The Plot Thickens in the Convoluted Saga of Section 101 Patent Eligibility: Where Do We Go From Here?

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I. INTRODUCTION

The United States Supreme Court's patent eligibility jurisprudence has significantly narrowed patentable subject matter, creating an unworkable standard that disincentivizes innovation and is contrary to

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public policy. The current framework for identifying what constitutes patentable subject matter is highly subjective, leading to arbitrary results and unpredictable outcomes. This has detrimentally impacted the biomedical technology industry by rendering medical diagnostic methods almost completely unpatentable.[1] Despite pleas from the United States Court of Appeals for the Federal Circuit, the Supreme Court has refused to reexamine patentable subject matter, leaving it up to Congress to solve.[2] This Comment explores the development of the common law patent eligibility doctrine, the issues the doctrine poses for medical diagnostic methods, and the possibilities for statutory reform.

II. BACKGROUND

A. The Foundations of Patentable Subject Matter

The basis for the American patent system flows from Article I, Section 8, Clause 8 of the U.S. Constitution, which grants Congress 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."[3] Thus, patent law follows a utilitarian framework by incentivizing innovation and the disclosure of new technology for the ultimate purpose of benefitting society.[4]

In accordance with its constitutional authorization, Congress enacted the Patent Act, which is codified in Title 35 of the United States Code.[5] The statutory provision governing patentable subject matter is found in Section 101 of this title, and provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[6] Section 101 is considerably brief and contains broad language, which seems to suggest a liberal interpretation of patent eligibility.[7]

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1. *See* Sanjeev Mahanta, *Patent Eligibility of Medical Diagnostic Inventions: Where Are We Now, and Where Are We Headed?*, IPWATCHDOG (Apr. 14, 2019), http://www.ipwatchdog.com/2019/04/14/patent-eligibility-of-medical-diagnostics-inventions-where-are-we-now-and-where-is-there-to-go/id=108263/.
2. Eileen McDermott, *It's Official: SCOTUS Will Not Unravel Section 101 Web*, IPWATCHDOG (Jan. 13, 2020), http://www.ipwatchdog.com/2020/01/13/scotus-will-not-unravel-section-101-web/id=117800/.
3. U.S. CONST. art. I, § 8, cl. 8.
4. *See id.*
5. *See* 35 U.S.C. §§ 1-390.
6. *Id.* § 101.
7. *See id.*

Indeed, the committee reports accompanying the 1952 Patent Act specify that Congress intended statutory subject matter to "include anything under the sun that is made by man."[8] However, the law of patent eligibility is almost entirely judge-made; thus, these provisions must be read in light of over two hundred years of case law.[9]

The Supreme Court has repeatedly acknowledged that Congress intended for patent laws to be given wide scope and that the legislative history supports a broad interpretation of these provisions.[10] Even so, courts have created three judicial exceptions that substantially limit the scope of patentable subject matter.[11] Specifically, courts have held that laws of nature, physical phenomena, and abstract ideas are not patentable.[12] Rather, these are the basic tools of scientific and technological advancement, and granting patents for such tools would "inhibit future innovation premised upon them."[13] Such patents would be at odds with the very purpose of the patent system, which is to promote creation.[14]

B. The Common Law Development of the Patent Eligibility Doctrine

The Supreme Court's Section 101 jurisprudence from the nineteenth through the twentieth century illustrates the common law development of the limitations on patentable subject matter.[15] The following subparts summarize some of these decisions and how they helped carve out the three judicial exceptions for laws of nature, physical phenomena, and abstract ideas.[16]

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8. S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952).

9. *See* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY 76-77 (7th ed. 2017).

10. *See* Bilski v. Kappos, 561 U.S. 593, 601 (2010); Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980).

11. *See* Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 70 (2012).

12. *Id.*

13. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 589 (2013) (quoting *Mayo*, 566 U.S. at 86).

14. *Id.* (citing *Chakrabarty*, 447 U.S. at 309).

15. *See generally* MERGES & DUFFY, *supra* note 9, at 75-165 (discussing the primary cases establishing the three judicial exceptions to patentable subject matter).

16. *See id.*

1. Laws of Nature

The Supreme Court first established the laws of nature exception to patentable subject matter in the 1853 case of *O'Reilly v. Morse*.[17] In this case, the Court upheld Samuel Morse's patent on his invention of the electro-magnetic telegraph.[18] However, the Court invalidated one of Morse's claims, which sought patent protection for electro-magnetism itself.[19] In coming to this conclusion, the Court reasoned that "the discovery of a principle in natural philosophy or physical science, is not patentable."[20]

Since *Morse*, the Court has repeatedly emphasized its concern that "patent law not inhibit further discovery by improperly tying up the future use of laws of nature."[21] Einstein's famous $E=mc^2$ equation and Newton's law of gravity are two examples of nonpatentable subject matter the Court has used to illustrate this judicial exception.[22] The Court has asserted that natural scientific principles like these are not patentable; however, a novel and useful invention that is created with the aid of such knowledge may be.[23]

2. Physical Phenomena

As with laws of nature, the exception for purely natural products and phenomena is well-established.[24] In the 1948 case of *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, the Supreme Court invalidated a patent involving the combination of certain strains of naturally-occurring bacteria used to assist in the growth of agricultural crops.[25] Prior to the patentee's invention in this case, it was believed that different strains of bacteria could not be packaged together because they were mutually inhibitive.[26] The patentee discovered that some strains of bacteria were not, in fact, mutually inhibitive and could be packaged together without harmful effects to the properties either.[27] He therefore patented a commercial product consisting of the combined bacteria strains in a

