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Two-Stepping Through *Alice's* Wasteland of Patent-Eligible Subject Matter: Why the Supreme Court Should Replace the *Mayo/Alice* Test

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— Note —

TWO-STEPPING THROUGH ALICE'S WASTELAND OF PATENT-ELIGIBLE SUBJECT MATTER: WHY THE SUPREME COURT SHOULD REPLACE THE MAYO/ALICE TEST

INTRODUCTION	731
I. THE NEED FOR A STRONG U.S. PATENT SYSTEM.....	734
II. THE DEVELOPMENT OF THE MODERN PATENT STATUTE.....	736
III. JUDICIAL TREATMENT OF ELIGIBLE SUBJECT MATTER	739
A. <i>Funk Brothers Approach to Eligible Subject Matter</i>	739
B. <i>Chakrabarty Approach to Eligible Subject Matter</i>	742
C. <i>The Federal Circuit's Interpretation of Conflicting Supreme Court</i> <i>Precedent</i>	744
IV. THE MAYO/ALICE TWO-STEP	745
V. TWO-STEPPING THROUGH THE PATENT-ELIGIBILITY WASTELAND ..	748
VI. DETERMINING PATENT ELIGIBILITY ON A MOTION TO DISMISS	752
VII. DRAFTING AROUND THE TWO-STEP	755
VIII. CONSEQUENCES OF NOT REPLACING THE MAYO/ALICE TWO-STEP .	758
IX. CORRECTING THE MAYO/ALICE TWO-STEP THROUGH STATUTORY AMENDMENT	759
CONCLUSION: REPLACING THE MAYO/ALICE TWO-STEP.....	765

INTRODUCTION

An expectant mother jolts awake as a sharp pain rips through her stomach. She feels the warm sensation of blood spreading down her leg, her hands frantically grasp her stomach as another contraction tears through her. Her inhuman wail pierces the night air and tears stream down her face as she realizes her worst nightmare is coming true; she is having a miscarriage.¹ She has lost the child she has wanted for so long,

1. See, e.g., *Miscarriage*, AM. PREGNANCY ASS'N, <http://americanpregnancy.org/pregnancy-complications/miscarriage/> [https://perma.cc/NST5-JXND] (last updated Dec. 5, 2017) (listing the symptoms of miscarriage).

less than forty-eight hours after having an amniocentesis to test for fetal abnormalities.²

Miscarriage is one of a multitude of serious complications expectant mothers must weigh when deciding if they should have an amniocentesis.³ To determine if her child has any number of genetic abnormalities, an expectant mother would have a long needle inserted into her stomach, the needle would penetrate the uterus and amniotic sac, and extract amniotic fluid for testing.⁴ This amniocentesis procedure carries serious risk of miscarriage, needle injury to the fetus, fetal infection, and other complications.⁵

Today, a revolutionary breakthrough in prenatal care means women no longer have to struggle to decide between important fetal testing and the catastrophic risks associated with amniocentesis. Drs. Lo and Wainscoat discovered that maternal plasma and serum, which had previously been discarded as medical waste, contained cell-free fetal DNA (cffDNA).⁶ Lo and Wainscoat were able to develop a method to detect the small fraction of paternally inherited cffDNA in maternal plasma to determine fetal abnormalities.⁷ This breakthrough has revolutionized prenatal care, offering women a safe alternative to high-risk, invasive testing; cffDNA testing is now offered in over ninety countries and is on track to be a first-tier prenatal screen for all pregnant women.⁸

There is no doubt that Lo and Wainscoat's invention has revolutionized prenatal care.⁹ The Supreme Court's current patent-

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2. See *Amniocentesis*, NHS, <https://www.nhs.uk/conditions/amniocentesis/risks/> [<https://perma.cc/BS4P-DSVD>] (last updated Apr. 21, 2016) (stating that most miscarriages due to amniocentesis occur less than three days after the procedure is done).
 3. See *Amniocentesis Risks*, MAYO CLINIC, <https://www.mayoclinic.org/tests-procedures/amniocentesis/about/pac-20392914> [<https://perma.cc/F4CH-FTSK>] (last updated Nov. 8, 2018).
 4. See *Amniocentesis*, JOHN HOPKINS MED., https://www.hopkinsmedicine.org/healthlibrary/test_procedures/gynecology/amniocentesis_procedure_92,P07762 [<https://perma.cc/2YXW-K2XE>] (last visited Jan. 19, 2019) (explaining what happens during an amniocentesis).
 5. MAYO CLINIC, *supra* note 3.
 6. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (Fed. Cir. 2015).
 7. *Id.*
 8. Robert Cook-Deegan & Subhashini Chandrasekharan, *Sequenom v. Ariosa—The Death of a Genetic Testing Patent*, 375 NEW ENG. J. MED. 2418, 2418 (2016).
 9. See *Ariosa*, 788 F.3d at 1379.

eligibility test, the *Mayo/Alice* two-step,¹⁰ however, threatens the future of such ground breaking inventions. The *Mayo/Alice* two-step analysis of patent eligibility first requires a determination of whether the claims at issue are directed to a law of nature, natural phenomenon, or abstract idea.¹¹ If the claims are directed to one of these patent-ineligible concepts, the second step of the analysis determines if there is an “inventive concept.”¹² The Court described an inventive concept as “an element or combination of elements that ‘is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.’”¹³

The *Mayo/Alice* two-step has proven to be unworkable and has resulted in significant uncertainty in biotechnology. The test has been described as “being both *indeterminate*, as no one is certain how it will be applied in any particular case, and *overly restrictive*,” as the test has been applied to invalidate a wide range of patents.¹⁴ As a result of the *Mayo/Alice* test, a large number of life-saving, meritorious inventions are being rejected or invalidated for being directed towards patent-ineligible subject matter.¹⁵ The uncertainty surrounding biotechnology patent protection has significantly contributed to the weakening of the U.S. patent system¹⁶ and has led to one commentator calling the *Mayo* decision “the worst, most wrongly decided case by the Supreme Court

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10. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012); *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014); see *Patent Subject Matter Eligibility*, USPTO, <https://www.uspto.gov/web/offices/pac/mpep/s2106.html> [<https://perma.cc/U4F4-2UMJ>] (last modified Jan. 24, 2018) (referring to the “*Alice/Mayo* two-part test”).
 11. *Alice*, 134 S. Ct. at 2355.
 12. *Id.*
 13. *Id.* (internal citations omitted).
 14. Kevin Madigan & Adam Mossoff, *Turning Gold into Lead: How Patent Eligibility Doctrine Is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939, 952 (2017).
 15. See Bernard Chao, *USPTO is Rejecting Potentially Life-Saving Inventions*, LAW360 (Dec. 18, 2014), <https://www.law360.com/articles/604808/uspto-is-rejecting-potentially-life-saving-inventions> [<https://perma.cc/DW8W-5P79>].
 16. See Gene Quinn, *The Top 3 Reasons the U.S. Patent System in Decline*, IPWATCHDOG (Apr. 26, 2017), <http://www.ipwatchdog.com/2017/04/26/top-3-reasons-u-s-patent-system-decline/id=82571/> [<https://perma.cc/VZ9F-6UV5>] (stating that, in 2017, the United States fell to a tenth-place tie with Hungary in the U.S. Chamber of Commerce world rankings for patent protection, and listing uncertainty in patent eligibility as a significant contributing factor to the decline in the strength to the U.S. patent system).

in the patent field ever.”¹⁷ Without a change to the current *Mayo/Alice* two-step approach to determining patent-eligible subject matter, the Supreme Court risks hindering the development of innovations, the very thing the patent system seeks to protect.¹⁸

Part I of this Note discusses why a strong U.S. patent system is crucial to the advancement of biotechnology and medical innovation. Parts II and III explore the development of the modern patent statute and the inconsistent judicial treatment of the eligible subject matter requirement. Parts IV and V describe the *Mayo/Alice* two-step and the effects of the test on patent eligibility. Part VI discusses the rise in the dismissal of claims based on motions to dismiss since the adoption of the *Mayo/Alice* two-step. Part VII compares the *Vanda* decision and the *Mayo* decision. Part VIII details the consequences of leaving the *Mayo/Alice* two-step intact. Part IX of this Note discusses the current push for overturning the *Mayo/Alice* test through statutory amendment and details why this is not an adequate solution. Finally, the Conclusion develops a new test for determining what constitutes patent-eligible subject matter and highlights the benefits of the proposed test.

I. THE NEED FOR A STRONG U.S. PATENT SYSTEM

Patents have been a driving force behind innovation in the United States since the country's founding. Patent rights, considered fundamental by the Framers, are recognized in the Intellectual Property Clause of the Constitution.¹⁹ The Framers believed patent rights to be so critical to the success of the United States that the only mention of the word “right” in the original Constitution is found in that clause.²⁰ The original patent statute was passed in the Second Session of the First Congress.²¹ Abraham Lincoln, a patent holder himself, recognized

17. Gene Quinn, *Mayo v. Prometheus: A Lawless Decision by an Omnipotent Court Wreaking Havoc on Patents*, IPWATCHDOG (Jan. 23, 2017), <http://www.ipwatchdog.com/2017/01/23/mayo-v-prometheus-lawless-decision-wreaking-havoc-patents/id=77438/> [https://perma.cc/PB5Y-AS49].

18. U.S. CONST. art. I, § 8, cl. 8 (granting Congress the power to issue patents “[t]o promote the Progress of Science and useful Arts”).

19. U.S. CONST. art. I, § 8, cl. 8; Gene Quinn, *Patents, Copyrights and the Constitution, Perfect Together*, IPWATCHDOG (Feb. 19, 2018), <http://www.ipwatchdog.com/2018/02/19/patents-copyrights-constitution/id=93941/> [https://perma.cc/NC2K-EQGT].

20. Quinn, *supra* note 19.

21. Act of Apr. 10, 1790, ch. 7, 1 Stat. 109 (“[P]romot[ing] the progress of useful Arts . . .”); Quinn, *supra* note 19.

that “[t]he patent system . . . added the fuel of interest to the fire of genius, in the discovery and production of new and useful things.”²²

Patent protection has played a major role in the development of some of the most prominent and ground-breaking inventions in the United States.²³ Patent rights are intended to “promote the Progress of Science and useful arts.”²⁴ By granting an inventor a limited right of exclusion, patent law provides incentive for inventors to risk the enormous costs involved in developing new technologies. This incentive promotes the development of new technologies, and has a positive impact on society.²⁵ To obtain this limited right of exclusion, an inventor must provide an adequate disclosure of the claimed invention.²⁶ Patent law thus encourages inventors to disclose their inventions to the public, rather than maintain them in secret for their own benefit. Such public disclosure stimulates ideas and leads to the eventual development of further significant advances in technology.²⁷

In a strong patent system, patent rights are granted to particular inventions in a predictable manner, and patent infringement similarly is enforced in a predictable manner. A predictable patent system provides inventors with the ability to protect their rewards for successful inventions and to make educated decisions on where to allocate resources when developing new technologies.²⁸

The United States has long been considered to have the “gold standard” patent system and to be the world leader in securing patent protection for innovative, next-wave technologies.²⁹ The United States developed its “gold standard” patent system “precisely because it consistently secured legal protections for the fruits of inventors’ labor.”³⁰

