St. Mary's Law Journal

Volume 53 | Number 4 Article 6

12-9-2022

From Patients to Patents: The Disappearing I of Innovation

Maggi Robert

COMMENT

FROM PATIENTS TO PATENTS: THE DISAPPEARING I OF INNOVATION

MAGGI ROBERT*

* Manderson School of Business, University of Alabama, M.B.A. 2017. Rollins School of Public Health, Emory University, M.P.H. 2018. St. Mary's University School of Law, J.D. 2022. The author would like to recognize her father—Steve Robert—whose hard work in and passion for healthcare inspired this piece; her mother—Rose Mary Robert—whose medical journey reminded the author of how personal and universal healthcare truly is; and her brother—Paco Gonzalez—whose constant questions and challenges helped develop this piece. Without the unwavering love, support, and encouragement of this family, the author's academic journey would not have been possible. Additionally, the author would like to acknowledge her friends whose companionship she is blessed to have and without whom she would not have succeeded. Special thanks to the Staff Writers, Senior Associate Editors, and Editorial Board—particularly Miss Katrina Christian—of Volume 53 for their edits to this Comment.

I. INTRODUCTION

Your father can learn of his risk for cardiovascular disease early enough to make a lifestyle change. Your mother's neurological condition was made easily diagnosable through antibody testing. Your sister can get genetically screened during pregnancy without an increased risk of miscarriage. These and other groundbreaking medical innovations have reframed healthcare. Through patents, treatment innovations like these improved patient outcomes, increased patient access, and revolutionized patient care. However, the future of these groundbreaking innovations is uncertain. With confusion surrounding the line differentiating patent eligible and ineligible subject matter, growing concern over the cost of treatment, and fear over a decrease in patient access due to patents, these innovations may soon be a thing of the past.

In the last ten years, patent eligibility has seen a resurgence as a topic of jurisprudence. Between 2010 and 2014, the Supreme Court made a series of decisions that severely limited the scope of patentable inventions,

reshaping the United States patent system.[1] The current patentability test, the *Mayo Collaborative Services v. Prometheus Laboratories, Inc./Alice Corp. v. CLS Bank International*[2] two-step test, has shrouded patent-eligibility in ambiguity.[3] The test strays from the constitutional and statutory language; and is, instead, built upon judicially-created exceptions.[4] The test first requires a determination of whether the claims at issue are directed to one of these judicially-created exceptions: "[a] law[] of nature, natural phenomenon, or abstract idea[]."[5] If the answer is yes, the Court looks to the additional elements of the claim, individually and as a whole ordered combination, to determine if it is enough to "transform the nature of the claim."[6] If the claim is transformed, the patents are directed to one of the patent-eligible exceptions.[7] This analysis is called the "search for an 'inventive concept.'"[8] The Court explained the inventive concept as being "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.'"[9] The test's application and outcome are the primary sources of concern for innovation and patient care in the realm of healthcare, directly impacting every one of our lives.

This Comment begins by discussing the relationship between innovation and patents. Examining the origination of the concept of using patents to incentivize innovation and build the economy. The Comment then goes on to describe the history of patent eligibility, from the enactment of current statutory language to the creation of the judicial exceptions that now frame patent law. Specifically, looking at the development of the current

1. 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, 946 (2017) ("Between 2010 and 2014, the Supreme Court issued four decisions that dramatically restricted the scope of inventions that can receive patent protection: *Bilski v. Kappos*, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, *Association for Molecular Pathology ("AMP") v. Myriad Genetics*, and *Alice Corp. v. CLS Bank International*.") (citations omitted).

2. Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208 (2014); Mayo Collaborative Servs. v. Prometheus Labs. Inc., 566 U.S. 66 (2012).

3. *See* Madigan & Mossoff, *supra* note 1, at 946 (positing the culmination of the decisions has injected legal uncertainty into the U.S. patent system).

4. *See* Shahrokh Falati, *To Promote Innovation, Congress Should Abolish the Supreme Court Created Exceptions to 35 U.S. Code Sec. 101*, 28 TEX. INTELL. PROP. L.J. 1, 9 (2019) (discussing the judicially created exceptions to Section 101).

5. *Alice Corp.*, 573 U.S. at 217.

6. *Id.* at 300.

7. *Id.*

8. *Id.*

9. *Id.* at 217–18.

Mayo/Alice test and its impact on both patent law and innovation. Next, this Comment analyzes the role the United States patent-system plays in healthcare space. Specifically, analyzing the importance of innovation, access to medicine, and cost as it impacts patient care. This Comment then turns to a review of some of the most notable cases of the last five years in the biomedical and software industries—particularly analyzing and comparing the use of the *Mayo/Alice* test in determining subject matter eligibility. Also contemplating its impact on innovation as a whole and in the healthcare space. Given this precedent, the Comment goes on to contemplate the *Mayo/Alice* test's future impact on innovation and patient access. Particularly, suggesting potential solutions to address concerns. Finally, the conclusion hones in on the best way to streamline patent subject matter eligibility in a way that continues to promote innovation, increase access to healthcare, and improve patient care overall.

II. AN ECONOMY BUILT FROM INNOVATION

Article 1 Section 8 of the United States Constitution states that Congress shall have the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . . ."[10] From the beginning of our great nation, the power of patents and innovation in building the economy has been known; though it took many years for this link to be fully exercised. The Patent Act of 1952 substantively and procedurally overhauled the obsolete patent system of the past.[11] The Act simplified, clarified, and codified the new, robust patent system.[12] Its enactment is considered to have started the "era of patent incentive and inclusion."[13] Shortly after, the United States—and the rest of the world—realized the benefits innovation provide to the national and global economy. Studies from 1957 showed that 50% to 60% of productivity growth could be attributed to technological change and innovation.[14] Thereafter, economists conducted a myriad of studies linking innovation and economic

10. U.S. CONST. art I, § 8 cl. 8.

11. Xuan-Thao Nguyen & Jeffrey A. Maine, *Attacking Innovation*, 99 B.U. L. REV. 1687, 1698–99 (2019).

12. *Id.*

13. *Id.*

14. *See* David Hounshell, *Innovation and Growth of the American Economy*, FOREIGN POL'Y RSCH. INST. (Feb. 27, 2009), https://www.fpri.org/article/2009/02/innovation-and-the-growth-of-the-american-economy/ [https://perma.cc/Y5FA-5E76] (discussing the finding of a study done by Robert Solow).

prominence. It is now stated as fact: "Innovation drives economic growth."[15] America's early, strong, innovation-incentivizing patent system has been listed as a primary reason for the country's rise to economic preeminence,[16] causing the United States to become the "gold standard" in innovation and economic growth.[17] As of late, however, the standard for innovation has decreased.[18] Recent years have seen diminished innovation across all fields. Given the importance of the relationship between innovation and economic growth to our nation's future, it is vital to address this topic. To further understand how to move forward, one must look to the past.

III. EARLY DAYS OF SUBJECT MATTER ELIGIBILITY

A. Funk Brothers Seed Co. v. Kalo Inoculant Co.[19]

In 1948, the Supreme Court made the first decision that began to shape the early days of patent-eligibility.[20] Despite predating the Patent Act of 1952,[21] the analysis of the claims plants the seeds for what would blossom into modern statutory language.[22] In this case, respondent brought a claim against petitioner for infringement on their patent for a mixed-culture of Rhizobia.[23] The respondents discovered unique genes in the varying species of Rhizobia that promoted nitrogen-fixing in different leguminous plants could be isolated and recombined to form a "super Rhizobia" that could be used across crops.[24] Here, the Court ultimately decided the super-strain was not patent-eligible as it was a manifestation "of laws of nature, free to all men and reserved exclusively to none."[25] The patent claimed

15. U.S. Chamber of Commerce Foundation, *Executive Summary* (2013), https://www.uschamberfoundation.org/enterprisingstates/assets/files/Executive-Summary-OL.pdf [https://perma.cc/UH6Z-8V5S].

16. *Id.*

17. *See* Madigan & Mossoff, *supra* note 1, at 946 (citing the United States patent system as the driving force behind the country's innovative revolution).

18. *See id.* (suggesting the United States patent system has plateaued in recent years).

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

20. *See id.* at 132 (holding "product claims do not disclose an invention or discovery within the meaning of the patent statutes").

21. 35 U.S.C. § 1 (2000).

22. Rebecca Lindhorst, Note, *Two-Stepping Through Alice's Wasteland of Patent-Eligible Subject Matter: Why the Supreme Court Should Replace the Mayo/Alice Test*, 69 CASE W. RES. L. REV. 731, 739 (2019).

23. *Funk Bros.*, 333 U.S. at 128–29.

24. *See id.* at 128–29 (describing the discovery, which gave rise to the patent claim in question).

25. *Id.* at 130.

nothing more than an enhanced-quality of the bacteria, which is inherently a work of nature. This clarified that for the discovery of a natural phenomenon to be patent-eligible, the same must be applied to achieve a "new and useful end."[26] The Court reasoned since the non-inhibiting species of Rhizobia could be combined to form a super-Rhizobia was not inventive or complex; it found the same was nothing more than "the discovery of some of the handiwork of nature and hence is not patentable."[27] The ideas and analysis proffered in this opinion led to the development of Sections 101 through 103, which focus on the definition of eligible subject matter and requirements that the invention be novel and non-obvious.

B. *The United States Code*

Section 101 of the United States Code, entitled "Inventions Patentable," does precisely that by providing the statutory language establishing the standards, requirements, and exceptions to patentability.[28] The current version of the statute was enacted in 1952;[29] though there have been many amendments since, the language remains relatively unchanged. The 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, subject to the conditions and requirements of this title."[30] Sections 102 and 103 provide two additional requirements for eligibility, novelty, and non-obviousness. Section 102 requires the subject matter be novel; more specifically, that the material must be unique, original, something never seen, used, or described in any official capacity.[31] Section 103 requires the subject matter be non-obvious; particularly, that the material must not be conspicuous to anyone with simple knowledge in the claimed patent's field.[32] The legal protection

26. *Id.*
27. *Id.* at 131.
28. *See* 35 U.S.C.A § 101 (2018) (outlining the conditions and requirements of obtaining a patent).
29. 35 U.S.C. § 1 (2000).
30. 35 U.S.C.A § 101.
31. 35 U.S.C.A § 102.
32. 35 U.S.C.A § 103.

and precedent stemming from these statutes established the United States as a leader in innovation.[33]

C. Parker v. Flook[34]

Thirty years after *Funk Brothers* and the enactment of the current statute, the Supreme Court once again addressed subject matter eligibility. In this case, respondent filed a patent claim on a "Method for Updating Alarm Limits."[35] The claim contained a newly-discovered mathematical formula inserted into an already known process for updating alarm limits.[36] The Court emphasized the importance of a proper interpretation of Section 101 and its objectives—reasoning a mathematical formula cannot be patented regardless of its "post-solution activity" or limitation to a particular industry or field.[37] The mathematical formula is a law of nature and as such, when added to any process, it is considered to have been part of the "prior art."[38] Here, the Court considered the entire process as a whole, including the formula, and reasoned that the claim was not patent-eligible, as the only distinction between the current process and the proposed patent claim is the use of a law of nature.[39]

> The 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 enacted to protect. The obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious. . . . Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, the discovery of

33. *See* Nguyen & Maine, *supra* note 11, at 1696 (referring to the enactment of patent law as key event in creating the robust patent system focused on incentivizing inventors); Madigan & Mossoff, *supra* note 1, at 942 (discussing the long-standing reputation of the United States as a leader in technology innovation and patenting).

34. Parker v. Flook, 437 U.S. 584 (1978).

35. *Id.* at 585.