17. *See* O'Reilly v. Morse, 56 U.S. 62 (1853).
18. *Id.* at 62.
19. *Id.* at 62-63.
20. *Id.* at 116.
21. Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 85 (2012).
22. *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).
23. *See* Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 94 (1939).
24. *See Chakrabarty*, 447 U.S. at 309.
25. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 132 (1948).
26. *Id.* at 129-30.
27. *Id.* at. 130-31.

powdered or liquid base.[28] However, the Court invalidated the patent on the basis that the non-inhibitive qualities of the bacteria were natural phenomena and therefore unpatentable subject matter; thus, the product in question was not sufficiently inventive.[29] Perhaps most notably, the Court opined that discoveries of physical phenomena are simply "manifestations of laws of nature, free to all men and reserved exclusively to none."[30]

Over three decades after its decision in *Funk Bros.*, the Supreme Court issued a landmark ruling in *Diamond v. Chakrabarty*.[31] Here, the Court held that a live, human-made micro-organism was patentable subject matter under Section 101.[32] In this case, microbiologist Ananda Chakrabarty sought patent protection for his invention of a genetically engineered bacterium that was capable of breaking down crude oil.[33] By virtue of the fact that no naturally occurring bacteria possessed this property, Chakrabarty's invention was believed to have significant value, particularly for the treatment of oil spills.[34] The Court held that Chakrabarty's micro-organism qualified as patentable subject matter because his claim was not directed toward some previously unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter.[35] His invention was deemed by the Court to be a product of human ingenuity possessing a distinctive name, character, and use.[36] The Court differentiated the facts in this case from those in *Funk Bros.* by pointing out that the invention in this case had "markedly different characteristics from any found in nature" and that Chakrabarty's discovery was "not nature's handiwork, but his own."[37]

Taken together, *Funk Bros.* and *Chakrabarty* illustrate the Supreme Court's view that natural products and phenomena may be patented as long as they are modified in a way that makes them sufficiently different from those found in nature.[38] As the Court noted in *Chakrabarty*, a newly

28. *Id.* at 129-30.
29. *Id.* at 130-31.
30. *Id.* at 130.
31. *See* Diamond v. Chakrabarty, 447 U.S. 303 (1980).
32. *Id* at 303.
33. *Id.* at 305.
34. *Id.*
35. *Id.* at 309.
36. *Id.* at 309-10 (citing Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887).
37. *Id.* at 310.
38. *See Chakrabarty*, 447 U.S. 303; Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

discovered plant or mineral is not patent eligible.[39] Yet, all human creations are ultimately composed of, and fundamentally based on, natural products and phenomena; thus, the critical consideration is the degree of human intervention and manipulation that is necessary to transform natural products into patentable inventions.[40] Although *Chakrabarty* seems to permit the patenting of physical phenomena provided that they are modified in some way, this broad rule has been substantially narrowed by subsequent decisions, which will be explored later in this Comment.[41]

3. Abstract Ideas

The third and final judicial exception to patentable subject matter is for abstract ideas.[42] This exception has proven to be especially relevant in the realm of computers and software, which have continuously been the focus of Supreme Court decisions.[43] Three cases illustrate the Court's development of this exception.[44] In the 1972 case of *Gottschalk v. Benson*, the Court established that mathematical algorithms or formulas are abstract ideas and therefore not patentable.[45] Six years after *Benson*, the Supreme Court again held that the discovery of a novel and useful mathematical formula was not patent-eligible subject matter in *Parker v. Flook*.[46] In this case, the Court further clarified that a process is not unpatentable simply because it contains an abstract idea.[47] However, the identification of a limited category of useful, post-solution applications of an otherwise patent-ineligible mathematic formula or algorithm does not make the process patentable.[48]

As evidenced above, *Benson* and *Flook* both seemed to indicate that computer programs implementing mathematic formulas were not patentable.[49] However, in 1981, the Supreme Court held that such a method was patentable.[50] In *Diamond v. Diehr*, the Court validated a

39. *Chakrabarty*, 447 U.S. at 309.
40. *See* MERGES & DUFFY, *supra* note 9, at 128.
41. *See Chakrabarty*, 447 U.S. 303.
42. *See id.* at 309.
43. *See* Diamond v. Diehr, 450 U.S. 175 (1981); Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U.S. 63 (1972).
44. *See Diehr*, 450 U.S. 175; *Flook*, 437 U.S. 584; *Benson*, 409 U.S. 63.
45. *See Benson*, 409 U.S. at 71-72.
46. *See Flook*, 437 U.S. at 584.
47. *Id.* at 590.
48. *Id.* at 584.
49. *See id.*; *Benson*, 409 U.S. 63.
50. *See* Diamond v. Diehr, 450 U.S. 175 (1981).

patent on a method to cure rubber that utilized a mathematical formula to determine the cure time.[51] The Court reasoned that unlike *Flook*, the respondents in this case were not attempting to patent a mathematical formula.[52] Rather, they sought patent protection for the novel steps of a process that utilized a mathematical formula.[53] The tension between the decisions in *Flook* and *Diehr* are clear.[54] Indeed, in his dissent in *Diehr*, Justice Stevens argued that the reasoning embraced by the majority in this case was expressly prohibited in *Flook*.[55] Despite this obvious friction, the Supreme Court did not issue another decision involving a software patent until *Alice Corp. v. CLS Bank International* in 2014, which will be discussed later on in this Comment.[56]

