

Notes

SCALPELS OVER SLEDGEHAMMERS: SAVING DIAGNOSTIC PATENTS THROUGH JUDICIAL INTERVENTION RATHER THAN LEGISLATIVE OVERRIDE

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ABSTRACT

Diagnostic tests have become indispensable in the rapidly growing field known as “precision medicine.” Precision medicine tailors treatments to individual patients by using these diagnostic tests to identify how a patient may respond to different therapies. Diagnostics are expensive to develop but show promise in optimizing patient treatment and creating healthcare savings. Even as the medical community has heralded precision medicine as the way of the future, the Supreme Court and Federal Circuit have handed down a dizzying array of decisions regarding attempts to patent diagnostics and precision medicine techniques. Subsequently, courts have struggled to apply the test for patent eligibility, leaving the interpretation of patentable subject matter under § 101 of the Patent Act in a state of chaos.

This chaos has created concerns that diagnostics may be unpatentable, providing minimal protection or incentive for pharmaceutical companies to invest in their development. To rectify this confusion, legislators have proposed overhauling the longstanding Patent Act and rewriting the patent-eligibility statute altogether. This Note argues that these legislative attempts are misguided. Though some remedy for the current patent-eligibility test is required, that solution should come from the courts, not the legislature. Courts can use a dynamic and nuanced common law approach to create a standard that can adapt to the continuously evolving technologies and scientific advancements that seek patent protection. A legislative override, on the

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other hand, could leave the patent statute in as much chaos as before. A judicial refinement of the patent-eligibility test would allow for the patenting of meritorious diagnostics, providing the necessary innovation incentives for their continued development.

INTRODUCTION

For decades, parents with high-risk pregnancies had only two options for prenatal genetic testing: amniocentesis, in which a needle is used to remove amniotic fluid from around the fetus for testing, or chorionic villus sampling, which uses a sample taken through the cervix or abdominal wall.¹ Both techniques are invasive and carry risks of miscarriage as well as other complications.² In 2011, a company called Sequenom brought to market a new noninvasive prenatal test called *MaterniT21*.³ This test could accurately detect many of the same genetic disorders, like Down syndrome, without the invasive procedures or their attendant risks.⁴ The test has become immensely popular and has been called “a global transformation of prenatal care.”⁵ Sequenom owned a patent on this new prenatal testing method, but when they attempted to assert it against competitors with similar

1. *Prenatal Genetic Screening Tests*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (Oct. 2020), <https://www.acog.org/Patients/FAQs/Prenatal-Genetic-Screening-Tests> [<https://perma.cc/MD94-NSSP>]; *High-Risk Pregnancy: Know What To Expect*, MAYO CLINIC (Feb. 8, 2020), <https://www.mayoclinic.org/healthy-lifestyle/pregnancy-week-by-week/in-depth/high-risk-pregnancy/art-20047012> [<https://perma.cc/B5E4-MH7B>].

2. *Amniocentesis*, MAYO CLINIC (Nov. 12, 2020), <https://www.mayoclinic.org/tests-procedures/amniocentesis/about/pac-20392914> [<https://perma.cc/F6PF-T9TJ>]; *Chorionic Villus Sampling*, MAYO CLINIC (Nov. 12, 2020), <https://www.mayoclinic.org/tests-procedures/chorionic-villus-sampling/about/pac-20393533> [<https://perma.cc/TVQ9-R2A4>].

3. Andrew Pollack, *A Less Risky Down Syndrome Test Is Developed*, N.Y. TIMES (Oct. 17, 2011), <https://www.nytimes.com/2011/10/18/business/sequenom-test-for-down-syndrome-raises-hopes-and-questions.html> [<https://perma.cc/F2VY-MB6D>].

4. *Id.* The current version of the test uses a blood sample to screen for Down syndrome and other chromosomal abnormalities. *MaterniT21 PLUS Test*, INTEGRATED GENETICS, <https://www.integratedgenetics.com/patients/pregnancy/maternit21plus> [<https://perma.cc/8GRM-A8FZ>].

5. Diana W. Bianchi & Rossa W.K. Chiu, *Sequencing of Circulating Cell-Free DNA During Pregnancy*, 379 NEW ENG. J. MED. 464, 464 (2018); see also Sarah Elizabeth Richards, *A Safe Prenatal Genetic Test Is Gaining Popularity with Young Moms-To-Be and Their Doctors*, WASH. POST. (Jan. 5, 2019, 8:00 AM), https://www.washingtonpost.com/national/health-science/a-safe-prenatal-genetic-test-is-gaining-popularity-with-young-moms-to-be-and-their-doctors/2019/01/04/746516a2-f4f2-11e8-bc79-68604ed88993_story.html [<https://perma.cc/AHP3-FWR4>] (“In 2017, nearly 60 percent of OB/GYNs prescribed” noninvasive prenatal testing “to younger women – up from 35 percent the year before.”).

tests, the Federal Circuit invalidated it.⁶ The company had raised over \$50 million to develop its revolutionary technology,⁷ but because the test focused on a “law of nature”⁸ in testing DNA, according to the court it was not eligible for patent protection.⁹

The technique at issue in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*¹⁰ is an example of an innovation in the rapidly growing field of pharmaceutical research known as “precision medicine,” also called “personalized medicine.”¹¹ Precision medicine involves “treatments that are tailored to specific characteristics of individuals, such as a person’s genetic makeup.”¹² These treatments often first employ an *in vitro* diagnostic test, which analyzes a patient’s blood or tissue sample.¹³ The analysis from the test helps predict how the patient will respond to a certain drug or evaluates their genetic susceptibility to a disease or condition.¹⁴ This assessment is then followed by an accordant adjustment in the patient’s treatment plan.¹⁵ In this context, the diagnostic is known as a “companion diagnostic,” as it accompanies a treatment.¹⁶ Doctors may also order diagnostics for pure assessment purposes, like with Sequenom’s MaterniT21.¹⁷ Overall, diagnostics and

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

7. See Denise Gellene, *Sequenom Raises \$51.6 Million as It Prepares To Restart Down Syndrome Test*, XCONOMY (May 12, 2010), <https://xconomy.com/san-diego/2010/05/12/sequenom-raises-51-6-million-as-it-prepares-to-restart-down-syndrome-test> [https://perma.cc/4A BR-LHLY].