36. *Id.* at 585–86.

37. *See* Bilski v. Kappos, 561 U.S. 593, 610–11 (2010) (holding the petitioner's patent application lacked patentability due to its mathematical nature); *see also Flook*, 437 U.S. at 590 (finding a "post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance").

38. *Flook*, 437 U.S. at 592–93.

39. *Id.* at 594.

> such a phenomenon cannot support a patent unless there is some other inventive concept in its application.[40]

The Court rationalized its findings by emphasizing a need for the broad interpretation of Section 101 and consideration of the process as a whole.[41] The Court asserted a narrow reading of Section 101 is flawed because it would allow subject matter eligibility to be determined a "draftsman's art."[42] With this opinion the Court reiterated the importance of the inventive element observed in *Funk Brothers*, even though such language is absent in the statute.

D. Diamond v. Chakrabarty[43]

Two years after *Flook*, a hallmark decision came in the subject matter eligibility case of the Biotech Age.[44] Along with expanding the scope of patentable inventions, the relationship between patents and innovation became abundantly clear following the Court's decision in *Chakrabarty*. In 1980, the Supreme Court ruled that living organisms, here a genetically modified micro-organism, fall under patent-eligible inventions.[45] The Court began its opinion by determining Section 101 was to be interpreted as having a wide-scope; however, the Court recognized the existence of some exceptions and limitations.[46]

> Congress plainly contemplated that the patent laws would be given wide scope. The relevant legislative history also supports a broad construction. . . . This is not to suggest that [Section] 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth, or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity.[47]

40. *Id.* at 593–94.
41. *Id.* at 594.
42. *Id.* at 593.
43. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
44. *See* Tup Ingram, Association for Molecular Pathology v. Myriad Genetics, Inc., *The Product of Nature Doctrine Revisited*, 29 BERKELEY TECH. L.J. 385, 395 (2014) (naming Chakrabarty as the revolutionary force beginning the biotech age).
45. *Chakrabarty*, 447 U.S. at 313.
46. Lindhorst, *supra* note 22, at 742.
47. *Chakrabarty*, 447 U.S. at 308–09.

In establishing the statutory interpretation of Section 101, the Court created the three judicial exceptions, framing the proceeding development of patent law.

The Court continued its opinion, addressing the particular claims at issue. The Court stated the language in the statute embraced the invention as it constituted a "manufacture" or a "composition of matter" beyond what organically exists in nature.[48] The Court arrived at the conclusion of patentability by looking at the claims as a whole, as opposed to individual elements.[49] *Chakrabarty* set a precedent of patent protection for pioneering researchers and innovators, leading to dramatic advances in the biotechnology and medical spaces.[50] In the following decade, the United Sates saw a surge of patents, which put the country at the forefront of the biotechnological field.[51]

E. Diamond v. Diehr[52]

Immediately following the *Chakrabarty* decision, the Supreme Court again expanded the scope of patent eligible inventions under Section 101. In *Diehr*, the Court held a computer program was not precluded from patent eligibility solely on the basis that it contained a known mathematical formula or algorithm.[53] The Court rationalized its decision by building on its precedent established in *Flook*, which held unpatentable mathematical equations and algorithms as abstract ideas, by considering the process as a whole.[54] Here, respondent sought to patent a manufacturing process for curing rubber; the process combined a commonly used and well-known mathematical equation with a series of other steps.[55] The Court highlighted that respondent did not seek to prevent the use of the equation, but "only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process."[56] Alternatively, in *Flook*, the Court asserted the patent was only for the mathematical formula as the claim did

48. *Chakrabarty*, 447 U.S. at 308.

49. Lindhorst, *supra* note 22, at 737 (quoting 35 U.S.C. § 101 (2012)).

50. *See* Madigan & Mossoff, *supra* note 1, at 943 (describing the increase in medical advances since the *Chakrabarty* decision using the "oncomouse" as an example).

51. *See id.* at 944 ("By first securing property rights in the fruits of biotech research, the U.S. became the birthplace of the biotech revolution.").

52. Diamond v. Diehr, 450 U.S. 175 (1981).

53. *Id.* at 187.

54. *Id.* at 188.

55. *Id.* at 178–79.

56. *Id.* at 187.

not provide any steps or information on the calculation and monitoring of the other variables.[57]

While *Diehr* significantly broadened the scope of patentability, as the Court recognized "a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made,"[58] it also highlighted the importance of language and specificity in patent claims.

These four Supreme Court decisions, among others, set an early precedent for strong legal protection of patent claims.[59] Innovation boomed as inventors saw the fruits of their labor recognized.[60] As a result, the United States became the "gold standard" for patent eligibility in the world.[61] However, since 2010, this standard has come into question.[62] Unbeknownst to all, hiding beneath these encouraging opinions were the seeds of uncertainty and chaos.

IV. DEVELOPMENT OF THE *MAYO/ALICE* TWO-STEP TEST

Almost three decades later, another series of four consecutive Supreme Court decisions turned subject matter eligibility upside down.[63] First, they severely narrowed the scope of patent eligible innovations.[64] The decisions created a new, more stringent test to evaluate eligibility, significantly detracting from the gains achieved in *Chakrabarty* and *Diehr*.[65] Second, the test also "injected tremendous legal uncertainty into the U.S. patent system . . . ."[66] The proper application and interpretation of the *Mayo/Alice* two-step test is still in question today.

57. Parker v. Flook, 437 U.S. 584, 586 (1948).

58. *Diehr,* 450 U.S. at 188.

59. *See* Nguyen & Maine, *supra* note 11, at 1706 (discussing the overall strength of the patent system following the enactment of the Patent Act of 1952, the establishment of the Federal Circuit for patent cases, and subsequent case law).

60. Madigan & Mossoff, *supra* note 1, at 946.

61. *Id.* at 939.

62. *See id.* at 946 (noting United States' recent case law as a major setback in technological innovation).

63. *See generally id.* (citing four different cases "dramatically restrict[ing] the scope of inventions that can receive patent protection . . . .").

64. *Id.*

65. *Id.*

66. *Id.* at 946–47.

A. Biliski v. Kappos[67]

In 2010, the Court heard an issue of first impression—whether new and useful business methods are patentable as a "process" under Section 101.[68] In *Biliski*, petitioner's patent application sought protection of a procedure "for instructing buyers and sellers [on] how to protect against the risk of price fluctuations in a discrete section of the economy."[69] The Court held business methods are patent-eligible so long as they meet the Act's other requirements: "novel, . . . nonobvious, . . . and fully and particularly described . . . ."[70] Despite this determination, the Court ultimately held that the claim in question was not patent-eligible as opposed to an "abstract idea."[71] In making its conclusion, the Court attempted to rely on precedent, when in actuality it "provided no legal guidance on how to determine what counts as an unpatentable 'abstract idea,' creating a[] [more] ambiguous legal precedent . . . ."[72] This lack of evidenced reasoning became the "rose-bud" from which uncertainty grew.[73] The Court's failure to provide a bright-line test for subject matter eligibility left the lower courts to flounder; offering no guidance other than if the claim is "connected to a specific machine or transforms an article,"[74] it *may* be patent eligible subject matter.[75] The following years saw "mass invalidation of patents on software, business methods, and diagnostic methods with vague or conclusory court opinions . . . ."[76] As such, the *Bilski* decision[77] marked the beginning of a downfall of innovation.

---

67. Bilski v. Kappos, 561 U.S. 593 (2010).

68. *Id.* at 598.

69. *Id.*

70. *Id.* at 602.

71. *Id.* at 598.

72. Madigan & Mossoff, *supra* note 1, at 947; *see* Alexa Johnson, Note, *A Crisis of Patent Law and Medical Innovation: The Category of Diagnostic Claims in the Wake of Ariosa v. Sequenom*, 27 HEALTH MATRIX 435, 445 (2017) (highlighting the conclusory style of the Court's opinion in reliance on prior precedent and lack of direction it provided); Lindhorst, *supra* note 22, at 745 (arguing the Court's reliance on prior case law on patent-eligible subject matter provided little instruction regarding the rejection of patents and the test overall).

73. *See* Madigan & Mossoff, *supra* note 1, at 948 (emphasizing *Binski's* creation of confusion and ambiguity surrounding patentability); *see also* Lindhorst, *supra* note 22, at 745 (describing the Court's reliance on prior patent-eligibility decisions as opposed to providing additional guidance on patent-eligible subject matter).

74. Stefania Fusoco, *Is* In re Bilski *a Déjà Vu?*, 2009 STAN. TECH. L. REV. 143, 143 (2009).

75. *See Bilski*, 561 U.S. at 598 (describing the machine-or-transformation test as useful but not a determinative tool).

76. Madigan & Mossoff, *supra* note 1, at 947–48.

77. Bilski v. Kappos, 561 U.S. 593, 606 (2010).

B. Mayo Collaborative Servs. v. Prometheus Labs., Inc.[78]

Two years later, the Court built on its *Bilski* decision. In this case, the Court determined whether processes that helped physicians determine proper dosage levels of thiopurine drugs used to treat autoimmune diseases were patent-eligible subject matter.[79] Unlike in *Bilski*, this was not a fundamental question of whether medical treatment methods as a whole are patentable.[80] Instead, this was a specific and directed claim question. This case saw the introduction of the two-step test for patent-eligible subject matter.[81] In the test, the Court first determines whether the claim is directed toward a patent-ineligible subject.[82] The patent-ineligible subjects consist of three judicially created exceptions, "a law[] of nature, abstract idea[], and physical phenomena . . . ."[83] If it is, the Court then analyzes whether there is something else in the claim that transforms it into patent-eligible subject matter.[84] The Court decided that the "method of treatment" in this case was not patent eligible as it was a "law of nature."[85] The analysis focused on whether the "law of nature" was significantly added to in order to transform the claim, the second step of the test.[86] Here, the Court provided a somewhat conclusory style opinion, relying, yet again, mostly on prior case law. Ultimately, the Court held the claim did not add "enough" to the law of nature but failed to describe what would constitute

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

79. *Id.* at 72.

80. *Bilski*, 561 U.S. at 610.

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

82. *See id.* at 77 (indicating determination of ineligible due to direction to one of the natural or abstract exceptions must occur first and triggers further analysis); *see also* Johnson, *supra* note 72, at 445 (describing the elements of the redefined test introduced in *Mayo*).

83. Johnson, *supra* note 72, at 436.

84. *See Mayo*, 566 U.S. at 77 (explaining after the Court determines ineligibility due to direction to one of the natural or abstract exceptions, the Court then asks "do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?"); *see also* Johnson, *supra* note 72, at 445 (explaining this must be more than just a natural phenomenon, for example).

85. *Mayo*, 566 U.S. at 89.

86. *See id.* at 77–78 ("If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. A patent, for example, could not simply recite a law of nature and then add the instruction 'apply the law.'"); *see also* Johnson, *supra* note 72, at 445 (introducing the confusion of courts and inventors alike when it comes to the "transformation" process).