C. The Supreme Court's Creation of a Test for Patentable Subject Matter

Over the past decade, the case law governing patent eligibility has evolved significantly, creating what many have called an unworkable doctrine, wrought with confusion and uncertainty.[57] It is the Supreme Court's contention that the patent eligibility inquiry is merely a "threshold test."[58] Accordingly, for many years, Section 101 was arguably only rarely used to invalidate issued patents or reject patent applications.[59] However, this is no longer the case, due in large part to a series of decisions issued by the Supreme Court limiting patentable subject matter.[60] From 2010 through 2014, the Court issued four decisions in rapid succession that substantially altered the landscape of

51. *Id.* at 175-76.
52. *Id.* at 187.
53. *Id.*
54. *See Diehr*, 450 U.S. 175; *Flook*, 437 U.S. 584.
55. *Diehr*, 450 U.S. at 212 n.36 (Stevens, J., dissenting).
56. *See* Alice Corp. v. CLS Bank Int'l, 573 U.S. 208 (2014).
57. *See Views from the Top: IP Leaders Sound Off on Supreme Court's Refusal to Wade into Patent Eligibility Debate*, IPWATCHDOG (Jan. 13, 2020), http://www.ipwatchdog.com/2020/01/13/views-from-the-top-ip-leaders-sound-off-on-supreme-courts-refusal-to-wade-into-patent-eligibility-debate/id=117815/; Gene Quinn, *Unintelligible and Irreconcilable: Patent Eligibility in America*, IPWATCHDOG (Nov. 4, 2018), http://www.ipwatchdog.com/2018/11/04/unintelligible-irreconcilable-patent-eligibility-in-america/id=102958/.
58. Bilski v. Kappos, 561 U.S. 593, 602 (2010).
59. JOHN R. THOMAS, CONG. RSCH. SERV., R44943, PATENTABLE SUBJECT MATTER REFORM 1 (2017).
60. *Id.*

patent eligibility.[61] These decisions, discussed below, illustrate the Court's renewed concern with preemption and its subsequent creation and application of a two-part test for determining patent eligibility under Section 101.[62]

In the 2010 case of *Bilski v. Kappos*, the Court revisited the law of patent eligibility for the first time since its decisions in *Chakrabarty* and *Diehr* nearly three decades earlier.[63] Here, the Court held that a business method for hedging risk in the field of commodities trading was unpatentable.[64] In the majority opinion, Justice Kennedy emphasized the Court's concern with preemption, opining that hedging was a fundamental economic practice, and thus allowing petitioners to patent it "would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea."[65] Furthermore, the Court rejected the Federal Circuit's test for identifying patentable processes, effectively making room for the establishment of a new standard.[66]

Less than two years after its decision in *Bilski*, the Court laid the framework for a two-part test to identify patentable subject matter in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[67] In this case, the Court contemplated the patent eligibility of a medical diagnostic method involving thiopurine, a drug used to treat autoimmune diseases.[68] Because individuals metabolize the drug differently, it was difficult for doctors to discern whether a particular patient's dosage was too high, risking harmful side effects, or too low, and thus likely ineffective.[69] The patents at issue claimed a method for determining optimal thiopurine dosages by adjusting the dosage amount based on the level of thiopurine metabolites in a patient's blood.[70] In a unanimous decision, the Court held that the method in question was not patentable subject matter under Section 101.[71] Two primary considerations informed

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61. *See Alice*, 573 U.S. 208; Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013); Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66 (2012); *Bilski*, 561 U.S. 593.

62. *See Alice*, 573 U.S. 208; *Myriad*, 569 U.S. 576; *Mayo*, 566 U.S. 66; *Bilski*, 561 U.S. 593.

63. *See Bilski*, 561 U.S. 593; Diamond v. Diehr, 450 U.S. 175 (1981); Diamond v. Chakrabarty, 447 U.S. 303 (1980).

64. *Bilski*, 561 U.S. at 611-12.

65. *Id.*

66. *See id.* at 612-13.

67. *See Mayo*, 566 U.S. 66.

68. *Id.* at 72.

69. *Id.* at 73.

70. *Id.* at 74-75.

71. *Mayo*, 566 U.S. 66.

the Court's determination in this case and ultimately served as the framework for its two-part patent eligibility test.[72]

First, the Court looked at the substance of the claims to determine whether they described natural laws.[73] The Court asserted that the fundamental principle behind this inquiry is that laws of nature are not directly patentable because doing so would preempt their use in other discoveries and inhibit future innovation.[74] Here, the Court found that the claims recited laws of nature, namely, the correlation that exists between metabolite levels in the blood and the likelihood that a thiopurine drug dosage will be effective or cause harm.[75] This relation is a consequence of how the body metabolizes this drug, which is an entirely natural process.[76]

The Court further opined that in order to transform an unpatentable law of nature into a patentable application, a patent must "limit its reach to a particular, inventive application of the law."[77] Accordingly, the Court's second consideration in this case involved determining whether the claimed process, though based on natural laws, contained additional elements "sufficient to ensure that the patent in practice amount[ed] to significantly more than a patent upon the natural law itself."[78] In this case, the Court found that the steps involved in the claimed process did not amount to an inventive concept.[79] Instead, they involved "well-understood, routine, conventional activity previously engaged in by researchers in the field."[80] For these reasons, the Court held that the patent claims at issue effectively claimed the underlying laws of nature themselves and were therefore invalid.[81]

Although the analysis in *Mayo* focused on laws of nature, the Court was quick to extend its reasoning to the remaining judicial exceptions for physical phenomena and abstract ideas, in *Association for Molecular Pathology v. Myriad Genetics, Inc.* and *Alice Corp. v. CLS Bank*

72. *See id.*
73. *Id.* at 77.
74. *Id.* at 85-86.
75. *Id.* at 77.
76. *Id.*
77. *Id.* at 67.
78. *Id.* at 72-73 (citing Parker v. Flook, 437 U.S. 584, 594 (1978)).
79. *Id.* at 73.
80. *Id.*
81. *Id.* at 92.

