Case Western Reserve Law Review

Volume 73 | Issue 1 Article 5

2022

# Biomarkers as Subject Matter: A Tailored Solution for Patent Ineligibility in Medical Diagnostics

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— Note —

# Biomarkers as Subject Matter: A Tailored Solution for Patent Ineligibility in Medical Diagnostics

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## Introduction

The courts have denied patent eligibility to an array of ingenious, lifesaving innovations over the past decade. Such innovations include: a method for the isolation and modification of specific DNA segments to detect a patient's risk of breast cancer;[1] a method to detect fetal genetic defects in otherwise discarded maternal blood;[2] and the retooling of known genetic methods to detect *Mycobacterium tuberculosis*—the organism behind the disease tuberculosis and a "major contributor to antimicrobial resistance worldwide."[3] All of these cases now instruct researchers, institutions, and investors where *not* to devote their time, money, and effort.

1. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 576–80 (2013).

2. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1373–74 (Fed. Cir. 2015).

3. Roche Molecular Sys., Inc. v. Cepheid, 905 F.3d 1363, 1365 (Fed. Cir. 2018); *Tackling the Drug-Resistant TB Crisis*, WHO, https://www.who.int/activities/tackling-the-drug-resistant-tb-crisis [https://perma.cc/AW8D-3SE3] (last visited Sept. 6, 2022).

Why have such innovations been denied patent eligibility? The answer lies with the Supreme Court's 2012 decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[4] *Mayo* was joined two years later by *Alice Corp. v. CLS Bank International*;[5] together they establish the *Mayo/Alice* test for patent subject matter eligibility.[6] The *Mayo/Alice* test instructs courts to look for a law of nature or abstract concept in a patent's claims.[7] If such elements are found, then the court must determine whether anything else within the claims is novel and unconventional, and whether the claims as a whole amount to more than the unpatentable abstract concept or law of nature.[8] The test goes beyond forbidding the direct claiming of laws of nature or abstract concepts to forbid the claiming of any process which contains them but does not contain some other inventive concept.[9] In the decade preceding the *Mayo* decision it was exceedingly rare for patents to be struck down on eligibility-based motions in district courts, with fewer than three such decisions occurring in any given year.[10] A statistical analysis revealed that 32 percent of patents were stuck down on eligibility-based motions in the twenty-four months following the *Mayo* decision; in the thirty-two months after *Alice*, 41 percent of patents were struck down, representing an additional ten-percent increase in ineligibility.[11] Because of a reliance on correlative biomarkers, the negative impacts of these trends on medical diagnostics have been described as "particularly severe."[12] The Supreme Court appears to be comfortable with the status quo, and if there is to be change, it will likely have to come from Congress. Unfortunately, current proposals for legislative change are overbroad. They would render eligible broad patents that lay claim to abstract concepts—particularly in software—for which recent eligibility

4. 566 U.S. 66, 92 (2012).

5. 573 U.S. 208 (2014).

6. Thomas Damario, *Subject Matter Eligibility Roundup in 2021*, LEXOLOGY (Mar. 3, 2022), https://www.lexology.com/library/detail.aspx?g=167104c6-0bb3-4de8-9616-4e74905e45b4 [https://perma.cc/M655-2Y3Q] (discussing several recent cases applying this framework).

7. Elizabeth Flanagan, Deanna Reichel & Jonathan Singer, *Section 101: Cert. Denied . . . Now What?*, FISH & RICHARDSON (Apr. 3, 2020), https://www.jdsupra.com/legalnews/section-101-cert-denied-now-what-68426/ [https://perma.cc/8FDT-4Q3H].

8. *Id.*

9. *Id.*

10. Jeffrey A. Lefstin, Peter S. Mennell & David O. Taylor, *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop: Addressing Patent Eligibility Challenges*, 33 BERKELEY TECH. L.J. 551, 576 (2018).

11. *Id.* at 576 tbl.1 (2018).

12. *Id.* at 582–84.

changes have proved an effective barrier.[13] A narrow exclusion for medical diagnostics is required.

Part I of this Note will provide background on medical diagnostics, biomarkers, and why patent eligibility is so crucial in this sector. Part II will give an account of the *Mayo/Alice* test and how it applies to diagnostics. Part III will address a recent response by the Federal Circuit to a particularly troubling diagnostics eligibility case. Part IV explains a "practical application" test, which forms a promising replacement for the current "inventive concept" test. Part V addresses the likelihood of a resolution of this issue by the Supreme Court. Part VI discusses several recently proposed legislative solutions. Part VII proposes a legislative amendment that could resolve the patent eligibility issue for medical diagnostics while preserving current doctrine for other subject matter.

The legislative solution proposed in Part VII would preclude the Court from denying eligibility to diagnostic processes under the *Mayo/Alice* test by adding biomarkers to section 101 patent-eligible subject matter. The patent eligibility of biomarkers would then be limited. A practical application test would guard against the broad preemption of any of the "basic tools of scien[ce]."[14] The requirement of a process not entirely within the human body would preclude any internal bodily processes, genomic sequences, or other purely natural phenomena from clearing the eligibility gate.

Most experts agree that medical diagnostics should become eligible.[15] This problem should not linger while the larger debate continues—the eligibility problem in medical diagnostics should be resolved with a specific exemption from the *Mayo/Alice* test.

## I. WHY MEDICAL DIAGNOSTICS?

The United States has a problem with healthcare costs. Even compared to similar countries, the United States has an outsized per capita expenditure on healthcare.[16] In 2020, U.S. health spending was $11,945 per person—an amount 67 percent greater than the next

13. *See generally* Mark A. Lemley & Samantha Zyontz, *Does* Alice *Target Patent Trolls?*, 18 J. EMPIRICAL LEGAL STUD. 47 (2021).

14. Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 71 (2012) (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)).

15. *See* Lefstin et al., *supra* note 10, at 595.

16. Emma Wager, Jared Ortaliza & Cynthia Cox, *How Does Health Spending in the U.S. Compare to Other Countries?*, PETERSON-KFF HEALTH SYS. TRACKER (Jan. 21, 2022), https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/#item-start [https://perma.cc/4GZA-Y4K7].

highest spender.[17] These costs are expected to grow.[18] One projection indicates that U.S. health costs will rise to $18,000 per capita and a total cost of $6.2 trillion by 2028, equivalent to 20 percent of the nation's estimated GDP at that time.[19] Despite these spiraling costs, the United States does not have better health outcomes than comparable countries; it even underperforms in certain indicators such as life expectancy and infant mortality.[20]

Measures that can be taken to improve health outcomes and lower costs should be encouraged to reverse this trend. One such policy is an increased focus on preventive medicine. Preventive medicine is a broad concept that includes behavioral modifications, early detection, and management of existing disease.[21] One report by the Institute of Medicine indicated that "roughly 30% . . . of healthcare spending was wasted on unnecessary treatments and spending that did not produce better health outcomes."[22] From the $765 billion of wasteful healthcare spending in the report, $55 billion was attributed to "missed prevention opportunities."[23]

Improving medical diagnostics can reduce this waste. A report by the National Academy of Sciences called diagnostics a "blind spot" in health care, stating: "Diagnostic errors—inaccurate or delayed diagnoses—persist throughout all settings of care and continue to harm an unacceptable number of patients."[24] The report indicated that 10 percent of all deaths in the healthcare setting are partially attributable

17. *Id.* Switzerland is the next highest per capita healthcare spender at $7,138. The comparable country average is $5,736. *Id.*

18. *Why Are Americans Paying More for Healthcare?*, PETER G. PETERSON FOUNDATION (Feb. 16, 2022), https://www.pgpf.org/blog/2022/02/why-are-americans-paying-more-for-healthcare [https://perma.cc/4BG3-SPZJ].