"enough."[87] The Court provided no guidance or explanation of their reasoning outside of that the process was a "well-understood, routine, conventional activity, previously engaged in by those in the field."[88] This rationalization stemmed from the comparison of this case to both *Flook* and *Diehr*, two seemingly irreconcilable cases.[89] Despite differing approaches and outcomes, the Court indicated *Flook* and *Diehr* accurately represented the precedent set for claims, including abstract ideas or the laws of nature.[90] In *Flook*, the Court inspected each element for something "more" but eventually held the method for adjusting alarm limits patent-ineligible; asserting the claim did little more than add a novel mathematical algorithm to an already-established process for adjusting alarm limits.[91] Conversely, in *Diehr*, the Court inspected the claim as a whole and held patentable a process for molding raw, uncured rubber into various useable products; asserting the claim, once again, added a novel mathematical equation into a process, but did so to a previously unestablished or non-obvious combination of widely-used steps.[92] The petitioner claimed the inclusion of a non-patentable law of nature or abstract idea into an "inventive" process transformed the claim into patent-eligible subject matter.[93] However, the Court determined the claim in question here more closely aligned with *Flook*—combining conventional steps in recognition of the

87. *See* Bernard Chao, *Moderating Mayo*, 107 NW. L. REV. COLLOQUY 82, 82 (2013) (emphasizing the lack of direction provided by the Court regarding subject matter eligibility); Timo Minssen & David Nilsson, *The US Supreme Court in* Mayo v. Prometheus*—Taking the Fire from or to Biotechnology and Personalized Medicine*, 2 QUEEN MARY J. INTELL. PROP. 376, 382 (2012) (highlighting the Court's lack of guidance in explaining its decision).

88. *Mayo*, 566 U.S. at 69.

89. *Id.* at 80; *see* Chao, *supra* note 87, at 89 (asserting the uncertainty surrounding subject matter eligibility stems from the use of two irreconcilable cases as guideposts for the conclusion); Ethan M. Weiner, *Defining a Natural Phenomenon after* Prometheus, 28 BERKELEY TECH. L.J. 643, 669 (2013) ("The vastly different approaches taken by *Flook* and *Diehr* render the *Prometheus* analysis internally inconsistent.").

90. *See Mayo*, 566 U.S. at 80 (stating both *Flook* and *Diehr* address claims involving an equivalent law of nature).

91. *Accord id.* (summarizing the holding of *Flook*); Weiner, *supra* note 89, at 669 ("But in application, the Court dissected the claims and examined each step for something more than conventional activity, precisely the methodology used in *Flook*.").

92. *Accord Mayo*, 566 U.S. at 80 (summarizing the holding of *Diehr*); Weiner, *supra* note 89, at 669 ("The *Prometheus* Court reiterated the requirement in *Diehr* that the claim should be analyzed as a whole, and even emphasized that a novel combination of known steps may still be patentable.").

93. *Mayo*, 566 U.S. at 81; *see* Johnson, *supra* note 72, at 448 (detailing the rationalization behind the *Mayo* Court's interpretation of *Diehr*).

biological relationship between thiopurine and metabolites to treat patients—than to *Diehr*, ruling it ineligible-patent subject matter.[94]

The Court begins to blur the line between subject matter eligibility, novelty, and non-obviousness by bringing back the "inventive concept" first discussed in *Flook*.[95] This focus on the "inventive" application of the patent goes beyond the statuary language of Section 101, which is solely concerned with whether the claim is directed toward a "process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[96] The reach beyond the statutory language, coupled with a lack of guidance outside established precedent, produced confusion.[97] The lower courts were left to navigate the waters of this new test with nothing more than the precedent they were already struggling to interpret and apply.[98] *Mayo Collaborative Servs.* is of particular impact and importance in medical diagnostic and therapeutic treatment methods, where individual steps of processes are often considered "laws of nature."[99] This decision only added to the confusion and uncertainty surrounding subject matter eligibility.[100] Moreover, like its predecessor, *Mayo Collaborative Servs.* led to high levels of patent invalidation.[101]

C. Association for Molecular Pathology v. Myriad Genetics[102]

In the following year, the Court once again addressed what is eligible subject matter under Section 101.[103] In *Myriad Genetics*, the Court was asked whether or not DNA that was isolated and used in a diagnostic process

94. *Mayo*, 566 U.S. at 82 ("The claim before us presents a case for patentability that is weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook*.").

95. Parker v. Flook, 437 U.S. 584 (1978).

96. 35 U.S.C.A § 101 (2018).

97. *See* Johnson, *supra* note 72, at 437 ("The lack of clarity means there is confusion between the USPTO, the district courts, the Federal Circuit, and the Supreme Court about which diagnostic methods are patent-eligible uses of a natural phenomenon.").

98. *See id.* (noting the excess of litigation that rose from the lower courts' attempt to provide clarity in the patent system).

99. *See id.* at 446 (highlighting the opinion of two Federal Circuit Court judges stating the *Mayo* test is not the appropriate standard in these fields as it may discourage innovation).

100. Madigan & Mossoff, *supra* note 1, at 948; *see* Weiner, *supra* note 89, at 644 ("Instead, the granting of certiorari was nothing more than the song of Sirens, leaving inventors shipwrecked on an island of patentable subject matter confusion. The *Prometheus* Court failed to deliver any clear rule controlling patentable subject matter for process claims.").

101. Madigan & Mossoff, *supra* note 1, at 948–49.

102. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

103. *Id.* at 579–80.

constituted a patent-eligible claim.[104] The patent in question is a prime example of the kind of innovation that saves lives. The isolated DNA segments were BRCA1 and BRCA2.[105] These specific DNA segments directly correlate to a women's predisposition for contracting breast cancer.[106] In previous, early twentieth-century decisions, "the isolation of molecules and other organic elements that were of valuable use in medical treatments, such as adrenalin and insulin, had long been recognized as patentable discoveries . . . ."[107] However, again following the trend of its more recent predecessors, the Court decided that the isolated DNA was a "law of nature" and therefore, ineligible for patent protection.[108] However, the complementary created, cDNA, was patent-eligible subject matter.[109] Once again, there was little guidance for this decision other than prior case law.[110] Here, the Court relied on *Funk Brothers* and *Chakrabarty* to establish precedent; these cases, though similar, had very different outcomes.[111] In *Chakrabarty*, the Court held patentable a genetically modified bacterium designed to more efficiently degrade oil; the claim was for a naturally occurring micro-organism that had four plasmids added to it to create a greater capacity for oil degradation.[112] The Court maintained the addition of these plasmids gave the bacterium "markedly different characteristics from any found in nature," transforming the micro-organism into patent-eligible subject matter.[113] Conversely, in *Funk Brothers* the Court held a "super-Rhizobia" designed to enable nitrogen fixing across various leguminous plants patent-ineligible; the claim was for a newly created species of Rhizobia, which was derived by isolating the non-inhibiting bacteria from the existing six species to allow for nitrogen fixation across

104. *Id.* at 580.

105. *Id.* at 583.

106. *Id.*

107. Madigan & Mossoff, *supra* note 1, at 949; *see* Falati, *supra* note 4, at 17 ("Going against three decades of practice to the contrary at the time, Justice Thomas for the Supreme Court held that while claims directed specifically to the complementary DNA (cDNA) for the breast cancer genes, BRCAl and BRCA2, were patent-eligible, claims to an isolated nucleic acid encoding the BRCAl/2 genes were not patent eligible because they are 'a natural product.'").

108. *Ass'n for Molecular Pathology*, 569 U.S. at 591.

109. *Id.* at 595.

110. Madigan & Mossoff, *supra* note 1, at 950.

111. *See Ass'n for Molecular Pathology*, 569 U.S. at 590–91 (discussing the applicability of precedent set in *Chakrabarty* and *Funk Brothers*).

112. *Accord id.* at 590 (summarizing the holding of *Chakrabarty*).

113. Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980).

crops.[114] The Court asserted that the new composition was not patent-eligible subject matter as the same did not create or alter anything that was not an already-present quality of the bacteria in nature, i.e., there was no transformation.[115] In *Myriad Genetics*, the Court found Myriad's isolation more analogous to the claim in *Funk Brothers*; the isolation of the genes did nothing to transform the naturally occurring character of the DNA.[116] Alternatively, the created cDNA had been transformed—the cDNA retains some of the naturally occurring characteristics—where "it is distinct from the DNA from which it was derived."[117]

Much like its predecessor, the focus on the inventive concept and the reliance on precedent, which provided minimal guidance, scarcely clarified the issue of patent-eligible subject matter.[118] *Myriad Genetics* left a cloak of ambiguity surrounding the future of thousands of current and pending patents.[119] Of particular concern was the impact of investments in research and development on innovation.[120]

> This fundamental legal uncertainty, the threat of zero legal protection, and the inability to recoup hundreds of millions of dollars in R&D expenditures, has placed the biotech and pharmaceutical industries in a quagmire that will swallow up and stifle future innovation like the discovery of the BRCA1 and BRCA2 genes.[121]

114. *Accord Ass'n for Molecular Pathology*, 569 U.S. at 591 (summarizing the holding of *Funk Bros*).

115. *See id.* ("The Court held that the composition was not patent eligible because the patent holder did not alter the bacteria in any way.").

116. *Id.*

117. *Id.* at 595.

118. *Id.* at 591.

119. Madigan & Mossoff, *supra* note 1, at 948–49; *see* Ashish M. Bakshi, *Gene Patents at the Supreme Court: Association for Molecular Pathology v. Myriad Genetics*, 1 J. L. & BIOSCIENCES 183, 183 (2014) (highlighting the array of litigation resulting from the uncertainty created by *Myriad*).

120. Arun J. Mohan, *Process Stories: Patenting Natural Law Processes under* Prometheus*—How Much Addition to a Patent Claim Is Enough?*, 96 J. PAT. & TRADEMARK OFF. SOC'Y 160, 161 (2014) ("The incentive [to innovate] has disappeared due to recent court decisions regarding the patentability of diagnostic methods involving biological processes.").

121. Madigan & Mossoff, *supra* note 1, at 950 (footnote omitted).

D. Alice Corp. Pty. Ltd. v. CLS Bank International[122]

These decisions culminated in 2014 with the establishment of the *Mayo/Alice* two-part test.[123] Presenting an issue of first impression, the Court in *Alice* set out to address the fundamental question of whether "computer-implemented schemes," or software programs, were patent-eligible under Section 101.[124] Despite an intention to broadly address the topic, the Court ultimately ruled on the specific patents in question.[125] The claims at issue in *Alice* concerned a "computer-implemented scheme for mitigating 'settlement risk' (*i.e.*, the risk that only one party to a financial transaction will pay what it owes) by using a third-party intermediary."[126] The Court ultimately decided the claims were not patent-eligible, as they were directed to an "abstract idea" and contained no transformative steps or processes to apply the idea.[127] To arrive at this conclusion, the Court applied and affirmed the two-step test first seen in *Mayo*.[128]

> 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?" To answer that question, we consider the elements of each claim both individually and "as an ordered combination" to determine whether the additional elements "transform the nature of the claim" into a patent-eligible application. 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]

Following the trend of its predecessors, the Court again provided little direct guidance, instead relying on prior case law. To support its conclusion

122. Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208 (2014).

123. *See* Ilija Ilijovski, *Perfecting U.S. Patentable Subject Matter—Merging the European Approach and the American Principles*, 19 CHI.-KENT J. INTELL. PROP. 182, 188 (2019) (asserting *Alice* is the most crucial of the current cases on subject matter eligibility).

124. *Alice Corp.*, 573 U.S. at 212.

125. *See* Madigan & Mossoff, *supra* note 1, at 950 (explaining the Court's narrow scope of determining this particular patents' validity instead of making determinations for the eligibility of computer-implemented inventions as a whole).

126. *Alice Corp.*, 573 U.S. at 212.

127. *Id.*

128. *See id.* at 217 (In *Mayo*, the Court "set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts.") (citation omitted).