International, respectively.[82] In *Myriad*, the Court held that a naturally occurring DNA segment that had been isolated was a product of nature and thus constituted unpatentable subject matter.[83] Conversely, synthetically created cDNA was nonnaturally occurring and was therefore patent eligible.[84] Similar to *Mayo*, the Court's analysis in *Myriad* focused on whether the claims attempted to patent underlying natural phenomena and whether the natural products claimed had been sufficiently altered to constitute patentable compositions of matter.[85]

Finally, in *Alice*, the Court expressly established its two-part test for determining patent eligibility, promulgating the framework it originally set forth in *Mayo*.[86] Writing for the Court, Justice Thomas explained that the first step of the test is to determine whether the claims at issue are directed to one of the patent-ineligible concepts, namely, laws of nature, physical phenomena, or abstract ideas.[87] If so, the Court must then determine whether the claims contain additional elements sufficient to transform them into patent-eligible applications of these concepts.[88] The Court described this second step of the analysis as a search for an inventive concept, consisting of "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.'"[89]

After detailing its test for patent eligibility, the Court examined the patents at issue in this case, which covered a computerized scheme for mitigating settlement risk in financial exchanges.[90] First, the Court concluded that the method claims were directed at the abstract idea of intermediate settlement, a fundamental economic practice.[91] Turning to the second inquiry, the Court concluded that the claims failed to transform this abstract idea into a patentable invention.[92] The Court reasoned that the claims in question did not contain an inventive concept; instead, they amounted to nothing more than an instruction to apply an

82. *See* Alice Corp. v. CLS Bank Int'l, 573 U.S. 208 (2014); Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013); *Mayo*, 566 U.S. 66.
83. *Myriad*, 569 U.S. at 576.
84. *Id.* at 576-77.
85. *See id.*; *Mayo*, 566 U.S. 66.
86. *See Alice*, 573 U.S. 208; *Mayo*, 566 U.S. 66.
87. *Id.* at 217 (citing *Mayo*, 566 U.S. at 77).
88. *Id.* (citing *Mayo*, 566 U.S. at 77-78).
89. *Id.* at 217-18 (alteration in original) (quoting *Mayo*, 566 U.S. at 73).
90. *Id.* at 213.
91. *Id.* at 219.
92. *Id.* at 221.

abstract idea using a computer.[93] Therefore, the Court held that the claims in this case were patent ineligible under Section 101.[94]

D. The Aftermath

The Supreme Court's decisions in *Bilski*, *Mayo*, *Myriad*, and *Alice* are widely recognized as having significantly narrowed the scope of patentable subject matter.[95] Compared to the five years prior to *Alice*, the five years after *Alice* saw a 1056% increase in the number of decisions finding ineligible claims and a 914% increase in the number of invalidated patents.[96] The consequences of these decisions have been considerable and their implications far-reaching.[97] The *Alice*/*Mayo* framework has garnered substantial criticism, and patent eligibility law has continuously been the subject of major reform efforts.[98] Furthermore, recent developments in this ongoing saga have raised additional concerns regarding the future of patentable subject matter under Section 101.[99]

1. Criticism & Consequences

The Supreme Court's Section 101 jurisprudence has been heavily criticized by a sizable group of patent law stakeholders.[100] Current and former Federal Circuit judges, former United States Patent and Trademark Office (USPTO) officials, patent attorneys, academics, and industry representatives alike have criticized these decisions on various grounds.[101] These critics raise four principal concerns regarding this case law.[102]

First, critics argue that the *Alice*/*Mayo* framework is overly vague, subjective, and difficult to administer, resulting in unpredictable

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93. *Id.* at 225-26.
94. *Id.* at 227.
95. KEVIN J. HICKEY, CONG. RSCH. SERV., R45918, PATENT-ELIGIBLE SUBJECT MATTER REFORM IN THE 116TH CONGRESS 2 (2019).
96. Robert Sachs, Alice*: Benevolent Despot or Tyrant? Analyzing Five Years of Case Law Since* Alice v. CLS Bank*: Part I*, IPWATCHDOG (Aug. 29, 2019), http://www.ipwatchdog.com/2019/08/29/alice-benevolent-despot-or-tyrant-analyzing-five-years-of-case-law-since-alice-v-cls-bank-part-i/id=112722/.
97. *See* HICKEY, *supra* note 95, at 2-4.
98. *See id.*
99. *See* McDermott, *supra* note 2.
100. HICKEY, *supra* note 95, at 20.
101. *Id.*
102. *Id.*

outcomes.[103] Key terms are left largely undefined, leading many to characterize the test as "hopelessly subjective and unworkable."[104] For example, the second prong of the test asserts that the inventive concept requirement is met when the claimed elements of the invention amount to "significantly more" than the ineligible concept itself.[105] Critics contend that this is a highly subjective standard and begs the question: precisely how much more is "significantly more"?[106] Critics have similarly argued that the case law fails to clearly define what an abstract idea is.[107] Many stakeholders believe the subjective nature of the test injects unpredictability and uncertainty into patent eligibility law.[108] This is evidenced, critics argue, by the uneven and unpredictable application of the *Alice*/*Mayo* framework by different panels of the Federal Circuit.[109] Thus, an overarching concern of many critics is that the Supreme Court's patentable subject matter jurisprudence and the Federal Circuit's implementation of it fail to create an objective, predictable standard for making patentable subject matter determinations.[110]

