural phenomena, or abstract idea. *Id.* The second part of the analysis is to search for an inventive concept sufficient to transform the abstract idea, law of nature, or natural phenomena into a patent-eligible application rather than just adding a conventional step. *Id.* at 2357. See also *Stone Container Corp. v. United States*, 229 F.3d 1345, 1349-50 (Fed. Cir. 2010) (stating it is difficult for Federal Circuit to overturn Supreme Court ruling). "[A]s a subordinate federal court, we may not easily dismiss [the Supreme Court's] statements as dicta but are bound to follow them." *Id.* *Rivers v. Roadway Express, Inc.*, 511 U.S. 298, 312 (1994) (stating the lower court is bound by the higher court's decision). "[O]nce the court has spoken, it is the duty of other courts to respect that understanding of the governing rule of law." *Id.*


\(^{37}\)See *Ariosa*, 809 F.3d at 1284-87 (describing laws of nature and abstract idea analysis to the present case). The concurring opinion stated that laws of nature such as Newton's laws of
Circuit Judge Dyk identified a problem with the application of Mayo because it did not recognize that a creative and novel discovery of a natural law could in fact be patent eligible.38

Judge Dyk also stated that although the Supreme Court applied the standard of review correctly in Mayo and Alice, the present case is not analogous and should not be granted the same standard of review.39 Furthermore, Judge Dyk said that a future case would likely cause the Supreme Court to reevaluate this standard.40 In his dissenting opinion, Circuit Judge Newman agreed that Ariosa is distinguishable from Mayo because it involved a novel and unconventional method that provided a significant contribution

motion or Ohm’s law should not be patent eligible, however “all physical steps of human ingenuity utilize natural laws or involve natural phenomena. . . . Those steps cannot be patent-ineligible solely on that basis because, under that reasoning, nothing in the physical universe would be patent-eligible.” Id. at 1285. In reference to abstract ideas the opinion states that “the fact that steps are well-known . . . does not necessarily make them abstract. Id. In the present case, the amplification and detection of cfDNA from maternal blood for prenatal diagnosis was not routine and conventional or abstract but was a novel process, which is a patent’s intended purpose to protect. Id. at 1286-87. The claims may be too broad because they do not specify how to amplify and detect, or how to separate, detect and diagnose, which is not a section 101 question but a section 112 question. Id. The court even provides recommendations on how to improve the claim by adding what is in the prior art and what the improvement is, for example “in a method of performing a prenatal diagnosis using techniques of fractionation and amplification, the improvement consisting of using the non-cellular fraction of a maternal blood sample.” Id.

38 See Ariosa, 809 F.3d at 1289 (stating the problem with Mayo). Judge Dyk states that Mayo is incorrect in ruling that an inventive concept cannot come from discovering something new in nature or identifying a previously unknown natural relationship or property. Id. Judge Dyk states that creativity and novelty of the discovery can be patent eligible because of the decision in Myriad and that the development of science relies on investigation of complex biological systems. Id. See also Myriad, 133 S. Ct. at 2112-13 (ruling naturally occurring gDNA sequences were patent ineligible). However, the court in Myriad ruled that new applications of knowledge in reference to the BRCA1 and BRCA2 genes could be patent eligible. Id. Myriad emphasized that the first party with knowledge of a natural law is “in excellent position to claim applications of that knowledge.” Id.

39 See Ariosa, 809 F.3d at 1292-93 (stating Mayo was a routine application to a well-known law of nature). In Mayo scientists already understood that levels of certain metabolites in a patient’s blood, the same ones listed in the claim, had a direct correlation that it was likely to be a dosage of a thiopurine drug that could cause harm or prove to be ineffective. Id. at 1292. A claimed application that is narrow in scope, actually invented, and reduced to practice has limited risk of undue preemption of the underlying idea, which will not prevent applications of the new natural law by others. Id. at 1291-92.