129. *Id.* at 217–18.

that the "computer-implemented scheme" was an abstract idea, the Court looked to *Bilski*.[130] In *Bilski*, the Court held the method for protecting against financial risk is patent-ineligible subject matter as an "abstract idea."[131] The Court provided no explanation other than that hedging the risk was common, "a fundamental economic practice long prevalent in our system of commerce and taught in introductory finance . . . ."[132] The Court analogized the "computer-implemented scheme for mitigating settlement risk" to the method for hedging against financial risk.[133] The Court asserted a third-party intermediated settlement is also an established practice in the commerce system.[134] This commonality and pervasiveness alone was sufficient for the claims to constitute "abstract ideas."[135]

After a conclusory determination of the claim as an "abstract idea," the Court then determined whether the claim had transformed into patent-eligible subject matter through the presence of an "inventive concept."[136] In this step, the Court looked to *Mayo*, *Flook*, and *Diehr* for support of its finding of ineligibility. In *Mayo*, the Court held patent-ineligible a method for properly determining the dosage of thiopurine to administer to autoimmune patients, asserting the claimed processes did little more than combine already established natural laws into a singular method.[137] The combination of conventional steps with an instruction to "apply it" is inadequate to transform the claim into an application of natural law.[138] As is the case here and in *Flook* and *Diehr*, the introduction of a computer does not impact the analysis.[139] In *Flook*, the Court held a computerized method for adjusting alarm limits patent-ineligible; asserting the claim simply added a novel mathematical algorithm to an already established, computerized process to monitor and adjust alarm limits.[140] Conversely, in *Diehr*, the Court held patentable a computer-implemented process for molding raw,

130. *Id.* at 218.

131. *See id.* at 219 (describing the courts' unanimous finding that the patent at issue was in fact an abstract idea).

132. Bilski v. Kappos, 561 U.S. 593, 611 (2010).

133. *See Alice Corp.*, 573 U.S. at 212, 219 (showing how risk hedging in *Bilski* is similar to the idea of intermediated settlement in *Alice*).

134. *Id.* at 219.

135. *Id.* at 221.

136. *Id.*

137. *Accord id.* (summarizing the holding in *Mayo*).

138. *Accord id.* at 222 (interpreting analysis of *Mayo*).

139. *See id.* ("[S]imply implementing a mathematical principle on a physical machine, namely a computer, [i]s not a patentable application of that principle.").

140. *Accord id.* (summarizing holding of *Flook*).

uncured rubber into various useable products; the claim once again added a novel mathematical equation into a known technological process.[141] However, the Court argued "the claims . . . were patent eligible because they improved an existing technological process, not because they were implemented on a computer."[142] The improvement of the existing technology, not the computer's presence, ultimately led to the determination of patent-eligibility.[143] The *Alice* Court provided that under precedent, the claim did nothing more than instruct the user "to apply the abstract idea of intermediated settlement using some unspecified, generic computer."[144] The Court first analyzed the claim's elements individually, finding the "function performed by the computer at each step of the process [were] '[p]urely conventional.'"[145] Next, the Court considered the claim as a whole, ordered combination, and found the method "simply recite[d] the concept of intermediated settlement as performed by a generic computer."[146] Like *Mayo* and *Flook*, the Court decided there was no "inventive concept" that transformed this claim.[147]

Alice is the cornerstone case for patent-eligible subject matter. Despite the establishment of a test, ambiguity persists in surrounding patent-eligible subject matter.[148] A significant portion of this ambiguity can be attributed to the Court's differing interpretations of *Diehr*.[149] In *Mayo*, the Court justified its ruling by interpreting the patentability of the claims in *Diehr* to stem from the addition of the natural law to a process not previously established.[150] While in *Alice*, the Court instead interpreted the patentability

141. *See id.* at 223 (describing the holding in *Diehr* and how the Court came to a different conclusion).

142. *Id.*

143. *Id.*

144. *Id.* at 226 (citation omitted).

145. *Id.* at 225 (quoting Mayo Collaborative Servs. v. Prometheus Labs. Inc., 566 U.S. 66, 81 (2012)).

146. *Id.*

147. *Id.* at 222–23.

148. *See* Madigan & Mossoff, *supra* note 1, at 951 (offering an explanation of why the lack of reasoning from the Court in Alice has led to ambiguity); *see also* Lindhorst, *supra* note 22, at 748 (recognizing the alarmingly high levels of patent invalidation following the implementation of the *Mayo/Alice* test); Christopher M. Holman, *Patent Eligibility Post-Myriad: A Reinvigorated Judicial Wildcard of Uncertain Effect*, 82 GEO. WASH. L. REV. 1796, 1822 (2014) (asserting the Court's lack of clarity in patent eligibility has created uncertainty at every level) [hereinafter Holman, *Patent Eligibility Post-Myriad*].

149. *See* Holman, *Patent Eligibility Post-Myriad*, *supra* note 148, at 1808 (explaining the Court's reference to *Diehr* in theory but not in practice).

150. *See Mayo*, 566 U.S. at 81 (2012) ("[T]he overall process [of the] patent [was] eligible because of the way the additional steps of the process integrated the equation into the process as a whole.").

of the claims to stem from the improvement of the existing process as a whole.[151] This is significant because it can alter the primary inquiry of the second step in the *Mayo/Alice* two-step test. If the characterization of *Diehr* in *Mayo* is used, the main inquiry is whether the process is novel and non-obvious.[152] This reaches past the statutory language of Section 101 into Sections 102 and 103, adding a much harsher limit on patentability. Alternatively, if the characterization in *Alice* is used, the main inquiry is whether the addition of the natural law improves the established process as a whole.[153]

Due to the confusion surrounding interpretation and application of the *Mayo/Alice* test, concern is growing among investors and inventors. Where previously, the United States stood out for its strong patent protection, it now stands out for "unstable and unpredictable standards in such fundamental areas as patentable subject matter and [eligibility] . . . ."[154]

E. *The Aftermath of* Alice

Never, in the history of the American-patent system, has there been a time of less clarity regarding patentable subject matter.[155] The lack of clarity and predictability is directly attributed to the judiciary. The Supreme Court reached far beyond the statutory language of Section 101, blurring the lines, and adding new ones. In its opinions, the Court has been incoherent and provided no guidance for untangling the lines of precedent justifying its decisions.[156] These decisions have led to a rise in subjectivity.[157] Some

151. *Alice Corp.*, 573 U.S. at 223.

152. *See* Johnson, *supra* note 72, at 449 (describing the effect of the Court viewing the patentability of claims as a combination of the conventional steps and natural principle components).

153. *Id.*

154. Daniel R. Cahoy, *Patently Uncertain*, 17 NW. J. TECH. & INTELL. PROP. 1, 3 (2019).

155. Jeffrey A. Lefstin, *The Three Faces of* Prometheus*: A Post-*Alice *Jurisprudence of Abstractions*, 16 N.C. J.L. & TECH. 647, 649 (2015).

156. *Id.* at 650.

157. *See* Scott Frederick Peachman, *The Patent Eligibility of Diagnostic Methods after* Prometheus*: A Redefined Test for Transformation*, 22 HEALTH MATRIX 589, 609 (2013) (discussing the danger of subjectivity that has arisen as a result of the Court's opinion); Andrew A. Toole & Nicholas A. Pairolero, *Adjusting to* Alice*: USPTO Patent Examination Outcomes After* Alice Corp. v. CLS Bank International 4 (Apr. 2020), https://www.uspto.gov/sites/default/files/documents/OCE-DH_AdjustingtoAlice.pdf [https://perma.cc/5M4U-J5VJ] ("The increase in uncertainty seems to reflect the interpretive latitude in the language of the *Alice* standard . . . .").

have said the only determining factor in subject matter eligibility rests on selection of the panel.[158]

In response to this lack of clarity, the Patent and Trademark Office (PTO) and courts rejected and invalidated countless patents covering innovation in various fields, namely, biotechnology, pharmaceuticals, and life sciences following *Alice*.[159] In an attempt to track the rate of these invalidations, a researcher conducted periodic reviews of the average invalidation rate among the three court levels at one-, two-, and five-years post-*Alice*.[160] The data showed that a year after *Alice* the average rate of invalidation was 82.9%.[161] The rate declined in both the two-year and five-year points, holding at 78.2% and 56.2%, respectively.[162] Though declining, an invalidation rate of over 50% does not breathe confidence into investors or inventors.

To further quantify the effects, two researchers conducted a study focusing on the invalidation of personalized medicine patents.[163] The data showed a sharp increase of subject matter invalidations following *Mayo*, with growth continuing after both *Myriad* and *Alice*.[164] More specifically, 86.4% of the office decisions issued by the PTO post-*Mayo* included rejections for subject matter eligibility, as opposed to 15.9% pre-*Mayo*.[165] In another study surveying Section 101 rejection data provided by the United States PTO, researchers found an uptick of rejections in both the software, including biotechnology, and medical diagnostic art units.[166] Particularly in the software and biotechnology art units, the month after *Alice* was decided,

158. *See* Holman, *Patent Eligibility Post-Myriad*, *supra* note 148, at 1823 (arguing the only determining factor regarding patent-eligibility is the selection of the panel leading to mass uncertainty and invalidation).

159. Madigan & Mossoff, *supra* note 1, at 951–52.

160. *See generally* Jasper L. Tran, *Software Patents: A One-Year Review of* Alice v. CLS Bank, 97 J. PAT. & TRADEMARK OFF. SOC'Y 532, 534 (2015) (providing the researcher "investigates *Alice*'s effects at its one-year anniversary by reviewing how the courts . . . have applied *Alice* since its issuance").

161. *Id.* at 540.

162. Jasper L. Tran, *Two Years After* Alice v. CLS Bank, 98 J. PAT. & TRADEMARK OFF. SOC'Y 354, 359 (2016); Jasper L. Tran & J. Sean Benevento, Alice *at Five*, 2019 PATENTLY- O PAT. L.J. 25, 27 (2019).

163. *See generally* Bernard Chao & Amy Mapes, *An Early Look at* Mayo*'s Impact on Personalized Medicine*, 2016 PATENTLY-O PAT. L.J. 10 (2016) (describing general set up, methods, and limitations of data used to assess invalidation rates post-*Mayo*).

164. *Id.* at 13.

165. *Id.* at 12.

166. *See generally* Colleen Chien & Jiun Ying Wu, *Decoding Patentable Subject Matter*, 2018 PATENTLY- O PAT. L.J. 1 (2018) (describing the general set up, methods, and limitations of the data used to assess Section 101 rejection rates).

Section 101 rejections increased from 25% to 81%; the level of rejections remained fairly consistent at or around 75% for the remaining months of data.[167] Similarly, in the month after *Mayo*, the medical diagnostic art unit saw an increase in Section 101 rejections from 7% to 32%; the level of rejections continued to rise, reaching a peak of 64% post-*Alice*.[168] Consequently, the United States is no longer the leader in patent protection rights.[169]

The *Mayo*/*Alice* test has developed a reputation for being uncertain and overly restrictive.[170] Moreover, there is no consistency in how the test is applied and interpreted,[171] and the test is overly restrictive by invalidating patents across nearly every sector.[172] However, even the Court warned against allowing the interpretation of Section 101 and application of the *Mayo*/*Alice* test to significantly impede innovation, which it clearly seems to be doing, particularly in the healthcare space.[173]

V. PATENTS AND PATIENTS

If innovation drives economic growth, then it follows that innovation in industries, which account for a large portion of the economy, are vital to an economy's stability and continued growth. One such industry is healthcare. Healthcare is consistently ranked as one of the top five industries in contributions to the gross domestic product (GDP) in the United States.[174]

---

167. *Id.* at 15.

168. *Id.*

169. *See* U.S. Chamber of Commerce's Global Innovation Policy Center, *Art of the Impossible* 45 (2020), https://www.uschamber.com/sites/default/files/023881_gipc_ip_index_2020_fullreport_final.pdf [https://perma.cc/6AV9-PQ4J] (inferring from the graph that the U.S. now ranks fifth in patent protection rights).

