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The “Inventive Concept” after *Mayo*: Where *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), Went Wrong

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Note*

The “Inventive Concept” After *Mayo*:
Where *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371
(Fed. Cir. 2015), Went Wrong

TABLE OF CONTENTS

I. Introduction	222
II. Background	223
A. Development of § 101	224
1. Laws of Nature, Natural Phenomena, and Abstract Ideas	224
2. The “Inventive Concept”	226
B. <i>Mayo Collaborative Services v. Prometheus Laboratories, Inc.</i>	228
1. Facts	228
2. The <i>Mayo</i> Test	230
C. <i>Alice Corp v. CLS Bank International</i>	231
D. <i>Ariosa Diagnostics, Inc. v. Sequenom, Inc.</i>	232
1. Facts	232
2. The Federal Circuit’s Decision	234
III. Analysis	236
A. The Inventive Concept After <i>Mayo</i>	237
B. Discovery as an Inventive Concept	238
1. Conformity with the Inventive Concept Framework	238
2. Addressing the Federal Circuit’s Concerns	240
3. Public Policy	241
C. Implications for Patentability	245
IV. Conclusion	246

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I. INTRODUCTION

The U.S. Constitution provides that “[t]he Congress shall have Power . . . 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.”¹ Under this authority, Congress has stated that a patent may be obtained for the invention or discovery of “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”² However, the Supreme Court has long held that laws of nature, natural phenomena, and abstract ideas are not patentable.³ For example, a newly discovered mineral or plant could not be patented.⁴ Nor could Einstein’s law that $E = mc^2$ or Newton’s law of gravity.⁵ These categories are not patentable because they are “the basic tools of scientific and technological work,”⁶ and granting a patent of these tools might “tend to impede innovation more than it would tend to promote it.”⁷ At the same time, courts are hesitant to construe these exclusions too broadly because lack of patent protection might just as easily hamper innovation.⁸

The courts have always toed the line between incentivizing innovation and allowing public access to innovations as inspiration for future inventions.⁹ The Supreme Court continued to toe this line in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,¹⁰ balancing the categories of patent-ineligible subject matter with inventive concepts that might transform them into patentable inventions.¹¹ Nonetheless, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,¹² the Federal

1. U.S. CONST. art. I, § 8, cl. 8.

2. 35 U.S.C. § 101 (2012).

3. *See, e.g.*, *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *O’Reilly v. Morse*, 56 U.S. 62, 116 (1853); *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852).

4. *Chakrabarty*, 447 U.S. at 309.

5. *Id.*

6. *Benson*, 409 U.S. at 67.

7. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012).

8. *See, e.g.*, *Parker v. Flook*, 437 U.S. 584, 590 (1978) (“[A] process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.”); *Funk Bros.*, 333 U.S. at 130 (“If there is to be invention from [the discovery of a law of nature], it must come from the application of the law of nature to a new and useful end.”).

9. *See* WILLIAM R. BALLARD, *THERE IS NO MYSTERY ABOUT PATENTS* 22 (1946) (“This reservoir of knowledge is both an aid and an inspiration to anyone interested in practicing or developing a particular art. And the knowledge that patents may be obtained is a stimulation to the making of still more and more inventions and disclosures.”).

10. 566 U.S. 66.

11. *See infra* section II.B.

12. 788 F.3d 1371 (Fed. Cir. 2015).

Circuit definitively tipped the scales in favor of public access, effectively eliminating any incentive to innovate in the life sciences.¹³ By implementing an overwhelmingly strict standard for inventive concepts, the Federal Circuit expanded *Mayo* to be as broad as the justices feared its “sweeping language” to be.¹⁴ After *Ariosa*, the Federal Circuit leaves life sciences innovation in dire straits, the consequences of which are yet to be fully realized.

This Note explores the inventive concept as revitalized by *Mayo* and attempts to refute the Federal Circuit’s misunderstanding of *Mayo*. Part II.A lays out the relevant background, outlining the traditional understanding of patentable subject matter under § 101 and the inventive concept. The discussion then turns to the *Mayo* test, with the remainder of Part II endeavoring to navigate the murky waters of *Mayo* and subsequent application of the *Mayo* standard by the courts. In response to the Federal Circuit’s understanding of the inventive concept in *Ariosa*, Part III discusses how—if at all—*Mayo* changed the inventive concept, and why discovery of a law of nature must satisfy it. Finally, this Note concludes with an examination of the consequences and aftermath of *Ariosa*’s restrictive interpretation of the inventive concept.

II. BACKGROUND

As interpreted today, the Patent Act does not authorize patent protection for laws of nature, natural phenomena, or abstract ideas.¹⁵ The Supreme Court has consistently recognized these exceptions to patentability for more than 150 years.¹⁶ This Part begins with a discussion of how each exception is interpreted by the courts, carving out areas of unpatentable subject matter without crossing the line into removing incentives to invent. This Part goes on to discuss the framework laid out by *Mayo*¹⁷ for analysis of patents directed at these traditionally unpatentable subject matters and the solidification of the *Mayo* framework in *Alice Corp. v. CLS Bank International*.¹⁸ Finally, this Part relates the Federal Circuit’s interpretation and application of the *Mayo* framework in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*¹⁹

13. See *infra* Part III.

14. *Ariosa*, 788 F.3d at 1380 (Linn, J., concurring); see *infra* section III.C.

15. *Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014).

16. *Id.*

17. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

18. *Alice*, 134 S. Ct. 2347.

19. *Ariosa*, 788 F.3d 1371.

A. Development of § 101²⁰

The development of § 101 jurisprudence began even before its passage in 1952. It took hundreds of years to mold the categories of patentable subject matter into what they are today, beginning with the Patent Act of 1793.²¹ The 1793 Act identified invention of “any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement on [the same], not known or used before application” as patentable subject matter.²² Although the Patent Act has endured various iterations,²³ these original classes of patentable subject matter remain substantially similar in the text of § 101 today.²⁴

1. *Laws of Nature, Natural Phenomena, and Abstract Ideas*

Over this great period of time, the Supreme Court has wrestled with how far patentability extends.²⁵ The journey began with *Le Roy v. Tatham*, in which the Court first excepted laws of nature from patentability:

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. Nor can an exclusive right exist to a new power, should one be discovered in addition to those already known.²⁶

The Court expanded upon the invalidity of laws of nature the following year in *O'Reilly v. Morse*.²⁷ *Morse* dealt with the famous Samuel Morse, who obtained a patent for his invention of the telegraph.²⁸ In the reissued patent, Mr. Morse claimed “the use of . . . electro-magnetism, however developed for marking or printing intelligible characters, signs, or letters, at any distances”²⁹ Although the Court

20. 35 U.S.C. § 101 (2012).

21. 1 Stat. 318 (1793).

22. *Id.*

23. See generally Stefan A. Riesenfeld, *The New United States Patent Act in the Light of Comparative Law I*, 102 U. PA. L. REV. 291, 291–97 (1954).

24. See § 101 (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”).

25. See generally Joshua A. Kresh, *Patent Eligibility After Mayo: How Did We Get Here and Where Do We Go?*, 22 FED. CIR. B. J. 521, 522–30 (2013); William J. Casey, Note, *The Sum of the Parts is Greater than the Whole: Why Courts Determining Subject Matter Eligibility Should Analyze the Patent-Eligible and Unpatentable Portions of the Claim Separately Instead of Treating the Claim as a Whole*, 5 HASTINGS SCI. & TECH. L.J. 107, 110–16 (2013).

26. 55 U.S. (14 How.) 156, 175 (1852).

27. 56 U.S. 62 (1853).

28. *Id.* at 69, 78.