Another major criticism of the *Alice*/*Mayo* framework is that it is legally flawed on several grounds.[111] Most notably, many commentators argue that it misinterprets Section 101 and fundamentally changes the law by imposing extra-statutory requirements for patent eligibility.[112] This is seen by many as going against congressional intent, which is for patentable subject matter to "include anything under the sun that is made by man."[113] Critics have also argued that the *Alice*/*Mayo* test is legally flawed because it conflates Section 101 patent eligibility with other requirements, such as novelty and nonobviousness, which are meant to be addressed by Sections 102 and 103, respectively.[114] Under this view, the determination of whether patent claims contain an inventive concept

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103. *Id.* at 20-21.

104. *See id.* at 21; U.S. PAT. & TRADEMARK OFF., PATENT ELIGIBLE SUBJECT MATTER: REPORT ON VIEWS AND RECOMMENDATIONS FROM THE PUBLIC 30 (2017).

105. Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 217-18 (2014) (quoting Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 73 (2012)).

106. HICKEY, *supra* note 95, at 21.

107. *Id.*

108. *Id.*

109. Gene Quinn, *Does the Supreme Court Even Appreciate the Patent Eligibility Chaos They Created?*, IPWATCHDOG (Nov. 12, 2018), http://www.ipwatchdog.com/2018/11/12/103256/id=103256/.

110. HICKEY, *supra* note 95, at 21.

111. *Id.*

112. *Id.*

113. *Id.*; S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952).

114. HICKEY, *supra* note 95, at 22.

under the *Alice*/*Mayo* framework requires courts to consider issues that are normally reserved for novelty or nonobviousness analysis.[115]

Another concern expressed by critics is that the uncertainty surrounding the *Alice*/*Mayo* test puts the United States at a competitive disadvantage relative to international competitors.[116] Stakeholders theorize that investors in certain industries will be drawn to other countries that have more favorable patent eligibility requirements.[117]

Lastly, and perhaps most importantly, critics argue that by narrowing the scope of patent eligibility, the *Alice*/*Mayo* test disincentivizes innovation and progress.[118] Most commentators agree that the consequences of this case law have been most detrimental in the biotechnology and computer technology industries.[119] In the biotechnology industry, many stakeholders assert that the *Alice*/*Mayo* framework has created patent eligibility issues for things like medical diagnostics, personalized medicine, and treatment methods.[120] Access to patents on computer technology inventions have been similarly limited, affecting innovations in computer software and artificial intelligence.[121] One commentator lamented that because of the Supreme Court's patent eligibility jurisprudence, "the most exciting scientific discoveries, technological advances and innovations of the twenty-first century are no longer patent eligible in America."[122]

2. Recent Attempts to Clarify and Reform Patent Eligibility Law

The Supreme Court's decisions in *Bilski*, *Mayo*, *Myriad*, and *Alice* have sparked substantial debate, bringing eligibility concerns to the forefront of patent law. Recent attempts to clarify and/or reform patentable subject matter law have infiltrated every avenue, resulting in significant administrative, legislative, and judicial developments.

In January of 2019, the USPTO issued its Revised Patent Subject Matter Eligibility Guidance to assist patent examiners in making subject

115. *See id.*
116. *Id.*
117. *Id.*
118. *See id.*
119. *Id.*
120. *Id.*
121. THOMAS, *supra* note 59, at 12; Quinn, *supra* note 109.
122. Quinn, *supra* note 109.

matter eligibility determinations.[123] In an effort to increase "clarity and consistency" in the application of the *Alice*/*Mayo* test, the USPTO revised the procedures for determining whether a patent claim is directed to a judicial exception.[124] Specifically, the USPTO attempted to further define what constitutes an abstract idea and what it means for a claim to be "directed to" ineligible subject matter.[125]

Additionally, the issue of patent eligibility has attracted significant interest from Congress.[126] In April and May of 2019, legislators released a "bipartisan, bicameral framework" for Section 101 reform and a "draft bill" that would abrogate the *Alice*/*Mayo* framework.[127] Then, in June of 2019, the Senate Judiciary Committee held three days of hearings on "The State of Patent Eligibility in America."[128] Following the hearings, legislators indicated that they intended to move forward with Section 101 congressional reform.[129] However, a revised formal bill has yet to be introduced.

Following these legislative developments, the debate over patentable subject matter continued with the Federal Circuit's denial of a petition for rehearing en banc of *Athena Diagnostics, Inc. v. Mayo Collaborative Services* (*Athena I*) in July of 2019.[130] Previously, the

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123. *See* 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019).

124. *Id.* at 50.

125. *Id.*

126. *See* HICKEY, *supra* note 95, at 33.