19. *NHE Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Aug. 12, 2022, 2:06 PM), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet [https://perma.cc/R4BG-GGX4].

20. *Why Are Americans Paying More for Healthcare?*, *supra* note 18.

21. Steven H. Woolf, *The Price Paid for Not Preventing Disease*, *in* THE HEALTHCARE IMPERATIVE: LOWERING COSTS AND IMPROVING OUTCOMES: WORKSHOP SERIES SUMMARY 220, 221 (Pierre L. Yong et al. eds., 2010).

22. ANAND K. PAREKH, PREVENTION FIRST: POLICYMAKING FOR A HEALTHIER AMERICA 28 (2019) (citing INST. OF MED., BEST CARE AT LOWER COST: THE PATH TO CONTINUOUSLY LEARNING HEALTH CARE IN AMERICA 101 (Mark Smith et al. eds. 2013)).

23. *Id.* (citing INST. OF MED., *supra* note 22, at 102 tbl.3-1).

24. NAT'L ACADS. OF SCIS., ENG'G, AND MED., IMPROVING DIAGNOSIS IN HEALTH CARE 19 (2015).

to diagnostic errors.[25] Catching disease early allows intervention before costlier and less effective treatments are the only remaining option.[26] Faster and more accurate diagnostic tests are needed to provide better patient outcomes; improvement would reduce healthcare costs through increased efficiency in treatment.

Central to medical diagnostics is the concept of biomarkers.[27] A biomarker is defined as "a characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention including therapeutic interventions."[28] Biomarkers can include things like blood pressure, body temperature, radiographic indication, and molecules such as cholesterol, DNA, or antibodies.[29] In the words of one researcher, "[T]he perfect sources of diagnostic information are the molecular contents of sweat, saliva, urine, and feces, naturally excreted every day and packed with information."[30] In one instance, the discovery of a biomarker in maternal blood samples—otherwise abandoned as medical waste—replaced the risky and invasive procedure of amniocentesis.[31] Biomarkers are a diagnostic tool that can be utilized in early diagnosis of a condition, evaluation of the current and future course of a disorder, or the tailoring of treatment

25. *Id.* at 356 (first citing Kaveh G. Shojania, Elizabeth C. Burton, Kathryn M. McDonald & Lee Goldman, *The Autopsy as an Outcome and Performance Measure, in* EVIDENCE REPORTS/TECHNOLOGY ASSESSMENTS, 4 (AGENCY FOR HEALTHCARE RSCH. & QUALITY 2002); and then citing Kaveh G. Shojania, Elizabeth C. Burton, Kathryn M. McDonald & Lee Goldman, *Changes in Rates of Autopsy-Detected Diagnostic Errors over Time: A Systematic Review*, 289 JAMA 2849, 2849–50 (2003)).

26. *Id.* at 51.

27. Lmar M. Babrak, Giovanni Nisato, Thomas Brenzikofer, Cornelia Schneider, Enkelejda Miho, Joseph Menetski, Marc Zinggeler, Laurenz Baltzer, Fabian Streiff, Michael Rebhan, Noè Brasier, Christian Vogler, Peter M.A. Groenen, Katja Baerenfaller & Leo Gschwind, *Traditional and Digital Biomarkers: Two Worlds Apart?*, 3 DIGIT. BIOMARKERS 92, 93 (2019).

28. *Id.*

29. *Id.*

30. Jennie Dusheck, *Diagnose This: A Health-Care Revolution in the Making*, STAN. MED., https://stanmed.stanford.edu/2016fall/the-future-of-health-care-diagnostics.html [https://perma.cc/LEL8-EDUL] (last visited Sept. 17, 2022).

31. *See* Rebecca Lindhorst, Note, *Two-Stepping Through* Alice*'s Wasteland of Patent-Eligible Subject Matter: Why the Supreme Court Should Replace the* Mayo/Alice *Test*, 69 CASE W. RSRV. L. REV. 731, 732 (2019) ("This breakthrough has revolutionized prenatal care, offering women a safe alternative to high risk, invasive testing . . . ."); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1373 (Fed. Cir. 2015).

to a particular patient.[32] The discovery of new biomarkers will result in earlier diagnoses, more effective treatments, and the more efficient use of resources.

The road from discovery to effective clinical use is not an easy one.[33] Discovery, investigation, and commercialization of biomarkers require large investments of time and money.[34] Estimates put the cost of developing and bringing to market a new biomarker-based diagnostic method at more than $100 million.[35] Many discoveries prove fruitless at some point during development.[36] The risk and expense inherent in the process lead investors to seek patentable innovations—those that can recoup losses and mitigate risk.[37]

Patent protection is especially important for small start-up companies and university spin-offs. They can leverage the promise of market exclusivity into investment funds that drive their research.[38] These seed investments are critical for the translation of promising research into clinical applications.[39] Since the value of diagnostic tests is inherently tied to a clinical setting, substantial studies are required

32. Sheryl L. Chow, Alan S. Maisel, Inder Anand, Biykem Bozkurt, Rudolf A. de Boer, G. Michael Felker, Gregg C. Fonarow, Barry Greenberg, James L. Januzzi, Jr., Michael S. Kiernan, Peper P. Liu, Thomas J. Wang, Clyde W. Yancy & Michael R. Zile, *Role of Biomarkers for the Prevention, Assessment, and Management of Heart Failure*, 135 CIRCULATION 1054, 1056 (2017).

33. *See* Gimon de Graaf, Douwe Postmus, Jan Westerink & Erik Buskens, *The Early Economic Evaluation of Novel Biomarkers to Accelerate Their Translation into Clinical Applications*, COST EFFECTIVENESS & RES. ALLOCATION, June 2018, at 1, 1–2.

34. *Id.*

35. *Id.* at 2 (citing Doug Dolginow, Katherine Tynan, Noel Doheny & Peter Keeling, *Mystery Solved! What is the Cost to Develop and Launch a Diagnostic?*, DIACEUTICS (Jan. 15, 2013), https://www.diaceutics.com/articles/mystery-solved-what-is-the-cost-to-develop-and-launch-a-diagnostic [https://perma.cc/3RC2-DBUX]).

36. *Id.* at 6.

37. Henry G. Grabowski, Joseph A. DiMasi & Genia Long, *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34 HEALTH AFFS. 302, 302 (2015).

38. *Patents and Innovation: Trends and Policy Challenges,* ORG. FOR ECON. COOP. & DEV. 22 (2004), https://www.oecd.org/science/inno/24508541.pdf [https://perma.cc/H5RX-NZLT].

39. Jonathan J. Fleming, *The Decline of Venture Capital Investments in Early-Stage Life Sciences Poses a Challenge to Continued Innovation*, 34 HEALTH AFFS. 271, 271 (2015).

to prove safety and reliability.[40] Small start-ups cannot finance their own way through clinical trials without the aid of these investments.[41]

While some argue that the exclusivity provided by patents can limit access to important diagnostics, this is also true in the absence of patent protection. Innovators are then inclined to protect their discoveries through trade secrets.[42] Patent requirements such as enablement and written description serve to disclose the information contained within a patentable discovery.[43] These mechanisms provide better dissemination of information and broader access to the fruits of discovery than the alternative secrecy.

Considering the strong arguments for patentability in medical diagnostics, it is unfortunate that current trends have made it exceptionally difficult to obtain a patent for biomarker discoveries in the United States.[44] The current state of patent eligibility doctrine has created "a landscape that further discourages rather than encourages investment in molecular testing."[45] This reality is the culmination of a narrowing of eligibility that began almost two decades ago.[46] It ultimately led to the defining case on the issue, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[47]

## II. THE *MAYO/ALICE* TEST AND PATENT ELIGIBILITY

*Mayo* involved a challenge to the validity of a patent containing a biomarker.[48] The claims in question tied the measured levels of a metabolite of a thiopurine drug in a patient to the proper dosage of the drug for that patient.[49] A patient who consumes a thiopurine drug metabolizes it, creating distinct byproducts—metabolites—which are

40. *Id.* at 273–74.

