Alice's Patent Puzzle: Unlocking Patent Eligibility for Diagnostic Methods Within Wonderland's Faulty Two-Step Framework

ABSTRACT

As it stands today, diagnostic tests and their methods are largely unpatentable. In 2012, the Supreme Court, in Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, redefined the scope of patent subject matter, leaving a profound impact in the context of medical diagnostics. The subsequent decision by the Court in* Alice Corporation v. CLS Bank International *two years later significantly expanded the range of judicially created exceptions to statutory patent eligibility criteria to encompass "abstract ideas," solidifying this "*Alice-Mayo*" framework as the definitive test to determine patent-eligible subject matter.*

But this shift has made it exceedingly difficult to secure diagnostic method patents and has led to a surge in patent invalidation under 35 U.S.C. § 101. The Alice-Mayo *framework has resulted in inconsistent outcomes as courts and the United States Patent and Trademark Office struggle to apply the framework to diagnostic methods. The persistent legal ambiguity underscores the need for clarity, with the patent law community clamoring for large-scale guidance from either the Supreme Court or Congress. This Note examines several proffered approaches to handling the legal ambiguity that persists in light of the* Alice-Mayo *framework, weighing the advantages of carving out exceptions against complete upheaval through congressional reform statutes. This Note's hybrid solution combines (i) a current practice under the two-step framework with the implementation of (ii) a new statutory exception and (iii) a compulsory licensing provision. It aims to create a narrow pocket that would allow diagnostic methods to be patent eligible so long as they are tied to a specific treatment and, at the same time, dispel accessibility concerns regarding the excessive costs of patented diagnostics.*

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Imagine a world where the invention of the MRI, the ultrasound, or the biopsy went unrecognized and unrewarded—a world where the keys to early detection, precision medicine, and cost-effective health care remained locked away. As our society undergoes a remarkable transformation driven by advances in biotechnology and medicine, the role of diagnostic methods in improving health care outcomes has become increasingly prominent.[1] These methods have evolved into indispensable tools that empower health care professionals to diagnose diseases, assess patient risks, and tailor treatments with unprecedented precision.[2] However, as the importance of diagnostic methods continues to grow, so too does the legal discourse surrounding their patent eligibility.[3]

1. *See* NAT'L ACADS. OF SCIS., ENG'G, & MED., IMPROVING DIAGNOSIS IN HEALTH CARE 38 (Erin P. Balogh et al. eds., 2016) ("Over the past 100 years, diagnostic testing has become a critical feature of standard medical practice.").

2. *See* Victoria Wurcel, Americo Cicchetti, Louis Garrison, Michelle M.A. Kip, Hendrik Koffijberg, Anne Kolbe, Mariska M.G. Leeflang, Tracy Merlin, Jorge Mestre-Ferrandiz, Wija Oortwijn, Cor Oosterwijk, Sean Tunis & Bernarda Zamora, *The Value of Diagnostic Information in Personalised Healthcare: A Comprehensive Concept to Facilitate Bringing This Technology into Healthcare Systems*, 22 PUB. HEALTH GENOMICS 8, 9 (2019).

3. *See* Shahrokh Falati, *Patent Eligibility of Disease Diagnosis*, 21 N.C. J.L. & TECH. 63, 67 (2020); Jo-an Chen, Note, *Expanding the Patent Eligibility of Diagnostic Tests and Their Methods*, 2021 B.C. INTELL. PROP. & TECH. F. 1, 3 (2021); Philip Hawkyard, Note, *The Collapse of Alice's Wonderland: Mayo's Faulty Two-Step Framework and a Possible Solution to Patent-Eligibility Jurisprudence*, 74 HASTINGS L.J. 1221, 1231 (2023).

What exactly *is* a diagnostic method? Diagnostic methods are processes involving the detection, measurement, or analysis of biological or medical data to make a diagnosis or identify a patient's medical condition.[4] Beyond the immediate clinical impact, these innovations have profound implications for public health.[5] They enable identification of diseases at their earliest stages—often before the onset of symptoms—empowering health care providers to initiate treatment measures earlier to reduce the burden of disease.[6] Diagnostic methods play a pivotal role in tailoring treatment plans to individual patients.[7] Genetic testing, for example, allows for the selection of therapies that are most likely to be effective while minimizing adverse effects.[8] Diagnostic processes also play a vital role in disease research; they provide critical insights into disease prevalence, progression, and trends, which then inform public health policies and research priorities.[9] In light of these crucial roles, patent eligibility of diagnostic methods is critical, as it directly impacts the incentives for innovation in this vital field.[10]

Despite their importance, the path to patenting these innovations is challenging. One of the most vexing issues in patent law is the lack of clarity in patent eligibility criteria, primarily governed by Section 101 of the US Patent Act.[11] The federal statute provides that "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" is eligible subject matter for patentability.[12] The vague language of the statute, coupled with the judicial precedent of the Supreme Court of the United States'

4. *See* Wurcel et al., *supra* note 2.

5. *See* NAT'L ACADS. OF SCIS., ENG'G, & MED., *supra* note 1, at 39.

6. *Id.* ("In many cases, diagnostic testing can identify a condition before it is clinically apparent; for example, coronary artery disease can be identified by an imaging study indicating the presence of coronary artery blockage even in the absence of symptoms.").

7. *Id.* at 31.

8. Nora Franceschini, Amber Frick & Jeffrey B. Kopp, *Genetic Testing in Clinical Settings*, 72 AM. J. KIDNEY DISEASES 569, 573 (2018).

9. *See* NAT'L ACADS. OF SCIS., ENG'G, & MED., *supra* note 1, at 31.

10. *See* Stuart J.H. Graham & Ted Sichelman, *Why Do Start-Ups Patent?*, 23 BERKELEY TECH. L.J. 1063, 1078 (2008) ("[I]ncreased patenting by venture-backed companies in the software and biotech industries is significantly correlated with total investment, total number of financing rounds, and firm longevity . . . .").

11. 35 U.S.C. § 101; *see* Ryan Davis, *Courts Can Resolve Patent Eligibility Problems, Iancu Says*, LAW360 (Apr. 11, 2019, 5:19 PM), https://www.law360.com/articles/1149185/courts-can-resolve-patent-eligibility-problems-iancu-says [https://perma.cc/LHW6-VHU6] ("[T]he current state of Section 101 is a problem." (quoting Andrei Iancu, former US Patent and Trademark Office Director)).

12. 35 U.S.C. § 101.

Alice-Mayo test,[13] has introduced ambiguity into the determination of one principal issue: whether innovations in medical diagnostic methods should be granted patent protection.[14] This ambiguity has led patent examiners and lower courts to inconsistently apply the subject matter eligibility standard, making it hard for innovators to predict whether a diagnostic method patent application will satisfy the subject matter eligibility criterion for approval.[15]

In addition to reducing divergent case law, further clarification of patent subject matter criteria would help to address and navigate public policy concerns implicated in patenting medical diagnostic methods.[16] Overly broad patents on diagnostic methods might stifle further research and development in the medical field, as researchers may fear infringement claims.[17] Additionally, the exclusivity granted through patents may limit patient access to important diagnostic tests, as the high cost of licensed tests could restrict their availability.[18] Diagnostic methods also often involve genetic or biological information, which raises ethical concerns about ownership of such data and its impact on patients' access to health care.[19] Balancing the interests of innovators, patients, and the public is essential to navigating this evolving patent landscape.

This Note addresses the varying approaches to the patent eligibility of diagnostic processes under the current *Alice-Mayo* framework. Part I paints the historical evolution of patent eligibility in the United States, highlighting the battle between the Supreme Court's

13. *See* Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 72 (2012); Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 215 (2014).

14. *See* Daryl Lim, Response, *The Influence of* Alice, 105 MINN. L. REV. HEADNOTES 345, 348–49, 357 (2021).

15. *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1334–35 (Fed. Cir. 2019) (denying en banc review across eight concurring and dissenting opinions).

16. *See Mayo Collaborative Servs.*, 566 U.S. at 72–73 (invalidating a patent claim because of the risk of "disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries").

17. *See id.*; *see also* Brenda M. Simon, *Patent Cover-Up*, 47 HOUS. L. REV. 1299, 1308 (2011) ("In a lawsuit filed against Myriad in May 2009, numerous other researchers stated that they would engage in analysis of Myriad's technology if doing so would not be an act of infringement.").

18. *See* ENSURING INNOVATION IN DIAGNOSTICS FOR BACTERIAL INFECTION 137 (Chantal Morel et al. eds., 2016) ("[P]atients who desire second-opinion testing from an independent laboratory cannot have such a test done if there is a sole licensee/provider controlling where the diagnostic test can be done and who can do it.").