29. *Id.* at 112.

found the claim to be void on other grounds,³⁰ it stated that an invention that makes use of a principle such as electromagnetism is generally valid, so long as the patent does not claim the principle itself.³¹ The Court later clarified that an invention that makes use of a principle need not be a machine but may be simply a process.³²

Over time, the Court also recognized the ineligibility of natural phenomena for patent protection. This exception was first held in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, in which the patent claimed a mixed culture of Rhizobia bacteria that were capable of inoculating various seeds.³³ The patentee did not invent the fact that various species of Rhizobium were capable of producing a mixed inoculant but rather discovered that natural phenomenon.³⁴ Since the Court could not allow a patent on “one of the ancient secrets of nature,” it held the patent to be invalid.³⁵ The Court later limited this holding, noting that where a claim is to a “nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use,’” patent protection is appropriate.³⁶

The Supreme Court has also made clear that abstract ideas are not patent eligible.³⁷ In invalidating a patent on a mathematical formula for converting binary-coded decimal numerals into pure binary numerals, the Court specifically stated that “one may not patent an

30. The Court found that this claim was void because it was too broad and would inhibit innovation. *See id.* at 113.

31. *See id.* at 119; *see also* *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939) (“While a scientific truth, or the mathematical expression of it, is not [a] patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.”).

32. *Tilghman v. Proctor*, 102 U.S. 707, 728 (1880) (upholding the validity of a patent claiming the formation of fat acids and glycerine from fatty bodies by the action of water at a high temperature and pressure).

33. 333 U.S. 127, 129 (1948). There are at least six species of Rhizobium bacteria, each of which will infect certain different pod-producing plants. *Id.* The traditional practice was to produce a substance containing one Rhizobium species which would prevent infection of specific plants by certain other Rhizobium species. *Id.* The patentee discovered that a mixture of Rhizobium species was effective in preventing disease across an array of plants. *Id.*

34. *See id.* at 132.

35. *Id.*

36. *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980) (alteration in original) (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)). The patentee in *Chakrabarty* claimed the invention of a “human-made, genetically engineered bacterium . . . capable of breaking down multiple components of crude oil.” *Id.* at 305. Because the patentee “produced a new bacterium with markedly different characteristics from any found in nature,” the Court found the microorganism patentable. *Id.* at 310.

37. *See, e.g., Bilski v. Kappos*, 561 U.S. 593, 609–12 (2010) (holding that a mathematical formula to hedge risk of price changes in the energy market was an unpatentable abstract idea).

idea.”³⁸ The Court went further, noting that even post-solution activity—such as adjustment of alarm limits based on the outcome of a formula—cannot be patent eligible.³⁹ At the same time, an application of an abstract idea is patentable, so long as the patent does not claim the idea itself.⁴⁰ Through well over a century of jurisprudence, the Supreme Court has properly concluded that patent protection is not appropriate when the invention is grounded in a law of nature, natural phenomenon, or abstract idea.

2. *The “Inventive Concept”*

While laws of nature, natural phenomena, and abstract ideas should generally be patent ineligible, the Supreme Court is also fearful that the exclusions might “swallow all of patent law.”⁴¹ Thus, where an invention falls in one of the three traditionally unpatentable areas of subject matter, the Supreme Court has sometimes upheld a patent that contains a sufficient “inventive concept.”⁴² The Court provided its first formulation of the inventive concept in *Gottschalk v. Benson*.⁴³ In *Benson*, the United States Patent and Trademark Office issued a patent for an invention related to “the processing of data by program and more particularly to the programmed conversion of numerical information’ in general-purpose digital computers.”⁴⁴ The patent claimed a method for converting binary-coded decimal numerals into pure binary numerals.⁴⁵ The claims purported to cover all such uses in any general-purpose digital computer.⁴⁶ The Court discussed the necessary inventive concept for the claimed method to be patent eligible, stating that “[t]ransformation and reduction of an article ‘to a different state or thing’ is the clue to the patentability of a process

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

39. *Parker v. Flook*, 437 U.S. 584, 590 (1978) (“The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance. A competent draftsman could attach some form of post-solution activity to almost any mathematical formula; the Pythagorean theorem would not have been patentable, or partially patentable, because a patent application contained a final step indicating that the formula, when solved, could be usefully applied to existing surveying techniques. The concept of patentable subject matter under § 101 is not ‘like a nose of wax which may be turned and twisted in any direction’” (quoting *White v. Dunbar*, 119 U.S. 47, 51 (1886))).

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

41. *Id.*

42. *See Casey*, *supra* note 25, for a discussion of the Court’s wavering between the sufficiency of an inventive concept and the approach of interpreting the claim as a whole.

43. 409 U.S. 63 (1972).

44. *Id.* at 64.

45. *Id.*

46. *Id.*

claim that does not include particular machines.”⁴⁷ The Court went on to provide examples of a sufficient transformation, including a mechanical process for expanding metal and a process for setting eggs in staged incubation with air currents.⁴⁸ Importantly, the Court clarified, “We do not hold that no process patent could ever qualify if it did not meet the requirements of our prior precedents.”⁴⁹ Rather, the claim in *Benson* was ineligible for patent protection because it would “wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.”⁵⁰

The Court provided more evidence of its understanding of the inventive concept in *Parker v. Flook*.⁵¹ In *Flook*, the patent claimed a method of updating alarm limits by making use of an algorithm.⁵² The Court began by explaining that implementation of a principle in a process does not automatically fall within the patentable subject matter of § 101.⁵³ The Court stated that the alarm limit method lacked an inventive concept because each of its component parts was well-known.⁵⁴ Furthermore, the method for calculating alarm limits was well-known, making the patent claim “comparable to a claim that the formula $2\pi r$ can be usefully applied in determining the circumference of a wheel.”⁵⁵ The Court determined that post-solution activity such as this lacks an inventive concept and thus cannot be patented.⁵⁶

Benson and *Flook* make evident that there is no clear formula for an inventive concept. *Benson* provided that high temperature–pressure systems to produce fatty acids, mechanical processes for expanding metal, and use of air currents in staged egg incubation

47. *Id.* at 70. The Court cited *Tilghman v. Proctor*, which upheld the process of “manufacturing fat acids and glycerine from fatty bodies by the action of water at a high temperature and pressure” as an example of an inventive concept. *Benson*, 409 U.S. at 70 (quoting *Tilghman v. Proctor*, 102 U.S. 707, 721 (1880)); see also *Tilghman*, 102 U.S. at 729 (“The chemical principle or scientific fact upon which it is founded is, that the elements of neutral fat require to be severally united with an atomic equivalent of water in order to separate from each other and become free. This chemical fact was not discovered by Tilghman. He only claims to have invented a particular mode of bringing about the desired chemical union between the fatty elements and water.”).

48. *Benson*, 409 U.S. at 70–71.

49. *Id.* at 71.

50. *Id.* at 72.

51. 437 U.S. 584 (1978).

52. *Id.* at 585.

53. *Id.* at 593.

54. *Id.* at 594.

55. *Id.* at 595. The circumference is the distance around the outside of a shape. For a circle, the circumference can be determined by multiplying half the distance across the circle (the radius, r) by twice the value of pi (π). Pi is a constant value equal to approximately 3.14 that is commonly used in mathematical formulas. The value of pi is derived from this relationship between the radius and circumference of a circle.

56. See *id.* at 590.

sufficiently transform the invention into patentable subject matter. *Flook*, meanwhile, added that merely providing a new method for calculating alarm-limit values is not sufficient. Thus, the inventive concept test appears to be quite subjective, preserving the requirement of novelty⁵⁷ and perhaps relying most strongly on avoiding preemption.⁵⁸ The Court has made clear that laws of nature, natural phenomena, and abstract ideas are not patentable, but it has been much more obscure in attempting to define what qualifies as an inventive concept sufficient to remove an invention from these categories and transform it into a patentable invention.

B. *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*⁵⁹

Decades after *Benson* and *Flook*, the Court returned to the inventive concept in *Mayo*. This case established a more specific framework for determining whether an invention aimed at unpatentable subject matter is in fact patent eligible. This section lays out the background of *Mayo* and goes on to outline the framework put forth by the Court. As discussed in this section, the *Mayo* analysis requires that the claims be directed at a patent-ineligible concept and that there be some inventive concept sufficient to transform the claim into a patentable invention.⁶⁰ This section concludes with an overview of the court's application of its new framework to the facts of *Mayo*.