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22. Abraham Lincoln, Second Lecture on Discoveries and Inventions (1858–59), in ABRAHAM LINCOLN ONLINE (original emphasis omitted), <http://www.abrahamlincolnonline.org/lincoln/speeches/discoveries.htm> [<https://perma.cc/V82V-7AMB>] (last visited Jan. 20, 2019).
 23. Maureen K. Ohlhausen, Comm’r, Fed. Trade Comm’n, Remarks at The Economic Contribution of Technology Licensing Conference: The Case for a Strong Patent System 4 (June 8, 2016), https://www.ftc.gov/system/files/documents/public_statements/958603/160608strongpatentsystem.pdf [<https://perma.cc/87SA-SCCT>].
 24. U.S. CONST. art. I, § 8, cl. 8.
 25. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974).
 26. 35 U.S.C. § 112 (2012); *Kewanee*, 416 U.S. at 480–81.
 27. *Kewanee*, 416 U.S. at 481.
 28. Richard S. Gruner, *Why We Need a Strong Patent System and When: Filling the Void Left by the Bilski Case*, 28 SANTA CLARA COMPUTER & HIGH TECH. L.J. 499, 543 (2011).
 29. *Madigan & Mossoff*, *supra* note 14, at 942.
 30. *Id.*

In the 1980s, when other countries were hesitating to grant patent protection to cutting-edge innovations in the emerging, highly controversial field of biotechnology, the U.S. Supreme Court held that these biotechnology innovations should be promoted and protected.³¹ The Supreme Court's holding in *Diamond v. Chakrabarty*³² recognized that the results of biotechnology research may be directed to eligible subject matter.³³ The *Chakrabarty* decision has been cited by commentators as a driving force behind revolutionary advances in life science technology and medical treatment.³⁴

After the Supreme Court's decision in *Chakrabarty*, Harvard College secured a patent on the oncomouse.³⁵ The oncomouse is a mouse that has been genetically modified to incorporate a cancer-promoting gene into its genome,³⁶ resulting in a multitude of opportunities to research cancer development and treatment.³⁷ While the United States issued a patent on the oncomouse approximately four years after the initial filing of the patent application,³⁸ other countries, such as Canada, rejected the application outright. The oncomouse patent was subject to a long series of rejections, court appeals, and remands before the European Patent Office ultimately granted the patent in 2004, nearly two decades after the issuance of the U.S. patent.³⁹ Europe's delay in granting patent protection gave the United States the edge in the biotechnology field. By securing patent rights in biotechnology inventions early on, the United States "became the birthplace of the biotech revolution" while Europe lost the "competitive and commercial edge in biotechnology."⁴⁰

II. THE DEVELOPMENT OF THE MODERN PATENT STATUTE

In order to obtain a patent, an inventor must file an application with the United States Patent and Trademark Office (USPTO) that

31. *Id.* at 943–44.

32. 447 U.S. 303 (1980).

33. *See infra* Part III(B) (discussing the *Chakrabarty* approach to eligible subject matter).

34. Madigan & Mossoff, *supra* note 14, at 943.

35. U.S. Patent No. 4,736,866 (issued Apr. 12, 1988).

36. *Id.* at col. 1 ll. 30–56.

37. *Id.* at col. 3 ll. 16–59.

38. *See* '866 Patent (showing a filing date of June 22, 1984 and an issuance date of April 12, 1988).

39. Madigan & Mossoff, *supra* note 14, at 944.

40. *Id.*

meets several requirements.⁴¹ The patent application is then examined by the USPTO to determine if the application meets the statutory requirements laid out in the patent statute.⁴²

The modern patent framework was adopted in the Patent Act of 1952.⁴³ Prior to the 1952 Patent Act, the statutory requirements for patentability were concise and grouped into only two statutory sections.⁴⁴ The Patent Act of 1952 organized the statutory requirements into their present, individual sections. The specification requirement necessitates that the specification “contain a written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same.”⁴⁵ This requirement also mandates that “[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor . . . regards as the invention.”⁴⁶ The invention must also be novel⁴⁷ and non-obvious to a person having ordinary skill in the art.⁴⁸

Additionally, an invention must satisfy the eligibility requirement of section 101 to be considered patentable.⁴⁹ Section 101 of the patent statute provides: “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”⁵⁰ Thus, to satisfy the eligibility requirement an invention must possess utility and be directed to eligible subject matter. The eligibility requirement is also referred to as patent-eligibility or the patent-eligible subject matter requirement.

The legislative history of the 1952 Patent Act reveals that section 101 merely identifies subject matter that may be patented, if the other

41. 35 U.S.C. § 111 (2012).

42. See *Patent Process Overview*, USPTO, <https://www.uspto.gov/patents-getting-started/patent-basics/types-patent-applications/utility-patent/patent-process-0> [<https://perma.cc/GB3B-LXYE>] (last modified Nov. 24, 2014) (outlining the process for obtaining a patent).

43. Pub. L. No. 82-593, 66 Stat. 792 (1952) (codified as amended at 35 U.S.C. §§ 1–390 (2012)).

44. Act of Apr. 10, 1790, ch. 7 §§ 1–2, 1 Stat. 109 (“[P]romot[ing] the progress of useful Arts”) (codified as amended at 35 U.S.C. §§ 100–105 (2012)).

45. 35 U.S.C. § 112(a) (2012).

46. § 112(b).

47. § 102.

48. § 103.

49. § 101.

50. § 101.

statutory requirements of the patent statute, such as novelty, are satisfied. Furthermore, “the drafters explained that while [section] 101 would still include the word ‘new,’ [section] 102 [novelty] provides ‘in effect, an amplification and definition of “new” in [section] 101.’”⁵¹

Satisfaction of section 101 alone is, therefore, not sufficient to grant an invention patent protection. After an invention satisfies the eligibility requirement, it must still be found to be novel and non-obvious as compared to prior art. To evaluate if an invention is patent eligible, one must understand the role of each section of the Patent Act and view each requirement in the context of the patent statute as a whole. It is not the sole job of section 101 to eliminate patentability for unmeritorious claims. Consequently, “there is no need to twist the language of [section] 101 for policy reasons to ensure that unmeritorious inventions are not patentable.”⁵² Rather, section 101 was meant to be the first stepping stone in determining if an invention is patent eligible.

However, case law has imposed more stringent restrictions on patent-eligible subject matter. Since the 1800s, courts have recognized exceptions to what subject matter is considered patent eligible. Notably, laws of nature, natural phenomena, mental steps, and mathematical algorithms are not considered to be directed to patent-eligible subject matter.⁵³ Courts have struggled, however, with determining what is a patent-eligible invention and an unpatentable principle since the beginning of the patent system.⁵⁴ This struggle has led the Supreme Court to take conflicting approaches to analyzing patent eligibility over the years.⁵⁵

51. David O. Taylor, *Confusing Patent Eligibility*, 84 TENN. L. REV. 157, 173 (2016).

52. *Id.* at 175.

53. Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591, 596 (2008) (citing multiple sources).

54. Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565, 566 (2015).

55. See, e.g., Michael A. Sanzo, *Patent Eligibility in Biotechnology: A Look Under the Hood*, 45 AIPLA Q.J. 1, 2 (2017) [hereinafter Sanzo, *Patent Eligibility*]; Michael A. Sanzo, *The Patenting of Gene Based Diagnostic Assays in a Post Mayo and Myriad World*, 16 J. MARSHALL REV. INTELL. PROP. L. 1 (2016) (discussing the Supreme Court’s inconsistent treatment of patent-eligible subject matter in different cases).

III. JUDICIAL TREATMENT OF ELIGIBLE SUBJECT MATTER

The Supreme Court's conflicting approach to the eligibility requirement is exemplified in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*⁵⁶ and *Diamond v. Chakrabarty*.⁵⁷

A. Funk Brothers Approach to Eligible Subject Matter

The *Funk Brothers* approach to analyzing patent eligible subject matter begins with analyzing each element of a claim individually to determine if the element encompasses an abstract idea, natural phenomenon, or law of nature. If one of these judicial exceptions is present in any individual element of the claim, the court determines if any other element of the claim conveys an inventive concept.⁵⁸ This approach to analyzing eligible subject matter has essentially been adopted by the Supreme Court in its *Mayo/Alice* framework.⁵⁹

The patent at issue in *Funk Brothers* claimed an inoculant comprised of a variety of different bacteria that had been individually isolated and recombined based on their compatibility.⁶⁰ The claimed inoculant was able to infect various types of leguminous plants and fix nitrogen to promote the plants' growth.⁶¹

While the *Funk Brothers* case was decided prior to the adoption of the modern patent statute, the Court's analysis seems to be clearly directed to patent eligibility.⁶² The Court found the patent claims at issue unpatentable, and therefore invalid, because "[t]heir qualities are the work of nature."⁶³ The qualities of the claimed bacteria were, the Court reasoned, "part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none."⁶⁴ The Court further found that a discovery of a law of nature only results in an invention if the law of nature is applied to "a new and useful end."⁶⁵

As the opinion continues, however, the Court's focus on patent eligible subject matter begins to overlap with the requirements of

56. 333 U.S. 127 (1948).

57. 447 U.S. 303 (1980).

58. *Funk Bros.*, 333 U.S. at 130.

59. Sanzo, *Patent Eligibility*, *supra* note 55, at 2.

60. *Funk Bros.*, 333 U.S. at 129–30.

61. *Id.* at 128–29.

62. Sanzo, *Patent Eligibility*, *supra* note 55, at 5.

63. *Funk Bros.*, 333 U.S. at 130.

64. *Id.*

65. *Id.*

novelty and non-obviousness. The Court found that the combination of the bacteria claimed did not result in any species of bacteria acquiring a different use and that each species maintained its original function.⁶⁶ This analysis seems to be directed to the concept of non-obviousness. An invention is obvious if it is a “combination of familiar elements according to known methods” that “does no more than yield predictable results.”⁶⁷ The Court goes on to analyze the novelty of the claimed bacteria combination, noting that while new, the claimed combination was still unpatentable.⁶⁸ The Court’s analysis suggests the concepts of novelty and non-obviousness, or “inventiveness,” and patent-eligible subject matter are considered jointly. This joint consideration of these distinct patentability requirements is unsurprising for the time, as these concepts were not separated into individual statutory requirements until four years after *Funk Brothers* was decided.⁶⁹ However, later decisions have continued to assume that these requirements are connected.⁷⁰

The Supreme Court’s decision in *Funk Brothers* caused a great deal of alarm in the patent community, particularly among those in the pharmaceutical industry. The patent community recognized that *Funk Brothers* required an inventive application as a condition of patentability, which departed from the historical standard of patent eligibility.⁷¹ The pharmaceutical industry was so concerned by *Funk Brothers* that it raised the issue in the hearings preceding the adoption of the 1952 Patent Act.⁷² A representative of the pharmaceutical industry urged Congress to clarify that newly discovered laws of nature remained patentable if they were embodied in new and useful applications.⁷³ While never explicitly stated, it is believed that with the adoption of sections 100 and 101 of the 1952 Patent Act, Congress intended to overrule *Funk Brothers*.⁷⁴ In section 100, Congress defined “invention” as an “invention or discovery.”⁷⁵ Additionally, the term

66. *Id.* at 131.

67. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

68. *Funk Bros.*, 333 U.S. at 131–32.

69. *Sanzo, Patent Eligibility*, *supra* note 55, at 5.

70. *Id.*

71. *Lefstin*, *supra* note 54, at 631–32.

72. *Id.* at 632.

73. *Id.* (citing *Patent Law Codification and Revision: Hearing on H.R. 3760 Before Subcomm. No. 3 of the Comm. on the Judiciary*, 82nd Cong. 116–18 (1951)) (statement of I. J. Fellner, Manager, Patent Department, Dr. Salsbury’s Laboratories).

74. *Id.* at 633–34.

75. 35 U.S.C. § 100(a) (2012).