19. *See* Shelly Simana, *Genetic Property Governance*, 25 YALE J.L. & TECH. 144, 153–55 (2023).

restrictive approach and the Federal Circuit's push for clarity.[20] Part II analyzes several approaches on how best to conceptualize diagnostic methods as patent eligible under Section 101, weighing the advantages and disadvantages of each existing and proposed approach.[21] This Note places a particular emphasis on federal solutions, either by Supreme Court action or congressional intervention. Part III proposes a hybrid solution: that Congress adopt a statutory exception that would recognize eligibility for diagnostic method patents integrated with specified treatment(s) in the patent claims,[22] as well as adopt a compulsory licensing provision for such patents.

I. BACKGROUND

A. Historical Background

Although the Patent Act has not expressly excluded any subject matter from patent protection for most of US history, courts have long recognized that the Act does have limitations.[23] In 1948, the Supreme Court in *Funk Brothers Seed Co. v. Kalo Inoculant Co.* excluded patent protection for natural products.[24] The Court explained that patents on the discovery of natural phenomena or on laws of nature are ineligible on the grounds that these phenomena are "free to all men and reserved exclusively to none"; in other words, these phenomena are of a character upon which the law does not recognize awarding a monopoly.[25] But the *Funk Bros.* Court also left open a small backdoor; if there is an *application* of the law of nature to a new and useful end, then that

20. *Compare* Diamond v. Diehr, 450 U.S. 175, 184 (1981) (establishing a narrow interpretation of patent eligibility by holding that a process involving a mathematical algorithm is patentable only if it results in a physical transformation), *with* Abbott Lab'ys v. Diamedix Corp., 47 F.3d 1128, 1129 (Fed. Cir. 1995) (adopting a broader interpretation of patent eligibility by allowing claims for certain diagnostic methods, reflecting the Federal Circuit's more flexible approach despite the Supreme Court's stricter standards).

21. *See* 35 U.S.C. § 101.

22. *See* Chen, *supra* note 3, at 1. The patent claims referred to in this Note differ from general claims in litigation. Patent claims specifically define the invention in a patent and its legal protection, while general claims in litigation refer to broader legal assertions made in a lawsuit. *See* Patent Cooperation Treaty art. 6, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231.

23. PETER S. MENELL, MARK A. LEMLEY, ROBERT P. MERGES & SHYAMKRISHNA BALGANESH, INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE: 2023 283 (2023); *see, e.g.*, Le Roy v. Tatham, 55 U.S. 156, 175 (1852) (setting forth the basic distinction between abstract "principles" and natural laws and practical applications of those principles); O'Reilly v. Morse, 56 U.S. 62, 62–63 (1853) (holding that a patent claim for Morse's telegraph system was invalid as too abstract and overbroad).

24. 333 U.S. 127, 130 (1948).

25. *Id.* at 132.

application may be patentable.[26] The Supreme Court in *Gottschalk v. Benson* later upheld these previously established limitations on natural phenomena and further established a bar on patent protection for abstract ideas, using its analysis to introduce the policy concern of preemption and patents that close off an entire field of research.[27]

Starting in the late 1970s and early 1980s, courts adopted a more permissive approach towards the scope of patentable subject matter.[28] This new approach started with *Parker v. Flook*, where the Supreme Court expressly embraced an inventive application doctrine.[29] Despite upholding the rejection of the patent at issue, the Court distinguished that although a natural phenomenon may be well known, an *inventive* application of the phenomenon may still be patentable.[30] The Court took this inventive application doctrine further in *Diamond v. Chakrabarty*, in which it read Section 101 broadly, in order to hold that genetically modified organisms may be patentable.[31] In doing so, the Court emphasized that the application of scientific principles to create the organism transformed the invention from a mere product of nature to a man-made invention with real-world utility.[32] The Court's reasoning focused on distinguishing a patentable "application" of a law of nature from the unpatentable law itself.[33] This reasoning later became the basis of the pre-*Alice-Mayo* framework called the *Diehr* framework, named after a case which implied the need for an inventive application but did not explicitly require an inventive concept as articulated in the *Alice-Mayo* framework.[34]

The Federal Circuit—which has exclusive appellate jurisdiction over patent cases—seized these small concessions and ran with them, substantially liberalizing the scope of patentable subject matter in the following decades, while the Supreme Court remained silent.[35] For instance, the Federal Circuit endorsed the US Patent and Trademark Office's (USPTO) stance on permitting patents on isolated DNA

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26. *Id.* at 130.

27. 409 U.S. 63, 71–72 (1972) (invalidating a patent on an algorithm so as to avoid the practical effect of "wholly pre-empt[ing a] mathematical formula").

28. *See* Parker v. Flook, 437 U.S. 584, 594 (1978); Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980).

29. 437 U.S. at 594.

30. *Id.* (emphasis added).

31. 447 U.S. at 308–10.

32. *Id.*

33. *Id.*

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

35. *See* MENELL ET AL., *supra* note 23, at 290 ("In the ensuing decades, the Federal Circuit gradually eroded patent eligibility limitations.").

molecules.[36] It also widened the door for patentability of certain diagnostic methods, emphasizing that a diagnostic method could be considered a "process" within the meaning of Section 101, so long as the method met other established criteria for patentability.[37]

But underlying these two chapters of patent law jurisprudence is a deeper, recurring concern—theoretically, nearly anything can be categorized as an application of nature.[38] First introduced in *Gottschalk*,[39] the preemption concern is that if nearly anything can be considered an application of nature, nearly anything is patentable, thus creating a possible chilling effect on innovation.[40] The chilling effect might forestall competitive development in certain fields out of fear of infringing on a plethora of patents, which could lead to a stagnation of progress.[41] Indeed, this issue set the stage for the Supreme Court to finally speak up against the Federal Circuit's expansive approach to patent eligibility.[42]

B. The Modern Alice-Mayo *Two-Step Framework*

In the late 2000s, the Supreme Court reentered the picture, veering away from the Federal Circuit's pro-patent approach and imposing stricter constraints on subject matter eligibility.[43] The Court also turned its attention to medical diagnostic processes in the pivotal case, *Mayo Collaborative Services v. Prometheus Laboratories, Inc*.[44] In *Mayo*, the Court attempted to solve the preemption problem by

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36. *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1219 (Fed. Cir. 1991).

37. *See* Abbott Lab'ys v. Diamedix Corp., 47 F.3d 1128, 1129 (Fed. Cir. 1995); *see also Diehr*, 450 U.S. at 184, 187 (recognizing that processes, including those involving computer technology, can be patentable when they meet certain criteria, such as involving a machine or involving a practical application that transforms or reduces an article to a different state or thing).

38. *See Diamond*, 447 U.S. 303, 316–18 (1980) (raising concerns about the broad scope of patent eligibility for living organisms); Gottschalk v. Benson, 409 U.S. 63, 72–73 (1972) (reflecting concerns that overly broad patents could cover fundamental mathematical concepts); Parker v. Flook, 437 U.S. 584, 588 (1978) (raising concerns that allowing patents for math processes and algorithms could open the door to an excessive number of patents on routine, non-inventive tasks performed by computers).

39. *See Gottschalk*, 409 U.S. at 67–68, 72.

40. *See* Arpita Bhattacharyya, *Unpatentably Preemptive? A Case Against the Use of Preemption as a Guidepost for Determining Patent Eligibility*, NE. U. L.J. EXTRA LEGAL (Apr. 23, 2014), http://nulawreview.org/extralegalrecent/unpatentably-preemptive-a-case-against-the-use-of-preemption-as-a-guidepost-for-determining-patent-eligibility [https://perma.cc/X46U-8L3S].

41. *See id.*

42. *See, e.g.*, *In re* Bilski, 545 F.3d 943, 958 (Fed. Cir. 2008), *aff'd but criticized sub nom.* Bilski v. Kappos, 561 U.S. 593 (2010).

43. *See id.*; Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 72 (2012); Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 212 (2014).

44. 566 U.S. at 72.

incorporating an "inventive" requirement to applications of nature.[45] The Court held that a natural law or natural phenomenon must be sufficiently added upon or transformed—i.e., contain an "inventive concept"—in order to make an idea, formula, mechanism, or test patentable.[46] Applying this principle to the diagnostic methods, the Court invalidated Prometheus Laboratories's patents as the claims merely described a process of observing the natural correlation between metabolite levels and drug efficacy.[47] The Court stressed that the additional procedural steps were "well-understood, routine, conventional activit[ies]" already engaged in by the scientific community, and that merely appending such routine steps to natural correlations was not sufficiently inventive to be patentable.[48]

The Supreme Court echoed and applied the *Mayo* holding to the realm of software patents in *Alice Corporation v. CLS Bank International*.[49] Despite the different subject matter in the two cases, *Alice* extended *Mayo*'s approach with respect to natural phenomena to encompass a broader range of subject matter, like abstract ideas.[50] It also outlined a definitive two-step test for determining whether a patent claims ineligible subject matter.[51] The first step in the *Alice-Mayo* framework addresses whether the patent claim is directed to a judicially-created exception to patentable subject matter, such as a law of nature, natural phenomenon, or abstract idea.[52] If not, the invention is patentable.[53] If the claim is directed to one of the ineligible categories, the second step asks whether the patent claim has an "inventive concept" such that it transforms the claim into something significantly more than the ineligible concept itself.[54] If the invention fails at the second step, it is patent ineligible.[55]

While the *Alice-Mayo* framework has been the definitive test for patentable subject matter since 2014, it is wrought with ambiguities.[56] These ambiguities underscore a growing demand for clarification,

45. *Id.* at 72–73.