41. *Id.* at 274, 276.

42. Javier Saladich Nebot, *Patents and Diagnostic Methods in the U.S.: The Subject Matter Eligibility Trap*, 25 J. COM. BIOTECHNOLOGY 49, 50 (2019).

43. Jason Rantanen, *Patent Law's Disclosure Requirement*, 45 LOY. U. CHI. L.J. 369, 370–71 (2013).

44. *See generally* Nebot, *supra* note 42, at 50.

45. *Id.*

46. *Id.* at 52. Justice Breyer's dissent from the Supreme Court's denial of certiorari as improvidently granted in *Lab'y Corps. v. Metabolite* voiced the idea that correlative diagnostic tests involving biomarkers constituted unpatentable natural phenomena. Lab'y Corp. of America Holdings v. Metabolite Lab'ys, Inc., 548 U.S. 124, 125–39 (2006) (Breyer, J., dissenting).

47. 566 U.S. 66 (2012).

48. *See id.* at 73–74.

49. *Id.*

then present in their bloodstream.[50] The claims in *Mayo* described a specific range of these metabolites that correlated with a proper dosage of the administered drug. If the measurements were above this range, the patient was likely to suffer harmful side effects—if they fell below the range, then the drug was likely to be ineffective.[51] Thus, the central inventive concept was the discovery of a correlation that existed naturally and independently from this formulation, but which had not previously been discovered and utilized.

Looking to the language of the governing statute, the discovery would appear to be patent eligible. Title 35 of the U.S. Code—the Patent Act—outlines patent eligibility in section 101, which states in full:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.[52]

Section 100 of the Patent Act defines "process" as including "*a new use of a known process,* machine, manufacture, composition of matter, or material."[53] Other sections outline additional requirements, such as novelty, non-obviousness, and specification.[54] While these additional requirements are key to patentability, patent eligibility is a distinct concept, and section 101 serves a gatekeeping function, preventing more complicated litigation of claims which clearly are not patentable.[55]

The Supreme Court has interpreted the language of section 101 to implicitly exclude laws of nature, natural phenomena, and abstract ideas.[56] These three judicial exceptions restrict the four otherwise broad

50. *Id.* at 73.

51. *Id.* at 73–74.

52. 35 U.S.C. § 101.

53. *Id.* § 100(b) (emphasis added).

54. *Id.* §§ 102(a), 103, 112. Section 102 requires that the claims of the patent be novel and not previously conceptualized and disclosed to the public, section 103 requires that the difference between the patent seeking material would not be obvious to "a person having ordinary skill in the art," and section 112 requires a written description of the patent's subject matter sufficient for a person skilled in the art to make and utilize the contemplated discovery or invention themself. *Id.*

55. Bruce Wexler & Edwin Mok, *The Gatekeeping Function of Patent Eligibility as Part of a More Complete Understanding of § 101 Principles*, PATENTLY-O (Apr. 24, 2016), https://patentlyo.com/patent/2016/04/wexler-gatekeeping-eligibility.html [https://perma.cc/PR5F-KJFX].

56. Ariosa Diagnostics, Inc. v. Seqeunom, Inc., 788 F.3d 1371, 1375 (Fed. Cir. 2015) ("In Mayo Collaborative Services v. Prometheus Laboratories, Inc., the Supreme Court set forth a framework for distinguishing patents that

categories of statutorily eligible patent subject matter: "process, machine, manufacture, [and] composition of matter."[57] While the claims in *Mayo* are indeed a discovered process—at the very least an improvement of a known process—they also centrally involve a law of nature: the naturally existent correlation between thiopurine metabolism and effective dosage.

Had the claims in *Mayo* involved only a discovered correlation, the case would have been simple. The Court acknowledged its previous holding in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*,[58] which stated that purely natural phenomena—equations or newly discovered minerals—are "manifestations of . . . nature, free to all men and reserved exclusively to none."[59] The Court also wrote in *Funk Brothers* that "[i]f there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end."[60] By this logic, if the claims at stake in *Mayo* applied the discovered correlation in a novel and practical way, they would still prove eligible in totality. The Court explained that its task in *Mayo* was to determine "whether the claimed processes have transformed these unpatentable natural laws into patent-eligible applications of those laws."[61] The principal concern was whether the claims were so broad as to cover application of the natural law in toto.[62] The Federal Circuit had determined that additional processes contained within the claims—injection of thiopurine and measurement of metabolite levels—were adequate to "confine the patent monopoly within rather definite bounds."[63] The Supreme Court disagreed.[64]

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claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to a patent-ineligible concept. If the answer is yes, then we next consider the elements of each claim both individually and 'as an ordered combination' to determine whether additional elements 'transform the nature of the claim' into a patent-eligible application.") (citations omitted) (quoting Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 78–79 (2012)).

57. *Id.* at 1375 (quoting 35 U.S.C. § 101).

58. 333 U.S. 127 (1948).

59. *Id.* at 130.

60. *Id.*

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

62. *Id.* The Court was concerned with ensuring that patent eligibility did not "depend simply on the draftsman's art." *Id.* (quoting Parker v. Flook, 437 U.S. 584, 593 (1978)).

63. Prometheus Lab'ys, Inc. v. Mayo Collaborative Servs., 581 F.3d 1336, 1346–47 (Fed. Cir. 2009) (quoting *In re* Bilski, 545 F.3d 943, 962 (Fed. Cir. 2008)).

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

In reversing the Federal Circuit's holding, the Supreme Court articulated the beginnings of a new test for patent eligibility. The Court stated that the additional steps in the claimed patent failed to "add [anything] of significance to the natural laws themselves."[65] The Court acknowledged that the laws of nature at issue were narrow and "may have limited applications."[66] It reasoned that judges are not in an "institutionally well suited" position to make scientific determinations such as the relative breadth of any particular natural law.[67] The Court preferred a bright-line rule against patent eligibility in similar cases. In subsequent decisions the Court cemented its new rule for patent eligibility; it has not proven to be as bright of a line as the Court had hoped.[68]

The Court underscored its new patent eligibility test in *Alice Corp. v. CLS Bank International*.[69] In *Alice*, the patented claims covered a business method for mitigating risk in settlements by using computers as an intermediary.[70] The Court determined that the claims involved a judicial exception—"the abstract idea of intermediated settlement."[71] It then looked to the other elements of the claims, both individually and "as an ordered combination."[72] The Court found that the other claims were "'well-understood, routine, conventional activit[ies]' previously known to the industry."[73] Without some additional inventive concept, there could be no patent eligibility in the claims.

In denying patent eligibility in *Alice*, the Court cemented its now-infamous two-step formula for determining patent eligibility—the *Mayo/Alice* test. The U.S. Patent and Trademark Office outlines the *Mayo/Alice* test as follows: (1) Do the claims involve a law of nature, natural phenomenon, or abstract idea? (2) If yes, then do the claims

65. *Id.* at 87.

66. *Id.* at 86.

67. *Id.* at 89.

68. *See* Shahrokh Falati, *Patent Eligibility of Disease Diagnosis*, 21 N.C. J.L. & TECH. 63, 98–100 (2020) ("This new *Mayo/Alice* test has been very difficult for patent stakeholders, including examiners, inventors, patent owners, patent lawyers and judges alike, to implement and/or interpret because it remains unclear what the boundaries of Section 101 are.").

69. 573 U.S. 208 (2014); Falati, *supra* note 68, at 98–99.