“process” was defined as a “process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”⁷⁶ The definitions laid out in this section of the 1952 Patent Act suggest that Congress heeded the warning of the pharmaceutical industry and abolished the inventive application required by *Funk Brothers*.⁷⁷

While it appears that Congress intended to overrule *Funk Brothers* when adopting the 1952 Patent Act, the Supreme Court continued to apply a *Funk Brothers* type of analysis when determining patent eligibility. In *Parker v. Flook*,⁷⁸ the Supreme Court persisted in its belief that patent eligibility and “inventiveness” are connected.⁷⁹ The claims in *Flook* were directed to a method for updating alarm limits. The only novel feature of the method, according to the Court, was a mathematical formula. The Court then analyzed whether the application of this formula made the claims eligible for patent protection.⁸⁰ The Court determined that the approach taken in *Funk Brothers* was the appropriate analysis for the *Flook* claims. The Court went on to find that the novelty of the mathematical formula is not a determining factor in patent eligibility, rather the process itself must be new and useful.⁸¹ The Court, therefore, analyzed the claims after excluding the mathematical formula and found them invalid because they contained no patentable invention.⁸²

Foreshadowing the response to the *Mayo/Alice* test, *Flook* argued that the Court’s analysis of patent-eligible subject matter improperly imported the concerns of sections 102 and 103 into its section 101 analysis.⁸³ The Court rejected this argument, finding that it was “based on two fundamental misconceptions.”⁸⁴ First, the Court stated that a narrow reading of section 101 was untenable because it would make a determination of patent eligibility depend on “draftsman’s art.”⁸⁵ Such an interpretation would not, according to the Court, serve the principles underlying the exclusion of patents on abstract ideas, laws of nature, and natural phenomena. The Court ignored the definition of invention

76. § 100(b).

77. Lefstin, *supra* note 54, at 634.

78. 437 U.S. 584 (1978).

79. Sanzo, *Patent Eligibility*, *supra* note 55, at 7.

80. *Flook*, 437 U.S. at 585.

81. *Id.* at 591.

82. *Id.* at 594.

83. *Id.* at 592–94.

84. *Id.* at 592.

85. *Id.* at 593.

and discovery outlined by Congress in section 100 of the 1952 Patent Act and reasoned, “[t]he rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of ‘discoveries’ that the statute was intended to protect.”⁸⁶ Second, the Court found that *Flook*’s argument was based on the flawed belief that the claim was rejected merely for the fact that one component consisted of unpatentable subject matter.⁸⁷ *Flook* argued that the Court’s analysis was inconsistent with decisions by the Court of Customs and Patent Appeals (the precursor to the Federal Circuit) that required claims to be considered as a whole. The Court maintained that, despite considering the individual elements of the claim without accounting for the mathematical formula, the claims were analyzed as a whole.⁸⁸

The approach to patent-eligible subject matter established in *Funk Brothers* and *Flook* blurred the line between patent eligibility and inventiveness. These cases made clear that inventiveness, while closely related to the concepts of novelty and non-obviousness, differs from these requirements because all the elements of the claim are not considered when determining inventiveness.⁸⁹ Elements present in the claim that are found to be excluded from section 101 are not taken into account when evaluating the inventiveness of the claim.⁹⁰

B. Chakrabarty Approach to Eligible Subject Matter

Just two years after deciding *Flook*, the Court took a different approach to analyzing patent-eligible subject matter in *Diamond v. Chakrabarty*.⁹¹ Chakrabarty invented a human-made, genetically engineered bacterium capable of breaking down crude oil. The ability to break down crude oil is not possessed by any naturally occurring bacteria, making Chakrabarty’s invention significantly valuable in treating oil spills.⁹²

Unlike its opinion in *Flook*, the Court in *Chakrabarty* began its analysis with a construction of 35 U.S.C. § 101. The Court determined, based on the text of the statute, as well as the legislative history, that “Congress plainly contemplated that the patent laws would be given wide scope” and “include anything under the sun that is made by

86. *Id.*

87. *Id.* at 593–94.

88. *Id.* at 594.

89. Sanzo, *Patent Eligibility*, *supra* note 55, at 6.

90. *Id.*

91. 447 U.S. 303 (1980).

92. *Id.* at 305.

man.”⁹³ Despite interpreting section 101 to have a wide scope, the Court acknowledged that section 101 has limits and does not embrace every discovery. Consequently, “a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not have patented his celebrated $E = mc^2$; nor could Newton have patented the law of gravity.”⁹⁴

After its statutory interpretation, the Court proceeded to analyze the claims of the patent. Unlike in *Funk Brothers* and *Flook*, however, the Court analyzed the claims in their entirety and not the individual elements of the claims. Consequently, the Court found that the claims “plainly qualif[y] as patentable subject matter” because they were directed to a non-naturally occurring manufacture or composition of matter.⁹⁵ In finding the claims patent eligible, the Court focused on the significant amount of human intervention in the claims, as well as the markedly different characteristics of the bacteria from any found in nature and the significant utility of the claimed bacteria.⁹⁶

Despite the differences in analysis between *Chakrabarty* and *Funk Brothers/Flook*, the Court fails to acknowledge these differences. Rather, the Court attempts to distinguish the cases based on factual differences.⁹⁷ The Court reasoned that the claims in *Funk Brothers* were directed to bacteria that existed in nature, while the bacterium claimed in *Chakrabarty* was not found in nature.⁹⁸ This analysis fails to recognize, however, that the bacteria in *Funk Brothers* were a component of the claimed invention, not the invention itself. The individual strains of bacteria in the *Funk Brothers* claim are, therefore, analogous to the genes used to create the bacterium in *Chakrabarty*. The distinction between *Funk Brothers* and *Chakrabarty*, therefore, lies in how the claims are analyzed and not the factual distinctions between the cases.⁹⁹

The *Chakrabarty* approach to patent-eligible subject matter was also embraced by the Court one year later in *Diamond v. Diehr*.¹⁰⁰ The claims in *Diehr* were directed to a process for curing synthetic rubber. The Court found the process in *Diehr* directed to patent-eligible subject matter because, while the claims employed a mathematical equation, they were not directed solely to the equation. The claims did not

93. *Id.* at 307–09.

94. *Id.* at 309.

95. *Id.*

96. *Id.* at 310.

97. Sanzo, *Patent Eligibility*, *supra* note 55, at 9–10.

98. *Chakrabarty*, 447 U.S. at 310.

99. Sanzo, *Patent Eligibility*, *supra* note 55, at 9–10.

100. 450 U.S. 175 (1981).

preempt every use of the equation, rather the claims only foreclosed use of the equation in combination with the other steps of the process.¹⁰¹ After finding the claims directed to patent-eligible subject matter, the Court explicitly stated the need to analyze claims as a whole when determining patent eligibility. Furthermore, the need to analyze claims as a whole is particularly relevant in a process claim “because a new combination of steps in a process may be patentable even though all the constituents of the combination are well known and in common use before the combination was made.”¹⁰² While this *Chakrabarty* whole-claim approach to patent-eligibility analysis remains contradictory to the *Funk Brothers/Flook* approach, the Court again attempted to distinguish these cases based on factual differences.¹⁰³ The Court fails to realize, however, that the claims in *Flook* may be found valid as directed to an improvement in a process under the *Chakrabarty/Diehr* approach. The difference in outcome between *Diehr* and *Flook*, thus, appears to be based on the analytical approach and not factual differences between the cases.¹⁰⁴

C. *The Federal Circuit's Interpretation of Conflicting Supreme Court Precedent*

For the next three decades the Supreme Court did not address eligible subject matter. During this time, the Federal Circuit searched for a workable test, consistent with the Supreme Court's conflicting precedent, to determine if a claim was directed to patent-eligible subject matter.¹⁰⁵ Ultimately, the Federal Circuit adopted the “machine-or-transformation” test as the sole test for determining patent eligibility. The Federal Circuit believed this test was consistent with Supreme Court's fluctuating precedent on patent-eligible subject matter.¹⁰⁶ Under the “machine-or-transformation” test, an invention is directed to patent-eligible subject matter if it is tied to a particular machine or it transforms a particular article into a different state or thing.¹⁰⁷

The Supreme Court, however, did not agree that the “machine-or-transformation” test was the sole means for determining patent-eligible

101. *Id.* at 187.

102. *Id.* at 188.

103. *Id.* at 185–87.

104. Sanzo, *Patent Eligibility*, *supra* note 55, at 5.

105. Gruner, *supra* note 28, at 583–92.

106. *Id.* at 590. See generally Benjamin J. McEniery, *The Federal Circuit in Bilski: The Machine-or-Transformation Test*, 91 J. PAT. & TRADEMARK OFF. SOC'Y 253 (2009) (discussing the Federal Circuit's adoption of the machine-or-transformation test).

107. *In re Bilski*, 545 F.3d 943, 961 (Fed. Cir. 2008).

subject matter. In *Bilski v. Kappos*,¹⁰⁸ the Court explicitly rejected the test as the sole means of determining patent-eligible subject matter. The “machine-or-transformation” test was, according to the Court, merely a helpful clue in determining patent eligibility.¹⁰⁹ Despite rejecting the test as the sole means of determining patent eligibility, the Court did not provide any additional guidance in how to analyze patent eligibility, and merely referred back to its prior patent-eligibility case law.¹¹⁰ After *Bilski*, however, the Court appeared to develop a renewed interest in patent eligibility and issued four opinions on the subject within four years.¹¹¹ These decisions culminated with the Court’s adoption of the *Mayo/Alice* two-step approach to analyzing patent-eligible subject matter.

IV. THE MAYO/ALICE TWO-STEP

In 2012, the Court issued a highly anticipated opinion in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,¹¹² a decision many in the patent community hoped would clarify how to analyze patent eligibility. *Mayo* concerned two patents directed towards the use of thiopurine drugs in the treatment of autoimmune disorders.¹¹³ The claims were directed to three steps: administering the drug, determining the amount of the drug in a patient’s blood sample, and a “wherein” step that correlates the drug level with a need to increase or decrease the amount of drug administered to the patient.¹¹⁴

In analyzing the claims, the Court first found that the patents “set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of thiopurine drug will prove ineffective or cause harm.”¹¹⁵ The Court then looked to see if the claims “do significantly more than simply describe the natural relations.”¹¹⁶ In analyzing this question, the Court found that the claims do not add significantly more to the law of nature:

108. 561 U.S. 593 (2010).

109. *Id.* at 604.

110. Gruner, *supra* note 28, at 592.

111. See generally *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012); *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347 (2014).

112. 566 U.S. 66 (2012).

113. *Id.* at 73.

114. *Id.* at 74–75.

115. *Id.* at 77.

116. *Id.*

“[T]he claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community”¹¹⁷ Additionally, “simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable.”¹¹⁸ What the Court failed to emphasize is that the steps in *Mayo* were “routine” and “conventional” because “scientists already understood that the levels in a patient’s blood of certain metabolites . . . were correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective.”¹¹⁹

The Court’s analysis of patent eligibility is driven by a concern of preemption. Consequently, claims that are directed to a law of nature, abstract idea, or natural phenomenon which preempt all other potential uses are not patent eligible.¹²⁰ The Court expresses concern that while granting patent rights for the discovery of new laws of nature may encourage their discovery, “there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them” and “otherwise foreclose[] more future invention than the underlying discovery could reasonably justify.”¹²¹

To support its preemption concern, the Court cites *O’Reilly v. Morse*.¹²² After inventing the telegraph, Morse attempted to claim the exclusive right to all devices using electricity to print characters at a distance.¹²³ The Court, however, held this claim invalid because it was too broad and preempted uses of the technology that Morse had not invented.¹²⁴ In *Mayo*, the Court uses this same logic to hold that the claims at issue preempt all uses of the law of nature and are invalid.¹²⁵ While the concern of preemption is valid, the reliance on *Morse* to support holding claims invalid under section 101 is misplaced. While *Morse* is concerned with preemption, the *Morse* Court anchors this concern in the requirements of written description and enablement, not in patent eligibility.¹²⁶

117. *Id.* at 79–80.