46. *See id.*

47. *See id.* at 79–80.

48. *Id.* at 82.

49. 573 U.S. 208, 217 (2014).

50. *See id.* at 217–19.

51. *See id.* at 217–18.

52. *Id.* When a patent claim is directed to something, it means the claim is specifically focused on or pertains to a particular subject matter or concept. *Id.* at 217.

53. *Id.*

54. *Id.* at 217–18.

55. *Id.* at 227.

56. *See* MENELL ET AL., *supra* note 23, at 307.

particularly when it comes to patenting diagnostic methods.[57] One key challenge is distinguishing what constitutes an "abstract idea" or "natural phenomenon" in the field of diagnostics, and what constitutes an *application* of that underlying concept.[58] The complication lies in the observational nature of diagnostic methods.[59] Observation and measurement of naturally occurring correlations is a fundamental part of these diagnostic processes.[60] Because of that, the line between interpreting data and applying a discovered correlation can blur, making it difficult to determine where the abstract idea ends and the application begins.[61] Another closely related challenge subject to a great deal of litigation is determining when a diagnostic method includes innovative and transformative elements beyond the basic correlation.[62] The evaluation of what constitutes an "inventive concept" in diagnostics can be a highly subjective and fact-specific inquiry; it is made worse by the fact that the Supreme Court has offered no clarification on what an inventive concept is.[63] This second step dominates the litigation surrounding diagnostic method patent eligibility, so much so that some scholars argue the *Alice-Mayo* two-step framework has collapsed into one step.[64]

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57. *See id.*

58. *See* Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. SCI. & TECH. L. 256, 267–69 (2015) ("Perhaps the Court does not recognize diagnosis alone . . . as an application.").

59. *See id.* at 271.

60. *Id.* at 269.

61. *Id.* ("Perhaps that is why the Court sees the claim as nothing more than the recital of a law of nature followed by a general instruction to 'apply the law:' [sic] Perhaps it is only the therapeutic intervention that the Court would recognize as a patent-eligible application of the law.").

62. *See* Scott J. Bornstein, Brian Prew & Giancarlo Scaccia, *After Seeking a Second Opinion, the Federal Circuit Continues to Struggle with Medical Diagnostic Patent Eligibility After* Mayo, GREENBERG TRAURIG (July 9, 2019), https://www.gtlaw.com/en/insights/2019/7/after-seeking-a-second-opinion-the-federal-circuit-continues-to-struggle-with-medical-diagnostic [https://perma.cc/HMU3-B36V] (highlighting the multiple diverging analyses of the inventive concept prong in Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333 (Fed. Cir. 2019)).

63. *See* Burman York Mathis III, Alice-*Insanity (Part One), or Why the* Alice-Mayo *Test Violates Due Process of Law*, IPWATCHDOG (Oct. 26, 2021, 4:15 PM), https://ipwatchdog.com/2021/10/26/alice-insanity-part-one-alice-mayo-test-violates-due-process-law/id=139229/# [https://perma.cc/NY87-74K6].

64. Hawkyard, *supra* note 3, at 1228 (asserting the position that the "framework is 'collapsing' into one step, with the Federal Circuit using step-two analysis to determine if patent claims fall within the ambit of step one").

*C. Post-*Alice-Mayo *Litigation & Non-Judicial Struggles*

Under the *Alice-Mayo* framework, there has been a dramatic uptick in both patent invalidations and rejections.[65] Diagnostic method patents have been hit particularly hard.[66] For example, in 2015, the Federal Circuit invalidated a patent on prenatal gender tests based on fetal DNA screening on the basis that DNA is considered natural phenomena.[67] In 2016, the same court invalidated a patent on a method of analyzing genomic DNA sequences, asserting that it was "directed to a natural law."[68] And in 2017, the Federal Circuit invalidated four patents because they were based on natural laws, specifically methods of diagnosing the presence of myeloperoxidase as a signifier of cardiovascular disease.[69] These cases not only exemplify that there is an increase in patent invalidations, but also that there is an overall increase in cases involving the question of patent-eligible subject matter, which was previously seen as a relatively obscure defense.[70] This increase is primarily because lower courts are struggling to apply the Supreme Court's *Alice-Mayo* framework, resulting in an array of inconsistent rulings.[71]

For instance, the Federal Circuit was "deeply divided" on how to properly apply the *Alice-Mayo* framework when it tried to interpret what constituted an "abstract idea" in both *Weisner v. Google LLC* and

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65. *See* Paul D. Ackerman & Gregory Miller, *Six Years After* Alice*, Are We Any Closer to Clarity on Patent Eligibility?*, WESTLAW TODAY (Dec. 16, 2020), https://1.next.westlaw.com/Document/If1cb81ca3b1511ebbea4f0dc9fb69570/View/FullText.html?VR=3.0&RS=cblt1.0&__lrTS=20241003030550344&transitionType=Default&contextData=%28sc.Default%29 [https://perma.cc/655B-GXFF] (finding that in the first year after Alice was decided, the Federal Circuit decided twenty two cases involving patent eligibility and found the asserted patents invalid twenty-one times).

66. *See* Shai Jalfin, *6 Years Later: The Effects of the Mayo Decision on Diagnostic Methods*, IPWATCHDOG (July 19, 2018, 12:10 PM), https://ipwatchdog.com/2018/07/19/6-years-later-effects-mayo-decision-diagnostic-methods/id=99206/ [https://perma.cc/C72F-EPGU] (calling attention to a growing number of diagnostic method patent invalidations in the six years after the *Alice-Mayo* framework was established).

67. *Id.*; *see* Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1376–77 (Fed. Cir. 2015).

68. Genetic Techs. Ltd. v. Merial L.L.C., 818 F.3d 1369, 1376 (Fed. Cir. 2016).

69. *See* Cleveland Clinic Found. v. True Health Diagnostics LLC, 859 F.3d 1352, 1362 (Fed. Cir. 2017).

70. Jalfin, *supra* note 66.

71. Sean Flood, *Supreme Court Declines Certiorari to Unlock Patent Eligibility*, ICEMILLER (July 28, 2023), https://www.icemiller.com/thought-leadership/supreme-court-declines-certiorari-to-unlock-patent-eligibility [https://perma.cc/A5MD-5NW4]; *see, e.g.*, Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743, 750–55 (Fed. Cir. 2019); Weisner v. Google LLC, 51 F.4th 1073, 1081–84 (Fed. Cir. 2022); Int'l Bus. Machs. Corp. v. Zillow Grp., Inc., 50 F.4th 1371, 1379–83 (Fed. Cir. 2022).

International Business Machines Corp. v. Zillow Group, Inc.[72] In *Weisner*, the Federal Circuit concluded that the claims in the first two of the four patents at issue were ineligible because they were directed to the abstract idea of "collect[ing] information on a user's movements and location history [and] electronically record[ing] that data"; they did nothing more than create a digital travel log.[73] Under *Alice-Mayo* step two, the court found that the body of the claim recited merely generic features of data accumulation—like a processing system that was connected to a telecommunications network, a URL, and a handheld mobile communication device—and failed to find any inventive concepts.[74] On the other hand, the court found that the claims in the remaining two patents were eligible because they were directed to creating and using travel histories to *improve* computerized search results; these claims added an inventive layer by implementing a specific solution to a problem stemming from computer technology and by providing a new technique for prioritizing the results of a conventional search.[75]

The majority's decision in *Weisner* also seems to provide some guidance on interpreting what "abstract idea" means in situations where the patented invention involves utilizing gathered data.[76] There was a key difference between the four patents: the first two patents were invalid because they focused solely on data collection, whereas the eligible two patents utilized the collected data to create a personalized experience for users.[77]

Immediately following *Weisner*, the Federal Circuit decided a similar case in *International Business Machines Corp.*, involving patents directed to technology allowing users to select and view results on a map.[78] Here, the court was even more explicit: it concluded that the "inventive concept" under step two of *Alice-Mayo* must involve using data in a way that solves a problem for its users.[79] Methods of collection, sorting, and displaying data do not meet the "inventive concept"

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72. Flood, *supra* note 71. *Compare* 51 F.4th at 1082, *with* 50 F.4th at 1379.