170. *See* Madigan & Mossoff, *supra* note 1, at 952 (determining the impact of the *Mayo*/*Alice* test and its restrictive nature on applied-for and issued patents).

171. *Id.*; *see* Holman, *Patent Eligibility Post-Myriad*, *supra* note 148, at 1823 (highlighting the disparities among circuit court judges regarding which test should be applied and the applicability of said test).

172. Madigan & Mossoff, *supra* note 1, at 952.

173. *See id.* ("Inventors, investors, and companies working in the innovation industries have little to no understanding how to create and commercialize the medical and high-tech innovation . . . [that is relied] on in the twenty-first century.").

174. *See* Benjamin Elisha Sawe, *The Biggest Industries in the United States*, WORLD ATLAS (Aug. 1, 2017), https://www.worldatlas.com/articles/which-are-the-biggest-industries-in-the-united-states.html [https://perma.cc/A5MW-A7K2] (listing health and social care as the fourth largest industry in the U.S. in 2017); Samuel Stebbins, *These are the Largest Industries in Every State*, USA TODAY (Aug. 31, 2018, 8:35 AM), https://www.usatoday.com/story/money/economy/2018/08/27/largest-industry-

Healthcare is also considered the top industry driving economic growth following the last recession.[175] The healthcare sector is an essential part of the United States' economy, and more importantly our lives. The innovations that flow from this sector do more than just grow the economy; they save lives, prolong life expectancy, and increase quality of life. Maintaining these innovations should be of the upmost importance.

Just as the United States is regarded as the leader in overall innovation, it is also the leader in healthcare innovation.[176] The country has the largest healthcare sector in the world and leads innovation in both the medical and scientific fields.[177] Yet, all of that is at risk. The weakening of the patent system by judicial interpretation has brought concern to investors and inventors in this sector.[178] In an industry where patents are considered the standard for protection, uncertainty in patentable-subject matter is the

in-each-state/37585051/ [https://perma.cc/9MK6-C7GH] (listing ambulatory and outpatient healthcare services as the second largest industry nationwide in 2018); Rumki Majumdar & Daniel Bachman, *Changing the Lens: GDP from the Industry Viewpoint*, DELOITTE INSIGHTS (July 25, 2019), https://www2.deloitte.com/us/en/insights/economy/spotlight/economics-insights-analysis-07-2019.html [https://perma.cc/SB4A-9P8W] (listing educational services, healthcare, and social assistance as the fifth largest GDP contributing group in 2019); *Biggest Industries by Revenue in the US in 2021*, IBIS WORLD, https://www.ibisworld.com/united-states/industry-trends/biggest-industries-by-revenue/ [https://perma.cc/QXS5-2R5V] (predicting three of the top ten industries of 2021 will be in the healthcare sector).

175. *See* Alison L. Deutsch, *The 5 Industries Driving the U.S. Economy*, INVESTOPEDIA (Oct. 6, 2020), https://www.investopedia.com/articles/investing/042915/5-industries-driving-us-economy.asp [https://perma.cc/7MQD-32AL] (explaining how the health sector added jobs and aided the economy in the aftermath of the financial crisis in 2008).

176. Grace-Marie Turner, *Though the U.S. Is Healthcare's World Leader, Its Innovative Culture Is Threatened*, FORBES (May 23, 2012, 2:29 PM), https://www.forbes.com/sites/gracemarieturner/2012/05/23/though-the-u-s-is-healthcares-world-leader-its-innovative-culture-is-threatened/?sh=6b4008d277eb [https://perma.cc/A4T6-DMQW].

177. *See* Gregg Girvan & Avik Roy, *United States: #4 in the World Index of Healthcare Innovation*, FOUND. FOR RSCH. ON EQUAL OPPORTUNITY (Sept. 4, 2020), https://freopp.org/united-states-health-system-profile-4-in-the-world-index-of-healthcare-innovation-b593ba15a96 [https://perma.cc/RUR9-9GPX] (providing data to show the U.S.'s rank and overall standing when it comes to medical innovation); *see also* Jasemine Chambers, *Patent Eligibility of Biotechnological Inventions in the United States, Europe, and Japan: How Much Patent Policy is Public Policy?*, 34 GEO. WASH. INT'L L. REV. 223, 225 (2002) (asserting the United States biotechnology sector is a world leader and pushing the development of international markets).

178. *See* Jeffrey A. Lefstin et al., *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop: Addressing Patent Eligibility Challenges*, 33 BERKELEY TECH. L.J. 551, 583 (2018) (asserting the judicial decisions are to blame for the erosion of patent protection in healthcare); *The Global Innovation Index 2019: Creating Healthy Lives—The Future of Medical Innovation*, Cornell Univ., INSEAD, & WIPO 53 (2019), https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2019.pdf [https://perma.cc/GL7P-UG7P] (stating the future of medical innovation lies in the hands of the judiciary and the legislature).

enemy.[179] Despite the optimistic links between patents, innovation, and economic growth, there is more to consider in the healthcare industry—the patient.

Since the beginning of the United States patent system, there has been concern over the role of patents in increasing patient cost, decreasing patient access, and hindering the innovation of life-saving treatments.[180] There is some truth in every fear; the key is knowing when the benefits exceed the potential negatives.

The perception is that patents afford the inventor, usually a very wealthy biotech or pharmaceutical company, the ability to charge astronomical rates for a necessary treatment, as they have a monopoly on the market. The reality is that this occurs only to an extent. Data shows that, following patent expiration, the average drug cost decreases 38% to 48%.[181] While in most cases the patent holders charge a premium, the intention of this patent monopoly is for the holder to recoup their investment cost.[182] Today the average biotech innovation costs anywhere from $300 million to $2.6 billion.[183] Without the opportunity to recapture these sunk costs, innovation would decrease. This is what we are seeing now. The uncertainty of patentable-subject matter has driven start-ups and investors

179. *See* Iain Cockburn & Genia Long, *The Importance of Patents to Innovation: Updated Cross-Industry Comparisons with Biopharmaceuticals*, 25 EXPERT OP. ON THERAPEUTIC PATS. 739, 741 (2015) ("Eighty-nine percent of respondents in the healthcare (including biotechnology, pharmaceuticals and medical) industry characterized patents as 'extremely important' in 'creating a competitive advantage for your organization . . . .'"); *see generally* Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 295 (2007) (arguing the importance of patents, particularly gene patents, in maintaining and incentivizing innovation).

180. *See generally* Cynthia M. Ho & Ann Weilbaecher, *An Introduction—Patents Versus Patients: Must We Choose?*, 18 ANNALS HEALTH L., at i, ii (2009) (describing each of the concerns regarding patents: cost, access, and innovation); *see also* Alice O. Martin & Sendil K. Devadas, *Patents with an "I" = Patients*, 18 ANNALS HEALTH L. 261, 274 (2009) (positing there is no empirical data to show patents have "any adverse effect on patient care or further innovation").

181. *Is Patent Protection Hindering or Helping Healthcare Management?*, WALDEN UNIV., https://www.waldenu.edu/programs/health/resource/is-patent-protection-hindering-healthcare-management#:~:text=Patent%20protection%20can%20raise%20healthcare%20costs.&text=Only%20when%20a%20patent%20expires,parts%20of%20the%20healthcare%20system [https://perma.cc/WE7U-YWN8].

182. *See* Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials*, 98 IOWA L. REV. 1399, 1421 (2013) (highlighting the quid pro quo nature of patents as justification for the increased cost caused by the monopoly).

183. Andrés Delgado et al., *Inequality Explained: The Trouble with Pharmaceutical Patents*, OPEN CAN. (Jan. 20, 2016), https://opencanada.org/inequality-explained-trouble-pharmaceutical-patents/ [https://perma.cc/Y5EE-C9C2]; *Is Patent Protection Hindering or Helping Healthcare Management?*, *supra* note 181.

to begin innovating outside of the United States.[184] As European and Asian countries follow suit in increasing patent protection, the lure for inventors and investors continues to rise.[185] An increase in cost to the patient may be necessary for the benefits patent protection provides; it not only aids in the growth of the national and global economies, but it also allows for continued innovation—an innovation that may one day save your life or the life of someone you love.

In line with the increased cost is the perception that, as a result, patient access to care and innovation is decreased. The logic follows that if there is an increased cost, the marginalized portion of the population will not be able to receive the treatment.[186] Once again, there is some truth to this perception. However, the distinction needs to be made between essential, life-saving drugs, and non-essential drugs to treat erectile disfunction access.[187] Since the Emergency Medical Treatment and Active Labor Act was passed, no patient who arrives at an emergency room may be denied treatment; this goes to essential access.[188] The argument stands that an individual should not have to go to an emergency room for essential care. A patient going to the E.R. for a diabetic coma is far more costly to the patient, the hospital, and taxpayers than preventative treatment.[189] However, much like with cost, the impact of lessening patent protection reaches beyond this concern. Cost and access boil down to legislative change; the government can aid in regulation of price and access to essential healthcare without impacting innovation.[190]

184. *See* Nguyen & Maine, *supra* note 11, at 1727 (explaining the motivation behind investors choosing other locations outside the U.S. to conduct innovations).

185. *Id.* at 1728.

186. *See* David Branigan, *Global Innovation Index 2019 Released, Focus On The Future of Medical Innovation* (July 24, 2019), https://healthpolicy-watch.news/global-innovation-index-2019-released-focus-on-the-future-of-medical-innovation/ [https://perma.cc/V6LD-MS4K] ("In the absence of swift action, innovation in health and medicine may become a significant source of inequality . . . .").

187. Colleen V. Chien, *The Inequalities of Innovation*, 1, 8 (Mar. 2, 2021) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3157983 [https://perma.cc/J9UX-ASKW].

188. Kimberly Amadeo, *Health Care Inequality in the US*, BALANCE (Nov. 2, 2020), https://www.thebalance.com/health-care-inequality-facts-types-effect-solution-4174842 [perma.cc/KN9M-A47P].

189. *Id.*

190. *See generally* Dhruv Khullar & Peter B. Bach, *3 Actions Congress Can Take to Reduce Drug Prices*, HARVARD BUS. REV. (Feb. 21, 2020), https://hbr.org/2020/02/3-actions-congress-can-take-to-reduce-drug-prices [https://perma.cc/VU77-BQAE] (discussing three legislative solutions for reducing healthcare costs).

Finally, some fear patents hinder the very thing they were designed to protect—innovation. The concern is that patents deter other inventors from using patented material as a building block for further innovations. Unlike cost and access, there is little evidence to support that such is the case.[191] In fact, surveyed data from scientists, executives, intellectual property practitioners, academics, and government personnel showed that patents do not impede innovation.[192] To reinforce this fact, data shows that infringement claims against other inventors are seldom brought to court.

Given the data, for some the answer is clear—the positives of patent protection for innovation outweigh the negatives. For others, it is less certain. So, what is the alternative? For healthcare, the alternative is trade secrets.[193] The broadening of the scope for trade secret misappropriation claims and the narrowing, uncertain scope of patent eligible subject matter has caused a number of companies to turn to trade secrets.[194] When a company is granted a patent, they receive exclusive rights to make, use, sell, or offer to sell the invention for a set period of time in exchange for full disclosure of the innovation.[195] Alternatively, trade secrecy hinges on the company's ability to keep the innovation a secret—if the information is disclosed, the value is destroyed.[196] This alternative seems to exacerbate

191. *See* François Lévêque & Yann Ménière, *Patents and Innovation: Friends or Foes?*, CERNA 66 (Dec. 2006), https://dx.doi.org/10.2139/ssrn.958830 [https://perma.cc/N2YT-S7LG] (expressing the false concern that patents deter innovation).