70. *Alice*, 573 U.S. at 213.

71. *Id.* at 225.

72. *Id.* (quoting *Mayo*, 566 U.S. at 79).

73. *Id.* (quoting *Mayo*, 566 U.S. at 73).

include additional elements that elevate the claim to substantially more than the judicial exception?[74]

If the Supreme Court's goal was to narrow the gateway of patent eligibility, it worked. In the two years following *Alice*, the Federal Circuit invalidated patents challenged under section 101 at a rate of 91.9 percent.[75] A study of medical diagnostic patents between 2007 and 2016 found a section 101 eligibility rejection rate of 15.9 percent before *Mayo* and 86.4 percent after *Mayo*.[76] Judge Moore of the Federal Circuit described diagnostic claims as now being "per se ineligible," noting that "[s]ince *Mayo* we have held every single diagnostic claim in every case before us ineligible."[77] Numerous petitions to the Supreme Court to reassess issues of section 101 eligibility have been denied.[78] Exactly what should be done to restore patent eligibility to medical diagnostics remains an open question.

## III. *ATHENA* AND JUDICIAL SPECULATION

Criticism for the current state of patent eligibility is not limited to those outside the judicial system. Multiple judges on the Federal Circuit have expressed discomfort with the *Mayo*/*Alice* test, most dramatically in the denial of en banc review in *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*.[79] While denials of en banc review are typically routine and short on explanation, this denial contained an

74. *§2106 Patent Subject Matter Eligibility [R-10.2019]*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/web/offices/pac/mpep/s2106.html [https://perma.cc/86VX-AQY3] (Jun. 25, 2020, 6:21 PM).

75. Jasper L. Tran, *Two Years After* Alice v. CLS Bank, 98 J. PAT. & TRADEMARK OFF. SOC'Y 354, 358 (2016).

76. Bernard Chao & Amy Mapes, *An Early Look at* Mayo*'s Impact on Personalized Medicine*, 2016 PATENTLY-O PAT. L.J. 10, 12 (2016).

77. Athena Diagnostics, Inc. v. Mayo Collaborative Servs., 927 F.3d 1333, 1352–54 (Fed. Cir. 2019) (Moore, J., dissenting from the denial of rehearing en banc) (collecting cases).

78. Anthony Blum & Jonathan Musch, Thompson Colburn LLP, *Will There Be Reform of* Alice *and* Mayo *in 2021?*, JDSUPRA (Mar. 22, 2021), https://www.jdsupra.com/legalnews/will-there-be-reform-of-alice-and-mayo-6981978/ [https://perma.cc/V888-JZME]; Flanagan et al., *supra* note 7 ("[T]he Court was asked to take up the issue in three high-profile patent eligibility cases: *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*, *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, and *Berkheimer v. HP Inc.* The Solicitor General recommended in amicus briefs that certiorari should be denied in *Vanda* and *Berkheimer* but granted in *Athena*. However, the Court ultimately denied certiorari in all three cases.") (citations omitted).

79. 927 F.3d at 1352; KEVIN RICHARDS, CONG. RSCH. SERV., LSB10344, JUDGES URGE CONGRESS TO REVISE WHAT CAN BE PATENTED 2–3 (2020).

unprecedented eight separate opinions, uniformly concerned with addressing the patent eligibility problem in medical diagnostics.[80]

In *Athena*, the court denied eligibility to a medical diagnostic patent under the *Mayo/Alice* test.[81] The discovery was a biomarker—antibodies associated with a cell membrane protein called MuSK—that indicated an autoimmune neurological disease called *Myasthenia gravis* (MG).[82] No other disease had ever been associated with MuSK or its corollary antibodies.[83] Examining the claims as a whole, the Federal Circuit found them to "recite only a natural law together with conventional steps to detect that law."[84]

By 2019 this analysis must have felt routine for the Federal Circuit. In *Cleveland Clinic Foundation v. True Health Diagnostics, LLC*,[85] it had similarly found ineligible a new method for diagnosing cardiac disease.[86] The same result occurred in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,[87] where application of the *Mayo/Alice* test rendered ineligible a method for diagnosing fetal genetic defects by amplifying DNA found in the mother's plasma and serum.[88] By the time *Athena* came around, the Federal Circuit clearly felt that its hands were tied by the *Mayo/Alice* test, but also that something clearly had to be done by either the Supreme Court or Congress to address the issue.

In the four opinions that concurred in the denial of en banc review in *Athena v. Mayo*, the judges presented their ideas for a more appropriate eligibility analysis. Judge Lourie wrote that "[i]f [he] could write on a clean slate," he would have found ineligible only claims directed towards natural laws themselves, leaving applications and detections of natural laws to a more thorough analysis under sections 102, 103, and 112.[89] Such a change would constitute a wholesale reversal of the *Mayo/Alice* test. Judge Lourie lamented that "as long as the [Supreme] Court's precedent stands, the only possible solution lies in the pens of claim drafters or legislators."[90] Judges Hughes, Prost, and

80. RICHARDS, *supra* note 79, at 4.

81. Athena Diagnostics, Inc. v. Mayo Collaborative Servs., 915 F.3d 743, 757 (Fed. Cir. 2019).

82. *Id.* at 746–47.

83. *Id.*

84. *Id.* at 757.

85. 859 F.3d 1352 (Fed. Cir. 2017).

86. *Id.* at 1355.

87. 788 F.3d 1371 (Fed. Cir. 2015).

88. *Id.* at 1373.

89. Athena Diagnostics, Inc. v. Mayo Collaborative Servs., 927 F.3d 1333, 1335 (Fed. Cir. 2019) (Lourie, J., concurring in denial of rehearing en banc).

90. *Id.* at 1336.

Taranto agreed that the "bottom line for diagnostic patents is problematic" and asked either Congress or the Supreme Court to find a way to distinguish discoveries utilizing natural laws from claims that would monopolize the natural laws themselves.[91] Several of the judges dissented, believing there may still be room for the Federal Circuit to reexamine the *Mayo/Alice* test.[92] Judge Chen observed that the Federal Circuit "would benefit from the Supreme Court's guidance . . . ."[93]

Judge Dyk offered a more specific approach. He found the *Mayo/Alice* framework effective in screening out overbroad claims, especially those involving abstract ideas like in *Alice*.[94] Judge Dyk wrote that the patentability requirements of novelty, non-obviousness, and written description could not always properly screen overbroad claims.[95] He further noted the value of early-stage eligibility thresholds in preventing costly and time-consuming litigation.[96] How then to preserve a rigorous eligibility threshold for overbroad claims, but still allow room for narrow applications of natural laws that are unlikely to cause excessive or unbounded preemption? Judge Dyk contrasted the less specific claims in *Mayo*, which did not confine their application to a specific utility and refined a known correlation, with those in *Athena*, which laid out their application with high specificity and involved the discovery of a completely novel biomarker.[97] He wrote, "For there to be a patent eligible application of a natural law, there must be a 'discover[y]' . . . and the claims must recite a specific application of that 'discovery' with established utility."[98] This practical application test has the support of many other commentators.[99]

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91. *Id.* at 1337 (Hughes, J., concurring in denial of rehearing en banc).

92. *Id.* at 1352 (Moore, J., dissenting from the denial of rehearing en banc) ("The majority of my colleagues believe that our hands are tied and that *Mayo* requires this outcome. I believe *Mayo* does not.").

93. *Id.* at 1344 (Chen, J., concurring in denial of rehearing en banc).

94. *Id.* at 1338 (Dyk, J., concurring in denial of rehearing en banc).

95. *Id.* ("Despite assertions to the contrary, the doctrines of novelty under § 102, obviousness under § 103, and enablement and written description under § 112 cannot adequately guard against the dangers of overclaiming.").