73. 51 F.4th at 1082.

74. *Id.* at 1082, 1084.

75. *See id.* at 1084, 1087–88.

76. *See id.* at 1082–86.

77. *See id.* at 1085–88; Nicole Poirot, Note, Weisner v. Google LLC*: An Effort to Provide Clarity Regarding Patent Subject Matter Eligibility*, 39 SANTA CLARA HIGH TECH. L.J. 279, 287 (2023).

78. *See* Int'l Bus. Machs. Corp. v. Zillow Grp., Inc., 50 F.4th 1371, 1374–75 (Fed. Cir. 2022).

79. Poirot, *supra* note 77, at 287–88; *see Int'l Bus. Machs. Corp.*, 50 F.4th at 1382.

requirement of the *Alice-Mayo* test.[80] These back-to-back rulings confirmed a new attitude: for a higher likelihood of passing *Alice-Mayo*, a patent's claim must show the method or system does more than merely sort or display data—it must also use the data in a specific way.[81]

Against the grain of *Mayo* came a milestone decision in *Vanda Pharmaceuticals v. West-Ward Pharmaceuticals International*.[82] A split Federal Circuit panel analyzed claims directed towards a method of treating schizophrenia, ruling that the claims were patent eligible because they were not directed to a natural phenomenon.[83] In upholding the patent, the *Vanda* court distinguished the drug dosage claims from those in *Mayo*, stating that the *Mayo* claims were directed at a method based on the relationships between concentrations of certain metabolites, not directed to a novel method of treating a disease.[84] In contrast, in *Vanda*, the drug dosage claims were directed to a method of using iloperidone to treat schizophrenia, and thus the inventor was not claiming the relationship between the drug and its metabolism, but rather the application of that relationship.[85] The majority found the claims were patent eligible because they were "directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome."[86]

The most prominent display of lower court confusion over the *Alice-Mayo* framework came in *Athena Diagnostics Inc. v. Mayo Collaborative Services, LLC*, in which the Supreme Court was asked to consider a new and specific method of diagnosing neurological disorders.[87] At the Federal Circuit, the dismissal of the petition for rehearing was accompanied by eight separate opinions from judges, four concurring in the denial of the petition and four dissenting.[88] Although the Federal Circuit majority held that its decision to find the claims ineligible was necessitated by the *Alice-Mayo* framework, its members explicitly pled with the Supreme Court to provide further

80. *Int'l Bus. Machs. Corp.*, 50 F.4th at 1383.

81. Poirot, *supra* note 77, at 288.

82. 887 F.3d 1117, 1136 (Fed. Cir. 2018); *see generally* Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66 (2012).

83. *Vanda Pharms.*, 887 F.3d at 1136.

84. MENELL ET AL., *supra* note 23, at 303.

85. *Id.*

86. *Vanda Pharms.*, 887 F.3d at 1136.

87. 915 F.3d 743 (Fed. Cir. 2019).

88. *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743, 749 (Fed. Cir. 2019), *cert. denied*, 140 S. Ct. 855 (2020).

guidance.[89] Such a blatant ask for help by the Federal Circuit is rare, underscoring the extreme struggles faced by the legal system in implementing the framework.[90] Many were hopeful this case would be the vehicle for the Supreme Court to shed needed light on the contours of medical diagnostic patent eligibility because "never before has the Federal Circuit been so splintered on a fundamental doctrine of patent law."[91] Yet, despite this clear call for help, the Supreme Court refused to revisit the patent eligibility of diagnostic methods and denied the petition for certiorari, demonstrating its reluctance in furnishing further guidance or clarification on the *Alice-Mayo* framework.[92]

Although the Federal Circuit has failed to sketch out the metes and bounds of the Supreme Court's subject matter eligibility criteria, the USPTO has undertaken its own efforts to provide appropriate clarification.[93] The USPTO's *2019 Revised Patent Subject Matter Eligibility Guidance* (Guidance) makes a distinction between expansive, generic patent claims that merely mention a judicial exception and those that are more confined or specific.[94] This Guidance focuses on assessing whether a judicial exception is integrated into a practical application.[95] The USPTO sought to reframe the first inquiry under *Alice-Mayo* by breaking it down into two distinct questions with the objective of determining whether a judicial exception is applied, relied upon, or used in a way that imposes a meaningful limitation on the judicial exception.[96] But although this Guidance is useful for those interacting with the USPTO, it is not binding in light of Federal Circuit and Supreme Court precedent.[97] Courts do not typically accord

89. *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1337 (Fed. Cir. 2019) (Hughes, J., concurring) (noting that Judge Hughes "would welcome further explication of eligibility standards in the area of diagnostics patents. Such standards could permit patenting of essential life-saving inventions based on natural laws while providing a reasonable and measured way to differentiate between overly broad patents claiming natural laws and truly worthy specific applications").

90. *See* Tolga Gulmen, *Strategies for Securing Patents Related to Diagnostic Methods in Light of Continuing Confusion from the Courts*, QUARLES & BRADY (Mar. 9, 2020), https://www.quarles.com/newsroom/publications/strategies-for-securing-patents-related-to-diagnostic-methods-in-light-of-continuing-confusion-from-the-courts [https://perma.cc/N8HY-ZM7Y].

91. *Id.* (quoting Brief of the Honorable Paul R. Michel (ret.) as Amicus Curiae in Support of Petitioners at 4, *Athena Diagnostics*, 915 F.3d 743).

92. Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 140 S. Ct. 855 (2020).

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

94. *Id.* at 54.

95. *Id.* at 53–54.

96. *See id.* at 54.

97. *See id.* at 51; Hale Melnick, Note, *Guidance Documents and Rules: Increasing Executive Accountability in the Regulatory World*, 44 B.C. ENV'T AFF. L. REV. 357, 357 (2017).

deference to USPTO guidance documents.[98] Indeed, despite this attempt to make the patentability criteria more clear, "the [USPTO] has admitted that it is challenging to predictably determine what subject matter is patent-eligible."[99] This illustrates the reverberating effects of the *Alice-Mayo* framework felt by countless legal entities, prompting more and more key stakeholders in the patent community to voice apprehension.[100]

D. More Recent Attempts at Clarification

What is the best next step forward? Two recent cases were viewed as potential candidates for the Supreme Court to clarify its *Alice-Mayo* framework in two key ways—by providing guidance on the appropriate level of generality in determining what constitutes an abstract idea, and by addressing the propriety of importing other patent law doctrines into this analysis.[101] In *Interactive Wearables, LLC v. Polar Electro Oy*, the Federal Circuit affirmed the lower court, which invalidated the patent on media-player technology, holding that the invention at issue was merely an abstract idea of providing information in conjunction with media content.[102] In determining whether technological inventions involved an abstract idea, this decision suggested that the court was more inclined to describe such inventions at a higher degree of *generality*, as opposed to higher specificity.[103]

Travel Sentry, Inc. v. Tropp involved a dispute over patents on a dual-access lock used when inspecting luggage.[104] While Tropp's invention was physical in nature, it, like the patent in *Interactive Wearables*, was also evaluated in the context of the abstract-idea exception.[105] But where the *Interactive Wearables* court's application of the abstract-idea exception was "criticized for

98. *See* Melnick, *supra* note 97, at 376.

99. Flood, *supra* note 71.

100. *Id.*

101. *Id.* (drawing specific attention to one practicing attorney's comparison of the *Interactive Wearables* and *Tropp* cases); Interactive Wearables, LLC v. Polar Electro Oy, No. 2021-1491, 2021 WL 4783803, at *1 (Fed. Cir. 2021); Travel Sentry, Inc. v. Tropp, No. 2021-1908, 2022 WL 443202, at *2 (Fed. Cir. 2022).

102. *See* 501 F. Supp. 3d 162, 175 (E.D.N.Y. 2020) ("[T]he claims here merely apply the abstract idea . . . 'to obtain more information' about a program while viewing it—to a content player, rather than 'provide[] a technological improvement' to the content player itself." (quoting Interval Licensing LLC v. AOL, Inc., 896 F.3d 1335, 1344 (Fed. Cir. 2018))), *aff'd*, No. 2021-1491, 2021 WL 4783803 (Fed. Cir. Oct. 14, 2021).

103. *See* Flood, *supra* note 71; *Interactive Wearables*, 501 F. Supp. 3d at 172–74, 176.

104. *See* 2022 WL 443202, at *2–3.