192. *See id.* at 67 (describing the method of defensive patenting and its' ultimate goal of creating an opportunity to bargain with other innovating firms).

193. *See id.* at 9 ("In fact, according to a US survey, secrecy and lead time are more popular than patents amongst R&D managers to protect product and process innovations."); *see also* James Pooley, *Choosing Between Patents and Trade Secrets, A Discussion Worth Revisiting*, IP WATCHDOG (Nov. 1, 2017), https://www.ipwatchdog.com/2017/11/01/patents-and-trade-secrets-revisited/id=89641/ [https://perma.cc/DWS2-EW3U] ("Patenting and secrecy are the two major methods of protecting technology that supports competitive advantage.").

194. *See* Rachel Harris, *Healthcare Industry Increasingly Using Trade Secret Litigation to Protect Intellectual Property Rights*, TRIAGE HEALTH L. (Aug. 13, 2018) https://www.triagehealthlawblog.com/life-sciences/healthcare-industry-increasingly-using-trade-secret-litigation-to-protect-intellectual-property-rights/ [https://perma.cc/34S7-8FQ6] ("The combination of the broadened rights of the DTSA and the narrowed scope of the Patent Act, may be leading more companies to use claims for trademark misappropriation to protect their rights in federal court—and healthcare companies appear to be at the forefront of this movement.").

195. Steven R. Daniels & Sharae' L. Williams, *So You Want to Take a Trade Secret to a Patent Fight? Managing the Conflicts between Patents and Trade Secret Rights*, AM. BAR ASS'N (Aug. 5, 2019), https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2018-19/july-august/so-you-want-take-trade-secret-patent-fight/ [https://perma.cc/J4LL-LEG4].

196. *Id.*

two of the main concerns of patents: access and innovation. By its nature, secrecy inhibits access and innovation because no one is aware of the workings, makeup, or composition of the innovation; it creates a monopoly of its own.[197] In the past, trade secrets have been used for "formulas or techniques to develop pharmaceuticals, biosimilars, drugs, vaccines, or medical devices; code for a medical technology software, testing results; and patient analyses."[198] Given that the alternative has the same concerns, some of which are bolstered by secrecy, patents become the clear choice for patients and innovation.

Patients and Patents, one letter, one link—innovation. A commitment to patients is a commitment to innovation. The United States is the choice of patients for quality and innovative healthcare.[199] Data shows that patients choose the United States for its world-leading access to new medical technology and treatment.[200] This access is a direct result of the patent system. Knowing the importance of patents and innovation to both people and the economy, the current uncertainty is unacceptable. As we look at cases from the last five years, the call on behalf of patients everywhere is for reform and clarity in restoring the patent system to its former glory.

197. *See* Todd Martin, *Patentability of Methods of Medical Treatment: A Comparative Study*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 381, 384–85 (2000) (inferring if patents disrupt the goal of free flowing information, trade secrets would further do so).

198. Rebecca Edelson et al., *Admonition to Members of the Healthcare Industry: Don't Give Trade Secret Protection the Short Shrift!*, SHEPARD MULLIN RICHTER & HAMPTON LLP (July 8, 2020), https://www.lexology.com/library/detail.aspx?g=43af1203-c026-4e08-b6a7-b3f489a6b0c6 [https://perma.cc/VF9Z-CUS3]; *see* Esha Bandyopadhyay & Bobby Hampton, *Trade Secrets and Patents: Similarities, Differences, and Interplay*, JDSUPRA (July 21, 2020), https://www.jdsupra.com/legalnews/trade-secrets-and-patents-similarities-20313/ [https://perma.cc/P8PL-84KQ] (highlighting the wide availability of trade secrets for all technologies).

199. *See* Girvan & Roy, *supra* note 177 (describing why patients choose to be treated in the United States).

200. *Id.*

VI. GOING BLIND: THE COURT FURTHER DIMINISHES THE I(NNOVATION)

With the establishment of the *Mayo/Alice* test, the Supreme Court provided little direction to courts on what constitutes patent-eligible subject matter. The murky language presented in both *Mayo* and *Alice* lent itself to an overbroad application within the circuit courts. The test created uncertainty and splits, not only amongst jurisdictions, but also within the Court of Appeals for the Federal Circuit. The test's application seems to be focused on the "inventive concept," which bleeds into the statutory requirements of novelty and non-obviousness. Both the test and the Court's explanation do little to illuminate what patent-eligible subject matter is outside of these already established requirements. The cases that follow highlight and underscore the uncertain and inconsistent application of the *Mayo/Alice* test in recent years.

A. Ariosa Diagnostics, Inc. v. Sequonom, Inc.[201]

Ariosa is often criticized as one of the many ground-breaking and life-saving patents invalidated under the *Mayo/Alice* test.[202] These claims stemmed from the discovery of "cell-free fetal DNA ('cffDNA') in maternal plasma and serum, the portion of maternal blood samples that other researchers had previously discarded as medical waste."[203] Two doctors discovered this DNA's presence and used the already established processes of amplification and detection to diagnose some genetic fetal disorders.[204] The development of this method for diagnosing conditions, such as Down's syndrome, reduced the risk to both mother and child.[205] Previously, these tests and diagnoses could only be confirmed via "samples from the fetus or placenta."[206] However, in applying the *Alice/Mayo* test, the Court of Appeals for the Federal Circuit ruled that the patent was invalid, as it was directed to natural phenomena.[207]

In its determination as directed to a natural phenomenon, the first step of the *Alice/Mayo* test, the court presented it as fact. Citing the patent

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

202. Lindhorst, *supra* note 22, at 750.

203. *Ariosa Diagnostics*, 788 F.3d at 1373.

204. *See id.* at 1376 (describing the discovery and origin of the methods of the patent in question).

205. *Id.* at 1381 (Linn, J., concurring).

206. *Id.* at 1373.

207. *Id.* at 1378.

descriptions themselves, the court stated the method in these claims both began and ended with natural phenomenon, cell-free fetal DNA, and paternally inherited cell-free fetal DNA, respectively.[208] Given this seeming clarity, they provided no other guidance and proceeded to step two. The court, relying on *Mayo*, ruled the steps and elements added were not sufficient for transformation of the claim.[209] Drawing a comparison to the appending of established methods for determining metabolite levels to the claim in *Mayo*, the court felt as though Sequenom did the same.[210] Ultimately, the appending of routine, conventional steps of amplification and detection to the cell-free fetal DNA, was inadequate to supply the necessary, transformative, and inventive concept.[211]

In a concurring opinion, Judge Linn expressed his strong disapproval of the test and its application.[212] While he agreed with the majority's analysis and conclusion under the *Mayo/Alice* test, Judge Linn "criticized [the test] as overly broad and resulting in the invalidation of otherwise valid, meritorious patents."[213] Judge Linn focused on the interpretation of the second step as presented in *Mayo*. He argued, that while warranted given the facts of that particular case, the exclusion of appending conventional steps to a natural phenomenon is overbroad.[214] In *Diehr*, the Court found that "a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made."[215] However, the blanket dismissal of the addition of conventional steps in *Mayo* does not leave room to distinguish cases that are more similar to *Diehr*.[216] Judge Linn posited the conventional steps appended in *Mayo*, those that the doctors were already doing—"administering the drug at issue, measuring metabolite levels, and adjusting dosing based on the metabolite levels"—fit into the

208. *Id.* at 1376.

209. *See id.* at 1376–77 (explaining the method under *Mayo* of how the natural phenomenon must be transformed to be patentable).

210. *See id.* at 1377 (discussing the analysis in *Mayo* and its applicability to the patent in question).

211. *Id.* at 1378.

212. *See id.* at 1380 (Linn, J., concurring) ("[T]he breadth of the second part of the test was unnecessary to the decision reached in Mayo."); *see also* Lindhorst, *supra* note 22, at 749 (highlighting the disapproval expressed by Judge Linn in his opinion).

213. *Ariosa Diagnostics*, 788 F.3d at 1380 (Linn, J., concurring); Lindhorst, *supra* note 22, at 749.

214. *See Ariosa Diagnostics*, 788 F.3d at 1380 (Linn, J., concurring) (discussing how the court should have limited its interpretation addition of post-conventional steps to the circumstances in *Mayo*).

215. *Id.* at 1380 (quoting Diamond v. Chakrabarty, 450 U.S. 175, 188 (1981)).

216. *Id.* at 1381 (Linn, J., concurring).

purpose for establishment of the *Mayo*/*Alice* test.[217] Alternatively, in *Ariosa*, while the steps were well-established, no one was performing these steps on the paternally-inherited free-cell DNA in the mothers' plasma and serum.[218] The distinguishing factor is the use of conventional steps in an application never used, like in *Diehr*, as opposed to conventional steps used on a new drug or gene as in *Mayo*. This view is congruent with the characterization of *Diehr* in *Alice*. Despite a petition, the Supreme Court denied certiorari.

There is no clarity on patent-eligible subject matter in these decisions; it is simply based on precedent without more direct explanation. *Ariosa* is a continued concern for those in biotechnology, pharmaceuticals, and life-sciences. If a court can recognize the importance of the innovation yet still determine that it is not patent-eligible, how are they to proceed? Without recognition for the fruits of their labor, why and how can inventors continue to innovate?

B. Genetic Techs. Ltd. v. Merial LLC[219]

Shortly after *Ariosa*, the Court of Appeals for the Federal Circuit once again faced the patent-eligible subject matter issue. In *Genetic Techs*, the claim in question covered "a method of detecting a coding region of a person's genome by amplifying and analyzing a linked non-coding region of that person's genome."[220] Respondent argued the methods covered in the patent provided various advantages to previously established methods, including providing more information using short non-coding sequences as opposed to longer DNA sequences.[221] Despite the value of the innovation, the court once again found the patent invalid. The court explained their findings using the reasoning of the *Mayo* and *Ariosa* decisions. Beginning with a comparison to *Mayo*, the court found that the claims were quite similar.[222] In *Genetic Technologies*, the Court dealt with claims that "required analysis of a biological sample (the blood of a patient being treated with a thiopurine drug) and in which the focus of the claimed advance over the prior art was allegedly newly discovered information about human biology: the likelihood that a patient could suffer toxic side effects from particular

217. *Id.* at 1380–81 (Linn, J., concurring).
218. *Id.* at 1381 (Linn, J., concurring).
219. Genetic Techs. Ltd. v. Merial LLC, 818 F.3d 1369 (Fed. Cir. 2016).
220. *Id.* at 1374.
221. *See id.* at 1373 (explaining the various advantages of the patent).
222. *Id.* at 1375.

doses of the drug."[223] Similarly, the court was facing a claim that required the analysis of a biological sample, the non-coding sequence, improving upon established prior art. As the Court in *Mayo* concluded, "the relationship at issue . . . was entirely a consequence of the body's natural processes . . . , so too is the correlation here."[224] To further support their conclusion, the court turned to *Ariosa* describing the claims as "remarkably similar."[225] Much like the claim in *Ariosa*—in which the patent did not claim the discovery of paternally inherited cell-free DNA but instead used the discovery to improve prior art—the claim here focused on the amplifying and analyzing the newly discovered link between non-coding and coding sequences in the genome.[226] As both methods begin and end with a naturally occurring biological law, the claims are unpatentable subject matter.[227]

In step two of the *Mayo/Alice* test, the court continued its comparisons. In *Mayo*, the Court held that "the 'wherein' clauses simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient."[228] Here, the court determined the patent in question similarly gave a directive to the relevant audience.[229] The claims simply provided the directive to amplify and analyze a newly-found non-coding sequences to make discoveries.[230] Once again, to further its finding, the court turned to *Ariosa*; *Ariosa* and *Genetic Techs* are nearly identical. In both cases, the methods involve the appendage of conventional steps of amplification and detection or analysis.[231] The court referred to these additional steps as mental processes.[232] These mental processes can be considered logical next steps, which would likely follow the discovery to make it useful and applicable.[233] As was ruled in *Ariosa*, which built off the *Mayo* analysis, these additions are insufficient to transform the claim.[234]

223. *Id.*
224. *Id.*
225. *See id.* ("The claims in *Ariosa* covered a method of detecting fetal DNA . . . .").
226. *Id.* at 1375–76.
227. *Id.* at 1376.
228. Mayo Collaborative Servs. v. Prometheus Labs. Inc., 566 U.S. 66, 78 (2012).
229. *See Genetic Techs.*, 818 F.3d at 1379 (explaining the directive given to the relevant audience).
230. *See id.* at 1378 (providing the directive instructions).
231. *See id.* at 1379 (explaining the similarities between the steps of *Ariosa* and *Genetic Tech*).
232. *Id.* at 1378.
233. *See id.* at 1379 (describing how the addition of a mental process does not constitute an inventive step).
234. *Id.*

In reaching the same fate as the patent in *Ariosa*, this claim is of concern in considering the future of medical innovation in the United States. There continues to be a lack of clarity surrounding the decisions, each one building off its predecessor, offering no clear insight.