1. *Facts*

Mayo arose as a challenge to a patent assigned to Hospital-Sainte-Justine in 2002⁶¹ for optimizing the treatment of immune-related gastrointestinal disorders such as inflammatory bowel disease (IBD).⁶² IBD generally occurs in young adults, with common symptoms of diar-

57. *Id.* at 591 (“The process itself, not merely the mathematical algorithm, must be new and useful.”).

58. *See* Gottschalk v. Benson, 409 U.S. 63, 72 (1972) (“[I]f the judgment below is affirmed, the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.”). This is a logical place for the Court to root its analysis, since preemption concerns provided the basis for establishing the categories of patent-ineligible subject matter to begin with. *See supra* section II.A.1.

59. 566 U.S. 66 (2012).

60. *Id.* at 73–77.

61. U.S. Patent No. 6,355,623, at [73].

62. *Id.* at col. 1 ll. 19–22, col. 2 ll. 16–18. Inflammatory bowel disease encompasses ulcerative colitis and Crohn's disease. Both diseases are characterized by inflammation of the digestive tract. Inflammatory bowel disease can be debilitating and potentially life-threatening. *Inflammatory Bowel Disease (IBD): Definition*, MAYO CLINIC (Feb. 18, 2015), <http://www.mayoclinic.org/diseases-conditions/inflammatory-bowel-disease/basics/definition/CON-20034908> [https://perma.unl.edu/9YV9-7VXC].

rhea, abdominal pain, and fever.⁶³ Physicians commonly prescribe thiopurine drugs for treatment of IBD.⁶⁴ The body metabolizes the drugs, forming metabolites in the bloodstream.⁶⁵ Each patient metabolizes thiopurines differently, so the same dose of a thiopurine drug can have varied effects.⁶⁶ A dosage that is too low for an individual can be ineffective for the patient,⁶⁷ while a dosage that is too high can result in harmful side effects.⁶⁸ Previously, studies suggested that measurement of certain metabolites could be used to predict the likelihood that a particular dosage of a thiopurine drug could be harmful or helpful for a particular patient.⁶⁹ However, scientists did not know the exact correlation between metabolite levels and efficacy or toxicity.⁷⁰

The patents at issue,⁷¹ solely and exclusively licensed to Prometheus Laboratories, Inc. (Prometheus),⁷² embody findings of specific concentrations of metabolite that indicate that a dosage is too high or too low for a particular patient.⁷³ The Court considered as representative claim 1 of the '623 Patent,⁷⁴ which effectively claimed a method of optimizing dosage comprising of: (1) administering a drug providing a certain metabolite, (2) determining the blood level of that metabolite, and (3) using the determined amount to adjust dosage.⁷⁵ Prometheus

63. U.S. Patent No. 6,355,623 col. 1 ll. 27–29.

64. Specifically, azathioprine (also known as Azasan or Imuran) and mercaptopurine (also known as Purinethol or Purixan) are most commonly used for treatment of IBD. *Inflammatory Bowel Disease (IBD): Treatment and Drugs*, MAYO CLINIC (Feb. 18, 2015), <http://www.mayoclinic.org/diseases-conditions/inflammatory-bowel-disease/basics/treatment/con-20034908> [https://perma.unl.edu/267D-VQK8]. The patents in question are specifically directed to dosage of 6-mercaptopurine drugs. U.S. Patent No. 6,355,623 col. 2 ll. 8–13; U.S. Patent No. 6,680,302 col. 2 ll. 10–15.

65. *Mayo*, 566 U.S. at 73.

66. *Id.*

67. U.S. Patent No. 6,355,623 col. 1 ll. 66–67.

68. Side effects can include allergic reactions, neoplasia, opportunistic infections, hepatitis, bone marrow suppression, and pancreatitis. *Id.* at col. 2 ll. 2–4.

69. *Mayo*, 566 U.S. at 73–74.

70. *Id.*

71. U.S. Patent No. 6,355,623; U.S. Patent No. 6,680,302.

72. *Mayo*, 566 U.S. at 75.

73. *Id.* at 74.

74. *Id.* at 74–75.

75. Claim 1 of the '623 Patent states in full:

We claim:

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

sells diagnostic tests that use the processes described in the patents.⁷⁶ Mayo Clinic Rochester and Mayo Collaborative Services (collectively Mayo) initially bought and used the tests sold by Prometheus but in 2004 announced that Mayo would begin using and selling its own substantially similar test.⁷⁷ Prometheus claimed that Mayo's test infringed upon Prometheus's patents.⁷⁸ The Court also considered whether the claims of Prometheus's patents were patentable to begin with,⁷⁹ as discussed in the following section.

2. *The Mayo Test*

In determining the patentability of the claims of Prometheus's patents, the *Mayo* court set forth a novel test. Under this new framework, a court must first determine whether the claims are directed to a patent-ineligible concept.⁸⁰ If so, there must be an inventive concept⁸¹ that transforms the nature of the claim.⁸² The inventive concept, whether considering the elements of the claim individually or as an "ordered combination,"⁸³ must "ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself."⁸⁴ Such an inventive concept requires more than "simply stat[ing] the law of nature while adding the words 'apply it.'"⁸⁵

The Supreme Court determined that Prometheus's patents did not pass this test.⁸⁶ The Court agreed that the test applied because the correlation between blood metabolite concentration and appropriate dosage is a patent-ineligible law of nature.⁸⁷ However, the patents failed to satisfy the second step. The first stage of the claimed method, administering the drug, only directs the relevant audience—namely doctors who use thiopurine drugs—to treat patients for certain diseases.⁸⁸ The portion of the claim stating whether the metabolite con-

wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

U.S. Patent No. 6,355,623 col. 20 ll. 10–25.

76. *Mayo*, 566 U.S. at 75.

77. *Id.*

78. *Id.*

79. *Id.* at 77.

80. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375 (2015); *see Mayo*, 566 U.S. at 77.

81. *Mayo*, 566 U.S. at 71–72.

82. *Id.* at 78.

83. *Id.* at 79.

84. *Id.* at 73.

85. *Id.* at 72 (citing *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972)).

86. *Id.* at 92.

87. *Id.* at 77. This satisfies step one of the framework—whether the claims are directed to a patent-ineligible concept—prompting the Court to consider whether the claims contain an inventive concept.

88. *Id.* at 78.

centration indicates a need to increase or decrease the dosage simply tells a doctor about the relevant natural laws, adding nothing to the law itself.⁸⁹ Furthermore, the step of determining the blood level of the metabolite indicates the use of “whatever process the doctor or the laboratory wishes to use,” which is an unpatentable “conventional or obvious pre-solution activity.”⁹⁰ Nor was the Court convinced by considering the steps as an ordered combination: “Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.”⁹¹ For these reasons, the claims lacked an inventive concept and were insufficient to “transform unpatentable natural correlations into patentable applications of those regularities.”⁹²

C. *Alice Corp. v. CLS Bank International*⁹³

The Supreme Court solidified the *Mayo* framework in *Alice* and extended its applicability to abstract ideas.⁹⁴ The patents at issue in *Alice* were directed to mitigating “settlement risk,” which is “the risk that only one party to an agreed-upon financial exchange will satisfy its obligation.”⁹⁵ The patents claimed the use of a computer system to track debits and credits of two parties to a financial exchange.⁹⁶ The system only allows transactions for which the system’s records “indicate sufficient resources to satisfy their mutual obligations.”⁹⁷ By only allowing transactions for which a party has sufficient assets, the system mitigates the risk that only one party will carry out its contractual obligations.⁹⁸

The Court determined that the patents at issue satisfied only the first step of the *Mayo* analysis. The first requirement was met because the patents were properly directed to a patent-ineligible abstract idea.⁹⁹ Specifically, the concept of intermediated settlement—using a third party to mitigate risk—is a common practice that is “squarely

89. *Id.* The Court effectively stated that the claims laid out the applicable law of nature—namely the correlation between metabolite concentration and drug efficacy—and told doctors to “apply it,” a practice which the Court has explicitly stated is not sufficient to produce an inventive concept. *See id.* at 72.