105. *See id.*

describing technological inventions at a high level of generality, potentially undermining innovative ideas," *Tropp*, despite involving a claim more readily dismissed as an abstract idea, applied greater specificity by examining how the invention implemented the specific *coordination* between physical devices (locks) and TSA personnel in the real world.[106]

Clear delineation between the patentability of technological concepts versus the patentability of non-technological concepts becomes a central concern in both cases, as the *Alice-Mayo* analysis hinges on accurately classifying the subject matter within the appropriate domain.[107] Yet, the Supreme Court denied certiorari in both.[108] This unfortunate decision leaves these issues unresolved and adds even more questions to the ever-growing post-*Alice* pile.[109]

II. ANALYSIS

There is a growing realization throughout the patent community in the post-*Alice* and *Mayo* era that federal intervention may be necessary to provide clarity and coherence to the circuitous patent landscape.[110] Due to the uncertainty regarding the boundaries of patent eligibility, scholars, practitioners, and industry stakeholders alike have recognized that the most effective solution will come from either Congress or the Supreme Court.[111] However, the prospect of Supreme Court action as a viable solution appears increasingly questionable, given the Supreme Court's arguably anti-patent stance, as reflected in its consistent denials of certiorari and the limited guidance provided in recent opinions.[112] Therefore, attention has shifted towards alternative approaches put forth by legal scholars to grant patent protection for diagnostic methods.[113]

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106. Flood, *supra* note 71 (quotation); 2022 WL 443202, at *2.

107. *See* Flood, *supra* note 71.

108. Interactive Wearables, LLC v. Polar Electro Oy, 143 S. Ct. 2482, 2482 (2023); Tropp v. Travel Sentry, Inc., 143 S. Ct. 2483, 2483 (2023).

109. *See, e.g.*, *Interactive Wearables*, 143 S. Ct. at 2482; *Tropp*, 143 S. Ct. at 2483.

110. *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1370 (Fed. Cir. 2019) (Newman, J., dissenting).

111. *See* Riddhi Setty, *Patent Eligibility Needs Congressional Action, PTO Director Says*, BLOOMBERG L. (Sept. 19, 2022, 5:37 PM), https://news.bloomberglaw.com/ip-law/patent-eligibility-needs-congressional-action-pto-director-says [https://perma.cc/8X9X-97FC] ("While guidance on subject matter eligibility under US patent law is essential, Vidal said, the question requires congressional action.").

112. *See Interactive Wearables*, 143 S. Ct. at 2482; *Tropp*, 143 S. Ct. at 2483.

113. *See, e.g.*, Michael Hammer, *Moving Past Mayo: US Diagnostic Method Patents in 2022*, MONDAQ (Aug. 5, 2022), https://www.mondaq.com/patent/1219124/moving-past-mayo-us-diagnostic-methods-patents-in-2022 [https://perma.cc/ME6T-E79H].

A. Approach 1: Integration with Treatment

Under current USPTO practice and in light of the Federal Circuit's decision in *Vanda*, one approach by patent attorney Michael Hammer suggests that "it is possible to obtain a claim that recites a diagnostic method, so long as it is within the context of a method of treatment."[114] In operation, Hammer notes that this would involve adding to the patent claim a treatment step that is "directed by the conclusion of the diagnosis steps."[115] In other words, the treatment step would be specifically determined or triggered based on the outcome or findings of the diagnostic steps. This theory posits that the link between the diagnostic and treatment steps constitutes an "inventive concept" because the treatment's value derives from its dependence on the diagnosis.[116] Without the diagnosis aspect, the claimed treatment would have no defined role, losing both context and necessity.[117] This theory would thus render the integrated process patent eligible without any further intervention by Congress or the Supreme Court.[118] This strategy, while a pragmatic response to the current legal landscape, is not without its drawbacks.[119] The primary concern arises from the requirement that the treatment aspect must be an integral part of the claim, potentially undermining the characterization of the claim as a pure diagnostic method.[120] Consequently, this raises the question of whether such claims genuinely embody diagnostic methods or if they represent a hybrid category that mandates the inclusion of both diagnostic and treatment elements just to make the innovative diagnostic method portion patentable.[121]

Despite this drawback, proponents of this approach argue that, given the current legal climate, it represents the most viable strategy for securing patent protection for medical diagnostic methods.[122] The

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114. *Id.*

115. *Id.* (noting a popular approach among practicing patent attorneys).

116. *Id.*

117. *Id.*

118. *See* Haley S. Ball, Gaby L. Longsworth & Michelle K. Holoubek, *Reviewing Patent Eligibility in Biotechnology: Recent Developments in Patenting Diagnostic Methods*, STERNE KESSLER GOLDSTEIN & FOX (Oct. 22, 2021), https://www.sternekessler.com/news-insights/publications/reviewing-patent-eligibility-biotechnology-recent-developments-patenting/ [https://perma.cc/U6YC-UM2X] ("The Federal Circuit has suggested that conventional methods may be used in unconventional ways to overcome patent ineligibility.").

119. *See* Hammer, *supra* note 113.

120. *See id.*

121. *See id.* ("Ten years after *Mayo*, obtaining a non-treatment-connected diagnostic method patent claim remains a challenge in the US.").

122. *See* Anusuya Das, Note, *Patentability Challenges in Personalized Medicine: A Fork in the Road*, 57 IND. L. REV. 455, 465 (2023).

bottom line is that patent applicants may be able to safeguard diagnostic methods by "framing them in a more specific or defined manner that exploits a natural phenomenon."[123] The Federal Circuit in *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.* has already shown a willingness to find patents eligible when directed to "a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome."[124] Thus, under this integrative approach, Hammer suggests that pending patent applications should take care to include a "detailed description" of the treatments intended to follow the diagnostic steps.[125]

B. Approach 2: Legislation

A more proactive approach is to implement legislation granting patent protection to diagnostic method patents.[126] US Senator Thom Tillis has stressed that "the Supreme Court has repeatedly failed to clarify the law, so Congress must act."[127] In fact, Senator Tillis introduced the Patent Eligibility Act of 2022 (Tillis Bill) (and its reintroduction as the Patent Eligibility Restoration Act of 2023), which attempts to address the confusion of patent eligibility through more specific patent eligibility standards.[128] The Tillis Bill seeks to eliminate the broad categories of ineligible matter established by courts and instead aims to create a narrower framework that specifically defines which subject matter is and is not patentable.[129] In seeking to replace the vague and confusing judicial common law doctrines with explicit statutory language, the proposed legislation is viewed as a positive step towards providing a more easily applicable framework.[130]

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123. Karen G. Potter, *Casting a New Light on Diagnostic Patents: "Methods of Preparation" Patent Eligible*, MORRISON FOERSTER (Aug. 12, 2020), https://www.mofo.com/resources/insights/200812-casting-new-light [https://perma.cc/JW4D-T33W].

124. 919 F.3d 1347, 1355 (Fed. Cir. 2019) (quoting Vanda Pharms. Inc. v. W. Ward Pharms. Int'l Ltd., 887 F.3d 1117, 1136 (Fed. Cir. 2018)).

125. Hammer, *supra* note 113.

126. *See* Press Release, Sen. Chris Coons, US Senate, Senator Coons, Tillis Introduce Patent Eligibility Restoration Act to Revitalize American Innovation (June 22, 2023), https://www.coons.senate.gov/news/press-releases/senators-coons-tillis-introduce-patent-eligibility-restoration-act-to-revitalize-american-innovation#:~:text=%E2%80%9CThe%20Patent%20Eligibility%20Restoration%20Act,telecommunications%2C%20to%20name%20a%20few [https://perma.cc/B7DH-752T].

127. *Id.*

128. Patent Eligibility Act of 2022, S. 4734, 117th Cong. (2022); Patent Eligibility Restoration Act of 2023, S. 2140, 118th Cong. (2023).

129. S. 2140.

130. *See* William J. Olson & Courtenay C. Brinckerhoff, *Would the Patent Eligibility Restoration Act Strike the Right Balance?*, FOLEY & LARDNER (July 24, 2023),

Within the context of diagnostic methods, a critical provision in the Tillis Bill addresses patent eligibility by declaring that a process which "occurs in nature wholly independent of, and prior to, any human activity" is ineligible for patent protection.[131] This provision has both positive and negative implications for diagnostic patents. On the positive side, as most diagnostic methods involve essential human activities, such as obtaining and processing biological samples, the Tillis Bill's language could potentially shield these inventions from invalidation.[132] The proposed language, by linking eligibility to human intervention, appears to acknowledge the innovative and transformative role played by human activities in the diagnostic process; this innovativeness is also emphasized in the "inventive concept" element of the *Alice-Mayo* framework.[133] However, a significant drawback arises from the absence of any explicit reference to "diagnostics" within the Tillis Bill itself.[134] Critics argue that this lack of specificity may leave room for courts to circumvent the legislation, potentially resulting in continued challenges to the patent eligibility of diagnostic methods.[135]

Despite the potential benefits of creating a more clear-cut statute, there are substantial hurdles to the adoption of the Tillis Bill.[136] The legislative process is notoriously intricate, and garnering sufficient widespread support to navigate and pass this statutory reform through both houses of Congress will be a formidable feat to accomplish, with some members of Congress likely hesitant to endorse such a massive upheaval of precedent.[137] Furthermore, eliminating all judicial

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https://www.foley.com/insights/publications/2023/07/would-patent-eligibility-restoration-act-balance/ [https://perma.cc/5E44-LG8W].