118. *Id.* at 82.

119. *Id.* at 73–74.

120. *Id.* at 85–87.

121. *Id.* at 86.

122. 56 U.S. (15 How.) 62 (1853).

123. *Id.* at 112.

124. *Id.* at 112–13.

125. *Mayo*, 566 U.S. at 86–87.

126. *Morse*, 56 U.S. (15 How.) at 113 (“[H]e claims an exclusive right to use a manner and process which he has not described and indeed had not

Despite outrage from the patent community following the decision in *Mayo*,¹²⁷ the Court doubled down on its two-step approach to eligible subject matter in *Alice Corp. v. CLS Bank International*.¹²⁸ The Court affirmed that the two-step approach established in *Mayo* was the appropriate test for all claims directed toward laws of nature, natural phenomena, and abstract ideas:

First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, “[w]hat else is there in the claims before us?” . . . We have described step two of this analysis as a search for an “inventive concept”—*i.e.*, an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.”¹²⁹

The Court continued to anchor the concern behind the exclusionary principle that inventions must be directed to patent-eligible subject matter as one of preemption. The Court noted that “[l]aws of nature, natural phenomena, and abstract ideas are the basic tools of scientific and technological work. [M]onopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it, thereby thwarting the primary object of the patent laws.”¹³⁰ Notably, the Court cautioned:

[W]e tread carefully in construing this exclusionary principle lest it swallow all of patent law. At some level, “all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.” Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept.¹³¹

invented, and therefore could not describe when he obtained his patent.”); *see, e.g.*, Jacob Adam Schroeder, *Written Description: Protecting the Quid Pro Quo Since 1793*, 21 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 63, 73–75 (2010) (discussing the historical development of 35 U.S.C. § 112).

127. *See, e.g.*, Gene Quinn, *Killing Industry: The Supreme Court Blows Mayo v. Prometheus, IPWATCHDOG* (Mar. 20, 2012), <http://www.ipwatchdog.com/2012/03/20/supreme-court-mayo-v-prometheus/id=22920/> [https://perma.cc/UR3X-S5Q5] (discussing how the Court’s decision in *Mayo* failed to take basic patent law principles into account and explaining why the case was wrongly decided).

128. 134 S. Ct. 2347 (2014).

129. *Id.* at 2355 (alteration in original) (citations omitted).

130. *Id.* at 2354 (internal quotations and citations omitted).

131. *Id.* at 2354 (citations omitted).

However, application of the *Mayo/Alice* two-step has proceeded to swallow biotechnology patents whole.¹³²

V. TWO-STEPPING THROUGH THE PATENT-ELIGIBILITY WASTELAND

Since the development of the *Mayo/Alice* two-step, patents are being rejected and invalidated at an alarming rate. The deleterious effects of the *Mayo/Alice* framework are being felt from the USPTO¹³³ to the Federal Circuit.¹³⁴

*Ariosa Diagnostics, Inc. v. Sequenom, Inc.*¹³⁵ is frequently cited as a clear illustration of the negative effect of the *Mayo/Alice* test on biotechnology patents.¹³⁶ The Federal Circuit held Sequenom's invention¹³⁷ invalid for not satisfying section 101 as analyzed under the *Mayo/Alice* framework, despite finding the invention "a significant contribution to the medical field."¹³⁸ The Federal Circuit found Sequenom's patent directed to a natural phenomenon—the presence of cffDNA in maternal plasma.¹³⁹ Consequently, the court proceeded to analyze the claims for an inventive step sufficient to transform the

132. See *infra* Parts VI–VIII.

133. See, e.g., James Cosgrove, § 101 Rejections in the Post-Alice Era, IPWATCHDOG (Mar. 7, 2017), <http://www.ipwatchdog.com/2017/03/07/101-rejections-post-alice-era/id=78635/> [<https://perma.cc/NV9A-FHDP>] (analyzing the increase in section 101 rejections issued by the USPTO post-*Alice* and the success rate of overcoming section 101 rejections).

134. See, e.g., Paul R. Gugliuzza & Mark A. Lemley, *Can a Court Change the Law by Saying Nothing?*, 71 VAND. L. REV. 765, 767 (2018) (stating that in post-*Alice* patent-eligible subject matter cases, the Federal Circuit has found only 7.7 percent of challenged patents valid).

135. 788 F.3d 1371 (Fed. Cir. 2015).

136. See, e.g., Gene Quinn, *Supreme Court Denies Cert. in Sequenom v. Ariosa Diagnostics*, IPWATCHDOG (June 27, 2016), <http://www.ipwatchdog.com/2016/06/27/70409/id=70409/> [<https://perma.cc/5YBF-9KPX>] (discussing how the Supreme Court denied certiorari despite the harm to the life sciences that the Federal Circuit's decision caused); Michael J. Flibbert & Emily R. Gabranski, *Ariosa Diagnostics v. Sequenom Among the Most Important Federal Circuit Decisions from 2015*, FINNEGAN: FED. CIR. IP BLOG (Jan. 8, 2016), <https://www.finnegan.com/en/insights/blogs/federal-circuit-ip/ariosa-diagnostics-v-sequenom-among-the-most-important-federal-circuit-decisions-from-2015.html#page=1> [<https://perma.cc/W934-CSYJ>] (discussing the importance of the *Ariosa* decision and how it could result in natural product and diagnostic method patents becoming more difficult to obtain and enforce).

137. See *supra* notes 1–13 and accompanying text.

138. *Ariosa*, 788 F.3d at 1379–80.

139. *Id.* at 1376.

naturally occurring phenomenon into a patentable invention. The Federal Circuit held that the steps of DNA amplification and detection were “well-understood, routine, and conventional activity” at the time the method was developed.¹⁴⁰ Consequently, the method “amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA.”¹⁴¹ Additionally, the Federal Circuit held “the only subject matter new and useful as of the date of the application was the discovery of the presence of cffDNA in maternal plasma or serum.”¹⁴² Furthermore, despite the Supreme Court’s emphasis on preemption driving the need for the *Mayo/Alice* test, the Federal Circuit found Sequenom’s argument that the claims of the patent have a narrow preemptive scope unpersuasive.¹⁴³

Judge Linn wrote a concurring opinion in which he agreed with the majority’s analysis under the *Mayo/Alice* test but expressed strong disapproval of the test and its result.¹⁴⁴ Linn criticized the *Mayo/Alice* two-step as overly broad and resulting in the invalidation of otherwise valid, meritorious patents.¹⁴⁵ Linn aptly noted that the claims at issue in Sequenom’s patent were unlike those in *Mayo*, because “*no one* was amplifying and detecting paternally inherited cffDNA using the plasma or serum of pregnant mothers.”¹⁴⁶ Consequently, Linn felt that Sequenom’s patent was “truly meritorious” and “deserving of patent protection.”¹⁴⁷

Sequenom appealed the Federal Circuit’s decision to the Supreme Court. Bolstered by Judge Linn’s critical concurring opinion, many in the patent community were hopeful the Supreme Court would grant certiorari.¹⁴⁸ In a decision that shocked many in the biotechnology and patent community, the Supreme Court denied certiorari.¹⁴⁹

140. *Id.* at 1377.

141. *Id.*

142. *Id.*

143. *Id.* at 1378–79.

144. *Id.* at 1380 (Linn, J., concurring).

145. *Id.* at 1380–81.

146. *Id.* at 1381.

147. *Id.*

148. See David Tellekson & Jessica Kaempf, *Litigation Alert: Federal Circuit’s Ariosa Decision, Good Chance for Rehearing En Banc*, FENWICK & WEST LLP (Nov. 4, 2015), <https://www.fenwick.com/publications/pages/federal-circuits-ariosa-decision.aspx> [<https://perma.cc/N8ZP-3A6M>] (stating that Judge Linn’s concurrence may be an invitation for further clarity from the Supreme Court regarding patent eligibility).

149. *Id.*

Ariosa is merely one example of truly meritorious, life-saving patents that have been refused patent protection by the USPTO or invalidated by the courts under the *Mayo/Alice* two-step.¹⁵⁰ These inventions are often directed to innovations that vastly improve diagnostics and treatments. The Patent and Trial Appeal Board (PTAB) has relied on the *Mayo/Alice* two-step to reject a method for diagnosing Alzheimer's disease.¹⁵¹ The method, based on measuring the amount of a metabolite in the cerebrospinal fluid of a subject, shows enhanced specificity and sensitivity over prior Alzheimer's diagnostic methods.¹⁵² The PTAB found the relationship between the metabolite level and Alzheimer's disease to be a law of nature. In its search for an inventive concept, the PTAB dissected and analyzed each element of the claims and found that the additional claimed steps were routine or conventional and did not amount to significantly more than the law of nature itself.¹⁵³

The groundbreaking cancer diagnostic method, BRCA testing, has also been held invalid as being directed to patent-ineligible subject matter. Certain mutations in the BRCA1 and BRCA2 genes are linked to the development of breast and ovarian cancer. By testing for mutations in the BRCA genes, doctors can often determine an individual's risk for developing breast or ovarian cancer.¹⁵⁴ Consequently, BRCA testing has become a critical tool in determining an individual's cancer risk.¹⁵⁵ In *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation*,¹⁵⁶ however, the Federal Circuit invalidated this meritorious diagnostic method.

The Federal Circuit analyzed the claims using the *Mayo/Alice* two-step. Under the first step of the test, the court held that the method claims recited an abstract mental process of comparing and analyzing

150. See, e.g., Chao, *supra* note 15 (discussing how in the wake of the Supreme Court's recent decisions regarding patent-eligible subject matter many patents that rely upon a law of nature have been declared patent-ineligible).

151. *Ex parte Myint*, No. 2013-009161, 2015 WL 5272660 (P.T.A.B. Aug. 26, 2015).

152. U.S. Patent Pub. No. 2011/0065202, at [0003] (filed Mar. 17, 2011).

153. *Myint*, No. 2013-009161, slip op. at 7–8.

154. *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 758 (Fed. Cir. 2014).

155. See *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NIH: NATIONAL CANCER INST., <https://www.cancer.gov/about-cancer/causes-prevention/genetics/brca-fact-sheet> [<https://perma.cc/F48H-99LV>] (last updated Jan. 30, 2018) (explaining the association of the BRCA genes with cancer risk, the process of BRCA testing, and who should get tested).

156. 774 F.3d 755 (Fed. Cir. 2014).

different gene sequences.¹⁵⁷ Proceeding to step two, the court dissected the claims into individual elements and held that the patent-eligible elements of the claims were not sufficient to make the claims, as a whole, patent-eligible; the techniques used to amplify and analyze the BRCA sequences were routine and ordinary.¹⁵⁸ Consequently, the Federal Circuit held that the method claims were invalid as being directed to patent-ineligible subject matter.¹⁵⁹

The invalidation of the BRCA patents was a particularly stinging blow as it came after the Supreme Court suggested such method claims would be patent-eligible. In *Association for Molecular Pathology v. Myriad Genetics, Inc.*,¹⁶⁰ the Court analyzed the eligibility of claims directed to the BRCA gene sequences. The Court held that the naturally occurring DNA sequence of the gene is a product of nature and not patent-eligible.¹⁶¹ In its decisions, however, the Court noted that the case did not “involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes” and “[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications.”¹⁶² This statement by the Supreme Court was dismissed by the Federal Circuit during its analysis of the BRCA method claims. The Federal Circuit reasoned that no method claims were actually before the Supreme Court in the *Myriad* case. Furthermore, the Federal Circuit noted that the method claims contemplated to be patent-eligible in *Myriad* were narrower in scope than the claims currently before them.¹⁶³ This reasoning further underscores the driving concern of preemption in the *Mayo/Alice* analysis of patent eligibility.