90. *Id.* at 79 (modifications omitted).

91. *Id.*

92. *Id.* at 80.

93. 134 S. Ct. 2347 (2014).

94. *Id.* at 2355.

95. *Id.* at 2352.

96. *Id.*

97. *Id.* (quoting *CLS Bank Int’l v. Alice Corp.*, 717 F.3d 1269, 1285 (Fed. Cir. 2013) (Lourie, J., concurring)).

98. *Id.*

99. *Id.* at 2356.

within the realm of ‘abstract ideas.’¹⁰⁰ However, the Court determined that the patents lacked an inventive concept: “[T]he mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention.”¹⁰¹ Since the claims do no more than “simply instruct the practitioner to implement the abstract idea of intermediated settlement on a generic computer,”¹⁰² the Court held the claims to be patent ineligible under § 101.¹⁰³

D. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*¹⁰⁴

Ariosa was a pivotal case in judicial application of the *Mayo* framework. After a reasonably anticipated result in *Alice*, *Ariosa* strictly—perhaps too strictly¹⁰⁵—interpreted the *Mayo* standard to preclude processes aimed at the discovery of a novel natural phenomenon. This section lays out the facts of *Ariosa* and details the Federal Circuit’s interpretation of the *Mayo* framework. Part III will go on to analyze whether the Federal Circuit properly interpreted *Mayo*.

1. *Facts*

The patented invention in *Ariosa*, commercialized by Sequenom as its MaterniT21 test,¹⁰⁶ was aimed at screening for fetal abnormalities and determining sex.¹⁰⁷ Traditionally, these types of tests have been carried out by invasive techniques, including amniocentesis.¹⁰⁸ Amniocentesis and other invasive tests create risks for the mother and the pregnancy.¹⁰⁹ Some techniques have emerged which test maternal blood or serum to screen for various fetal abnormalities, but these techniques are expensive or time-consuming.¹¹⁰ Unlike existing blood tests, the patent is built upon the researchers’ recent discovery that

100. *Id.* at 2356–57.

101. *Id.* at 2358.

102. *Id.* at 2359.

103. *Id.* at 2360.

104. 788 F.3d 1371 (Fed. Cir. 2015).

105. *See infra* Part III.

106. *Ariosa*, 788 F.3d at 1373.

107. U.S. Patent No. 6,258,540 col. 1 ll. 6–14.

108. *Id.* at col. 1 ll. 12–15. Amniocentesis is a procedure in which a physician inserts a needle through the abdominal wall and uterus to extract amniotic fluid for testing. *Amniocentesis: What You Can Expect*, MAYO CLINIC (Oct. 30, 2015), <http://www.mayoclinic.org/tests-procedures/amniocentesis/basics/what-you-can-expect/prc-20014529> [https://perma.unl.edu/NX9W-76X4]. Amniocentesis procedures include many risks, including a slight risk of miscarriage or infection. *Amniocentesis: Risks*, MAYO CLINIC (Oct. 30, 2015), <http://www.mayoclinic.org/tests-procedures/amniocentesis/basics/risks/prc-20014529> [https://perma.unl.edu/E2L6-NPA2].

109. U.S. Patent No. 6,258,540 col. 1 ll. 15–16.

110. *Id.* at col. 1 ll. 18–37.

fetal DNA¹¹¹ can be detected in maternal serum or plasma samples.¹¹² This cell-free fetal DNA (cffDNA) circulates freely in a pregnant woman's bloodstream.¹¹³ The finding of fetal DNA in plasma was unexpected since plasma is routinely discarded in other noninvasive procedures.¹¹⁴

The patent does not claim cffDNA;¹¹⁵ nor could it.¹¹⁶ Rather, the patent claims certain methods of using cffDNA.¹¹⁷ The patent describes a process by which to collect cffDNA in order to perform tests for fetal abnormalities. In this process, health professionals take a small amount of plasma from maternal blood using standard techniques.¹¹⁸ They then extract nucleic acids from the sample by one of a number of suitable methods.¹¹⁹ Finally, they amplify the fetal DNA sequences in the sample by a standard nucleic-acid amplification system, preferably polymerase chain reaction.¹²⁰ The method can be used to determine sex,¹²¹ detect any paternally-inherited genetic sequences

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111. DNA (deoxyribonucleic acid) is made up of hereditary information in the form of genes. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013). DNA is generally found in the form of a double helix consisting of chemically joined nucleotides. *Id.* Sequences of nucleotides serve as instructions for a cell to build proteins. *Id.* Human genes are present in cells in twenty-three pairs of chromosomes. *Id.* Changes to the nucleotide sequence are called "mutations." *Id.* at 2112. Mutations vary greatly in their effect but can cause disease or an increased risk of disease. *Id.*
112. U.S. Patent No. 6,258,540 col. 1 ll. 50–51.
113. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (Fed. Cir. 2015).
114. U.S. Patent No. 6,258,540 col. 1 ll. 51–54.
115. *See id.*
116. *See Myriad Genetics*, 133 S. Ct. 2107 (holding that naturally occurring segments of DNA are not patentable).
117. *Ariosa*, 788 F.3d at 1373. Specifically, the claims at issue on appeal are claims 1, 2, 4, 5, 8, 19–22, 24, and 25, *id.*, which involve "[a] method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female," as well as several variations on the method and other related techniques. U.S. Patent No. 6,258,540 col. 23 ll. 60–63. At the core of this dispute is claim 21, which provides a method for prenatal diagnosis of certain conditions performed by separating a maternal blood sample into a cellular and a noncellular fraction, detecting cffDNA in the noncellular fraction, and "providing a diagnosis based on the presence and/or quantity and/or sequence of the [cffDNA]." *Id.* at col. 26 1 ll. 14–15.
118. U.S. Patent No. 6,258,540 col. 2 ll. 19–27.
119. *Id.* at col. 2 ll. 27–41.
120. *Id.* at col. 2 ll. 42–47. Polymerase chain reaction—commonly referred to as PCR—is a method in which the two strands of the DNA helix are separated and copied. The DNA strands are copied by DNA polymerase, which carries out the same function within human cells. The process is set up to be cyclic in nature, allowing for rapid amplification of the original DNA sample. *See* R.K. Saiki et al., *Enzymatic Amplification of Beta-Globin Genomic Sequences and Restriction Site Analysis for Diagnosis of Sickle Cell Anemia*, 230 SCIENCE 1350 (1985); F. Sanger & A.R. Coulson, *A Rapid Method for Determining Sequences in DNA by Primed Synthesis with DNA Polymerase*, 94 J. MOLECULAR BIOLOGY 441 (1975).
121. U.S. Patent No. 6,258,540 col. 2 ll. 48–56.

not possessed by the mother,¹²² screen for Down's Syndrome,¹²³ and catch other chromosomal aneuploidies.¹²⁴ The MaterniT21 test marketed by Sequenom created a safer alternative for fetal testing compared to invasive techniques.¹²⁵

Ariosa Diagnostics (Ariosa) and Natera produce substantially similar tests to Sequenom's MaterniT21.¹²⁶ Sequenom claimed that the tests made by Ariosa and Natera infringed the '540 Patent.¹²⁷ Ariosa and Natera filed separate declaratory actions, alleging that they did not infringe.¹²⁸ After various procedural steps,¹²⁹ the district court determined that the claims in the '540 Patent did not satisfy the *Mayo* test and noted concerns that the claims posed a risk of preempting a natural phenomenon.¹³⁰ Sequenom appealed to the Federal Circuit.¹³¹

2. *The Federal Circuit's Decision*

Upon review, the Federal Circuit agreed with the district court that the claims at issue in the '540 Patent are ineligible for protection under § 101.¹³² Method claims—such as those claimed in the '540 Patent—are generally patentable.¹³³ However, since the method begins and ends with cfDNA, which is unquestionably a natural phenome-

122. *Id.* at col. 2 ll. 57–61.