131. S. 2140.

132. *See* Wurcel et al., *supra* note 2.

133. *See* S. 2140 (stating that processes that "occur[] in nature wholly independent of, and prior to, any human activity" are ineligible for patent protection); Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 217–18 (2014).

134. *See* S. 2140.

135. *See* Schwegman, Lundberg & Woessner, P.A., *Tillis Bill Tries to Fix Section 101*, NAT'L L. REV. (Aug. 8, 2022), https://www.natlawreview.com/article/tillis-bill-tries-to-fix-section-101 [https://perma.cc/Y68B-42E7] (raising the ongoing concern of "whether or not the 'outlaw' status of claims to diagnostic methods . . . has been clearly lifted by this bill").

136. *See* Eileen McDermott, *House Judiciary Chief IP Counsel Tells IPWatchdog LIVE Attendees Eligibility Companion Bill to Be Introduced Soon*, IPWATCHDOG (Sept. 18, 2023, 2:15 PM), https://ipwatchdog.com/2023/09/18/house-representatives-chief-ip-counsel-ipwatchdog-live-eligibility-companion-bill-introduced-soon/id=166872/ [https://perma.cc/X6QQ-5LQ7] ("Commenting that the chances of PERA moving ahead soon are slim considering the lack of consensus, Matal noted there is currently no House version of the bill.").

137. *See* Michael J. Teter, *Congressional Gridlock's Threat to Separation of Powers*, 2013 WIS. L. REV. 1097, 1102, 1108 (2013); Eileen McDermott, *Witnesses Clash Over Potential Pros and*

exceptions to patent eligibility may send a message that the existing judicial exceptions are merely examples of judicial activism, rather than crucial safeguards against unjustified expansion of patent rights.[138] This perspective might imply that the courts' efforts were unjustified, potentially undermining the rationale behind those judicial exceptions.

C. Approach 3(a): Retain Alice-Mayo*, but Create a Separate Legislative Exception for Diagnostic Methods*

An alternative proposal for Congress, as described by scholar Jo-an Chen, would be to maintain the *Alice-Mayo* framework, but implement a separate legislative exception to the established framework for patenting diagnostic methods.[139] While it has several faults, the *Alice-Mayo* framework does serve as an effective filter for patents that are overly broad and insufficiently meritorious.[140] Still, one could argue that while the framework helps eliminate problematic patents, it may also unintentionally curb innovation in fields like personalized medicine, where diagnostics are essential to patient care.[141] Establishing a separate exception primarily for diagnostic methods would enable the patenting of medically beneficial discoveries.[142] However, this legislative exception would not exempt all diagnostic methods—it too must have its limits. In carving out this exception, Congress should be cognizant of "prevent[ing] the monopolization of naturally occurring correlations between certain

Cons of PERA in Senate IP Subcommittee Hearing, IPWATCHDOG (Jan. 23, 2024, 6:15 PM), https://ipwatchdog.com/2024/01/23/witnesses-clash-potential-pros-cons-pera-senate-ip-subcommittee-hearing/id=172334/# [https://perma.cc/YLY9-SBNW] ("Other stakeholders argue the status quo is working and that changing the law would result in upheaval in certain sectors."); *see also* Carl Hulse, *Senate Approves Changes Intended to Ease Gridlock*, N.Y. TIMES (Jan. 27, 2011), https://www.nytimes.com/2011/01/28/us/politics/28cong.html [https://perma.cc/BN3D-JKZ8].

138. Burman York Mathis III, *Is the Supreme Court Going to Declare the Patent Eligibility Restoration Act Unconstitutional?*, IPWATCHDOG (Oct. 10, 2023, 7:15 AM), https://ipwatchdog.com/2023/10/10/supreme-court-going-declare-patent-eligibility-restoration-act-unconstitutional/id=168079/ [https://perma.cc/CT8N-E4LC] ("The question therefore arises as to whether the Supreme Court's exceptions to patent eligibility are necessary to comply with the Constitution, or whether the various judicial exceptions to patent eligibility are unconstitutional judicial activism.").

139. Chen, *supra* note 3, at 13.

140. *Id.*

141. *See* Dorota Stefanicka-Wojtas & Donata Kurpas, *Personalised Medicine—Implementation to the Healthcare System in Europe (Focus Group Discussions)*, J. PERSONALIZED MED., Feb. 2023, at 1, 2 ("PM allows tailoring healthcare interventions to patient groups based on their disease susceptibility, diagnostic and/or prognostic information, or response to treatment.").

142. Chen, *supra* note 3, at 13.

biomarkers and their associated diseases."[143] This is especially significant when considering the potential to lock up fundamental scientific relationships, which could prevent open research and exploration of important diagnostic tools.[144] Chen, for instance, notes that future legislation could instruct the USPTO to deny diagnostic method patent applications when they are tied too closely to disease diagnosis itself.[145] Instead, patents could be granted for specific methods ("like extracting, utilizing, analyzing samples and data from the human body"), provided that these methods remain distinct from any medical diagnoses.[146] This separation between the method and the diagnosis would promote medical innovation while ensuring that physicians retain the freedom to interpret and apply diagnostic information.[147] Chen argues that this limitation would help mitigate concerns about preempting natural laws and phenomena[148]—it would ensure that diagnostic methods remain solely focused on identifying specific biomarkers while leaving the clinical interpretation of the correlation between those markers and related diseases to expert physicians.[149] Drawing a definitive line between the inventive method and the medical diagnosis would prevent the closing off of an entire field of research and the monopolization of health care access.[150]

While the proposed exception holds promise for addressing certain issues, it is essential to acknowledge both the legislative obstacles it will face in implementation and the additional questions it will raise from legal practitioners in the field. Like the proposed Tillis Bill, this exception will face significant challenges in securing approval from both chambers of Congress.[151] It is especially noteworthy that the most significant exceptions to patent eligibility and ineligibility have arisen from judicial interpretation rather than legislative amendment.[152]

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143. *Id.*; *see* Christopher M. Holman, *The Critical Role of Patents in the Development, Commercialization and Utilization of Innovative Genetic Diagnostic Tests and Personalized Medicine*, 21 B.U. J. SCI. & TECH. L. 297, 315–16 (2015).

144. *See* Bhattacharyya, *supra* note 40 (discussing the preemption concerns surrounding claims with overly broad impacts on downstream innovation).

145. Chen, *supra* note 3, at 13.

146. *Id.*

147. *See The Diagnostic Process*, SOC'Y TO IMPROVE DIAGNOSIS IN MED., https://www.improvediagnosis.org/processes/the-diagnostic-process/ [https://perma.cc/JQ64-JX4G] (last visited Oct. 21, 2024).

148. Chen, *supra* note 3, at 13.

149. *Id.* at 13–14.

150. *Id.*; *see* Gottschalk v. Benson, 409 U.S. 63, 69 (1972).

151. *See* Teter, *supra* note 137.

152. *See* discussion *supra* Section II.A (dissecting the historical background of patent eligibility and the evolution of judicial exceptions to patentability); Funk Bros. Seed Co. v. Kalo

There are also several questions and concerns about how the proposed exception would work in practice. The proposed exception is not sufficiently clear in terms of where the delineation between the diagnostic method and the diagnosis will occur; the line between the two is sometimes blurry, as method claims often encompass aspects of diagnostic correlation, at least in part.[153] Nor is it clear how the line will be drawn and by whom. Should Congress have final say on where the line falls? Should Congress defer to professionals in the medical diagnostics field? If so, how should the law weigh the opinions of professionals who have differing opinions? Congress will need to consider these questions if drafting an exception like the one proposed. Congress will also need to balance its own lack of institutional competency in diagnostic methods against the possibility of receiving an overwhelming abundance of information and opinions from experts well versed in the field.[154]

D. Approach 3(b): Amend Section 101 or Abolish the Non-Statutory Supreme Court Exceptions to the US Patent Act

In contrast to the previous solution's aim to *add* an exception to Section 101, scholar Shahrokh Falati offers two alternative solutions: (i) *remove* the Supreme Court-promulgated exceptions altogether, or (ii) *amend* the statutory provision's language.[155] Falati first touches upon a complete upheaval of Section 101.[156] He notes that many scholars consider the Patent Act "unworkable and . . . outdated," since it has remained largely the same since the eighteenth century.[157] Echoing the Intellectual Property Owners Association's position, Falati tosses out the idea of "reversing the Supreme Court decisions and restoring the

Inoculant Co., 333 U.S. 127, 130 (1948) (establishing a bar on patent protection of natural products).