In another recent blow to biotechnology and diagnostic patents, the Federal Circuit upheld a district court decision invalidating three Cleveland Clinic Foundation patents as being directed to patent-ineligible subject matter.¹⁶⁴ The patents claim methods of assessing a patient's risk of cardiovascular disease based on detection of

157. *Id.* at 763–64.

158. *Id.* at 764–65.

159. *Id.* at 765.

160. 133 S. Ct. 2107 (2013).

161. *Id.* at 2111.

162. *Id.* at 2120 (alteration in original) (quoting Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 689 F.3d 1303, 1349 (Fed. Cir. 2012) (Bryson, J., concurring in part and dissenting in part)).

163. *In re BRCA*, 774 F.3d at 765.

164. *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 2621 (2018).

myeloperoxidase (MPO), an early symptom of cardiovascular disease, in the patient's blood sample.¹⁶⁵ This new diagnostic method is a groundbreaking innovation and a substantial breakthrough in the early detection of cardiovascular disease.¹⁶⁶

The Federal Circuit applied the *Mayo/Alice* two-step analysis and determined the claims were directed to a law of nature—the presence of MPO correlates with cardiovascular disease.¹⁶⁷ Under step two, the Federal Circuit dissected the claims into individual elements and determined there was no inventive concept present because the claims used known techniques that were routine and conventional. These routine techniques, consequently, did not suffice to transform the claimed invention into a patentable method.¹⁶⁸

Despite the repeated focus on preemption driving the exclusionary principle of section 101, the Federal Circuit found no significance in the fact that the claims of Cleveland Clinic's diagnostic methods, analyzed as a whole, had a narrow preemptive scope.¹⁶⁹ The Federal Circuit focused instead on the individual elements of the claims and reasoned that, “[w]here a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, as they are in this case, preemption concerns are fully addressed and made moot.”¹⁷⁰

VI. DETERMINING PATENT ELIGIBILITY ON A MOTION TO DISMISS

Since the adoption of the *Mayo/Alice* two-step, patent eligibility has increasingly been decided on Rule 12(b)(6) motions.¹⁷¹ The Federal Circuit has repeatedly recognized that determination of patent eligibility under section 101 on a Rule 12(b)(6) motion is proper.¹⁷²

165. *Id.* at 1355.

166. Corrected Brief of Plaintiffs-Appellants at 56, *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017) (No. 16-1766).

167. *Cleveland Clinic Found.*, 859 F.3d at 1360.

168. *Id.* at 1362.

169. *Id.* at 1363.

170. *Id.* (quoting *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015)).

171. See, e.g., Edward Tulin & Leslie Demers, *A Look at Post-Alice Rule 12 Motions over the Last 2 Years*, LAW360 (Jan. 27, 2017); Michael Wilburn et al., *Pretrial Dismissals and Judgments in Post-Alice Courts*, LAW360 (Apr. 23, 2015), <https://www.law360.com/articles/642593/pretrial-dismissals-and-judgments-in-post-alice-courts> [<https://perma.cc/Z25A-NTCH>].

172. See *Genetic Tech. Ltd. v. Merial LLC*, 818 F.3d 1369, 1373–74 (Fed. Cir. 2016) (citing *OIP Tech., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1362 (Fed. Cir. 2015)); *Content Extraction & Transmission LLC v. Wells*

Based on Supreme Court precedent,¹⁷³ the Federal Circuit has treated patent eligibility as a threshold legal question based on the claims and not a predominantly factual inquiry.¹⁷⁴ The Federal Circuit has also stated, however, that subject-matter eligibility can be determined prior to any formal claim construction, noting that “claim construction is not an inviolable prerequisite to a validity determination under [section] 101.”¹⁷⁵

Determining patent eligibility on a motion to dismiss is believed to save the court and the parties time and money, increase judicial efficiency, and quickly dispose of weak patents which do not meet the statutory requirements for patentability.¹⁷⁶ The Federal Circuit has recently found, however, that determining patent eligibility before fact finding and claim construction may be problematic.¹⁷⁷ In *Berkheimer v. HP Inc.*,¹⁷⁸ the Federal Circuit found that while patent-eligible subject matter is a question of law, the question of whether a claim or claim element is well-understood, routine, or conventional is a factual determination.¹⁷⁹ Furthermore, a factual issue may arise where the specification demonstrates that the claims do not describe well-understood, routine, and conventional activities.¹⁸⁰ A finding of a factual dispute based on information provided in the specification goes against Federal Circuit precedent that patent eligibility can be determined by looking solely at the claims.¹⁸¹ This finding is consistent, however, with

Fargo Bank, Nat'l Ass'n, 776 F.3d 1343, 1351 (Fed. Cir. 2014); *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350, 1355 (Fed. Cir. 2014).

173. *Bilski v. Kappos*, 561 U.S. 593, 602 (2015); *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72–73 (2012).

174. Appellee's Petition for Rehearing En Banc at 8–9, *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. Mar. 12, 2018) (No. 17-1437).

175. *Merial*, 818 F.3d at 1374 (quoting *Bancorp Servs., LLC v. Sun Life Assurance Co. of Canada (U.S.)*, 687 F.3d 1266, 1273 (Fed. Cir. 2012)).

176. THE SEDONA CONFERENCE, THE SEDONA CONFERENCE COMMENTARY ON PATENT LITIGATION BEST PRACTICES: SECTION 101 MOTIONS ON PATENTABLE SUBJECT MATTER CHAPTER 2 (2016); Appellee's Petition for Rehearing En Banc at 15–16, *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. Mar. 12, 2018) (No. 17-1437).

177. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368–69 (Fed. Cir. 2018); *Aatrix Software, Inc. v. Green Shades Software*, 882 F.3d 1121, 1125–28 (Fed. Cir. 2018).

178. 881 F.3d 1360 (Fed. Cir. 2018).

179. *Id.* at 1368–69.

180. *Id.* at 1369.

181. See *supra* notes 171–175 and accompanying text.

the well-established standard that claims are interpreted in light of the specification.¹⁸²

Less than a week after issuing the *Berkheimer* decision, the Federal Circuit issued another opinion involving underlying issues of fact in patent eligibility in *Aatrix Software, Inc. v. Green Shades Software, Inc.*¹⁸³ The Federal Circuit reaffirmed that patent eligibility is a question of law with significant, subsidiary factual questions which must be resolved prior to making a legal determination.¹⁸⁴ In *Aatrix*, the Federal Circuit embraced the consideration of extrinsic evidence when determining patent eligibility. After acknowledging that whether a claim is well-understood or conventional, the Federal Circuit stated that, in the current case, this “question cannot be answered adversely to the patentee based on the sources properly considered on a motion to dismiss, such as the complaint, the patent, and materials subject to judicial notice.”¹⁸⁵

The recent acknowledgment by the Federal Circuit that patent eligibility is in part a fundamentally factual inquiry and that the *Mayo/Alice* two-step is based upon questions of fact appears at odds with other Federal Circuit decisions.¹⁸⁶ This conflicting approach was noted, in dissent, by Judge Reyna in *Aatrix*.¹⁸⁷ Judge Reyna stated that the Federal Circuit’s precedent makes clear that the section 101 inquiry is one of law.¹⁸⁸ Furthermore, shifting the section 101 analysis from a legal to a factual inquiry “opens the door in both steps of the *Alice* inquiry for the introduction of an inexhaustible array of extrinsic evidence, such as prior art, publications, other patents, and expert opinion.”¹⁸⁹ The discrepancy has resulted in heightened confusion in the already murky waters of patent-eligibility analysis as lower courts attempt to discern when patent-eligibility can be decided prior to fact finding.¹⁹⁰

182. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005).

183. 882 F.3d 1121 (Fed. Cir. 2018).

184. *Id.* at 1128.

185. *Id.*

186. *See, e.g.*, *OIP Tech., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359 (Fed. Cir. 2015) (reviewing a section 101 appeal as only an issue of law); *Intellectual Ventures I LLC v. Capital One Fin. Corp.*, 850 F.3d 1332 (Fed. Cir. 2017) (same).

187. *Aatrix*, 882 F.3d at 1130 (Reyna, J., dissenting).

188. *Id.*

189. *Id.*

190. *See, e.g.*, *Vaporstream, Inc. v. Snap Inc.*, No. 2-17-CV-00220-MLH (KSx), 2018 WL 1116530, at *6 (C.D. Cal. Feb. 27, 2018); *Sycamore IP Holdings LLC v. AT&T Corp.*, 294 F. Supp. 3d 620, 650 (E.D. Tex. 2018).

VII. DRAFTING AROUND THE TWO-STEP

The Federal Circuit recently provided a glimmer of hope for the patent eligibility of diagnostic methods and personalized methods. In *Vanda Pharmaceuticals v. West-Ward Pharmaceuticals International*,¹⁹¹ the Federal Circuit addressed the patent eligibility of claims that are very similar to the claims in *Mayo*. *Vanda Pharmaceuticals* is the owner of an exclusive license on a U.S. patent directed to a method of treating schizophrenics with the drug iloperidone, wherein the dosage is determined based on the patient's genotype.¹⁹² The cytochrome P450 2D6 gene (CYP2D6) encodes an enzyme which metabolizes numerous drugs, including iloperidone. Certain mutations in the CYP2D6 gene can result in lower CYP2D6 activity. A patient with lower CYP2D6 activity will be a poor metabolizer of drugs.¹⁹³ Based on this discovery, the patent at issue claims a method of treating poor metabolizers, identified through a genetic test, with lower doses of iloperidone.¹⁹⁴

While the claims in *Vanda* are similar to the patent-ineligible claims in *Mayo*, the Federal Circuit held the *Vanda* claims patent eligible.¹⁹⁵ Both the *Vanda* and *Mayo* claims correlate a patient's ability to metabolize a drug with the proper dosage for the individual.¹⁹⁶ Despite the similarities in the claims, the Federal Circuit found that, unlike *Mayo*, the *Vanda* claims did not set forth merely a natural law. Rather, the *Vanda* claims are directed to a method of treating schizophrenia based on genotyping. The Federal Circuit noted, "[t]he inventors recognized the relationship between iloperidone [and] CYP2D6 metabolism [], but that is not what they claimed. They claimed an application of the relationship. Unlike the claim at issue in *Mayo*, the claims here require a treating doctor to administer iloperidone."¹⁹⁷ While the claim in *Mayo* recited administering the drug to a patient, in *Vanda* "the claim as a whole was not directed to the administration of a drug to treat a particular disease."¹⁹⁸ The administering step in *Mayo*

191. 887 F.3d 1117 (Fed. Cir. 2018).

192. *Id.* at 1121.

193. *Id.*

194. *Id.*

195. *Id.* at 1136.

196. See Stephanie Sivinski, *Vanda v. West-Ward: This Time, Dosage Adjustment Claims Are Patent Eligible Subject Matter*, IPWATCHDOG (May 16, 2018), <https://www.ipwatchdog.com/2018/05/16/vanda-v-west-ward-dosage-adjustment-claims-patent-eligible/id=97117/> [<https://perma.cc/436S-KHTF>] (comparing the claims in *Mayo* and *Vanda*).