127. *See* Press Release, Sen. Thom Tillis, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Section 101 Patent Reform Framework (Apr. 17, 2019), http://www.tillis.senate.gov/2019/4/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-section-101-patent-reform-framework [hereinafter Section 101 Reform Framework Press Release]; Sen. Thom Tillis et al., Draft Outline of Section 101 Reform, http://www.tillis.senate.gov/services/files/3491a23f-09c3-4f4a-9a93-71292704c5b1 [hereinafter Section 101 Reform Framework]; Press Release, Sen. Thom Tillis, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act (May 22, 2019), http://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act [hereinafter Section 101 Draft Bill Press Release]; Sen. Thom Tillis et al., Draft Bill for Section 101 Reform, http://www.tillis.senate.gov/services/files/E8ED2188-DC15-4876-8F51-A03CF4A63E26 [hereinafter Section 101 Draft Bill].

128. *See The State of Patent Eligibility in America: Part I: Hearing Before the S. Judiciary Comm., Subcomm. on Intell. Prop.,* 116th Cong. (2019); *The State of Patent Eligibility in America: Part II: Hearing Before the S. Judiciary Comm., Subcomm. on Intell. Prop.,* 116th Cong. (2019); *The State of Patent Eligibility in America: Part III: Hearing Before the S. Judiciary Comm., Subcomm. on Intell. Prop.,* 116th Cong. (2019).

129. HICKEY, *supra* note 95, at 37.

130. *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs. (*Athena II*), 927 F.3d 1333 (Fed. Cir. 2019) (per curium), *denying reh'g and reh'g en banc to* 915 F.3d 743 (Fed. Cir. 2019).

Federal Circuit had invalidated Athena's patent on a new method of diagnosing a serious neuromuscular disease.[131] Following a 7-5 vote, the Federal Circuit issued an order denying rehearing which totaled eighty-six pages and included eight separate opinions—four concurring and four dissenting.[132] The major points of contention in these opinions revolved around how to apply the *Alice*/*Mayo* framework and the extent to which it governed the outcome of the case.[133] However, the opinions also reflected two significant points of agreement.[134] First, all of the judges agreed that Athena's invention, a medical diagnostic method, is the kind of subject matter that should be patentable.[135] Second, all of the judges advocated for a change in the law from either Congress or the Supreme Court.[136]

Most recently, on January 13, 2020, the Supreme Court considered five pending petitions for certiorari on patent eligibility cases, including *Athena I*, which was thought to have the best chance of being granted.[137] Despite the urging of the Federal Circuit and the recommendation of the Solicitor General, the Supreme Court denied certiorari to *Athena I*, essentially rendering medical diagnostics unpatentable.[138] The Court also denied the four other pending petitions for certiorari on patent eligibility cases.[139] In doing so, the Court has made it clear that it does not intend on changing the patent eligibility standard it created in *Mayo*; thus, any hope for reform is squarely in the hands of Congress.[140]

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131. Athena Diagnostics, Inc. v. Mayo Collaborative Servs. (*Athena I*), 915 F.3d 743 (Fed. Cir. 2019), *cert. denied. mem.*, 140 S.Ct. 855 (2020).

132. *See Athena II*, 927 F.3d 1333.

133. *See id.*

134. *See id.*

135. *See id.*

136. *See id.*

137. *See* McDermott, *supra* note 2.

138. *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs. (*Athena III*), 140 S.Ct. 855 (2020) (mem.), *denying cert. to* 915 F.3d 743 (Fed. Cir. 2019); McDermott, *supra* note 2.

139. *See* Garmin USA, Inc. v. Cellspin Soft, Inc., 140 S.Ct. 907 (2020) (mem.), *denying cert. to* 927 F.3d 1306 (Fed. Cir. 2019); Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc., 140 S.Ct. 911 (2020) (mem.), *denying cert. to* 887 F.3d 1117 (Fed. Cir. 2018); HP Inc. v. Berkheimer, 140 S.Ct. 911 (2020) (mem.), *denying cert. to* 881 F.3d 1360 (Fed. Cir. 2018); Power Analytics Corp. v. Operation Tech., Inc., 140 S.Ct. 910 (2020) (mem.), *denying cert. to* 748 F. App'x 334 (Fed. Cir. 2019) (mem.).

140. *See* KEVIN T. RICHARDS, CONG. RSCH. SERV., LSB10344, JUDGES URGE CONGRESS TO REVISE WHAT CAN BE PATENTED 4 (2020).

III. ANALYSIS

The Supreme Court's recent decisions in *Bilski*, *Mayo*, *Myriad*, and *Alice* have significantly narrowed the scope of patentable subject matter, disrupting the delicate balance between incentivizing innovation and the social costs of exclusive rights.[141] The application of the *Alice*/*Mayo* framework has had detrimental consequences in the biomedical technology industry, particularly for medical diagnostic methods.[142] Since *Mayo*, lower courts have consistently found that medical diagnostic methods are not patentable subject matter.[143] This Part analyzes the issues that the *Alice*/*Mayo* framework poses for medical diagnostics and the profound effects it has on biomedical innovation and public health.