96. *Id.* (citing Bilski v. Kappos, 561 U.S. 593, 602 (2010)).

97. *Id.* at 1342–43.

98. *Id.* at 1341.

99. *See, e.g.*, *id.* (citations omitted) ("Requiring a specific application mitigates against the risk of granting patents too early—that is, before the patent applicant has devised a specific application of the natural law . . . ."); *Patentable Subject Matter Reform: Hearing on the State of Patent Eligibility in America Before the S. Subcomm. on Intell. Prop.*, 116th Cong. 2 (2019) (statement of Mark A. Lemley, Dir. of the Stanford University School of Law Program in Law, Science & Technology) [hereinafter Lemley Testimony] ("A conservative approach to patentable

## IV. THE PRACTICAL APPLICATION TEST

The theory of the practical application test is this: if preemption of "the basic tools of scientific . . . work"[100] is the primary concern addressed by the natural law exception, then why not provide eligibility to claimed processes that stake out a sufficiently specific practical application? To the extent such claims include the natural law within them, the application is necessarily narrow—preempting little.

This concept was acknowledged in *Mayo*.[101] The Court stated that a process containing a natural law cannot be patent eligible unless "[the] process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself."[102] The concern was that a patent could claim a natural law and recite additional claims that merely amount to an instruction to "apply the [natural] law."[103] It distinguished a case in which the integrated steps of a process amounted to something more than the natural law from one where the additional steps were so routine or obvious as to merely mask the true claim.[104] The additional

subject matter would focus narrowly on identified problems in the medical diagnostics business, rendering significant new medical discoveries patentable when they have a practical application but otherwise leaving the law unchanged."); David O. Taylor, *Amending Patent Eligibility*, 50 U.C. DAVIS L. REV. 2149, 2206–07 (2017) ("[A]gain to meet the principle of restraint on judicial intervention, any amendment to articulate a standard focusing on practical utility would need to include additional language explaining that the requirement—the claimed subject matter be a practical, as opposed to an inventive, application of a natural law, physical phenomena, or abstract idea . . . .").

100. Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 71 (2012) (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)).

101. *Id.* at 88–89.

102. *Id.* at 77.

103. *Id.* at 77–78.

104. *Id.* at 80–82 (discussing Diamond v. Diehr, 450 U.S. 175 (1981)). The Court looked to precedent, where it had found a process of molding and curing rubber products patent eligible. The patented process involved "(1) continuously monitoring the temperature on the inside of the mold, (2) feeding the resulting numbers into a computer, which would use the Arrhenius equation to continuously recalculate the mold-opening time, and (3) configuring the computer so that at the appropriate moment it would signal 'a device' to open the press." *Id.* at 80 (citing *Diehr*, 450 U.S. at 177–79). Although applying the Arrhenius equation through a computer program was clearly unpatentable—merely applying an abstract concept—the equation was utilized in a process whose combined steps made it more than the application of the equation. The patent in *Mayo* involved taking blood samples, measuring thiopurine metabolite levels, and adjusting the dosage as needed to align with the findings, an analogous feedback mechanism. *Id.* at 80–82. The opening and closing of

elements of the process must create what amounts to an "inventive concept."[105] The Court clearly prefers to require an inventive concept—despite the resulting problems—rather than a narrow practical application.

This may be reasonable in some circumstances, but consider the claims in *Athena*.[106] Those claims involved a natural law—specifically, the correlation between MuSK antibodies and the likelihood a patient suffered from MG.[107] Eighty percent of patients with MG were already diagnosable through detection of known acetylcholine receptor antibodies.[108] For 20 percent of patients, the disorder would go unnoticed until their face began to droop, their speech began to slur, and they began to complain of muscle weakness and double vision.[109] The discovery of the correlation in *Athena* allowed for early detection in this 20 percent of patients for whom no diagnostic had been available.[110] There was no other known medical diagnostic correlation for MuSK—it had never before been associated with a disease.[111] When the correlation in question deals with the relationship between a distinct molecule and a subpopulation of patients with a specific disorder—and that correlation is carried out through a specific process identified within the patent's claims—should the fear of preemption really be enough to deny patent eligibility?

In *Mayo*, the Court held that a separate inventive concept was necessary to prevent preemption, even when "[t]he laws of nature at issue . . . are narrow laws that may have limited applications . . . ." Thus, a narrowly claimed practical application would be no defense.[112] The Court also reasoned that a narrow natural law would necessarily

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a mold to manage heat conditions would seem to constitute "well-understood, routine, conventional activity, previously engaged in by those in the field." *Id.* In *Diehr,* such steps rendered the application of a natural law patent eligible, while in *Mayo* they merely constitute an instruction to "apply the law somehow." *Id.* at 82.

105. Athena Diagnostics, Inc. v. Mayo Collaborative Servs., 927 F.3d 1333, 1339 (Fed. Cir. 2019) (Dyk, J., concurring in denial of rehearing en banc). ("*Mayo* left no room for us to find typical diagnostic claims patent eligible, absent some inventive concept at *Mayo* step two.").

106. *Athena*, 915 F.3d at 746–47.

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.* at 747.

111. *Id.*

112. *See* Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 86–88 (2012).

be equally narrow in its potential value.[113] It is worth noting that patients suffering from MG might perceive a different level of value in this particular correlation. Regardless, patent eligibility must be viewed with an eye to opportunity cost. It powerfully informs the choice to invest time, money, and effort in one research endeavor over another. A broad elimination of the patent incentive has an impact beyond the scope of any one discovery. The actual number of lifesaving discoveries that are lost without such an incentive is unknown. The accumulated loss of many diagnostic discoveries—though each may be quite narrow in scope—creates an incalculable impact on the lives of patients and their loved ones and upon the healthcare system as a whole.

The Court expounded an additional concern for a practical application test in *Mayo*. It perceived a danger in "interpreting patent statutes in ways that make patent eligibility 'depend simply on the draftsman's art' . . . ."[114] This is a specious argument. First, the "draftsman's art" is exactly what patent eligibility should depend on; it is the law that must guide the drafters in the desired direction.[115] Further, if the form of the claims outlines a specific application, that application is the monopolized concept or process, not any individual feature contained within them.[116] With this in mind, the Court's principled refusal to engage in scientific endeavors such as the relative breadth of a natural law sounds more like missing the point. The Court need only analyze the language of the claims to understand whether a specific practical application is included. The *Mayo/Alice* test already requires courts to look to the claimed steps in a process in order to determine whether those other than the natural law amount to more than "well-understood, routine, conventional activity previously engaged in by scientists who work in the field."[117] Are courts and judges really more "institutionally well suited" to determine what constitutes standard practice in a niche scientific field than whether the claims of a patent stake out a sufficiently narrow practical application?[118] Unfortunately, the Court appears unlikely to address such questions in the foreseeable future.

113. *See id.* ("A patent upon a narrow law of nature may not inhibit future research as seriously as would a patent upon Einstein's law of relativity, but the creative value of the discovery is also considerably smaller.").

114. *Id.* at 72 (quoting Parker v. Flook, 437 U.S. 584, 593 (1978)).

115. *See* Taylor, *supra* note 99, at 2174 ("In this regard, the Supreme Court's criticism of the claim drafting of patent prosecutors sounds like criticism of corporate attorneys who exploit tax loopholes.").

116. *See id.* at 2176 ("The form of the claim—every word in the claim—matters, for example, because the language of the claim identifies *how* to determine whether there is invalidity and infringement.").

117. *Mayo*, 566 U.S. at 79.

118. *Id.* at 89.