153. *See, e.g.*, Genetic Techs. Ltd. v. Merial L.L.C., 818 F.3d 1369, 1373–74 (Fed. Cir. 2016) (where the patent claims were directed at a *method* for analyzing *correlations* between different regions of DNA).

154. *See* M. Anthony Mills, *Congress Must Reassert Its Role in Science and Technology Policy*, NAT'L REV. (May 30, 2021, 6:30 AM), https://www.nationalreview.com/2021/05/congress-must-reassert-its-role-in-science-and-technology-policy/ [https://perma.cc/BV33-2SFG] (calling Congress's lack of scientific and technological expertise a "brain drain," thereby highlighting the need to make science and technology policy a top priority of the federal government).

155. Falati, *supra* note 3, at 71.

156. *See id.* at 136 ("There is a clear chorus amongst the patent bar, drumming for change to the current patent eligibility laws.").

157. *Id.*

scope of subject matter eligibility to that intended by Congress."[158] This move would clarify the scope of patent subject matter eligibility and simplify the eligibility analysis.[159]

Acknowledging the radical nature of the first approach, Falati then recommends a second approach that would direct Congress to amend Section 101 by deleting the word "new."[160] The goal is to instead draw more focus to the word "useful."[161] Doing so would underline that Section 101 is "separate from and different to the 'new' requirement of [Section] 102," thereby reducing any potential confusion between the two patentability criteria.[162] This approach would also avoid any convoluted determinations of what constitutes "routine conventional activity" and what would be "significantly more" and "inventive."[163]

Falati shows that this second approach would effectively swap out the *Alice-Mayo* framework for the older *Diehr v. Diamond* jurisprudence, which implied but did not explicitly require an inventive application.[164] Given the Supreme Court's heavy reliance on and partiality towards the *Alice-Mayo* framework in invalidating patents over the past decade, it does not seem as though the Court would take kindly to Congress flipping the script.[165] Moreover, the *Diehr* framework has its own problems. If the Supreme Court believed *Diehr* was perfect, it would not have implemented the *Alice-Mayo* framework in the first place.[166] And despite being good law, *Diehr* appears to "defy logic in the face of the Court's [other] tests"; for instance, its opinion is in direct conflict with *Flook*.[167] Justice Stevens, the author of *Flook*, wrote a dissent in *Diehr* making clear that the *Diehr* majority "trivialize[d]" *Flook* and *Benson*.[168] Falati's approach, which effectively

158. *Id.* (quoting Michael Risch, *Nothing Is Patentable*, 67 FLA. L. REV. F. 45, 45 (2015)); *see also* Michael R. Woodward, *Amending* Alice*: Eliminating the Undue Burden of "Significantly More*,*"* 81 ALB. L. REV. 329, 329–30 (2017).

159. Falati, *supra* note 3, at 136.

160. *Id.* at 138; 35 U.S.C. § 101.

161. 35 U.S.C. § 101.

162. Falati, *supra* note 3, at 138; *see* 35 U.S.C. § 102(a).

163. Falati, *supra* note 3, at 138.

164. *Id.*; Diamond v. Diehr, 450 U.S. 175, 191–92 (1981).

165. *See* Ackerman & Miller, *supra* note 65; Jalfin, *supra* note 66.

166. *See* Michael Borella & Ashley Hatzenbihler, *On the Nature of Prior Art in the 35 U.S.C. § 101 Inquiry*, PATENT DOCS (Aug. 10, 2021), https://www.patentdocs.org/2021/08/on-the-nature-of-prior-art-in-the-35-usc-101-inquiry.html [https://perma.cc/66GT-9BSZ] (describing how, while *Alice* did not explicitly overrule *Diehr*, its new framework contradicts *Diehr* in highly impactful ways with respect to evaluating eligibility).

167. 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, 448 (2017).

168. 450 U.S. at 205 (Stevens, J., dissenting).

sets aside *Alice-Mayo*, does nothing to reconcile the *Diehr* framework with the other cases from its time period, like *Flook*.[169] And on top of that, this solution has the same drawback as the Tillis Bill in that it does not directly address any affirmative steps to grant patent protection for diagnostic methods in particular.[170]

E. Approach 4: The "Technological Arts" Test

A fourth and final solution looks outside the United States to the existing "technological arts" test used in Europe.[171] As analyzed in the research conducted by scholar Philip Hawkyard, under this test, a patent is subject matter eligible if it "claims an advance in science or technology (i.e., an application of scientific principles or natural laws), but ineligible if it is drawn to the application of principles outside the scientific realm such as business, law, sports, sociology, or psychology."[172] In essence, the test seems to emphasize advances in fields that rely on more traditionally tangible scientific or technological principles, while excluding those rooted in traditionally abstract fields like sociology and business.[173] As noted by Hawkyard, Judge Mayer, a former Chief Judge and current senior judge on the Federal Circuit, is the most vocal advocate for this test, pushing for it pre- and post-*Alice*.[174]

To implement a clear framework for the technological arts test, Congress or the Supreme Court could look to the European Patent Convention's (EPC) version of the test.[175] Hawkyard points out that the EPC grants patents for inventions in all fields of technology, except anything that falls under the non-exhaustive list of items that are not considered inventions: "discoveries, scientific theories and mathematical methods; aesthetic creations; schemes, rules and

169. John M. Golden, Flook *Says One Thing,* Diehr *Says Another: A Need for Housecleaning in the Law of Patentable Subject Matter*, 82 GEO. WASH. L. REV. 1765, 1781 (2014) ("In short, there are clear tensions within the language of single opinions such as that for the Court in *Diehr*, as well as between the differing language and holdings of *Diehr* and its predecessor *Flook*.").

170. *See* Schwegman, Lundberg & Woessner, P.A., *supra* note 135.

171. Hawkyard, *supra* note 3, at 1243–44.

172. *Id.* at 1244; I/P Engine, Inc. v. AOL Inc., 576 F. App'x. 982, 993 (Fed. Cir. 2014) (Mayer, J., concurring).

173. *See* Hawkyard, *supra* note 3, at 1244.

174. *Id.*; *see I/P Engine*, 576 F. App'x. at 992 (Mayer, J., concurring) ("*Alice* . . . for all intents and purposes, recited a 'technological arts' test for patent eligibility."); Ultramerical, Inc. v. Hulu, LLC, 772 F.3d 709, 717 (Fed. Cir. 2014) (Mayer, J., concurring); DDR Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245, 1265 (Fed. Cir. 2014) (Mayer, J., dissenting); *In re* Marco Guldenaar Holding B.V., 911 F.3d 1157, 1166 (Fed. Cir. 2018) (Mayer, J., concurring).

175. Convention on the Grant of European Patents (European Patent Convention) art. 52, Oct. 5, 1973, 1065 U.N.T.S. 199 [hereinafter EPC].

methods for performing mental acts, playing games or doing business, and programs for computers; [and] presentation of information."[176] Diagnostic methods do not fall into one of the aforementioned excluded categories, and thus, under the technological arts test, would very clearly be patentable.[177] Moreover, Hawkyard points out a crucial—and helpful—nuance in the EPC: exclusions only apply if they are claimed "as such."[178] This framework offers a broader yet more refined scope for eligibility, particularly compared to the more rigid exclusions found under US law.[179] Thus, even if diagnostic methods were somehow considered a non-invention, so long as "'one technical feature' is claimed in the patent that involves [the diagnostic non-invention], then the patent is considered an invention within the meaning" of the technological arts test.[180] This nuance is significant because it allows for a dynamic approach that can adapt as technology evolves, ensuring that the legal framework remains relevant as new innovations emerge.

But there is a massive hurdle in the way of the technological arts test—the Federal Circuit already rejected the test once in *In re Bilski*.[181] According to Hawkyard's analysis, in *In re Bilski*, the Federal Circuit stressed two deeply troubling concerns that are still relevant today—(i) the Supreme Court never "explicitly adopted" the test, and (ii) the term "technology" remains vague, its definition evolving constantly to reflect its dynamic nature.[182] This lack of judicial endorsement and definitional clarity complicates the implementation of the test, creating uncertainties for patent applicants and the courts alike.[183] While proponents of the test counter that the Supreme Court may have nevertheless implied a technological arts test in *Alice*, further issues persist, preventing the adoption of this test.[184] It is unclear how the test will address advancements in existing or emerging technologies; for example, European patent examiners reversed their original stance on artificial intelligence, ultimately deciding to include it within the scope

176. *Id.* art. 52(2); *see* Hawkyard, *supra* note 3, at 1246.