The compartmentalized approach of the *Alice*/*Mayo* framework systematically disadvantages medical diagnostic methods.[144] The first step of the *Alice*/*Mayo* test looks at whether claims are directed at patent-ineligible subject matter.[145] As Judge Newman opined in her dissent in *Athena I*, "medical diagnostic methods are so tightly bound to underlying natural laws and phenomena, they are especially susceptible to undue expansion of the eligibility standards."[146] This is to say that medical diagnostics, by their very nature, are directed to natural laws and phenomena, which are ineligible subject matter.[147] Thus, medical diagnostic methods necessarily fail the first part of the inquiry and must advance to step two.[148]

The second part of the *Alice*/*Mayo* test looks at whether the claims contain an inventive concept.[149] Unfortunately, medical diagnostic methods don't fare much better here. The crux of medical diagnostic methods is the application of newly discovered natural correlations to

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141. *See* HICKEY, *supra* note 95, at 17.

142. *See id.*

143. Leslie Kushner, *Patenting Diagnostic Tests: Can We Expect Changes?*, LAW.COM (Jan. 13, 2020, 03:26 PM), http://www.law.com/2020/01/13/patenting-diagnostic-tests-can-we-expect-changes/.

144. *See* Mahanta, *supra* note 1.

145. Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 217 (2014).

146. *Athena I*, 915 F.3d at 763 (Newman, J. dissenting) (alteration in original) (quoting Brief of *Amicus Curiae* Five Life Sciences Patent Practitioners in Support of Plaintiffs-Appellants and Reversal at 6-7, *Athena I*, 915 F.3d 743 (Fed. Cir. 2019) (No. 2017-2508)), *cert. denied mem.*, 140 S.Ct. 855 (2020).

147. *See id.*

148. *See id.*

149. *Alice*, 573 U.S. at 217.

provide practical benefits.[150] Yet, they use conventional techniques and methods in this application and don't necessarily improve upon the existing technology.[151] Therefore, they almost never survive part two of the *Alice*/*Mayo* test.[152] This cycle repeats, invalidating patent after patent.[153]

Medical diagnostic methods are almost always denied patent protection under the current patent eligibility case law.[154] And yet, they undoubtedly serve the purpose of the patent system. As the Federal Circuit has asserted, "providing patent protection to novel and non-obvious diagnostic methods would promote the progress of science and useful arts."[155] Medical diagnostics are achieving significant advances that ultimately benefit the public; nevertheless, they are consistently denied patent protection.[156] For example, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the patent claims were directed to a method for determining fetal characteristics using cell-free fetal DNA (cffDNA) taken from the mother's bloodstream.[157] The method was based on the discovery that cffDNA could be found in the mother's blood.[158] The method claims related to amplifying and detecting the cffDNA, which were known laboratory techniques on their own.[159] The invention was significant because prior art prenatal diagnosis methods were risky and invasive.[160] Even so, the Federal Circuit found that the claims were directed towards naturally occurring phenomena and that the method steps were conventional, so there was no inventive concept.[161] Therefore, the court held that the method was not patentable subject matter.[162] The court came to this conclusion despite the fact that before this method, the very existence of the cffDNA was unknown, as was the exact process for preparing the cffDNA for analysis.[163] The court disregarded a substantial

150. *See* Mahanta, *supra* note 1.
151. *See id.*
152. *See id.*
153. *See id.*
154. *See id.*
155. *Athena I*, 915 F.3d at 753 n.4.
156. *See* Mahanta, *supra* note 1.
157. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1373 (Fed. Cir. 2015).
158. *Id.*
159. *Id.* at 1373-74.
160. *Id.* at 1381 (Linn, J. concurring).
161. *Id.* at 1378 (majority opinion).
162. *Id.*
163. *See id.* at 1376, 1379.

biomedical discovery that significantly improved upon the prior art based on the arbitrary standard set forth in *Mayo*.

The current state of patent protection for medical diagnostic methods may have a detrimental effect on innovation and development in diagnostic medicine.[164] Patent protection is necessary to incentivize the biomedical industry to invest in these methodologies, owing to the fact that developing these diagnostic tests is very costly.[165] Furthermore, these methods are extremely valuable to public health, by providing things like options for disease treatment and information on disease progression.[166] Failure to incentivize medical diagnostic methods could have a significant impact on human health in the long run.[167]

IV. RECOMMENDATION

Given the fact that the Supreme Court recently denied all pending petitions for certiorari on cases concerning patent eligibility, Section 101 reform and the future of diagnostic patents are now entirely dependent upon congressional intervention.[168] This Part will explore three possible options for structuring patent eligibility reform and what the law governing patentable subject matter could look like moving forward.

A. A Statutory List

One potential route for reform is to replace the *Alice*/*Mayo* framework with an explicit list of what is and isn't patentable subject matter.[169] This method would provide increased clarity and specificity by setting out a laundry list of categories, leaving less for courts and USPTO examiners to decipher.[170] Furthermore, this method would allow for the inclusion of the three judicially created exceptions to an extent, by retaining the notion of ineligible subject matter.[171] However, these exceptions would have to be defined differently and very precisely, resulting in a much broader standard than the current case law allows.[172] Assuming that the exceptions are more clearly articulated, this method would allow for more predictable outcomes in patent eligibility

164. Kushner, *supra* note 143.
165. *Id.*
166. *Id.*
167. *See id.*
168. *See* McDermott, *supra* note 2.
169. HICKEY, *supra* note 95, at 26.
170. *See id.* at 28.
171. *See id.*
172. *See id.*

determinations.[173] However, codifying patent-eligible and ineligible subject matter presents unique challenges. For example, it runs the risk of becoming an inflexible standard.[174] Moreover, if terms aren't sufficiently defined and differentiated, it could result in a standard altogether too similar to the *Alice*/*Mayo* framework.