40 See id. at 1293.
to the medical field.\textsuperscript{41} Although en banc review was denied, the reasoning in \textit{Ariosa}
created an impediment on the patent eligibility of medical diagnostics and recognized the inevitability of changes to its future.\textsuperscript{42}

The \textit{Ariosa} decision reluctantly reinforced \textit{Mayo} and \textit{Alice}, while also identifying weaknesses in its application.\textsuperscript{43} Judge Dyk suggested that drafting a narrower claim and reducing the invention to practice would provide an alternative approach by allowing limited medical diagnostics to be patent eligible.\textsuperscript{44} The majority opinion, however, agreed that a restrictive test could discourage innovation.\textsuperscript{45} The majority's decision

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\begin{enumerate}
\item \textsuperscript{41} See \textit{Ariosa}, 809 F.3d at 1293. \textit{Mayo} involved a medicinal product and its metabolites that were previously known, which left little room for innovation while the present case claimed a method and diagnostic knowledge that was not previously known. \textit{Id} at 1294. This diagnostic method was labeled as a novel and unforeseen, providing a significant contribution to the medical field; and a "breakthrough" in the medical field. \textit{Id}.
\item \textsuperscript{42} \textit{Ariosa}, 809 F.3d at 1284. In \textit{Ariosa}, the opinion by Judge Dyk states that there is some truth to a crisis of patent law and medical innovation. \textit{Id} at 1285. Too restrictive a test may cause discouragement to develop new diagnostic and therapeutic methods in the life sciences. \textit{Id} at 1287. The court in \textit{Ariosa} stated that "a future case is likely to present a patent claim where the inventive concept resides in a newly discovered law of nature or natural phenomenon, but the claim is narrowly drawn and actually reduced to practice. That case will hopefully provide the Supreme Court with an opportunity to revise the \textit{Mayo}/\textit{Alice} framework in this one limited aspect." \textit{Id} at 1293.
\item \textsuperscript{43} See \textit{id.} at 1293 (stating that the court needs to revisit \textit{Mayo}/\textit{Alice} to review applications for weaknesses). Judge Dyk agrees that the framework in \textit{Mayo} and \textit{Alice} is essential to invalidate improperly issued and anticompetitive patents but also shares concerns that too restrictive a test would discourage medical diagnostic development. \textit{Id}. Judge Dyk claims that although he believes the application to be erroneous that the Federal Court of Appeals is bound by the Supreme Court's judgment. \textit{Id}. at 1293. Judge Dyk also identifies that \textit{Mayo} may be too restrictive. \textit{Ariosa}, 809 F.3d 1282 at 1287. Finally, Judge Dyk proposes her own approach that if a complaint is narrowly drafted and the invention is reduced to practice that it could be patent eligible. \textit{Id}. at 1288.
\item \textsuperscript{44} See \textit{Ariosa}, 809 F.3d at 1291 (stating Judge Dyk's alternative approach to analyzing patent eligibility). Judge Dyk states that claims which are too broad and reduced to practice should be invalid. \textit{Id} at 1291. Instead, Judge Dyk established that, as long as the claim is "narrowly tailored to what the patent applicant has actually invented and reduced to practice, there is limited risk of undue preemption of the underlying idea." \textit{Id}.
\item \textsuperscript{45} See \textit{Ariosa}, 809 F.3d at 1285.
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\end{footnotesize}
presents an issue because the alternative approach enables a restrictive analysis by suggesting novelty, non-obviousness, and specification are integrated into section 101.46

The strict interpretation of section 101 may be attributable to the ambiguity left by the failure of the Supreme Court and Federal Circuit Court of Appeals to provide definitions of a law of nature, natural phenomena, abstract idea, or an inventive concept.47 Due to this lack of clarity, the federal courts have reasoned that a claim under section 101, involving a natural law, must also provide evidence of an inventive concept, which is the equivalent to novelty and non-obviousness.48 Congress did not intend to integrate novelty, non-obviousness, and specification when drafting section 101, which is why Congress separated the three qualifications.49 This integration of patent law sections allowed the Federal Circuit to deny an en banc review based on the claim being too broad, which is not a deterrent for adhering to section 101.50

46 See id. at 1284-85. The Federal Court of Appeals states that the claims may be too broad because they do not identify a specified way to amplify and detect, or how to separate, detect, and diagnose, but also state these questions can be answered using a filter under section 112 specification and not section 101. Id. Judge Dyk suggests an alternate approach in order to narrowly draft the claim and reduce it to practice so the claim can be considered patent eligible. Id. See also infra note 49 (defining sections 102, 103, and 112).