123. *See Down Syndrome: Definition*, MAYO CLINIC (Apr. 19, 2014), <http://www.mayoclinic.org/diseases-conditions/down-syndrome/basics/definition/con-20020948> [<https://perma.unl.edu/N75S-YTVV>] (“Down syndrome is a genetic disorder caused when abnormal cell division results in extra genetic material from chromosome 21. This genetic disorder, which varies in severity, causes lifelong intellectual disability and developmental delays, and in some people it causes health problems.”).

124. U.S. Patent No. 6,258,540 col. 3 ll. 25–28. An aneuploidy is an abnormal number of chromosomes in an individual. Chromosomal aneuploidy may cause any number of conditions, the most common of which is Down syndrome. *See* A.J.F. GRIFFITHS ET AL., AN INTRODUCTION TO GENETIC ANALYSIS (7th ed. 2000), <http://www.ncbi.nlm.nih.gov/books/NBK21870>.

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

126. Ariosa produces the Harmony Test, which diagnoses certain fetal characteristics. *Id.* at 1374. Natera produces the Non-Invasive Paternity Test, which is used to determine paternity of a fetus. *Id.*

127. *Id.*

128. *Id.*

129. *See id.* at 1374–75.

130. *Id.* at 1375; *see also* *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972) (invalidating a patent on a computer process for converting binary-coded decimal numbers into pure binary numerals because the patent “would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself”).

131. *Ariosa*, 788 F.3d at 1375.

132. *Id.* at 1380.

133. *Id.* at 1376.

non,¹³⁴ the claims are directed to a patent-ineligible concept.¹³⁵ As such, the claims easily satisfy the first step of the *Mayo* test.¹³⁶

Because the claims are directed to naturally occurring phenomena, the court proceeded to step two of the *Mayo* framework, which requires an inventive concept.¹³⁷ The court found essential the fact that the use of methods like polymerase chain reaction for amplification of DNA was “well-understood, routine, conventional activity.”¹³⁸ The court stated that the methods claimed in the ‘540 Patent essentially amount to “a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA.”¹³⁹ According to the court, this clearly means that the method of detecting paternally inherited cffDNA is not new and useful.¹⁴⁰

The court acknowledged that the *discovery* of cffDNA in maternal plasma or serum—as opposed to the method for its analysis—is new and useful,¹⁴¹ but was still not convinced that it passed muster under the *Mayo* framework. The main reason that the court came to this conclusion was that the claims were broad examples of techniques for detecting cffDNA in maternal plasma.¹⁴² The court asserted that:

[A]ppending routine, conventional steps to a natural phenomenon, specified at a high level of generality, is not enough to supply an inventive concept. Where claims of a method patent are directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine and well understood applications in the art.¹⁴³

The court noted that preemption analysis was unnecessary, since it is inherent in the § 101 analysis.¹⁴⁴

The court also addressed other arguments put forth by Sequenom. Sequenom maintained that prior to the ‘540 Patent, maternal plasma or serum was being used by no one to detect cffDNA.¹⁴⁵ The court replied that Sequenom’s argument “implic[d] that the inventive con-

134. *See Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

135. *Ariosa*, 788 F.3d at 1376.

136. *See supra* section II.B.2.

137. *Ariosa*, 788 F.3d at 1376.

138. *Id.* at 1377.

139. *Id.*

140. *Id.*

141. *Id.*

142. *Id.* at 1378.

143. *Id.*

144. *Id.* at 1379. *See generally* subsection II.A.1. However, preemption also plays a role in defining the inventive concept, since the inventive concept arises out of the general § 101 inquiry. *See* subsection II.A.2. If the court had properly recognized the role preemption plays in the inventive concept analysis, *see generally infra* section III.A., perhaps it may have been more inclined to recognize an inventive concept here. *But see infra* note 147.

145. *Ariosa*, 788 F.3d at 1379.

cept lies in the discovery of cffDNA in maternal plasma or serum.”¹⁴⁶ However, whether or not the inventive concept is taken to be such, the court stated that the ‘540 Patent does not claim this invention, and the argument is irrelevant.¹⁴⁷ Furthermore, Sequenom argued that the invention is a “significant human contribution.”¹⁴⁸ The court acknowledged the importance of the invention, but rejoined that “[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”¹⁴⁹ The Federal Circuit denied rehearing en banc,¹⁵⁰ and the Supreme Court denied Sequenom’s petition for writ of certiorari.¹⁵¹

III. ANALYSIS

The key concern arising out of *Ariosa* is that “a too restrictive test for patent eligibility under . . . § 101 with respect to laws of nature . . . may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new and natural phenomena.”¹⁵² *Mayo* breathed new life into the inventive concept but did little to alter its traditional inventive concept framework. Despite the open door that the Supreme Court left in *Mayo*, the Federal Circuit very narrowly defined the inventive concept and refused to recognize discovery of laws of nature as a sufficient inventive concept. This Part begins with a discussion of the inventive concept requirement and how *Mayo* affects it. This Part then goes on to clarify why discovery of a law of nature should—indeed, *must*—qualify as an inventive concept. Finally, this Part analyzes the consequences and aftermath of the Federal Circuit’s decision.

146. *Id.*

147. *Id. But see Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1289–90 (Fed. Cir. 2015) (Dyk, J., concurring) (assuming that the inventive concept may arise out of the discovery of a law of nature without claiming the discovery itself). Note again that the court did in fact agree that the discovery of cffDNA in maternal plasma or serum was new and useful, *Ariosa*, 788 F.3d at 1377, but the court circumvented a full analysis of the issue by stating that the ‘540 Patent did not technically claim the discovery of cffDNA. *But cf. infra* note 169.

148. *Ariosa*, 788 F.3d at 1379.

149. *Id.* (alteration in original) (quoting *Ass’n for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107, 2117 (2013)).

150. *Ariosa*, 809 F.3d 1282.

151. *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 136 S. Ct. 2511 (2016).

152. *Ariosa*, 809 F.3d at 1287 (Dyk, J., concurring).

A. The Inventive Concept After *Mayo*

The Court in *Mayo* did not define what constitutes an inventive concept beyond citation to precedent.¹⁵³ This precedent reveals that the Court has no set formula for determining what constitutes an inventive concept.¹⁵⁴ So long as a patent does not claim ineligible subject matter itself, the inventive concept is satisfied if the process “transforms” the process into something patentable.¹⁵⁵ The Court has provided several instances where such a transformation is present¹⁵⁶ and noted that post-solution activity is not sufficient.¹⁵⁷ At the same time, the Court has explicitly stated that precedent does not provide an exhaustive list.¹⁵⁸ The inventive concept analysis more generally focuses on preemption¹⁵⁹ and novelty.¹⁶⁰ So long as an invention provides some new and useful process and does not broadly prevent use of an unpatentable principle, the inventive concept is satisfied.¹⁶¹

Seemingly ignoring *Benson* and *Flook*, the Federal Circuit incorrectly interpreted *Mayo* to restrict the inventive concept narrowly as to exclude detection of cffDNA in maternal plasma.¹⁶² Rather, *Mayo* only holds that instructions to doctors to adjust drug dosage based on metabolite levels does not qualify as an inventive concept.¹⁶³ Again, judicial precedent does not provide a comprehensive catalogue of appropriate inventive concepts.¹⁶⁴ *Mayo* does nothing more to alter the inventive concept than to provide an additional example of a nonqualifying process.¹⁶⁵

153. See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72–73 (2012) (citing *Gottschalk v. Benson*, 409 U.S. 63 (1972); and then citing *Parker v. Flook*, 437 U.S. 584 (1978)). See generally *Casey*, *supra* note 25.

154. See *supra* subsection II.A.2.

155. See *Benson*, 409 U.S. at 70.

156. See *id.* at 70–71.

157. *Flook*, 437 U.S. at 590 (“The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance.”)

158. See *Benson*, 409 U.S. at 71 (“We do not hold that no process patent could ever qualify if it did not meet the requirements of our prior precedents.”)

159. See *id.* at 72 (“[I]f the judgment below is affirmed, the patent would wholly preempt the mathematical formula and in practical effect would be a patent on the algorithm itself.”)