In the beginning of its Section 101 reform efforts in April of 2019, Congress released its first framework for patent eligibility, which follows the statutory list concept described above.[175] The framework suggests replacing the judicial exceptions with five exclusive categories of patent-ineligible subject matter: (1) fundamental scientific principles; (2) products that exist solely and exclusively in nature; (3) pure mathematical formulas; (4) economic or commercial principles; and (5) mental activities.[176] Furthermore, the framework includes a "practical application" test that would allow the patenting of a practical application of ineligible subject matter. This framework was met with mixed reactions, with some arguing for the complete elimination of the ineligible categories rather than the codification of them.[177]

B. A New Standard

Another option that has been advanced for Section 101 reform is to replace the *Alice*/*Mayo* framework with an entirely new standard for assessing patent eligibility.[178] For example, some proposed new standards have suggested limiting patent eligibility to inventions that "result from human effort" or that "do not preempt all practical uses of a law of nature, abstract idea, or natural phenomenon."[179] This option provides the benefit of a new slate, almost completely disregarding the current convoluted case law.[180] However, critics argue that a new standard may not be able to provide greater clarity and predictability while still being adaptable to new innovations.[181]

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173. *See id.*
174. *See id.*
175. *See* Section 101 Reform Framework Press Release, *supra* note 127; Section 101 Reform Framework, *supra* note 127.
176. *See* Section 101 Reform Framework Press Release, *supra* note 127; Section 101 Reform Framework, *supra* note 127.
177. HICKEY, supra note 95, at 34.
178. *Id.* at 29.
179. HICKEY, supra note 95, at 29.
180. *See id.*
181. *Id.*

The American Intellectual Property Law Association has formulated a Section 101 reform proposal following this framework.[182] This proposal suggests replacing the *Alice*/*Mayo* framework with a rule delineating that an invention is patent-ineligible "if and only if the claimed invention as a whole (i) exists in nature independently of and prior to any human activity or (ii) is performed solely in the human mind."[183]

C. Eliminate Exceptions

Lastly, and most drastically, a final option is to eliminate the judicially created exceptions and the *Alice*/*Mayo* framework entirely, without implementing a new standard.[184] One argument advanced for this alternative is that the exceptions to patentable subject matter under Section 101 serve no real purpose.[185] The existing statutory requirements of utility, novelty, nonobviousness, written description, definiteness, and enablement, if applied rigorously and consistently, cover the issues dealt with in the *Alice*/*Mayo* analysis.[186] However, critics argue that Section 101 serves its own distinct purpose in applying the judicial exceptions.[187]

In May of 2019, after receiving feedback on its initial patent reform framework, Congress proposed a "draft bill" for Section 101 legislative reform.[188] This bill follows the model described above, eliminating all judicial exceptions to patentability in favor of a broad scope of eligibility.[189] Furthermore, the bill suggests striking the word "new" from Section 101 and establishing that patentable subject matter must be determined "considering the claimed invention as a whole" without regard to requirements and considerations in other sections.[190] This

182. *See Joint AIPLA-IPO Proposal on Patent Eligibility*, AM. INTELL. PROP. L. ASS'N (May 2018), http://www.aipla.org/advocacy/legislative/joint-aipla-ipo-proposal-on-patent-eligibility.

183. *Id.*

184. HICKEY, supra note 95, at 30.

185. *Id.*

186. *See id.*

187. *Id.*

188. *See* Section 101 Draft Bill Press Release, *supra* note 127; Section 101 Draft Bill, *supra* note 127.

189. *See* Section 101 Draft Bill Press Release, *supra* note 127; Section 101 Draft Bill, *supra* note 127.

190. Section 101 Draft Bill Press Release, *supra* note 127; Section 101 Draft Bill, *supra* note 127.

proposal advocates for sweeping reform, essentially overturning two centuries of judicially created common law exceptions to Section 101.[191]

As drastic as Congress's draft bill sounds, it would bring much needed certainty, clarity, and predictability to patent eligibility.[192] Implementing this reform would allow us to untangle the convoluted mess that is patentable subject matter case law. Getting rid of the judicially created exceptions would be a significant advancement with respect to encouraging innovation in many industries, including biotechnology.[193] This would align with the constitutional purpose of patents, which is to promote progress for the public good.[194] Congress intended for patentable subject matter to be broad enough to "include anything under the sun that is made by man."[195] It is time to abandon the Supreme Court's extra-statutory test and get back to what Congress, and the Constitution, intended.

V. CONCLUSION

The patent eligibility doctrine is broken. The Supreme Court jurisprudence has created a narrow, unworkable standard that disincentivizes innovation and is contrary to public policy. The consequences, particularly for biotechnology, have been severe.[196] The *Alice*/*Mayo* framework has essentially rendered medical diagnostics unpatentable.[197] Despite pleas from the Federal Circuit, the Supreme Court has refused to reexamine patentable subject matter.[198] Now the responsibility is on Congress to implement meaningful Section 101 reform that gets rid of the *Alice*/*Mayo* framework once and for all.

191. *See* Section 101 Draft Bill Press Release, *supra* note 127; Section 101 Draft Bill, *supra* note 127.
192. *See* HICKEY, supra note 95, at 35.
193. *See id.*
194. *See* U.S. CONST. art. I, § 8, cl. 8.
195. S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952).
196. *See* HICKEY, supra note 95, at 22.
197. *See* Mahanta, *supra* note 1.
198. *See* McDermott, *supra* note 2.