## V. AN ANSWER FROM ON HIGH

Some commentators hold hope that this issue may yet be suitably addressed by the courts.[119] In the words of Allen Lo, Deputy General Counsel of Patents for Google:

> As the Federal Circuit issues more decisions . . . the line between patent-eligible and patent-ineligible software claims will become more and more predictable. This is the nature of the common law process on which our legal system is built. And we would want to allow the courts more time to work this out.[120]

It is often analysts in the software sector who express the desire to leave patent eligibility to the courts.[121] This is partly because software is far less reliant on patents than medical diagnostics.[122] Other considerations include the lifesaving nature of medical innovations and the need for preventive medicine within the U.S. healthcare system. There is an urgency in biomedical innovation that does not exist to the same degree in other fields. Unfortunately, the courts have now been given a decade to "work this out," and no change or clarification appears likely in the foreseeable future.[123]

If the Supreme Court were to address a case on patent eligibility, it would likely uphold its previous opinions through stare decisis.[124] In cases involving patent eligibility, the Court has already required an even greater justification than normal to depart from precedent.[125] In the time since the Court established the *Mayo/Alice* test, Congress has yet to make a change to the Patent Act in response.[126] Neither society nor the law has moved to such a degree that the *Mayo/Alice* test appears a vestigial appendage, ripe to be overturned. The Court is unlikely to change course on this issue in the foreseeable future.

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119. *See, e.g.*, Lindhorst, *supra* note 31, at 733–34; U.S. PAT. & TRADEMARK OFF., PATENT ELIGIBLE SUBJECT MATTER: REPORT ON VIEWS AND RECOMMENDATIONS FROM THE PUBLIC 39 (2017) [hereinafter PTO SUBJECT MATTER REPORT].

120. U.S. PAT. & TRADEMARK OFF., ROUNDTABLE 2: EXPLORING THE LEGAL CONTOURS OF PATENT SUBJECT MATTER ELIGIBILITY (2016) [hereinafter PTO ROUNDTABLE].

121. PTO SUBJECT MATTER REPORT, *supra* note 119, at 39.

122. Lemley Testimony, *supra* note 99, at 1.

123. PTO ROUNDTABLE, *supra* note 120, at 213–14, 253.

124. Taylor, *supra* note 99, at 2158 ("[I]t seems likely that the Court would rely upon *stare decisis* to reject any argument for it to overturn its precedent on § 101.").

125. *Id.* at 2159 (citing Kimble v. Marvel Ent., LLC, 576 U.S. 446, 455–56 (2015)).

126. *Id.* at 2160.

The Court has so far demonstrated a resolute unwillingness to alter or even clarify its *Mayo/Alice* test. By mid-2019, the Court had denied more than forty petitions for certiorari on the issue of section 101 eligibility.[127] The Court remains comfortable denying eligibility to various innovative, lifesaving diagnostic processes.[128] The eight separate opinions written by the judges of the Federal Circuit in *Athena* together constitute a plea for the Supreme Court to revisit the matter. On January 13, 2020, the Court denied certiorari in *Athena Diagnostics, Inc. v. Mayo Collaborative Services* without comment.[129] This is the kind of silence that communicates a great deal. If there is to be a change in section 101 eligibility for medical diagnostics, it must come from Congress.

## VI. PROPOSED LEGISLATIVE SOLUTIONS

The debate over section 101 patent eligibility came to a head in 2019. It was, of course, the year that the eight-opinion denial of en banc review in *Athena* was handed down by the Federal Circuit.[130] The Senate Judiciary Committee also held three hearings in June of 2019 to discuss potential legislative action.[131] These hearings constituted a thorough debate among numerous experts representing various sectors of the economy.[132] A picture emerged of stakeholders' concerns regarding the form an amendment might take. One area of tension became particularly clear: while those in the life sciences preferred a dramatic expansion in patent eligibility, experts in the software industry were concerned about losing the *Mayo/Alice* test as a filter for "bad patents and patent troll litigation."[133]

Before discussing the more specific proposals that formed the backdrop of the debate, it will be helpful to take a broader look at what

127. Eileen McDermott, *Todd Dickinson: SCOTUS Has Denied 42 Section 101 Petitions Since* Alice*, so It's up to Congress*, IP WATCHDOG (June 4, 2019, 3:10 PM), https://www.ipwatchdog.com/2019/06/04/todd-todd-dickinson-congress-must-act-because-scotus-has-denied-42-section-101-petitions-since-alice/id=109957/ [https://perma.cc/KQ8Z-QD4T].

128. *See supra* notes 1–4.

129. RICHARDS, *supra* note 79, at 1.

130. Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1335 (Fed. Cir. 2019).

131. Jared P. Rifis, Courtenay C. Brinckerhoff, George C. Beck & Gilberto M. Villacorta, *The State of Patent Eligibility—Report on Senate Hearings*, FOLEY & LARDNER LLP (June 19, 2019), https://www.foley.com/en/insights/publications/2019/06/state-of-patent-eligibility-senate-hearings [https://perma.cc/L584-NP4K].

132. *Id.*

133. KEVIN J. HICKEY, CONG. RSCH. SERV., R45918, PATENT ELIGIBLE SUBJECT MATTER REFORM IN THE 116TH CONGRESS 34 (2019).

eligibility reform legislation could look like. There are four main categories under which subject matter eligibility reform might fall.[134] First, there is the option to abstain from legislative action and pursue change through the courts. This option is supported by some in the software industry but is not an option for those in life sciences—as expounded upon more thoroughly above.[135] Second, the blurry subject matter eligibility of section 101 could be replaced with a specific list of what is eligible or ineligible. This approach is comparable to that taken by the European Patent Office, which has upheld patents for diagnostic processes much like those rejected by the U.S. Patent Office.[136] Third, Congress could eliminate the *Mayo/Alice* test by amending the text of section 101. Options under this approach include substituting a requirement that subject matter must "exist outside the human mind" or that it must "contribute to the technical arts."[137] Fourth, some have argued that the other requirements of patentability—novelty, utility, written description—contained in the Patent Act are sufficient; that the language of section 101 should include nothing more than the four categories of subject matter currently listed.[138] This approach would ostensibly prevent the courts from performing a novelty or utility analysis at the eligibility stage by removing "new and useful" as a modifier of the subject matter categories.[139]

Due to the difficulty in reaching consensus among various interest groups, it seems that a middle approach—some combination of the options listed above—is most likely to result.[140] A proper approach would preserve enough of the *Mayo/Alice* test to appease software

134. *Id.* at 26.

135. *See id.* at 24 ("[S]ome stakeholders in industries (such as computer software) affected by litigation by patent assertion entities argue that Section 101 is a useful and important tool for weeding out overly broad or vague patents at the outset of litigation.") (footnote omitted); *see also supra* notes 122–26 and accompanying text.

136. *See supra* note 1 and accompanying text; PTO SUBJECT MATTER REPORT, *supra* note 119, at 20–21 ("[T]he Technical Board of Appeal held that a method for diagnosing predisposition for breast cancer, by looking for a mutation in a specific gene in a tissue sample taken from a subject, was patent eligible because the steps of a 'technical nature' were carried out in vitro and not directly on the subject."); HICKEY, *supra* note 133, at 28.

137. HICKEY, *supra* note 133, at 26.

138. 35 U.S.C. §§ 101, 102, 103, 112. The currently listed categories are "process, machine, manufacture, [and] composition of matter." *Id.* § 101.

139. *Id.*

140. *See* Jeffrey Costellia, George Dandalides & Paulina Starostka, *Public Opinion on Patent Eligibility Law—Far from a Consensus*, NIXON PEABODY (Oct. 26, 2021), https://www.nixonpeabody.com/en/ideas/articles/2021/10/26/uspto-comments-on-patent-eligibility-law [https://perma.cc/XZQ6-PD5E].

industry leaders while broadening the scope of eligibility enough to let medical diagnostic innovations through the gate.