160. *Flook*, 437 U.S. at 591 (“The process itself, not merely the mathematical algorithm, must be new and useful.”)

161. For example, the *Mayo* Court acknowledged that a process for molding rubber contained an inventive concept because it did not preempt use of the Arrhenius equation and “transformed the process into an inventive application of the formula.” *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 80–81 (2012).

162. *Ariosia Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1378 (Fed. Cir. 2015).

163. *Mayo*, 566 U.S. at 82.

164. See *Benson*, 409 U.S. at 71.

165. *Mayo* in no way attempts to add to, detract from, or modify inventive concept jurisprudence. See generally *supra* subsection II.B.2.

B. Discovery as an Inventive Concept

The inventive concept of the *Mayo* analysis can and should be satisfied by the discovery of a law of nature itself.¹⁶⁶ This section begins with a discussion of how discovery fits into the existing framework of the inventive concept. This section goes on to address the Federal Circuit's concerns with adopting this approach and concludes with a discussion of the strong public policy supporting discovery as a sufficient inventive concept.

1. Conformity with the Inventive Concept Framework

Discovery of a law of nature fits neatly within the existing inventive concept analysis promulgated by the Supreme Court. As noted above, the Court's approach focuses strongly on preemption and novelty.¹⁶⁷ The Court in *Myriad* has already implied "that an inventive concept can sometimes come from discovery of an unknown natural phenomenon, not just from unconventional application of a phenomenon."¹⁶⁸ Here, the discovery of the previously unknown presence of cffDNA in maternal blood is clearly such a discovery that would warrant designation as an inventive concept. The discovery is obviously novel, and use of the cffDNA to perform genetic tests for diagnosis of certain conditions does not preempt use of cffDNA in other inventions for other purposes.

Of course, a newly discovered law of nature should not itself be patentable.¹⁶⁹ However, the primary concern regarding patents of laws of nature is preempting use of that principle.¹⁷⁰ This concern is of little consequence since it falls squarely within the balancing act of the entirety of patent law. While questions of preemption and other limitations on future innovation must be taken into consideration, the goal of patent law has always been "[t]o promote the Progress of Sci-

166. See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1289 (Fed. Cir. 2015) (Dyk, J., concurring) ("[A]n inventive concept can come not just from creative, unconventional application of a natural law, but also from the creativity and novelty of the discovery of the law itself."). However, Judge Dyk incorrectly surmises that *Mayo* "concludes that [an] inventive concept cannot come from discovering something new in nature." *Id.* As discussed *supra*, *Mayo* is not as restrictive as the justices of the Federal Circuit have made it out to be.

167. See *supra* subsection II.A.2.

168. *Ariosa*, 809 F.3d at 1290 (Dyk, J., concurring); see also *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2120 (2013) (stating that, although patents on cDNA were invalid, "patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes" were not precluded by the decision).

169. *Ariosa*, 809 F.3d at 1290 (Dyk, J., concurring); see *supra* subsection II.A.1. This is precisely why the '540 Patent did not claim discovery of cffDNA in maternal plasma and serum. Rather than disregard the discovery because the patent did not explicitly claim it, the court should have featured this new and useful discovery more centrally in its inventive concept analysis. Cf. *supra* note 147.

170. *Ariosa*, 809 F.3d at 1290 (Dyk, J., concurring).

ence and useful Arts.”¹⁷¹ The aim of the inventive concept is to consider this balancing act in awarding patents for inventions directed at traditionally unpatentable subject matter. A patent cannot issue for gravity or mathematical equations or DNA.¹⁷² Such patents would be overly broad and unduly limit the access of citizens to the very fundamentals of thought and nature. However, *failure* to issue a patent for discovery of a law of nature may be just as restrictive on access to the “building blocks of human ingenuity.”¹⁷³ Without incentives, scientists may not be able to obtain funding to pursue research in the life sciences. Without life science discoveries, laypersons cannot access medical tests and treatments that may very well be lifesaving. In the complicated and necessary world of life science research, patent protection is vital.

Generally speaking, “an invention arises when there is a degree of mental effort or observation, or an amount of work greater than what is given by the average journeyman in the art to such problems.”¹⁷⁴ Furthermore,

where there has been an inhibition in the minds of workers in the art or belief that a certain thing could not be done or could not be done a certain way, and when thereafter someone comes along and shows the error of that way of thinking and achieves a successful result, the presence of invention is rather plainly indicated.¹⁷⁵

Although not judicially ordained, this formulation of an invention is common sense. Patent protection must extend to discoveries that were previously thought unfeasible, which is clearly demonstrated by the use of a mother’s blood to carry out genetic testing of her fetus. Even if happenstance, this discovery clearly has sufficient “novelty and value”¹⁷⁶ for an inventive concept, thus entitling it to patent protection. While a patent cannot broadly claim all uses of the discovery,¹⁷⁷ the discovery itself is plainly a sufficient inventive concept to render

171. U.S. CONST. art. I, § 8, cl. 8.

172. *See Myriad Genetics*, 133 S. Ct. at 2107; *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

173. *Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014).

174. CHESTER H. BIESTERFELD, *PATENT LAW FOR LAWYERS, STUDENTS, CHEMISTS AND ENGINEERS* 4 (2d ed. 1949).

175. *Id.* at 7.

176. *See id.* at 8 (“Invention involves a mental effort or concept, and in its higher forms a ‘flash of genius,’ and the fundamental rule is that it must transcend what the average journeyman in the art would do in view of the problem presented. A discovery, such a devising a new chemical process, involves the same kind of mental effort, but there are some types of chemical discoveries that are the result of accident, or unexpected occurrence in the course of other operations. Here we cannot so readily apply the rule of the average journeyman in the art, but must rather judge the discovery from the standpoint of its novelty and value.”).

177. *See Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972) (stating that preemption of use of a law of nature must be avoided).

patentable specific claims invoking the newly discovered law of nature.

2. Addressing the Federal Circuit's Concerns

In its review of *Ariosa*, the Federal Circuit presented concerns that the claims utilize common techniques and that the claims were overly broad. Each of these concerns is easily dismissed. The use of “routine” and “conventional”¹⁷⁸ techniques has traditionally persuaded courts that an invention lacks an inventive concept. However, in setting out the *Mayo* standard, the Supreme Court acknowledged that an inventive concept could be realized in the use of an existing drug in a new way.¹⁷⁹ Later, in its specific consideration of patents involving DNA, the Court also implied that an inventive concept could arise from “new applications of knowledge about . . . genes.”¹⁸⁰ The Supreme Court obviously recognizes that an inventive concept may not always arise from application of new techniques but rather from application of existing techniques to a new discovery. With such a robust library of life sciences methods already developed, the future of research lies in application of these routine and conventional processes to solve newly discovered problems. It is only logical to recognize these inventions as containing an inventive concept in order to support the development of new life science innovations.

Beyond the focus on routine and conventional steps, the Federal Circuit also seemed to be concerned with reining in overly broad claims.¹⁸¹ Breadth is of particular concern where an inventive concept may arise out of discovery, which may “extend far beyond the utility demonstrated by the patent”¹⁸² such that they “preempt the use’ of the underlying idea by others.”¹⁸³ These concerns of preemption hail back to the infancy of § 101.¹⁸⁴ However, these very concerns of

178. *See Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1378 (Fed Cir. 2015) (“[A]ppending routine, conventional steps to a natural phenomenon . . . is not enough to supply an inventive concept.”).

179. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 87 (2012).

180. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2120 (2013).

181. *See Ariosa*, 788 F.3d at 1378 (“[A]ppending routine, conventional steps to a natural phenomenon, *specified at a high level of generality*, is not enough to supply an inventive concept.” (emphasis added)).

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

183. *Id.* (quoting *Mayo*, 566 U.S. at 72).