197. *Vanda*, 887 F.3d at 1135.

198. *Id.* at 1134.

was merely a limitation telling doctors to apply a known natural relationship and “the patent claims do not confine their reach to particular applications of those laws.”¹⁹⁹

Additionally, the *Vanda* claims do not preempt every use of the natural relationship between CYP2D6 and iloperidone metabolism. They “do not ‘tie up the doctor’s subsequent treatment decision.’”²⁰⁰ The *Mayo* claims, however, merely recognized a need to alter a dose based on drug metabolism. Thus, the *Mayo* claims did not actually involve doctors using the natural relationship between drug metabolism and dosage. The *Vanda* claims explicitly recite the limitation of carrying out a dosage regimen based on genotype testing.²⁰¹ The claims require a doctor to administer a certain amount of iloperidone if a patient is a poor metabolizer and a different amount if the patient is not a poor metabolizer. This limitation contrasts with the limitation in *Mayo*, which merely stated that thiopurine metabolism indicates a need to adjust the administered dosage.²⁰²

In dissent, Chief Judge Prost argued that the majority in *Vanda* did not heed the Supreme Court’s warning that patent eligibility should not depend on drafting efforts.²⁰³ Chief Judge Prost found that the addition of a treatment step with specific dosages of iloperidone was not sufficient to make the claims patent eligible and did not distinguish the claims from those in *Mayo*.²⁰⁴ Additionally, according to the Chief Judge Prost, while some methods of treatment may be patent eligible, the Federal Circuit “remain[s] beholden to the holding of *Mayo*, which [] requires [the Federal Circuit] to find the claims directed to a natural law at step one.”²⁰⁵ Furthermore, “the end result of the claimed process is no more than the conclusion of a natural law” and “[t]he recitation of the specific dosages adds no more than a conventional application of that natural law.”²⁰⁶ West-Ward filed a petition for writ of certiorari echoing Chief Judge Prost’s dissent and asking the Supreme Court to address whether “patents that claim a method of medically treating a

199. *Id.* at 1135 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 87 (2012)).

200. *Id.* at 1135 (quoting *Mayo*, 566 U.S. at 86).

201. *Id.*

202. *Id.*

203. *Vanda*, 887 F.3d at 1142 (Prost, C.J., dissenting).

204. *Id.* at 1142–43.

205. *Id.* at 1143.

206. *Id.*

patient automatically satisfy section 101 of the Patent Act, even if they apply a natural law using only routine and conventional steps.”²⁰⁷

If the Federal Circuit decision stands, *Vanda* sets a precedent that diagnostics may be patent eligible if they include a method of treatment step. In the wake of the *Vanda* decision, the USPTO issued a memorandum addressing the decision and its impact on the patent eligibility of method of treatment claims.²⁰⁸ The memorandum states that claims that include a method of treatment step should be considered patent eligible and are not directed to patent-ineligible subject matter.²⁰⁹ The *Vanda* decision, as well as the USPTO memo, imply that diagnostic claims, such as those in *Ariosa*²¹⁰ and *Cleveland Clinic*²¹¹ would have been patent eligible if the claims included a method of treatment step after diagnosis.

The *Vanda* decision has provided hope for the patent eligibility of diagnostic method claims, especially as the Federal Circuit has relied on *Vanda* to uphold the validity of claims including a method of treatment.²¹² However, it is too soon to determine the impact the case will have on the future of patent eligibility. The addition of a method of treatment step to make, an otherwise ineligible, claim patent-eligible, if reviewed by the Supreme Court, may be viewed as mere “draftsman’s art.” In *Mayo*, the Court cautioned that patent statutes should not be interpreted “in ways that make patent eligibility ‘depend simply on draftsman’s art’ without reference to the ‘principles underlying the prohibition against patents for [natural laws].’”²¹³

207. Petition for Writ of Certiorari, *Hikma Pharms. v. Vanda Pharms.*, 877 F.3d 1117 (2018) (No. 18-817).

208. U.S. Patent & Trademark Office, Memorandum on Recent Subject Matter Eligibility Decision: *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals* (June 7, 2018), <https://www.uspto.gov/sites/default/files/documents/memo-vanda-20180607.PDF> [<https://perma.cc/2SZQ-ESBH>].

209. *Id.* at 2–3.

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

211. *Cleveland Clinic Found. v. True Health Diagnostics*, 859 F.3d 1352 (Fed. Cir. 2017).

212. *Endo Pharm. Inc. v. Teva Pharm. USA, Inc.*, 919 F.3d 1347 (Fed. Cir. 2019); *Natural Alternatives Int’l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338 (Fed. Cir. 2019).

213. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72 (2012) (alteration in original) (quoting *Parker v. Flook*, 437 U.S. 584, 593 (1978)).

VIII. CONSEQUENCES OF NOT REPLACING THE *MAYO*/*ALICE* TWO-STEP

The *Mayo*/*Alice* two-step has bred uncertainty and fear in American inventors and investors. The uncertainty permeating the U.S. patent system has resulted in the United States continuing its fall in the ranks of global patent protection.²¹⁴ The United States is no longer the “gold standard” for patent protection and will likely continue its decline if some degree of certainty is not injected into what inventions are patent eligible.

Under the *Mayo*/*Alice* two-step, the oncomouse patent, a driving force behind the biotechnology boom in the United States,²¹⁵ would be invalid for being directed to patent-ineligible subject matter under section 101. Under the first step of the *Mayo*/*Alice* test, the claims are directed to a law of nature—the expression of oncogenes promotes the development of malignant tumors.²¹⁶ Proceeding to step two, the remaining elements of the claim recite routine, conventional activity—introducing an oncogene into germ cells and somatic cells in a non-human mammal.²¹⁷ Researchers had been introducing non-native DNA into cells through various methods for years prior to the development of the oncomouse.²¹⁸ Consequently, the additional elements of the oncomouse claims do not add sufficiently more to transform the patent-ineligible law of nature into a patent-eligible invention.

Even Chakrabarty's oil-destroying bacterium, which paved the way for the patenting of the oncomouse, would be ineligible under today's *Mayo*/*Alice* two-step.²¹⁹ This ineligibility would, furthermore, affect the majority of patents that paved the way for the biotechnology industry in the United States.²²⁰ Under today's patent-eligibility standards, revolutionary breakthroughs that sit at the leading edge of innovation are being denied patent protection in the United States. Many of these

214. See, e.g., Gene Quinn, *U.S. Patent System Falls to 12th Place in Chamber Global IP Index for 2018*, IPWATCHDOG (Feb. 8, 2018), <http://www.ipwatchdog.com/2018/02/08/u-s-patent-system-falls-12th-place-chamber-global-ip-index-2018/id=93494/> [https://perma.cc/9BLM-LTGY] (stating that the United States fell in the U.S. Chamber of Commerce's annual Global IP Index for the second year in a row).

215. See *supra* Part I.

216. U.S. Pat. No. 4,736,866 col. 1 ll. 37–42 (filed June 22, 1984).

217. *Id.* at col. 1 ll. 33–34.

218. *Id.* at col. 1 ll. 4–28.

219. See Brief of Dr. Ananda Chakrabarty as Amicus Curiae Supporting Petitioner at 11, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (Fed. Cir. 2015) (No. 15-1182).

220. *Id.*

innovations, however, are being protected in places such as Europe and China.²²¹ No longer the “gold standard” in patent protection, the United States has found itself in the same position as Europe when the Europe Patent Office hesitated to patent the oncomouse. As inventors and investors worry about protecting their intellectual property and recouping their investment, they are sending investments and innovations overseas to nations with stronger patent protection.²²² The uncertainty in patent eligibility is hampering the progress of diagnostic, medical, and life science developments in the United States at a time when the whole world is vying to lead the way in innovation.²²³

The overreach of the *Mayo/Alice* framework continues to cause upheaval and uncertainty for those seeking patent protection in the life sciences. The Supreme Court’s refusal to grant certiorari in a number of patent-eligibility cases suggests that the uncertainty, rejections, and invalidations will continue to plague life science patents. Without an intervention and change to the current *Mayo/Alice* two-step approach, the U.S. patent system will continue to weaken and we will hamper the progress of life-saving medical innovation.

IX. CORRECTING THE *MAYO/ALICE* TWO-STEP THROUGH STATUTORY AMENDMENT

Despite the need for a new patent-eligibility test, the Supreme Court appears hesitant to revisit the *Mayo/Alice* approach to eligible subject matter. Consequently, some in the patent community have begun advocating for Congress to overturn the *Mayo/Alice* two-step through statutory amendment.²²⁴ It is unlikely, however, that amending

221. Gene Quinn, *Have We Gone Too Far to Eradicate Weak Patents?*, IPWATCHDOG (Mar. 8, 2017), <http://www.ipwatchdog.com/2017/03/08/gone-too-far-eradicate-weak-patents/id=79248/> [https://perma.cc/6LVR-DTFE].

222. *See, e.g., id.*; Rana Foroohar, *A Better US Patent System Will Spur Innovation*, FIN. TIMES (Sept. 3, 2017), <https://amp.ft.com/content/74114a6c-8f28-11e7-9084-d0c17942ba93> [https://perma.cc/6CBD-5DTP].

223. Steve Brachmann, *Patent-Ineligibility of Medical Diagnostics, Life Sciences Discoveries Arrests U.S. Progress*, IPWATCHDOG (Jan. 7, 2018), <http://www.ipwatchdog.com/2018/01/07/patent-ineligibility-medical-diagnostics-life-sciences-discoveries/id=90805/> [https://perma.cc/8GET-4LQ].

224. *See, e.g.,* Taylor, *supra* note 51 (discussing the unworkability of the *Mayo/Alice* approach to eligible subject matter and proposing the time has come to amend the patent statute); David O. Taylor, *Amending Patent Eligibility*, 50 U.C. DAVIS L. REV. 2149 (2017) (discussing why the Supreme Court is unlikely to grant certiorari on a case involving patent eligibility and proposing legislative amendments to the patent statute); Gene Quinn, *IPO Adopts Resolution Supporting Legislation to Amend 35 U.S.C. § 101*, IPWATCHDOG (Jan. 31, 2017), <http://www>.

the patent statute will adequately solve the problems surrounding the Supreme Court's treatment of eligible subject matter.

The Supreme Court's repeated denial of certiorari in patent-eligibility cases has caused many in the patent community to lose hope that the Court will address patent eligibility in the foreseeable future.²²⁵ Hope that the Supreme Court will grant certiorari to address section 101 should not be abandoned quite yet, however. With the recent split in the Federal Circuit regarding the underlying factual issues in patent eligibility, the use of draftsman's art to make diagnostic method claims patent eligible, and the continued uncertainty surrounding patent eligibility, the time seems ripe for the Court to readdress patent-eligible subject matter. With multiple petitions for certiorari addressing patent eligibility currently pending before the Court, there is hope that the Court may find that the time has come to resolve the uncertainty surrounding patent eligibility.²²⁶ Furthermore, the Federal Circuit's split decision in *Vanda* seems likely to catch the Court's attention in light of their previous warning regarding draftsman's art in *Mayo*. A prominent patent law commentator has even called the *Vanda* decision "a high flaunting of Supreme Court precedent."²²⁷

An analysis of all of the Supreme Court's patent law cases since 2005 further supports the Supreme Court addressing patent eligibility in 2018; when there is patent-related legislation pending, the Supreme Court takes at least one provision from the pending legislation and implements it as law.²²⁸ There are currently multiple patent-related bills

ipwatchdog.com/2017/01/31/ipo-adopts-resolution-legislation-amend-101/id=77818/ [https://perma.cc/9TBA-CZST]; Robert Stoll, *Patent Bar Groups Propose Legislation to Fix Patent Subject Matter Eligibility Problems*, IPWATCHDOG (July 25, 2017), <http://www.ipwatchdog.com/2017/07/25/patent-bar-groups-propose-legislation-fix-patent-subject-matter-eligibility-problems/id=86015/> [https://perma.cc/H8LL-4TWR].