47 See 35 U.S.C. § 101 (1952) (stating the exceptions in the notes, but not defining them); see also supra note 17 (outlining the exceptions in case law but not defining them). See also GEORGE MASON, supra note 3 (stating that courts broad definition of natural phenomena in Mayo is extremely problematic).

48 See generally supra notes 29 & 30 (outlining inventive concept and novelty, non-obviousness and specification).


50 See 35 U.S.C. § 101 (Westlaw through P.L.114-219219221) (providing requirement for section 101). See also Ariosa, 809 F.3d at 1286-87 (reasoning that the claim was too broad to be patent eligible).
Consequentially, this heightened analysis imposes a barrier on medical diagnostic claims, when similar claims such as business methods, are eligible. The majority opinion in *Ariosa* establishes that only the Supreme Court can amend its analysis in a future case. Meanwhile, courts are misapplying the application of this analysis to inventions involving natural laws, such as medical diagnostics. Judge Dyk’s alternative approach, although identifying a limited number of patentable claims, presents a challenge because it incorporates specification into section 101, which leaves a large portion of medical diagnostics unprotected by patents. This heightened standard forces medical diagnostic companies, which cannot obtain patents, to protect their intellectual property rights by trademark and trade secret law. *Ariosa* neglects to address the critical and important negative effects patent eligibility has on the medical diagnostic field by rejecting review en banc.

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51 See *Myriad*, 133 S. Ct. at 2116-171718 (ruling isolating DNA patent ineligible); *Mayo*, 132 S. Ct. at 1302 (ruling a method for administering a drug patent ineligible); *Ariosa*, supra note 17, at 1287 (ruling a method for prenatal testing patent ineligible); *State St. Bank*, 149 F.3d at 1375 abrogated on other grounds by In re Bilski, 545 F.3d 943, 959 (5th Cir. 2008) (ruling that business methods were patent eligible, which was added to section 101 by Congress); 35 U.S.C. § 101 (Westlaw through P.L.114-219219221).

52 See *Ariosa*, supra note 17, at 1287 (noting that the court was bound by the Supreme Court). The court also states that they hope a future case regarding the same issue will have to be decided by the Supreme Court, which will give them an opportunity to review the framework set out in *Mayo* and *Alice*. Id. at 1293. However, the dissent states that the Federal Circuit is not bound by the Supreme Courts precedent because the facts from the precedent diverge from the facts in *Ariosa*. Id.

53 See id. at 1289 (stating the problem with the *Mayo* application). Discovery of a natural law previously unknown does not make it a law of nature subject to patent ineligibility because inventions in science mandate some kind of method to discovery of natural laws. Id. See generally *Flook*, supra note 29, at 594 (stating just because a natural law is involved does not mean it is patent ineligible).

54 See 35 U.S.C. § 112 (noting the description of the patent cannot be overly broad).

55 See BUSINESS INSIDES, supra note 3 and accompanying text (providing trademark and trade secret alternatives to intellectual property protection for medical diagnostics).

56 See Fed. R. Civ. P. 35(a)(2)(stating an en banc review is granted when dealing with an issue of exceptional importance).
Furthermore, Ariosa mentions concerns about promoting innovation, but does not address the importance of affording sufficient patent protection to incentivize funding.\(^57\) Companies selling diagnostics will have to use trademarks as an alternative, which incentivizes them to be first in the market, build their brand, and become a reliable choice to the public.\(^58\) Even so, this method requires millions of dollars in marketing, which may limit the amount of companies willing to invest.\(^59\) The other alternative is trade secret law, which can protect how the company creates the diagnostic, as long as the secret is not revealed or discovered.\(^60\) This is problematic, however, because it could prevent the public from obtaining this information as long as the secret is kept hidden, though also adds the risk that the secret will be revealed, making the secret essentially worthless.\(^61\) Although these options provide diagnostics with some protection, they are not as lucrative to investors as patents.\(^62\)

Additionally, by denying review en banc the court failed to address the correlation between patent ineligibility and the consequences of decreased funding for medical diagnostics.\(^63\) Lack of patent protection could be detrimental to funding because the largest share of funding for research and development in the United States

\(^{57}\) See George Mason, supra note 3 at 5. Innovators in diagnostics “rely heavily on venture capital to fund the years of research, development, and validation necessary to bring a novel diagnostic product to the market, and the decision of whether to invest is heavily dependent upon the availability of effective patent protection.” See id.