184. *See, e.g., Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852) (“A patent is not good for an effect, or the result of a certain process, as that would prohibit all other persons from making the same thing by any means whatsoever. This, by creating monopolies, would discourage arts and manufactures, against the avowed policy of the patent laws.”).

breadth are already explicitly addressed in § 112.¹⁸⁵ It is quite clear that patent law already prohibits patents which lay out claims at a “high level of generality.”¹⁸⁶ Here, as always, preemption is the ultimate concern. The distinction to be made is the point in patent analysis at which the breadth of the claim should be considered. As to subject matter, a direct claim to the law of nature, natural phenomenon, or abstract idea itself would preempt use of the underlying law or idea and should defeat the inventive concept analysis. However, questions of breadth, concerned that the patent claims are not narrowly focused on the claimed invention, are better examined by the “finer filter of § 112 . . . rather than reviewing them under the less-defined eligibility rules.”¹⁸⁷ Although a claim may run into trouble at § 112 down the line, the mere breadth of a claim does not demonstrate that it contains patent-ineligible subject matter.

3. *Public Policy*

The foregoing analysis aside, the Federal Circuit would be well-advised to interpret the vague language of *Mayo* in a way that is consistent with the intents and purposes of patent law itself.¹⁸⁸ Patent law exists to incentivize innovation.¹⁸⁹ Such incentives are beneficial for inventors and the public alike. Inventors see their blood, sweat, and tears repaid in the exclusive ownership of rights in their invention for a period of years.¹⁹⁰ The public likewise benefits as scientists, confident in future patent protections and building on previously disclosed inventions, continue to pursue new ideas, churning out cutting-edge technology and medical breakthroughs.¹⁹¹ This incentive is particularly powerful in the area of life sciences, simultaneously allowing inventors to make abundant profits and bringing about new ways for the public to live longer, happier, and healthier lives.

185. 35 U.S.C. § 112(a) (2012) (“The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.”).

186. *Ariosa*, 788 F.3d at 1378.

187. *Ariosa*, 809 F.3d at 1286 (Lourie, J., concurring).

188. See BALLARD, *supra* note 9, at 21–26 (discussing the purpose of patents).

189. See *id.* at 24–25 (“So then it is *the fact of granting* of patents in appropriate cases that promotes the progress of science and the useful arts, not something done with them afterwards.”).

190. See *id.* at 25 (“Human nature being what it is, the public cannot expect to get many new inventions unless it offers a fair price for them, a price which holds some promise of profit on the time, risk and expense of the inventor.”).

191. See *id.* at 22 (“The thing that benefits the public is the full and detailed disclosure of the invention in a permanent public record with the privilege of using the invention freely after the limited term.”).

While *Mayo* certainly does not prohibit the Federal Circuit from adopting a narrow construction of the inventive concept, it is exceedingly unwise to do so. Life sciences innovation is essential to continued progress in medical sciences. As discussed below, the growth of gene technology, the necessity for access to genetic information for its development, and incentives to invest in this highly useful technology support a broad inventive concept in order to promote innovation.¹⁹²

First, “[g]enetic information is the basis for the coming era of personalized medicine, a nascent industry that requires patents to promote investment and development.”¹⁹³ As research in the area of life sciences progresses, science is becoming increasingly able to implement personalized medicine, use genetic testing to predict the onset of diseases, and make better therapeutic choices.¹⁹⁴ The human genome is used in a multitude of applications, many—if not most—of which depend on the identification of underlying natural laws.¹⁹⁵ However, without proper patent protection, further developments are unlikely to be “effectively developed into viable commercial products.”¹⁹⁶ The inventive concept standard adopted by the Federal Circuit acts as a “complete ban” on the important claims at issue in this case.¹⁹⁷ The result is “uncertainty in [the life sciences] industry, a reduced likelihood of patent protection, and concomitant reduced incentives for investment and public disclosure” that is certainly at odds with the constitutional mandate to “promote the Progress of Science and useful Arts.”¹⁹⁸

Second, broadly applying the Federal Circuit’s formulation of the inventive concept “would promote suppression of genetic information relevant to diagnostic and therapeutic applications.”¹⁹⁹ Without the availability of patent protection, researchers will likely turn to trade secret protection for the most important discoveries.²⁰⁰ This will dis-

192. See generally Brief of the Biotechnology Industry Organization as Amicus Curiae Supporting Appellants and in Favor of Reversal at 4, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) (Nos. 2014-1139, 2014-1142, 2014-1144) [hereinafter Biotechnology Brief].

193. *Id.*

194. *Id.* at 4–5. Diagnostic testing, predictive and pre-symptomatic testing, carrier testing, prenatal testing, newborn screening, pharmacogenomics testing, and research genetic testing can provide a plethora of information that is beneficial for both individuals and the progress of medicine as a whole. See *Frequently Asked Questions About Genetic Testing*, NAT’L HUM. GENOME RES. INST. (Aug. 27, 2015), <https://www.genome.gov/19516567/#al-3> [<https://perma.unl.edu/KPM2-EW7J>].

195. Biotechnology Brief, *supra* note 192, at 5.

196. *Id.*

197. *Id.*

198. *Id.* at 6 (quoting U.S. CONST. art. I, § 8, cl. 8).

199. *Id.*

200. *Id.* at 6. If researchers do not resort to trade secret or some other alternative, nonpatented inventions will quickly lose their value as they are stolen by competitors and unable to be easily licensed, sold, or transferred. See *What Happens If*

courage publication of important techniques that might be beneficial for current use or lead to discovery of better diagnostics or therapeutic methods. Incentives to move to trade secret protections cut directly against the goal of disclosure that is fundamental to patent protection.²⁰¹ This is especially troubling considering that genetic testing could serve as an indicator of risk for “diabetes, cardiovascular disease, autism, Parkinson’s disease, Alzheimer’s disease, immunological disorders, asthma, and most form of cancers.”²⁰² Indeed, “it can be expected that most human diseases will involve many genes or other biological markers.”²⁰³ The genetic studies to date are only the beginning of molecular-diagnostics technology²⁰⁴ and are in great need of patent protection. Without it, incentives to disclose innovations will be practically nonexistent, greatly hindering progress in genetic diagnostics²⁰⁵ and hampering patient access to the most effective methods.

Third, and perhaps most importantly, “[l]ack of patent protection will reduce investment in diagnostic methods and preclude the effective use of genetic information for preventing and treating human disease.”²⁰⁶ The costs of gene diagnostics of even simple genetically

You Do Not Patent Your Inventions?, WORLD INTELL. PROP. ORG., http://www.wipo.int/sme/en/ip_business/importance/risks.htm [<https://perma.unl.edu/6BUE-5WSB>]; see also Worth Wade, *History of the American Patent Incentive System*, 44 J. PAT. OFF. SOC’Y 67, 70 (1962) (“Patents avoid the necessity for secrecy. It is difficult to maintain trade secrets or prevent their unauthorized use, when exposed. Inventions should not be treated like money in a miser’s sock; they should be put in safe-keeping in the U.S. Patent Office.”).