C. Vanda Pharmaceutical Inc. v. West-Ward Pharmaceutical International Ltd.[235]

Two years following *Genetic Tech.*, a case was brought to the United States Court of Appeals for the Federal Circuit that strongly resembled the patent claims in *Mayo*. In *Vanda Pharmaceutical Inc.*, the '610 patent filed by Vanda claims a method for treating schizophrenia patients with iloperidone.[236] The patent included "analyzing the patient's genotype and determining the proper iloperidone dosage based on that genotype."[237] The *Mayo* claims, held as ineligible subject matter, were directed at a method for helping physicians determine proper dosage levels of thiopurine drugs used to treat autoimmune diseases.[238] Given the identicalities, the result seems obvious. However, the '610 patent was held as patent-eligible subject matter, demonstrating just how thin the line between eligible and ineligible subject matter is.

The court spent a majority of the opinion distinguishing *Mayo* from *Vanda*, identifying three differentiating factors. First, the claims were directed to a method of treating a disease.[239] While in *Mayo*, the claims were instead directed to a diagnostic method of optimizing treatment.[240] Both patent claims rely on determining an individual's ability to metabolize a drug in order to determine the correct dosage of that drug; the difference is in the language.[241] The majority felt that while the '610 patent recognized the relationship between iloperidone and levels of metabolites in the body,

235. Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd., 887 F.3d 1117 (Fed. Cir. 2018).

236. *Id.* at 1121.

237. Stephanie Sivinski, Vanda v. West-Ward: *This Time, Dosage Adjustment Claims are Patent Eligible Subject Matter*, IP WATCHDOG (May 16, 2018), https://www.ipwatchdog.com/2018/05/16/vanda-v-west-ward-dosage-adjustment-claims-patent-eligible/id=97117/ [https://perma.cc/C78C-UZ9F].

238. *See* Mayo Collaborative Servs. v. Prometheus Labs. Inc., 566 U.S. 66, 72 (2012) (explaining the method doctors used).

239. *Vanda Pharm.*, 887 F.3d at 1135.

240. *See id.* at 1134 (Fed. Cir. 2018) ("*Mayo* claimed a method for 'optimizing' the dosage of thiopurine drugs by administering thiopurine drugs to a patient and measuring the level of certain metabolites in the blood . . . .").

241. *See* Sivinski, *supra* note 237 ("Both claims correlate an individual's ability to metabolize the drug with the proper dosage for that individual.").

it did not claim this relationship, only an application of it, in the treatment of a particular disease.[242] Alternatively, the court asserted the *Mayo* patent sought to claim the natural relationship.[243] Second, the court focused on use as opposed to observation. The majority observed that, unlike in Mayo where the claim "did not go beyond recognizing . . . a need to increase or decrease a dose[,]" the '610 patent involved the doctors using the natural relationship.[244] The claims in *Mayo* were said to "broadly 'tie up the doctor's subsequent treatment decision[,]'" while the claims in *Vanda* did not.[245] Third, the court looked at the specificity of each patent. The '610 patent instructed physicians to administer one of two dose ranges depending on the genotype results, explaining how the dosage ranges correlate with the risks.[246] In *Mayo*, the claim instead stated the "metabolite level in the blood simply 'indicates' a need to increase or decrease dosage, without prescribing a specific dosage regimen . . . ."[247] This generality left the claim too broad. All of these "distinguishing" factors led to the conclusion that the '610 patent was not directed to a natural law. Rather, the claim was a method of treatment that is patent-eligible subject matter. As such, the court found no need to proceed to the second step.

The fine line drawn between *Mayo* and *Vanda* emphasizes the difficulty courts have had in applying the *Mayo*/*Alice* test.[248] Particular language and a certain level of specificity appear to transform ineligible subject matter into eligible subject matter. Various articles were written attempting to understand the distinguishing factors the majority observed were so clear.[249] Chief Judge Prost felt the majority was splitting hairs and many

242. *See Vanda Pharm.*, 887 F.3d at 1135 (providing the recognized relationship between iloperidone and level of metabolites in the body).

243. *See id.* (highlighting the differences in *Vanda* claiming an application of a natural relationship and *Mayo* claiming the relationship).

244. *Id.*

245. *See id.* (quoting Mayo Collaborative Servs. v. Prometheus Labs. Inc., 566 U.S. 66, 86 (2012)).

246. *See id.* (describing the two dose ranges).

247. *Id.*

248. *See* Sivinski, *supra* note 237 ("While the ultimate patentability conclusions are opposite, the claims in *Vanda* and *Mayo* are very similar, highlighting the thin–and often unpredictable–line that divides eligible and ineligible subject matter.").

249. *See* Caroline L. Masili, *The Federal Circuit Skips the* Mayo *in Upholding* Vanda's *Fanapt Patent*, CARLSON CASPERS (Apr. 26, 2018), https://www.carlsoncaspers.com/federal-circuit-skips-the-mayo-in-upholding-vandas-fanapt-patent/ [https://perma.cc/26XC-3BRH] (asserting the distinguishing factors were nothing but language tweaks that allowed the patent to "skip" Mayo); *see also* Sivinski, *supra* note 237 (attempting to decipher the distinguishing features highlighted by the majority); Courtenay C.

agreed with her. In her dissent, she asserted the majority conflated the inquiry of steps one and two of the *Mayo/Alice* test.[250] In Chief Judge Prost's view, the claim was directed to a law of nature, and the question was whether an "inventive step" existed to transform the claim.[251] Even then, she felt the distinguishing factors relied on were not enough to constitute this "inventive concept" and did not withstand scrutiny.[252] The basis of the claims being nearly identical, along with discord between judges, results in the fear of uncertainty stemming from the *Mayo/Alice* test to permeate further.

Brinkerhoff, *Federal Circuit Upholds Method Of Treatment Claims Under* Vanda *And Distinguishes* Mayo, FOLEY & LARDNER, LLP (Mar. 26, 2019), https://www.foley.com/en/insights/publications/2019/03/federal-circuit-upholds-method-of-treatment-claims [https://perma.cc/PD6K-J5MG] (discussing the murky language that surrounds eligibility for method of treatment claims following *Vanda*); Warren Woessner, *Federal Circuit Circumvents Mayo/Alice Rule in* Vanda v. West-Ward, PATENTS4LIFE (Apr. 17, 2018), https://www.patents4life.com/2018/04/federal-circuit-circumvents-mayo-alice-rule-vanda-v-west-ward/ [https://perma.cc/AUS3-SCVR] (interpreting the holding in terms of future method of treatment claims).

250. *Vanda Pharm.*, 887 F.3d at 1140 (Prost, J., dissenting).

251. *See id.* at 1143 (Prost, J., dissenting) ("[T]he end result of the claimed process is no more than the conclusion of a natural law.").

252. *Id.* at 1140 (Prost, J., dissenting).

D. Natural Alternatives. International, Inc. v. Creative Compounds, LLC[253]

A year later, the United States Court of Appeals for the Federal Circuit doubled down on its holding *Vanda*. *Natural Alternatives* had a series of patents challenged for subject matter eligibility under Section 101; the patents included methods of treatment claims, product claims, and manufacturing claims—all of which were deemed subject matter eligible. Natural Alternatives' patents were all related to the amino acid beta-alanine.[254] More specifically, "[t]he claimed patents generally relate to the use of beta-alanine in a dietary supplement to 'increas[e] the anaerobic working capacity of muscle and other tissue.'"[255]

The court began by addressing the "method claims."[256] Relying on its holding in *Vanda*, the court reinforced that method of treatment claims are patent-eligible. In *Natural Alternatives*, the patent encompassed the administration of the specified dosage in the specified form in the specified manner in order to alter "the athlete's physiology to provide the described benefits."[257] This language is reminiscent of that in the *Vanda* claim, which required a genetic test to determine the appropriate level of iloperidone to selected and administered from those denoted in the patent.[258] The court focused on reinforcing the difference between *Vanda* and *Mayo*. *Mayo* involved the administration of a prior art drug-based to a subject, measuring the level of metabolite, and using the metabolite levels to indicate an increase or decrease in the dosage.[259] However, the patent did not directly require the dosage level be altered as a result of the test, leaving it short of a method of treatment claim.[260] Alternatively, *Vanda* and *Mayo* affirmatively require the administration of the specified dosage to alter the patient's natural state, it is "a specific method of treatment for specific patients using a specific

253. Nat. Alts. Int'l, Inc. v. Creative Compounds, LLC, 918 F.3d 1338 (Fed. Cir. 2019).

254. *Id.* at 1349.

255. *Id.* at 1341 (quoting U.S. Patent No. 5965596 A (issued Oct. 12, 1999)).

256. *Id.* at 1343.

257. *Id.* at 1344.

258. *See* Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd., 887 F.3d 1117, 1121 (Fed. Cir. 2018) (explaining the method for treating a patient with iloperidone).

259. *See* Mayo Collaborative Servs. v. Prometheus Labs. Inc., 566 U.S. 66, 74 (2012) ("The patent claims at issue here set forth processes embodying researchers' findings that identified these correlations with some precision.").

260. *See id.* at 75–76 (providing the courts findings that the test did not require a change in dosage).

compound at specific doses to achieve a specific outcome."[261] The court found that here, "the Method Claims contain specific elements that clearly establish they are doing more than simply reciting a natural law."[262]

The product claims were found patent eligible as they too were not directed at a natural law. The court held that "[a] claim to a manufacture or composition of matter made from a natural product is not directed to the natural product where it has different characteristics and 'the potential for significant utility.'"[263] As the method claims are directed toward the application of a natural law, the product claims are directed to a specific formulation that contains a natural product but has different characteristics and increases its utility.[264] The court took care to differentiate this from *Funk Brothers*, where the "mixture of two naturally occurring bacteria were held not patent eligible."[265] In *Funk Brothers*, the claimed combination did little to increase the range of utility or improve their natural function.[266] Here, there is evidence that shows the product will have both increased utility and additional effects that would not be realized by the two natural products individually.[267]

Finally, the court quickly found the manufacturing claims to be patent eligible as they are "even further removed from the natural law and product of nature at issue in the Method Claims and Product Claims, respectively."[268] The court highlighted that the claims in question were to a dietary supplement, "not a product of nature[,] and the use of the supplement to achieve a given result is not directed to a law of nature."[269]

Despite its reliance on a case that increased uncertainty, *Natural Alternatives* provided some guidance on what patent eligible subject matter is. By doubling down on *Vanda*, the court provided answers regarding how to use language to transform a claim into a method of treatment, which by definition is patent eligible. For the first time in a long time, the court made a stride in defining the line.