\(^{58}\) See Business Insides, supra note 3 (stating companies use trademarks to protect their products from competitors and protect their reputation). See also USPTO, supra note 3.(consumers identify with products that are familiar).

\(^{59}\) See Business Insides, supra note 3 (stating the disadvantages of trademarks when each company must be distinctive for consumers to distinguish a product from others).

\(^{60}\) See WIPO, supra note 3 (providing the advantages of trade secret law).

\(^{61}\) See WIPO, supra note 3 (providing the disadvantages of trade secret law).

\(^{62}\) Id.

\(^{63}\) See PMC, supra note 13 (stating that without adequate funding reliable diagnostics would not be possible).
comes from the business sector. In theory, funding from the business sector will likely diminish if the investment is less profitable due to the lack of patent protection. This is corroborated by the aftermath of Chakrabarty, which resulted in funding for biotechnology to flow into the industry and could be evidence that the reverse effect may occur for medical diagnostics. There also will likely be a decrease in patent applications filed for medical diagnostics and a potential decrease in the number of new medical diagnostics being released to the public. Even though the federal court outlines a narrow alternative that will allow limited medical diagnostics to be patent eligible, it also increases the risk a patent will be denied, thus creating an unsecure investment.

Whether a medical diagnostic contains enough of an inventive concept so that the claim does not patent a natural law will continue to be challenged due to the disparity in the application of the analysis between the Supreme Court and federal

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64 See Nat'l Sci. Found., supra note, 36 at 4-5 (providing statistics about where funding for research and development comes from). The business sector's percentage in research and development peaked in 2000 at 75% but has mostly remained above 70% from 2000 to 2006. Id. Research and development performed by the business sector reached 226.2 billion in 2005. Id.

65 See Holman, supra note 33, at 4 (outlining the problems patent ineligibility causes medical diagnostics). The article states venture capitalists would likely be disinterested in investing hundreds of millions of dollars into a medical diagnostic start-up company because patents are unable to protect competition by free-riders, who will use alternate, unpatented methods for detecting that are the same methods the start-up is investing their money into. Id.

66 See Robinson, supra note 24 at 13 (stating the immense growth of funding for biotechnology after the Chakrabarty decision).

67 See Robinson, supra note 24 at 13 (stating the amount of patents granted rose from 2,160 in 1989 to 7,763 in 2002). See also Holman, supra note 33, at 1. "Those involved in the development and commercialization of innovative molecular diagnostics stress the important role of effective intellectual property rights in attracting the substantial capital investment required to bring these products to market." Id.

68 See supra note 65 and accompanying text (stating the issues investors face due to patent ineligibility). Innovators rely heavily on capital to fund their research and investors rely heavily on the availability of effective protection. Id. at 5.
courts’ disparity in the application of its analysis.\textsuperscript{69} The Supreme Court will have to recalibrate and clarify their analysis in \textit{Mayo} and \textit{Alice} in order for medical diagnostics to be patent eligible, because medical diagnostics require some form of natural law.\textsuperscript{70} In the meantime, medical diagnostic companies will have to utilize creative ways to protect their products, and secure funding without the assistance of patents.\textsuperscript{71} Due to this predicament, the public will likely be disadvantaged with less access to innovative medical diagnostics while waiting for a future case to alter the analysis in \textit{Mayo} and rule medical diagnostics as patent eligible.\textsuperscript{72}

\textsuperscript{69} See \textit{Ariosa}, 809 F.3d at 1284-85 (disagreeing in its reasoning with the Supreme Court’s application of \textit{Mayo}); \textit{Myriad}, 133 S. Ct. at 2116-18 (disagreeing with the Federal Circuit’s ruling of patent eligibility); \textit{Mayo}, 132 S. Ct. at 1301-02 (disagreeing with the Federal Circuit’s ruling of patent eligibility).

\textsuperscript{70} See \textit{Ariosa}, 809 F.3d at 1286-87.

\textsuperscript{71} See Weick, \textit{supra} 36 and accompanying text (citing medical diagnostics can be funded using grants and other unconventional methods).

\textsuperscript{72} See \textsc{George Mason, supra} note 3 at 1 (stating releasing diagnostics to market is dependent on investments based on the availability of patents).