225. See, e.g., Quinn, *supra* note 136; Dennis Crouch, *Denied Certiorari on Section 101*, PATENTLYO (Oct. 2, 2017), <https://patentlyo.com/patent/2017/10/denied-certiorari-section.html> [https://perma.cc/97M7-DBLB]; Jeffrey A. Lefstin et al., *The Need for Legislative Reform: The Berkeley Section 101 Workshop*, PATENTLYO (Oct. 10, 2017), <https://patentlyo.com/patent/2017/10/legislative-berkeley-workshop.html> [https://perma.cc/PP4B-2EW3].

226. See, e.g., Petition for Writ of Certiorari, *Hikma Pharms. v. Vanda Pharms.*, 877 F.3d 1117 (No. 18-817); Petition for Writ of Certiorari, *Berkheimer v. HP Inc.*, 881 F.3d 1360 (Fed. Cir. 2018) (No. 18-415).

227. Dennis Crouch, *Vanda on Rehearing: Will the Federal Circuit Defy SCOTUS?*, PATENTLYO (June 27, 2018), <https://patentlyo.com/patent/2018/06/rehearing-federal-circuit.html> [https://perma.cc/NJM2-CFWC].

228. Paul Morinville & Gene Quinn, *Will the Supreme Court Continue to Be Influenced by Patent Reform?*, IPWATCHDOG (Jan. 2, 2018), <http://www.ipwatchdog.com/2018/01/02/supreme-court-influenced-patent-reform/id=91501/> [https://perma.cc/7W7T-WGG5].

pending in Congress, all of which tackle patent-eligibility reform, suggesting the Supreme Court may address patent eligibility in the near future.²²⁹

If the Supreme Court does grants certiorari in a patent-eligibility case, those advocating for a legislative amendment to the patent statute believe that stare decisis will prevent the Supreme Court from altering the *Mayo/Alice* framework.²³⁰ In *Kimble v. Marvel Entertainment, LLC*,²³¹ the Court addressed the role of stare decisis in the context of patent law. While *Kimble* addressed the issue of licensing fees for expired patents, and not statutory requirements for patentability, the Court emphasized stare decisis in deciding not to overrule established precedent in cases involving property law.²³² The refusal to overturn precedent went against overwhelming evidence that the precedent was wrongly decided.²³³ The Court quoted Justice Brandeis that “it is usually ‘more important that the applicable rule of law be settled than that it be settled right.’”²³⁴ To overturn precedent, the Court stated, there must be “‘special justification’—over and above the belief ‘that the precedent was wrongly decided.’”²³⁵ The Court repeatedly emphasized that it is the role of Congress and not the Court to “correct any mistake it sees” in the Court’s interpretation of a patent statute.²³⁶ Additionally, the Court noted that “the choice of what patent policy should be lies first and foremost with Congress.”²³⁷

The *Kimble* decision, however, does not destroy all hope of the Supreme Court changing its patent-eligibility precedent. The Court noted that the established precedent had not proved “unworkable,”²³⁸ which is a “traditional justification” for overruling precedent.²³⁹ Since the Court’s adoption of the *Mayo/Alice* two-step, the precedent has

229. *Id.*

230. See Taylor, *supra* note 224, at 2157–62 (discussing the Supreme Court’s treatment of stare decisis in patent law cases and why it is unlikely to change the *Mayo/Alice* framework).

231. 135 S. Ct. 2401 (2015).

232. *Id.* at 2405; see also Taylor, *supra* note 224, at 2159–60.

233. *Kimble*, 135 S. Ct. at 2412; Taylor, *supra* note 224, at 2159.

234. *Kimble*, 135 S. Ct. at 2409 (quoting *Burnet v. Coronado Oil & Gas Co.*, 285 U.S. 393, 406 (1932) (Brandeis, J., dissenting)).

235. *Id.* (quoting *Halliburton Co. v. Erica P. John Fund, Inc.*, 134 S. Ct. 2398, 2407 (2014)).

236. *Id.*

237. *Id.* at 2414.

238. *Id.* at 2411.

239. *Id.* (citing *Patterson v. McLean Credit Union*, 491 U.S. 164, 173 (1989)).

proved entirely unworkable.²⁴⁰ The *Mayo/Alice* test lacks administrability and has caused substantial confusion in patent eligibility. The test fails to provide objective guidelines and leaves the patent-eligibility determination to the subjective opinion of a judge or patent examiner.²⁴¹ The confusion caused by the *Mayo/Alice* test has even led one law professor to refer to the test as “gobbledygook,” a term borrowed from Justice Scalia in connection with another patentability test.²⁴² The unworkability of the current patent-eligibility test may provide the Supreme Court the “special justification” needed to overturn its wrongly decided precedent.

Furthermore, *Kimble* was not a unanimous decision; three justices dissented from the Court’s decision to uphold its established precedent.²⁴³ Justice Alito criticized the majority’s decision to employ *stare decisis* to “reaffirm a clear case of judicial overreach.”²⁴⁴ He cautioned that “*stare decisis* is not an ‘inexorable command.’”²⁴⁵ In an argument equally applicable to the *Mayo/Alice* precedent, Alito noted that the established precedent in *Kimble* created economic barriers that stifle innovation.²⁴⁶ Also, the *Kimble* precedent was based on policy-making more than actual interpretation of the Patent Act, so the Court should be more open to reconsidering the precedent.²⁴⁷ This argument is equally applicable to the patent-eligibility precedent—while the *Mayo/Alice* test appears to be an interpretation of section 101, the driving force behind the test was the Court’s concern with preemption.

240. See, e.g., Taylor, *supra* note 51, at 227–35; J. Gibson Lanier, *Further Guidance and the Light at the End of the Tunnel*, SMITH, GAMBRELL, & RUSSELL, LLP, <http://www.sgrlaw.com/further-guidance-and-the-light-at-the-end-of-the-tunnel/> [https://perma.cc/DF4V-5MNZ] (last visited Jan. 24, 2018); Alex E. Breger, *ABA Sends Letter to USPTO Director Proposing Amendment to Resolve Ambiguity in § 101 Statutory Interpretation*, LANDO & ANASTASI (Apr. 3, 2017), http://www.lalaw.com/news_resources/aba-letter-to-uspto-director/ [https://perma.cc/3RCQ-L8VG]; Gene Quinn, *Supreme Court “Abstract Idea Doctrine” Is Unworkable*, IPWATCHDOG (Feb. 13, 2014), <http://www.ipwatchdog.com/2014/02/13/supreme-court-abstract-idea-doctrine-is-unworkable/id=47980/> [https://perma.cc/4R8S-AHN2].

241. Taylor, *supra* note 51, at 227.

242. *Id.* (citing Transcript of Oral Argument at 41, *KSR Int’l v. Teleflex Inc.*, 550 U.S. 398 (2007) (No. 04-1350)).

243. *Kimble*, 135 S. Ct. at 2415 (Alito, J., dissenting).

244. *Id.*

245. *Id.* at 2417 (quoting *Payne v. Tennessee*, 501 U.S. 808, 828 (1991)).

246. *Id.*

247. *Id.* at 2418.

There has been a recent bipartisan push for a legislative solution to the issues surrounding patent eligibility.²⁴⁸ In April 2019, Senators Tillis and Coons, as well as Representatives Collins, Johnson, and Stivers, released a draft outline of a potential legislative reform to patent eligibility.²⁴⁹ The proposed framework is a positive step towards resolving the current problems with patent eligibility. The draft includes proposals that claims should be considered as a whole and that the words “new and useful” be removed from the statute and replaced with a simple requirement that the invention meet existing statutory utility requirements.²⁵⁰ However, some language in the draft may perpetuate the current issues with patent eligibility, rather than resolve them. For example, the framework proposes to “statutorily abrogate judicially created exceptions to patent eligible subject matter in favor of exclusive statutory categories of ineligible subject matter.”²⁵¹ The proposed statutory exceptions would include: fundamental scientific principles; products that exist solely and exclusively in nature; pure mathematical formulas; economic or commercial principles; and mental activities.²⁵² These proposed statutory exceptions closely mirror the current judicially created exceptions: abstract ideas, natural phenomena, and laws of nature. Therefore, claims that are currently rejected as being directed to natural phenomena or laws of nature will likely continue to be rejected as being directed to a fundamental scientific principle. The proposed framework also includes a “‘practical application’ test to ensure that the statutorily ineligible subject matter is construed narrowly.”²⁵³ However, the current *Mayo/Alice* approach is already supposed to be construed narrowly, to avoid swallowing all

248. Gene Quinn, *America's Patent System Favors the Few and Inhibits Innovation—But Change Could Be Coming*, IPWATCHDOG (Mar. 28, 2019), [https://www.ipwatchdog.com/2019/03/28/americas-patent-system-favors-the-few-inhibits-innovation-but-change-could-be-coming/id=107807/\[https://perma.cc/XZ96-D6PF\]](https://www.ipwatchdog.com/2019/03/28/americas-patent-system-favors-the-few-inhibits-innovation-but-change-could-be-coming/id=107807/[https://perma.cc/XZ96-D6PF]).

249. Press Release, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Section 101 Patent Reform Framework, Thom Tillis (Apr. 17, 2019), <https://www.tillis.senate.gov/public/index.cfm/press-releases?ID=B521846C-594A-46BE-B17A-0E11393D23AD> [https://perma.cc/SKA2-TH9E].

250. Draft Outline of Section 101 Reform, https://www.tillis.senate.gov/public/_cache/files/3491a23f-09c3-4f4a-9a93-71292704c5b1/outline-of-101-reform.pdf [https://perma.cc/JZE3-KXFL].

251. *Id.*

252. *Id.*

253. *Id.*

of patent law.²⁵⁴ Consequently, it seems unlikely that courts will narrowly construe the statutory exceptions when the current judicial exceptions are not narrowly construed. Furthermore, the framework includes the proposal that “simply reciting generic technical language or generic functional language does not salvage an otherwise ineligible claim.”²⁵⁵ This proposal echoes the Court’s finding in *Mayo* that “simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable.”²⁵⁶ Therefore, the amendment, as currently proposed, would likely be implemented in the same way the current *Mayo/Alice* test is implemented. Thus, the current proposed framework highlights the challenges that a legislative amendment is likely to face.

Resorting to legislative amendment in an attempt to fix patent eligibility will provide, at best, a temporary solution to the chaos of the *Mayo/Alice* two-step. In its implementation of the current patent-eligibility framework, the Court has largely ignored the text of section 101, as well as the role of the other sections of the Patent Act. The *Mayo/Alice* two-step, however, is grounded, not in a solid interpretation of section 101, but in the Supreme Court’s patent policy agenda of preventing preemption.²⁵⁷ The Court appears to believe that the current approach to patent eligibility is the only way to eliminate overly broad patents that preempt the building blocks of technology.²⁵⁸ Consequently, amending section 101 to overrule *Mayo* and *Alice* will not prevent the Supreme Court from interpreting the new statute in a manner that fits its policy agenda. This is of particular concern if the amendment incorporates language, as currently proposed, stating that generic technical or functional language will not salvage an otherwise ineligible claim.²⁵⁹ The Supreme Court has already embraced the idea that newly drafted patent statutes should be interpreted in a manner consistent with precedent; in *Flook*, the Supreme Court embraced the patent-eligibility standard developed in *Funk Brothers* in spite of the

254. *Alice Corp. v. CLS Bank, Int’l*, 134 S. Ct. 2347, 2354 (2014) (“we tread carefully in construing this exclusionary principle lest it swallow all of patent law”).