An early potential amendment came in 2017 as a joint proposal from the Intellectual Property Owners Association (IPO) and the American Intellectual Property Law Association (AIPLA).[141] This approach would combine several of the approaches listed above in order to significantly broaden patent eligibility. First, it would remove the word "new" from section 101.[142] Second, it would add the word "only" such that the end of section 101 would read: "[S]ubject only to the conditions and requirements set forth in this title."[143] It would supply an explicit list of ineligibility for when a "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."[144] The amendment would also use negative statutory language in order to forbid the search for an "inventive concept" in the eligibility standard.[145] Various other small changes are suggested, but the thrust of the amendment is clear enough from those listed here.[146] It both implicitly and explicitly prohibits the search for an inventive concept. It lists as "sole exceptions" its own substitutes for the Court's implicit exceptions and clearly states that a "claimed invention is ineligible . . . if and only if" such explicit exceptions are found.[147] This is an amendment that seeks to thoroughly preclude the Supreme Court from applying implicit exceptions or using the *Mayo/Alice* test to search for an inventive concept.

The legislative amendments introduced during the 2019 Senate hearings go even further. In April of 2019, congressmen Thom Tillis, Chris Coons, Doug Collins, and Hank Johnson released a framework for section 101 reform.[148] This became known as the First Tillis-Coons

141. *Joint AIPLA-IPO Proposal on Patent Eligibility*, AM. INTELL. PROP. L. ASS'N (May 2018), https://www.aipla.org/advocacy/legislative/joint-aipla-ipo-proposal-on-patent-eligibility [https://perma.cc/XC2N-2SU5] [hereinafter *Joint AIPLA-IPO Proposal*].

142. *Compare id.*, *with* 35 U.S.C. § 101.

143. *Compare Joint AIPLA-IPO Proposal, supra* note 141, *with* 35 U.S.C. § 101.

144. *Joint AIPLA-IPO Proposal*, *supra* note 141.

145. *Id.*

146. *See id.*; 35 U.S.C. § 101.

147. *Joint AIPLA-IPO Proposal*, *supra* note 141.

148. Press Release, 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), https://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 [https://perma.cc/M99V-Q3XB] [hereinafter Tillis-Coons Press Release].

Proposal.[149] In May of 2019, following feedback on the First Tillis-Coons Proposal, a draft of legislative language to reform eligibility standards was released and became known as the Second Tillis-Coons Proposal.[150] The Second Tillis-Coons Proposal was the subject of the three-day 2019 Senate hearings titled "The State of Patent Eligibility in America."[151] Like the AIPLA-IPO joint proposal, the Second Tillis-Coons Proposal eliminated the word "new" from the language of section 101 but retained the four listed categories of eligible subject matter.[152] It went further than the AIPLA-IPO joint proposal by explicitly forbidding all of the judicial exceptions that the Supreme Court had read into the statute.[153] Notably, it sought to define the term "useful" as "any invention or discovery that provides specific and practical utility in any field of technology through human intervention."[154] The proposal explicitly stated that "the provisions of section 101 shall be construed in favor of eligibility."[155]

Altogether, these changes are intended to effect a wholesale derogation of implicit judicial exceptions and substitute a claim-based practical application test.[156] Perhaps to alleviate the concerns of those in the software community, the proposal also attempted to restrict broad, function-based claims through edits of section 112 of the Patent Act.[157] Unsurprisingly, the Second Tillis-Coons proposal was met with mixed reactions.[158] Those in the life sciences were pleased with the

149. HICKEY, *supra* note 133, at 33.

150. *Id.* at 34. The Second Tillis-Coons Proposal ultimately resulted in the introduction of the Patent Eligibility Restoration Act to the Senate on August 2, 2022. *See* S. 4734, 117th Cong. (2022).

151. *See* Rifis, *supra* note 131.

152. *See id.*; *Joint AIPLA-IPO Proposal*, *supra* note 141.

153. *See* Tillis-Coons Press Release, *supra* note 148; *Joint AIPLA-IPO Proposal*, *supra* note 141.

154. Tillis-Coons Press Release, *supra* note 148.

155. *Id.*

156. *See id.* (describing that in addition to the new definition for the term "useful," the draft proposal would add a clause under section 101 stating: "Eligibility under this section shall be determined only while considering the claimed invention as a whole, without discounting or disregarding any claim limitation").

157. *Id.*; 35 U.S.C. § 112.

158. HICKEY, *supra* note 133, at 36 (citing Bruce M. Wexler, Yar R. Chaikovsky, Philip Ou, Alexandra Cho & Iman Kholdebarin, *Senate Hearing on "The State of Patent Eligibility in America": Analysis of Viewpoints on Looming Section 101 Change*, PAUL HASTINGS (June 25, 2019), https://www.paulhastings.com/insights/client-alerts/senate-hearing-on-the-state-of-patent-eligibility-in-america-analysis-of-viewpoints-on-looming-section-101-change [https://perma.cc/P4UY-9SBH]).

dramatic breadth in eligibility the new language would supply.[159] Others were concerned with an increase in "unmeritorious patent litigation."[160] The American Civil Liberties Union expressed concerns over the possibility that the proposal could facilitate patents on the human genome.[161] Questions were also raised about the patentability of such things as artificial intelligence and quantum computing.[162]

Professor Mark Lemley of Stanford Law School provided perhaps the starkest outline of the debate during his testimony at the 2019 Senate hearings. Lemley noted that the majority of the impact of the *Mayo/Alice* test has "been in software and business method patents and . . . medical diagnostics patents."[163] While acknowledging the negative impact of the test on medical diagnostics, he praised *Alice* in particular for alleviating a pandemic of "patent trolls" that had plagued the software industry. He noted the benefits of "weed[ing] out weak patent claims more quickly and cheaply than before."[164] Since the *Mayo/Alice* test made a broader array of patents subject to patent eligibility analysis—a matter of law—more ill-fated patents could be resolved on a motion to dismiss.[165] Indeed, statistical analyses demonstrate the benefit of the *Mayo/Alice* test in reducing the type of bad-faith patent litigation associated with patent trolls.[166] In addition to removing this benefit, Lemley argued that the proposed "bill sweeps away two hundred years of rules that have prevented patent law from locking up the fundamental building blocks of nature."[167] A narrower approach would be less risky and could maintain existing protections against bad-faith patent holders.[168] Such an approach, Lemley argued, "would focus narrowly on identified problems in the medical diagnostics business, rendering significant new medical discoveries patentable when they have a practical application . . . ."[169]

This is the wisest approach to patent eligibility reform at this time. The variety of stakeholders in the patent system makes it difficult to

159. *Id.*

160. *Id.*

161. *Id.* at 37.

162. *Id.* (quoting Sen. Chris Coons & Sen. Thom Tillis, *What Coons and Tillis Learned at Patent Reform Hearings*, LAW360 (June 21, 2019, 8:10 PM), https://www.law360.com/articles/1171672/print?section=corporate [https://perma.cc/T94T-4NGY]); Costellia et al., *supra* note 140.

163. Lemley Testimony, *supra* note 99.

164. *Id.*

165. *Id.*

166. *See generally* Lemley & Zyontz, *supra* note 13, at 67, 89.

167. Lemley Testimony, *supra* note 99.

168. *Id.*

169. *Id.*

reach consensus. This is a good thing; the myriad concerns related to preemption and incentive in fields as varying as software and life sciences should all be considered in any legislative reform. Patent eligibility for medical diagnostics has a broader consensus than other subjects.[170] In any event, a narrow exception would be preferable to the uncertainty that would result from a wholesale abandonment of current eligibility doctrine. Finally, the *Mayo/Alice* test has proven beneficial in the realm of software patents by more quickly dispatching frivolous litigation.[171] While the debate rages on over the broader issues of eligibility reform, section 101 language should be amended to restore patent eligibility to medical diagnostics.