261. *Vanda Pharm.*, 887 F.3d at 1136.

262. *Creative Compounds*, 918 F.3d at 1345.

263. *Id.* at 1348 (quoting Diamond v. Chakrabarty, 447 U.S. 303 (1980)).

264. *Id.*

265. *Id.* at 1349.

266. *See id.* ("The combination of the bacteria into the same package did 'not improve in any way their natural function.'").

267. *See id.* (conveying the record indicating the effects to the products individually).

268. *Id.* at 1350.

269. *Id.*

E. Endo Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.[270]

Shortly after *Natural Alternatives*, the United States Court of Appeals for the Federal Circuit again declared method of treatment claims patent eligible subject matter. *Endo Pharmaceuticals* claimed a treatment method using oxymorphone to safely and effectively treat the pain of patients with impaired kidney function, also known as renal impairment.[271] Following the lead of *Natural Alternatives*, the court once again relied on *Vanda* to distinguish this claim as a method of treatment, emphasizing the language and specificity of the patent. The patent title, abstract, and claims all include language to the effect of "[a] method of treating pain in a renally impaired."[272] Additionally, the claim requires specific steps: "(a) providing a pharmaceutical[;] (b) testing the patient for a disease state[;] and then (c) administering the pharmaceutical . . . based on the [results]."[273] Despite using broader language, the court held the claims contained enough limiting language to make them as specific as those in *Vanda*. The court continued with a comparison to *Ariosa*, noting the distinction in the method of treatment and the method of detection. In *Ariosa*, the claims were directed to the natural law; they start and end with naturally occurring phenomenon, instructing doctors to apply conventional techniques to plasma which was previously considered waste.[274] Here, the claims do not start and end with a naturally occurring phenomenon and require the physician to administer dosage based on test results.[275] While *Ariosa* is a method claim, it is a method of detection claim equating to little more than a claim on the natural phenomenon.[276]

Similar to *Natural Alternatives*, *Endo* further underlined the importance of language and specificity in patent claims. The case provided further guidance to inventors and legal professionals on the application and expectations regarding *Mayo/Alice* and method of treatment claims.

Despite slight improvements regarding the method of treatment claims, patent-eligible subject matter is still as uncertain as ever. Given the prevalence of healthcare related innovations in recent cases, such as those

270. Endo Pharm. Inc. v. Teva Pharm. USA, Inc., 919 F.3d 1347 (Fed. Cir. 2019).

271. *See id.* at 1349 ("[T]he inventor's treatment method advantageously allows patients with renal impairment to ingest less oxymorphone while still treating their pain.").

272. *Id.* at 1353 (quoting U.S. Patent No. 8808737 B2 (issued Aug. 19, 2014)).

273. *Id.*

274. *See id.* at 1356 (providing the holding from *Ariosa*).

275. *Id.*

276. *Id.*

above, this uncertainty will inevitably have a direct impact on the economy and patients. The uncertainty, coupled with the increasing costs of research and development, is destined to lead to the disappearance of innovation in healthcare. The question is, how can we alter the course before innovation is truly gone.

VII. ONE I ON THE ROAD

Patents, innovation, and the legislature are a crossroads. Congress heard the call from inventors, investors, academics, and judges to take action against the uncertainty of patent-eligible subject matter.[277] They have proposed a two-step test to address the concerns: (1) whether the *Mayo/Alice* framework should be repealed; and (2) if/how should Section 101 reformed? As with all things, there are pros and cons to each.

A. *The First Step: To Repeal or Not Repeal*

As discussed, this test for patentable subject-matter has received criticisms from numerous sources. However, the principal complaints are the same: (1) vague and subjective; (2) over-reaching; (3) diminishing innovation; and (4) uncertainty and chaos.[278]

First, the framework has been repeatedly admonished for its lack of clarity.[279] The Court failed to define key terms, such as "abstract idea," or what constitutes enough to transform a claim, i.e., "an inventive concept."[280] While a framework existed, there was no objective criteria. Instead, judges were left to analyze the language and specificity of the claims. All of this meant that the eligibility of your patent was largely determined by the panel of judges assigned.[281] In response, defenders of the framework interpret the vagueness and subjectivity as flexibility and adaptability to new technologies.[282]

277. *See* Tran & Benevento, *supra* note 162, at 30 (highlighting judges, confused by the application of the Mayo/Alice test, are calling for congressional intervention).

278. *See generally* Kevin J. Hickey, *Patent-Eligible Subject Matter Reform in the 116th Congress*, CONG. RSCH. SERV. 20–23 (Sept. 17, 2019), https://fas.org/sgp/crs/misc/R45918.pdf (describing the four principal criticisms of the *Mayo/Alice* framework).

279. *See id.* at 21 (explaining the elements of the framework that led to a lack of clarity).

280. *Id.*

281. *See id.* ("T[he] subjectivity, in the view of critics, injects unpredictability and uncertainty into whether an invention is of a type that is patentable.").

282. *Id.* at 23.

Second, the framework reaches far beyond the statutory language for subject matter eligibility.[283] In fact, the test is focused on the three judicially created exceptions, "law of nature, natural phenomenon, or abstract idea," and the "inventive concept," none of which exist in the statute.[284] Further, the framework blends the analyses of subject matter eligibility, novelty, and non-obviousness through the "inventive concept" requirement.[285] Here, defenders rely on stare decisis.[286] While the language may not be included in the statute, it has been treated as such for years. Additionally, commentators argue that the "inventive concept" analysis goes beyond the novel and non-obvious requirements to consider future impact and moral dilemma.[287]

Third, the framework has diminished innovation.[288] This impact was particularly felt in the healthcare sector. Given the claims in the cases described above, it is clear that the biotechnology, medical device, and pharmaceutical industries have been severely affected.[289] Without promise of protection, inventors in these industries are looking elsewhere.[290] Defenders assert that the framework prevents the issuance of overbroad claims, which slow innovation.[291]

Fourth, the framework has caused uncertainty and chaos.[292] The uncertainty led to a weakened patent system, which in turn led to the loss of the competitive edge the United States had as a global innovation leader.[293] Defenders relish the thought of increasing national competition, lowering costs, and increasing access to innovations as the weakened patent system fails to protect innovation.[294]

283. *See id.* at 21–22 (listing the reasons some interpret the *Mayo/Alice* test as legally flawed).

284. *Id.* at 16.

285. *See id.* at 22 (explaining the analyses through the "inventive concept" thoroughly).

286. *Id.* at 25.

287. *Id.* at 24.

288. *See id.* at 22 (providing evidence of the impact the framework had on innovations in the biotechnology region).

289. *See* Falati, *supra* note 4, at 36 (comparing the affected industries with other countries whose patent eligibility laws are more robust than the United States).

290. Nguyen & Maine, *supra* note 11, at 1727.

291. Hickey, *supra* note 278, at 25.

292. *Id.* at 22.

293. Cahoy, *supra* note 154, at 3.

294. *See* Hickey, *supra* note 278, at 24 (establishing the defenders' arguments).

B. *The Second Step: Section 101 Reform?*

This option may be surprising given that the statutory language of Section 101 has remained virtually unchanged since before the enactment of the Patent Act of 1952. In evaluating whether and how to reform Section 101, it is important to consider the reason a call for reformation was made in the first place—not the statutory language, but instead the judicial framework. Parallel to the four principal criticisms of the framework, there are four potential statutory reformations.

First, stay out of it. Congress can leave Section 101 unchanged and allow the courts to continue to define patent-eligible subject matter.[295] This option will please those who support the *Mayo/Alice* framework, those who feel the court is on the path to clarity, and those who fundamentally believe that the language of Section 101 fits the framework's purpose.[296]

Second, make a list. Congress can choose to replace the *Mayo/Alice* framework with an amended Section 101 that contains a list of subject matter that is or is not patent-eligible.[297] This option would provide concrete, objective criteria for eligibility. In doing so, however, it would completely take away any flexibility.[298]

Third, a new framework. Congress can repeal the *Mayo/Alice* framework in favor of a new, legislative standard.[299] This option would leave the statutory language as is and provide a new test for subject matter eligibility. However, the determination and eventual impact of the new standard leave room for uncertainty.

Finally, goodbye *Mayo/Alice*. Congress can simply repeal the *Mayo/Alice* framework, leaving the statutory language as the guide for patent-eligible subject matter.[300]

C. *Through the Patient's Eyes*

Every individual approaches a decision with a unique perspective influenced by upbringing, ethnicity, socioeconomic status, etc. But one perspective that everyone can relate to is that of being a patient. At some point in our lives, we have all felt, seen, or experienced the impact of medical

295. *Id.* at 26.

296. *See id.* at 27 (describing the various supporters of allowing the judicial law to continue to develop).

297. *Id.* at 26.

298. *Id.* at 28.

299. *Id.* at 26.

300. *Id.*

innovation. With that in mind, the first step of the Congress-proposed two-step solution is easy—repeal the *Mayo/Alice* framework. This test created hysteria in the healthcare sector, diminished innovation, pushed research and development out of the United States, and cost the country its innovation crown. The fact is, innovation spurs economic growth, and the healthcare industry is one of the country's most innovative. These innovations, protected by patents, pushed the United States to be a first choice amongst patients as they seek access to the newest tests and treatments.[301] The United States has a reputation for providing quality, innovative healthcare to every patient.

The second step of the solution, while not as clear given the possibilities, is still discernable—leave the statute alone. The United States rose to innovative healthcare prominence on the coattails of a strong patent system created by the language in Section 101. The history of patent-eligible subject matter under the statute was clear, understandable, and easily applicable. In the years before *Mayo/Alice*, the statute allowed for various medical patents ranging from diagnostic tests to gene therapy. There was no reason to fix what was not broken. A return to the strong patent system that built our healthcare sector is in the interest of all patients and people. Despite the slight increase in cost and slight decrease in access, patents create quality healthcare and push innovation. When healthcare innovation booms, patients win—which means we all win.

VIII. CONCLUSION

The creation of the *Mayo/Alice* two-step test for patent eligible subject matter flipped the patent world upside down. Following its establishment, invalidation rates soared—particularly in the healthcare sector—impacting patients everywhere.[302] The importance of patents in healthcare innovation and innovation generally has been emphasized as the consequences of this framework are realized. The United States is no longer seen as a clear leader in innovation, and as a result, the economy is at risk. Start-ups and investors have turned to foreign nations where return on their investments in innovation are protected.[303] This level of uncertainty regarding patents has never been seen in the United States. As a country that has emphasized the

301. Girvan & Roy, *supra* note 177.

302. *See* Falati, *supra* note 4, at 36 (providing a list of additional impacted fields).

303. *See* Nguyen & Maine, *supra* note 11, at 1727 (explaining why start-ups and investors are turning to foreign nations).

importance of cutting-edge quality care for patients, all that we know is in question. To preserve the healthcare industry, Congress must step-up; in repealing the *Mayo/Alice* framework, there is hope that the patent system may return to its former glory. But it is up to us, the patients, to fight for the healthcare that we deserve. Our lives, the lives of the ones we love, and the lives of those we don't know are impacted by this. Focus the patents back on the patients and return the "I" of innovation.