255. Draft Outline of Section 101 Reform, *supra* note 250.

256. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 82 (2012).

257. Taylor, *supra* note 51, at 188–91.

258. See Taylor, *supra* note 224, at 2172–82 (explaining the Supreme Court’s explicit rejection that the patent statute, rather than non-statutory exceptions to patent eligibility is sufficient to address the Court’s concern of preemption).

259. See *supra* notes 249–256 and accompanying text.

intervening passage of the 1952 Patent Act.²⁶⁰ The Court reasoned, “[i]t is our duty to construe the patent statutes as they now read, in light of our prior precedents.”²⁶¹ Similarly, a statutory amendment to section 101 is likely to be read in light of the Court’s prior precedent in *Mayo* and *Alice*. Consequently, any reference in an amendment which is suggestive of the Court’s current eligibility test is likely to be read into the new statute, even if that was not the intent of the drafters. This is even more likely, despite its insistence that Congress should determine patent policy, since the Court seems more than willing to set its own policy agenda in regards to patent eligibility.

CONCLUSION: REPLACING THE *MAYO*/*ALICE* TWO-STEP

In order to strengthen the U.S. patent system, encourage innovation, and foster advancements in life-saving technologies, a new standard for patent-eligibility needs to be established. To help ensure a stable, enforceable patent eligibility standard, the Supreme Court needs to realize the error in pushing their own policy on patent eligibility and replace the *Mayo*/*Alice* two-step with a new standard. This standard should be consistent with the text of section 101 and the Patent Act as a whole, as well as the patent policy embraced by Congress during the passage of the 1952 Patent Act.

In replacing the *Mayo*/*Alice* two-step, the Court needs to expressly overrule its decisions in *Mayo* and *Alice*. Any attempt by the Court to continue to reconcile its conflicting precedent will result in drastic variation in the application of any new test as lower courts grapple with how to reconcile conflicting precedent. This variation in application will result in continued uncertainty surrounding patent eligibility.

After overruling *Mayo* and *Alice*, the Court should establish a patent-eligibility test consistent with the *Chakrabarty*/*Diehr* precedent, which led to the rise of innovation and technology in the United States. The new eligibility test should depend on an analysis of the claims as a whole and not on individual claim elements. Under the new test, section 101 should function as a gate-keeper and very coarse preemption filter.

A determination of patent eligibility should begin with claim construction to determine the scope of the claims as a whole. The claims of a patent define a patentee’s property rights; they delineate what the invention is and what the patentee’s right to exclusion encompasses. Dissecting claims into individual elements in search of an inventive concept to transform patent-ineligible laws of nature into patent-eligible inventions ignores what the patentee is actually able to assert as a property right. If the driving force behind the exclusionary principle of section 101 is to prevent preemption of the basic building blocks of science and technology, the focus of the analysis should be on what the

260. See *supra* notes 78–90 and accompanying text.

261. *Parker v. Flook*, 437 U.S. 584, 596 (1978).

patentee's exclusionary right encompasses. The patentee does not have an exclusionary right in each individual element of a claim, the exclusionary right lies in the claim as a whole. Consequently, to determine if a claim preempts a law of nature or abstract idea, judges must evaluate what a patentee is able to exclude the public from doing in regards to the claimed invention.

The Court should also make clear that patent eligibility, while a legal question, has significant factual underpinnings. Dismissal or final judgment on claims prior to fact finding and formal claim construction is, therefore, improper. A correct understanding of the claims and the boundaries of a patentee's property rights is essential to determining if the claim is directed to a law of nature, abstract idea, or natural phenomena. Despite current precedent, it is inconsistent with other patent law principles to interpret claims in a vacuum with no reference to the patent specification or prior art. Claim language is given its ordinary and customary meaning as understood by a person having ordinary skill in the art (PHOSITA), in light of the specification.²⁶² In interpreting claims, it is appropriate to rely on intrinsic and extrinsic evidence.²⁶³ Claim construction carries significant importance considering that district judges, who are charged with claim construction,²⁶⁴ are not PHOSITAs and will likely not understand the ordinary and customary meaning of claim language without context. Even PHOSITAs must interpret the claim in light of the specification. Furthermore, district judges rarely have technical backgrounds, which would aid them in claim construction, and even judges with specialized technical backgrounds may struggle with understanding technology outside of their area of expertise. A thorough understanding of the claim and the boundaries of a patentee's property rights is critical to any analysis of patent validity.²⁶⁵

Despite the importance of claim construction, some commentators and practitioners continue to advocate that determining patent eligibility prior to proper claim construction is necessary to save resources and increase judicial efficiency.²⁶⁶ Courts should not, however, be invalidating meritorious patents in the name of increasing judicial efficiency. If increasing judicial efficiency in patent law cases is needed,

262. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005).

263. *Id.* at 1317.

264. *See Markman v. Westview Instruments*, 517 U.S. 370 (1996); *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015).

265. After all, "the name of the game is the claim." Giles S. Rich, *The Extent of the Protection and Interpretation of Claims-American Perspectives*, 21 INT'L REV. INDUS. PROP. & COPYRIGHT L. 497, 499 (1990).

266. *See supra* note 176 and accompanying text.

other solutions, which do not invalidate good patents, should be implemented to address these concerns.²⁶⁷

After claim construction, the Court should analyze patent eligibility by applying section 101 in the manner it was intended, as a coarse filter. Section 101 was not meant to be a burdensome, highly exclusionary test. Patent eligibility is the gateway to determining patentability and should let in everything except claims directed solely to the judicial exceptions of abstract ideas, laws of nature, or natural phenomenon; any applications of these exceptions, however, should be patent-eligible under section 101. The “machine-or-transformation” test, while not the only means of determining if a claim is directed solely to a judicial exception or an application of the exception, provides an important clue in this analysis. In readdressing patent eligibility, the Court should make clear that, despite pulling back on the *exclusive* use of the “machine-or-transformation” test in *Bilski*, the test is still applicable and should carry significant weight in determining eligibility.

Finding a claim patent-*eligible* under section 101, however, does not mean the claim is *patentable*. A claim must still satisfy the written description, enablement, novelty, and non-obviousness requirements of the Patent Act. These statutory requirements for patentability should do the bulk of the work of determining a claims’ patentability on their own and not be lumped into a section 101 analysis. While section 101 serves as a very coarse filter and excludes claims that attempt to preempt *every* use of a judicial exclusion, a finer tuned preemption analysis should be conducted under the written description and enablement requirement of section 112. As evidenced in *Morse*, which the Court has so heavily relied upon in pushing its current section 101 analysis, the written description and enablement requirement are aptly suited for determining the scope of a claim and controlling the preemption of basic scientific ideas. *Morse*’s claim was invalid, not for being directed to ineligible subject matter, but because *Morse* failed to describe and enable the claim. Thus, the Court should leave section 101 as a coarse filter to exclude claims that attempt to patent *every* use of a judicial exception and allow section 112 to address more nuanced concerns of claim scope and preemption.

Patent eligibility should, additionally, not be used to analyze the novelty or non-obviousness of a claim. These patentability requirements are established in sections 102 and 103, respectively, and should not be erroneously conflated with a patent-eligibility analysis under the guise of an “inventive concept.” As opposed to the vague “inventive concept” found in the *Mayo/Alice* test, which the Supreme Court admits

267. Increasing judicial efficiency may be better addressed through the patent pilot program or specialization of the patent court.

overlaps with novelty and non-obviousness,²⁶⁸ analysis under sections 102 and 103 is better defined and based on objective standards.²⁶⁹ The inventive concept should, therefore, be eliminated from eligibility analysis and this concern left to sections 102 and 103. While section 101 mentions “any *new* and useful process, machine, manufacture, or composition of matter,”²⁷⁰ the legislative history makes clear that the word “new” is duplicative of section 102, which outlines how to define novelty. The “inventive concept,” therefore, has no place in a patent eligibility analysis.

In determining patent eligibility, *Chakrabarty* focused on the level of human intervention in the claimed invention. The Court should re-embrace this element of the *Chakrabarty* approach to patent eligibility. Significant human intervention in a claim, along with the “machine-or-transformation” test, provides critical insight into whether a claim is directed solely to a patent-ineligible judicial exception. Furthermore, assessing human intervention is consistent with the intention of the drafters of the 1952 Patent Act that everything under the sun *made by man* is patent eligible.

The proposed patent-eligibility test effectively excludes claims directed solely to laws of nature, abstract ideas, and natural phenomena from patent protection. The test does, however, open the door to groundbreaking applications and uses of these ineligible concepts.

Under the proposed test, a claim directed to Einstein’s theory of relativity would be found patent ineligible. A hypothetical claim directed to the theory of relativity reads as follows:

A method for determining a kinetic energy E of a body, the method comprising the steps of:

Calculating a value c^2 , wherein the value c^2 is equal to the speed of light squared;

Multiplying the value c^2 by a value m , wherein the value m is equal to the mass of the body; and

Wherein the kinetic energy E of the body is equal to a product of the value c^2 multiplied by the value m .

The claim, analyzed as a whole, is directed to calculating kinetic energy, which encompasses both an abstract idea—the algorithm—and a law of nature—kinetic energy. This claim would be excluded under section 101’s coarse filter because it preempts every use of calculating

268. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 90 (2012).

269. *See Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342 (Fed. Cir. 1999); *Graham v. John Deere Co.*, 383 U.S. 1 (1966); *KSR Int’l v. Teleflex Inc.*, 550 U.S. 398 (2007).

270. 35 U.S.C. § 101 (2012) (emphasis added).

kinetic energy with the claimed algorithm. This claim illustrates, however, why no one tool for analyzing patent eligibility is dispositive; the claim is likely to pass the “machine-or-transformation” test because it “transforms” the raw data into a new form, the value of kinetic energy of a body. However, the claim preempts *every* use of the algorithm and has little human intervention and is, consequently, patent ineligible.

Similarly, a claim directed to a newly discovered rock that claims a composition of matter comprised of individually listed elements, would also be found patent ineligible under the proposed test. Such a claim would preempt *every* use of the claimed composition, would fail the “machine-or-transformation” test, and would have no human intervention. A new application or method involving either of these claims *would* pass the proposed eligibility test and its patentability would be decided based on sections 112, 102, and 103. Similarly, while the claims in *Mayo* or *Alice* would pass section 101 analysis under the proposed test, the claims would be found invalid, as they originally should have been, under the other statutory requirements for patentability.

The proposed eligibility test will help restore certainty to the U.S. patent system. The test involves a workable standard that is notably absent in the *Mayo/Alice* two-step. This workable standard will allow inventors and investors to have confidence in where to invest their time and resources. The proposed test will also protect valid, meritorious patents from the unwarranted invalidations that result from the current *Mayo/Alice* two-step. Patents directed to groundbreaking medical discoveries, such as Sequenom’s method for determining fetal abnormalities based on detection of cffDNA in maternal blood, would be found eligible under the proposed test. Protecting these types of groundbreaking innovations will promote further research and development in medical diagnostics and treatments. By replacing the *Mayo/Alice* two-step, the Supreme Court can restore the United States “gold-standard” patent protection and foster the development of life-saving new technologies.

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