201. See DANIEL C.K. CHOW & EDWARD LEE, INTERNATIONAL INTELLECTUAL PROPERTY 252 (2d ed. 2012) (“[T]he grant of a patent is often described as a *quid pro quo* or bargain, with the patentee receiving exclusive rights to his or her invention for a limited time in exchange for the disclosure to the public of how to make and use the invention.”); Giulio Mandich, *Venetian Patents (1450–1550)*, 30 J. PAT. OFF. SOC’Y 166, 178 (1948) (discussing disclosure as a duty, rather than a “mere right to report”).
202. Biotechnology Brief, *supra* note 192, at 7–8 (citations omitted); see also *What Are Genome-Wide Association Studies?*, U.S. NAT’L LIBR. MED. (Apr. 11, 2017), <https://ghr.nlm.nih.gov/primer/genomicresearch/gwastudies> [<https://perma.unl.edu/6ZY3-VB67>] (noting that studies of single nucleotide polymorphisms have contributed to knowledge about diabetes, heart abnormalities, Parkinson’s disease, and Crohn’s disease).
203. Biotechnology Brief, *supra* note 192, at 8.
204. *Id.*; see also *What Are the Next Steps in Genomic Research?*, U.S. NAT’L LIBR. OF MED. (Apr. 11, 2017), <https://ghr.nlm.nih.gov/primer/genomicresearch/nextsteps> [<https://perma.unl.edu/2UJJ-VFL7>] (discussing the wide range of future goals for genetic research); *What Is Pharmacogenomics?*, U.S. NAT’L LIBR. OF MED. (Apr. 11, 2017), <https://ghr.nlm.nih.gov/primer/genomicresearch/pharmacogenomics> [<https://perma.unl.edu/8DWT-QAHR>] (discussing the nascent field of pharmacogenomics, which focuses on how drug response is affected by genetics).
205. Biotechnology Brief, *supra* note 192, at 8–9.
206. *Id.* at 9. Privately funded research tends to give rise to the most commercially valuable innovations. Without the “assurance that [innovators] can recoup their investments,” private investors are unlikely fund innovation in the first place.

related diseases can stretch into the hundreds of millions of dollars.²⁰⁷ As the complexity of genetic links for diseases increases—such as genetic interactions associated with diabetes, heart disease, and some forms of cancer—companies will have to make an even more substantial investment to commercialize future genetic diagnostic testing.²⁰⁸ “Developing new drugs is a risky, lengthy, and costly endeavor,”²⁰⁹ and it is irrational to think that companies will undertake these risks without patent protection as a basis for a financially reasonable return on their investment.²¹⁰ This concern has been essential to patent law from its very origins in Venice.²¹¹ As investors become wary of financing high-risk research with no guarantee of patent protection, life sciences innovation may indeed come to a grinding stop, greatly limiting patient access to potentially lifesaving developments.

In sum, it is essential to encourage continued innovation in the life sciences. Of all subject matter within the purview of patent law, life

See Omar Al Ubaydli, *Economics 101: Privately Funded Research and Development Leads to the Most Useful Innovation*, THE NAT'L, Oct. 15, 2016, <http://www.thenational.ae/business/economy/economics-101-privately-funded-research-and-development-leads-to-the-most-useful-innovation> [<https://perma.unl.edu/H6JB-NJ3V>].

207. Biotechnology Brief, *supra* note 192, at 9 n.18.

208. *Id.* at 9–10.

209. *Id.* at 10 (quoting *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1300 (11th Cir. 2012)); *see also id.* (“Only one in every 5,000 medicines tested for the potential to treat illness is eventually approved for patient use, and studies estimate that developing a new drug takes 10 to 15 years and costs more than \$1.3 billion.” (quoting *Watson Pharm.*, 677 F.3d at 1300)); *id.* at 11 (“In addition, recent efforts by the FDA to regulate offerings by genetic diagnostics companies implicate additional costs . . . that can be expected to significantly increase as this industry develops.”); Kim Thomas, *The Price of Health: The Cost of Developing New Medicines*, THE GUARDIAN, Mar. 30, 2016, <https://www.theguardian.com/health-care-network/2016/mar/30/new-drugs-development-costs-pharma> [<https://perma.unl.edu/A2MC-RB2U>] (describing the process of developing a drug).

210. Biotechnology Brief, *supra* note 192, at 10; *cf. American Patent Incentive System*, 40 J. PAT. OFF. SOC'Y 187, 187–88 (1958) (“This incentive, hope or reward, or encouragement, which can be gained for said ‘limited times’ has caused inventors and discoverers and their financial backers to expend the time, energy and funds to develop and to produce their inventions, etc., and to avail themselves of the protection of patent.”); *see also id.* at 189–90 (discussing the strong incentives inherent in patent protection). Even if the traditional notion of patent incentives is generally a fiction, as suggested by Professor Eric Johnson, *see generally* Eric E. Johnson, *Intellectual Property and the Incentive Fallacy*, 39 FLA. ST. U. L. REV. 623 (2012), life sciences innovations rather plainly fall into the exception by any measure. *Cf. id.* at 661–66. The life sciences business is certainly one of those “certain industries” that relies heavily on patents to profit from inventions. *See id.* at 663.

211. *Cf. Mandich*, *supra* note 201, at 176 (“[I]f provision were made for the works and devices discovered by such persons, so that others who may see them could not build them and take the inventor’s honor away, more men would then apply their genius, would discover, and would build devices of great utility and benefit to our commonwealth.” (quoting the Venetian Patent Act of 1474)).

science inventions have perhaps the most direct and beneficial impact upon individual lives. The judiciary—indeed, the government as a whole—has a moral obligation to promote development in this area to improve the lives of people around the world. With a narrow interpretation of the inventive concept, the Federal Circuit takes a treacherous step down an exceedingly slippery slope that is sure to effectively halt life sciences innovation.

C. Implications for Patentability

Ariosa has not been well received,²¹² and rightly so. Although the inventive concept standard was never required to be narrowly applied,²¹³ the Federal Circuit’s opinion has now made the *Mayo* standard as overwhelmingly restrictive as the judges feared it to be. The repercussions—of which many can be imagined—have already begun to manifest themselves. For example, the Federal Circuit used this enhanced inventive concept standard to strike down a method based on the discovery that certain DNA sequences within a gene are linked to certain noncoding regions of DNA.²¹⁴ The court stated that “the physical steps of DNA amplification and analysis of the amplified DNA to provide a user with the sequence of the non-coding region do not, individually or in combination, provide sufficient inventive concept to render [the claim] patent eligible.”²¹⁵ Due to *Ariosa*’s focus on the patent ineligibility of routine and conventional methods, the Federal Circuit again glossed over the obvious inventive concept in the discovery of the utility of noncoding regions which had previously been considered “junk DNA.”²¹⁶

As the Federal Circuit continues to strike down patents on inventions aimed at discoveries of novel and useful phenomena in the life sciences, the incentive to invent in these areas is likely to dry up. Without a reasonable expectation of patent protection, it will become increasingly difficult for researchers to obtain funding for life sciences research that is exceedingly costly. Without funding, research will

212. See, e.g., Devlin Hartline, *Federal Circuit Should Reconsider Ariosa v. Sequenom: The Panel Decision Threatens Modern Innovation*, IP WATCHDOG (Aug. 30, 2015), <http://www.ipwatchdog.com/2015/08/30/federal-circuit-should-reconsider-ariosa-v-sequenom-the-panel-decision-threatens-modern-innovation/id=61171>; Sue D. Nym, *Ariosa Is a Good Example of Outcome-Driven § 101 Decisions*, IP WATCHDOG (Aug. 9, 2015), <http://www.ipwatchdog.com/2015/08/09/ariosa-is-a-good-example-of-outcome-driven-%24-101-decisions/id=60433>; Patent Publius, *Federal Circuit Threatens Innovation: Dissecting the Ariosa v. Sequenom Opinion*, CTR. FOR PROTECTION INTELL. PROP. (June 23, 2015), <http://cpip.gmu.edu/2015/06/23/federal-circuit-threatens-innovation-dissecting-the-sequenom-v-ariosa-opinion> [<https://perma.unl.edu/W2X7-CAPW>].

213. See *supra* section III.A.

214. *Genetic Techs., Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016).

215. *Id.* at 1377.

216. *Id.* at 1372.

surely shift to other areas for which scientists *can* obtain grants, bringing life sciences innovation to a standstill. Whether the inventive concept was born out of sound jurisprudence or not, the reality is that *Ariosa* will have grave effects on the ground.

IV. CONCLUSION

Since the nation's inception, U.S. courts have carefully walked the line between incentivizing innovation and not unduly limiting access to scientific principles. *Mayo* itself continued to tread carefully, never limiting the "innovative concept" so far that motivation to create, design, and discover is extinguished. Nonetheless, in *Ariosa*, the Federal Circuit took one step too far, effectively cutting off any incentive for future innovation in the life sciences. Unless and until the Federal Circuit recognizes the error of its ways—or is instructed to do so by the Supreme Court—*Ariosa* sets a dangerous stage for the life sciences. The inventive concept that arises from *Ariosa* may have grim consequences in the years to come.