## VII. A TAILORED AMENDMENT FOR MEDICAL DIAGNOSTICS

Having established the benefits of an exception for medical diagnostics, what might such an amendment might look like? The most important considerations for such an amendment should be breadth, clarity, and actual restriction of the judiciary.[172]

First, the amendment must expand subject matter eligibility sufficiently to include claims comparable to those in *Athena*. The scope of eligibility has been narrowed to such a degree by the *Mayo/Alice* test that key innovations are denied patentability before they leave the gate. Still, an effective amendment must not expand the breadth of eligibility to such a degree as to abrogate the *Mayo/Alice* test in its entirety. It should leave the test intact to continue combatting bad-faith software patent litigation and those patents which actually seek to claim fundamental laws of nature. Further, it must not allow features of the human body such as genes or internal processes to be rendered patentable.

Second, the language must be clear; an amendment should reduce the uncertainty around what is and is not eligible. Clear statutory language will avoid the uncertainty that has plagued innovators and stakeholders as a result of the *Mayo/Alice* test.[173] The goal is to

170. *See id.*

171. Lemley & Zyontz, *supra* note 13, at 66.

172. Taylor, *supra* note 99, at 2189, 2191–93.

173. *E.g.*, Costellia et al., *supra* note 140 ("[T]he former director of the USPTO, Andrei Iancu, [also] posits that the current state of the law on patentable subject matter 'has created a more unpredictable patent landscape that is hurting innovation and, consequently, investment and job creation.'") (quoting Andrei Iancu, Dir., U.S. Pat. & Trademark Off., Keynote Address at U.S. Chamber of Commerce Patent Policy Conference: Role of U.S. Patent Policy in Domestic Innovation and Potential Impacts on Investment (Apr. 11, 2018) (transcript available at: https://www.uspto.gov/about-us/news-updates/remarks-director-andrei-iancu-us-chamber-commerce-patent-policy-conference [https://perma.cc/GBY3-D638])).

motivate progress in medical diagnostics, and "[b]lurry lines do not induce inventors and their supporters to invest in research and development; blurry lines create risk, which suppresses investment."[174]

Third, the amendment must actually confine the courts as intended. The Court has demonstrated its willingness to depart from the statutory text. Congress eliminated the requirement for an "invention" in the 1952 Patent Act, but the Court has read back in a requirement for an "inventive concept" nonetheless.[175] Any section 101 amendment must fully prevent the Court from reading in an equally problematic expansion of its "implicit exception[s]."[176]

A statutory amendment could begin by adding "biomarkers" to the four listed categories of subject matter in section 101. The Supreme Court cannot apply an implicit exception to a category that is explicitly eligible. The Court, of course, *has* applied such exceptions to the term "process," but the term "biomarker" refers explicitly to the types of correlations the Court has found to be natural laws. To apply the natural law exception to "biomarkers" outright would be to ban a whole category of subject matter that Congress had explicitly made patent eligible.

Of course, it would not be desirable to supply patent eligibility to what amounts to a category of natural laws. The breadth of this addition should therefore be cabined by defining "biomarkers" in 35 U.S.C. § 100. The subject matter category "process" is already defined in section 100;[177] it would not be strange to include an additional definition there for a new category of subject matter. The definition would need to narrow the breadth of the category, avoid supplying eligibility to pure natural laws, provide clarity to the term, and guide the courts in determining eligibility. Such a definition could take the form of the following insertion into 35 U.S.C. § 100:

> The term "biomarker" means a correlation between a measurable substance in a human subject and the likelihood of a certain disease or disorder, utilized in a process with at least one technical step occurring separate from the human body, narrowly claimed through a practical application.

This definition borrows from a number of other proposals but is limited to the now-explicit subject matter category of biomarkers. The practical application test incorporated here has been endorsed in other

174. Taylor, *supra* note 99, at 2192.

175. *Id.* at 2195.

176. *Id.* at 2193 (quoting Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 70 (2012) (collecting cases)).

177. 35 U.S.C. § 100(b) ("The term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.").

contexts by Judge Dyk of the Federal Circuit, Mark Lemley, and others.[178] The purpose of the language "narrowly claimed" is to avoid the implication that the Court must make judgments to which it is "not institutionally well suited," such as determining the relative breadth of a natural law.[179] Instead, the claims of the patent are required to stake out a process and a narrow application to a "certain" disease or disorder. Therefore—regardless of the speculative breadth of the natural law—the patent may only monopolize a process that utilizes the correlation in application to a specified disease or disorder. The language that requires a technical step separate from the human body is inspired by Article 53 of the European Patent Convention (EPC).[180] The EPC excludes medical diagnostics "practised on the human . . . body," but allows them when they are performed through a process that occurs at least partially outside of the body.[181] Permissible processes under these guidelines include variations on the common diagnostic procedure of collecting blood or tissue samples and then analyzing them in vitro in order to reach medical conclusions.[182] This language prevents the possibility of supplying eligibility for physical structures or processes of the human body—metabolic pathways or genetic alleles. Altogether, these changes to sections 100 and 101 of the Patent Act would achieve the goal of returning subject matter eligibility to medical diagnostics while restricting application of the *Mayo/Alice* test to other types of subject matter.

178. *See supra* note 99 and accompanying text.

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

180. Convention on the Grant of European Patents art. 53, Nov. 29, 2000, https://www.epo.org/law-practice/legal-texts/html/epc/2020/e/ma1.html [https://perma.cc/9GQF-UBUC].

181. *Guidelines for Examination: Diagnostic Methods*, EUR. PAT. OFF., https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_4_2_1_3.htm [https://perma.cc/6ZEU-8X3B] (Mar. 1, 2022) ("Additionally, a method is only regarded as a diagnostic method within the meaning of Art. 53(c), and thus excluded from patentability, if all method steps of a technical nature belonging to the preceding steps which are constitutive for making the diagnosis . . . satisfy the criterion 'practised on the human or animal body.'").

182. *Guidelines for Examination: Limitations of Exception Under Art. 53(c)*, EUR. PAT. OFF., https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_4_2_1.htm [https://perma.cc/UV9B-LLPG] (Mar. 1, 2022) ("To be excluded from patentability, a treatment or diagnostic method must actually be carried out on the living human or animal body. A treatment of or diagnostic method practised on a dead human or animal body would therefore not be excluded from patentability by virtue of Art. 53(c).").

## Conclusion

The legislative amendment proposed above would provide clarity to the courts when they look to patent eligibility in medical diagnostics. A court would first look at a challenged claim and determine whether it involves a correlation or natural law such as those that disqualified the patents in *Athena*, *Mayo*, and other related cases. It would then analyze the claims to determine whether they limit the patent to a specific application in diagnosing a particular disease or disorder. That application would be examined to ensure that the claimed process was one not occurring entirely within the human body. If all of these conditions are met, the patent would clear the eligibility bar, but would still be subject to further analysis under the remaining sections of the Patent Act.

The approach described here is a conservative one. It does not seek to fully abrogate the *Mayo/Alice* test. In fact, it preserves it in whole for other subject matter such as software and business methods. It adds biomarkers as explicitly eligible subject matter but limits the types of claims that can qualify. Only those that are narrowly tailored may pass the section 101 gate. It does not seek to address eligibility for artificial intelligence, artificially grown human organs, or quantum computing, but it does preclude the possibility of problematic patents on the human genome and other internal bodily structures and processes. The field of medical diagnostics should not continue to suffer from the intractability of the larger debate on patent subject matter eligibility. This proposed amendment would restore much-needed clarity and eligibility to life-saving diagnostics, while leaving various stakeholders free to continue the broader debate over subject matter eligibility reform.

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