177. *See* EPC, *supra* note 175, art. 52(2); Hawkyard, *supra* note 3, at 1246.

178. EPC, *supra* note 175, art. 52(3); Hawkyard, *supra* note 3, at 1246.

179. *See supra* Part II (outlining the strict contours of the two steps of the *Alice-Mayo* test).

180. Hawkyard, *supra* note 3, at 1246; *see* EUR. PAT. OFF., GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE pt. G, ch. 2, pt. 2 (2022).

181. 545 F.3d 943, 960 (Fed. Cir. 2008).

182. *Id.*; Hawkyard, *supra* note 3, at 1245 (citing *In re* Bilski, 545 F.3d 943, 958 (Fed. Cir. 2008)).

183. *See* Hawkyard, *supra* note 3, at 1245.

184. *Id.* at 1245, 1249.

of eligibility.[185] Who can say which advancements will be the next to be redefined or reclassified? Despite having some dynamic traits, this unpredictability underscores that the test still retains *rigid* aspects that will pose challenges when applied to a field in constant flux.[186] Reflected in Hawkyard's research, this raises another question: can "technological" even be clearly delineated?[187] Not only would it be burdensome to execute a case-by-case approach outlining the outer bounds of technology, but in addition, every change in the definition of "technology" will require some kind of reexamination of early patents that were initially deemed ineligible.[188] This would be extremely time-consuming.[189]

Ultimately, the array of proposed solutions reflects the multifaceted nature of the patent eligibility debate, demanding a careful weighing of their respective merits and pitfalls to craft a comprehensive and effective path forward. While none of the proffered approaches are a perfect fit, each of them underscores the urgent need for a federal fix, one that can provide consistent guidance and resolve the lingering uncertainties with binding effect.

III. SOLUTION

In addressing the persistent challenges surrounding patent subject matter eligibility, particularly in the context of diagnostic methods, it is imperative to harken back to the foundational principles underpinning the Patent Act and the US Constitution's Patent Clause.[190] The overarching goal of both the Patent Act and the Patent Clause is to *promote* the progress of "useful Arts," thereby incentivizing innovation and advancement in technology and science.[191] However, the evolution of patent eligibility jurisprudence, particularly under Section 101, has created uncertainty and inconsistency, hindering rather than fostering innovation.[192]

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185. *Id.* at 1249; Jeffrey A. Lefstin, Peter S. Menell & David O. Taylor, Workshop Report, *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop: Addressing Patent Eligibility Challenges*, 33 BERKELEY TECH. L.J. 551, 597 (2018).

186. *See* Hawkyard, *supra* note 3, at 1249.

187. *Id.*

188. *See id.*

189. *See id.*

190. *See* Patent Act, 35 U.S.C. § 101; U.S. CONST. art. I, § 8, cl. 8.

191. U.S. CONST. art I, § 8, cl. 8 ("To promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.").

192. *See supra* Part I (emphasizing the pre- and post-*Alice* struggles to outline the contours of patent-eligible subject matter).

While some advocate for a judicial solution through Supreme Court intervention, the most effective path forward lies in congressional action.[193] By leveraging its authority to amend the Patent Act, Congress can provide a clearer framework that aligns with contemporary technological developments and societal needs.[194] A hybrid solution emerges as a pragmatic approach, one that acknowledges the supremacy of congressional legislation over ever-changing judicial doctrine.

The cornerstone of this hybrid solution lies in the introduction of a statutory exception tailored exclusively to diagnostic methods, similar to Approach 3(a).[195] Unlike previous blanket exceptions, this exception would incorporate the "integration of specific treatment" requirement from Approach 1.[196] Specifically, to be eligible for patent protection, diagnostic methods must demonstrate a direct correlation to the development or administration of targeted therapeutic interventions.[197] This criterion ensures that patents are granted only for innovations that directly contribute to improved patient outcomes, thus aligning with the constitutional mandate to promote progress in the "useful Arts."[198] Furthermore, this is merely taking a practice that has already been shown to work,[199] and codifying it.

While the slow-moving congressional bottleneck remains an obstacle to this solution, it is likely to pose a challenge regardless of the substance of *any* proposed legislation.[200] Additionally, while this solution requires an additional component to satisfy, rather than just recognizing pure diagnostic methods,[201] it is a necessary burden, since history proves an *in toto* exception for all diagnostic methods would have more difficult hurdles to overcome.[202] This hybrid solution presents the most practical compromise. Moreover, there is an added bonus: this solution would disrupt the *Alice-Mayo* framework the

193. *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 140 S. Ct. 855 (2020) (denying petition for certiorari and refusing to revisit diagnostic method patent eligibility).

194. *See* U.S. CONST. art. I, § 8, cl. 18 (giving Congress the power to make, and amend, all laws necessary and proper).

195. *See* proposed solution *supra* Section II.C.

196. *See* proposed solution *supra* Section II.A; Hammer, *supra* note 113.

197. *See* proposed solution *supra* Section II.A; Hammer, *supra* note 113.

198. *See* U.S. CONST. art. I, § 8, cl. 8.

199. *See* Endo Pharms. Inc. v. Teva Pharms. USA, Inc., 919 F.3d 1347, 1354 (Fed. Cir. 2019).

200. *See* Teter, *supra* note 137; Hulse, *supra* note 137.

201. *See* proposed solution *supra* Section II.A; Hammer, *supra* note 113.

202. *See supra* Section II.C; Chen, *supra* note 3, at 13 ("Congress should limit the scope of this exception for diagnostic tests to prevent the monopolization of naturally occurring correlations between certain biomarkers and their associated diseases.").

least—by confining the exception to the narrow scope of diagnostic method patents integrated with treatment, it leaves the Supreme Court's preferred framework intact and applicable for all other kinds of technology and arts (e.g., software, business methods, chemical compounds, etc.).

The second piece of this proposed solution would include an element that none of the previously discussed proposals address—integration of a compulsory licensing mechanism to address concerns regarding access and affordability.[203] Under this provision, patent holders of diagnostic methods deemed essential for public health would be required to grant licenses to qualified third parties at reasonable rates.[204] One of the broader concerns surrounding diagnostic methods was that patent exclusivity would impose excessive costs on patients trying to obtain access to the more expensive licensed tests.[205] This proposed provision ensures that patients have access to vital diagnostic technologies without undue financial burden, while still providing incentives for innovation through fair compensation for patent holders.[206] It not only mitigates the potential negative impact on access to essential health care, but also reflects a broader commitment to balancing patent rights with public interest considerations.[207] By integrating both a statutory exception and compulsory licensing, Congress can enact a comprehensive solution whose moderate nature and adherence to constitutional principles make it a viable compromise in the face of a tumultuous legal landscape.

IV. CONCLUSION

The significance of diagnostic methods in the medical field cannot be overstated; they are the linchpin of modern healthcare,

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203. *See* Tahir Amin, *The Problem with High Drug Prices Isn't 'Foreign Freeloading,' It's the Patent System*, CNBC (June 27, 2018, 9:08 AM), https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html [https://perma.cc/Y9CY-LKA3].

204. *See, e.g.*, *Compulsory Licensing of Pharmaceuticals and TRIPS*, WTO, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm#:~:text=Compulsory%20licensing%20is%20when%20a,the%20patent%2Dprotected%20invention%20itself [https://perma.cc/H7D5-VNXS] (last visited Sept. 11, 2024) (illustrating one example of how to implement compulsory licensing programs, specifically within the context of medical pharmaceuticals).

205. *See* ENSURING INNOVATION IN DIAGNOSTICS FOR BACTERIAL INFECTION, *supra* note 18, at 142–43.

206. *See id.*

207. *Intellectual Property and the Public Interest*, WTO, https://www.wto.org/english/tratop_e/trips_e/trips_and_public_interest_e.htm [https://perma.cc/STP8-LEUZ] (last visited Sept. 11 , 2024) ("Intellectual property systems should balance the protection and enforcement of intellectual property rights with public interest considerations.").

enabling early detection, personalized treatment, and improved patient outcomes. However, the convoluted landscape of patent eligibility, as exemplified by the *Alice-Mayo* framework, has hindered innovation and access to critical diagnostic technologies. By embracing the principles of innovation, accessibility, and equity in the medical field, the proposed hybrid solution offers a beacon of clarity, representing a comprehensive and pragmatic solution to the challenges surrounding diagnostic method patents. Through targeted legislative action that recognizes the eligibility of diagnostic methods as patentable subject matter, Congress can uphold the original intent of the Patent Act, while fostering a patent system that truly serves the interests of both innovators and the public.

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