8. *Sequenom*, 788 F.3d at 1376–79.

9. See *infra* Part I.A.

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

11. See generally Geoffrey S. Ginsburg & Kathryn A. Phillips, *Precision Medicine: From Science to Value*, 37 HEALTH AFFS. 694 (2018) (detailing the current state of precision medicine and global areas of development).

12. *Precision Medicine*, FDA (Sept. 27, 2018), <https://www.fda.gov/medical-devices/vitro-diagnostics/precision-medicine> [https://perma.cc/6X8V-7FC9].

13. *In-Vitro Diagnostics*, FDA (Oct. 25, 2019), <https://www.fda.gov/medical-devices/products-and-medical-procedures/vitro-diagnostics> [https://perma.cc/Y2KA-S3XW].

14. Ulrich-Peter Rohr, Carmen Binder, Thomas Dieterle, Francesco Giusti, Carlo Guiseppe Mario Messina, Eduard Toerien, Holger Moch & Hans Hendrik Schäfer, *The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report*, PLOS ONE 2 (Mar. 4, 2016), <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0149856&type=printable> [https://perma.cc/CJU7-VTLG].

15. *Id.*

16. *Companion Diagnostics*, FDA (Dec. 7, 2018), <https://www.fda.gov/medical-devices/vitro-diagnostics/companion-diagnostics> [https://perma.cc/H5XW-JLYN].

17. The test can be ordered for early risk assessment of Down syndrome and other chromosomal abnormalities. *Early Risk Assessment of Down Syndrome and Other Conditions*,

precision medicine can “optimize[] treatment selection by focusing specific therapies on those most likely to benefit and decrease[] treatment harms by avoiding treatment in those unlikely to respond or predicted to have an adverse reaction to treatment.”¹⁸ This optimization can create cost savings that could “bend the health care cost curve.”¹⁹

Attempts to patent such diagnostic methods and precision medicine techniques have resulted in a dizzying array of decisions from the Supreme Court and the Federal Circuit.²⁰ These cases leave open the question: Are diagnostic methods patent-eligible subject matter?

Patent subject matter eligibility is governed by 35 U.S.C. § 101, which reads:

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.²¹

Facially, the statute allows for a wide expanse of patentable subject matter. This has been limited, however, by judicially created “implicit exception[s].”²² Namely, that “‘laws of nature, natural phenomena, and abstract ideas’ are not patentable.”²³ These limits aim to prevent the patenting of subject matter that are “the basic tools of scientific and technological work” and necessary for future innovation.²⁴

In the 2012 decision *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,²⁵ the Supreme Court established a two-step test for determining patent subject matter eligibility.²⁶ First, is the patent claim

INTEGRATED GENETICS, <https://www.integratedgenetics.com/patients/pregnancy/matemit21plus> [<https://perma.cc/N8EG-GZ8Z>].

18. COMM. ON POL’Y ISSUES IN THE CLINICAL DEV. & USE OF BIOMARKERS FOR MOLECULARLY TARGETED THERAPIES, NAT’L ACADS. OF SCI., ENG’G & MED., BIOMARKER TESTS FOR MOLECULARLY TARGETED THERAPIES 28–29 (Laurene A. Graig, Jonathan K. Phillips & Harold L. Moses eds., 2016).

19. *Id.* at 29 (citation omitted).

20. *See infra* Part II.

21. 35 U.S.C. § 101 (2018).

22. *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66, 70 (2012).

23. *Id.* (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).

24. *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014).

25. *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66 (2012).

26. *See id.* at 77–78 (determining that the disputed patents “set forth laws of nature” and then asking whether they “do significantly more than simply describe these natural relations”).

“directed to” a law of nature, natural phenomenon, or abstract idea?²⁷ If so, does it involve an “inventive concept” that transforms the claim into something more than a mere recitation of that law of nature?²⁸ The patent at issue in *Mayo* involved a diagnostic method that correlated the concentration of drug metabolite in a patient with a dosing regimen.²⁹ The Court held that the patent was invalid on subject matter grounds because the correlation itself was a law of nature, and the additional steps of adjusting the doses were “well-understood, routine, conventional activity” that were “not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.”³⁰

The decision immediately inspired worries that diagnostics and other precision medicines were similarly nonpatentable. Like the patent at issue in *Mayo*, many of these diagnostics are based on biological correlations or detectable biomarkers, which are both measurable indicators of the presence of a disease and how a patient is responding to treatment.³¹ Thus, as one practitioner predicted, *Mayo* could make it “very difficult to patent predictive diagnostic methods that depend on the presence or absence of a marker [in a patient’s system] . . . and diagnostic methods that compare the level of a biomarker to a normal or abnormal level of the marker.”³² Examples

27. *Alice*, 573 U.S. at 217 (applying the *Mayo* framework).

28. *Mayo*, 566 U.S. at 77–78, 82 (quoting *Parker v. Flook*, 437 U.S. 584, 594 (1978)).

29. *Id.* at 73–74. After a patient takes a drug, it is broken down (“metabolized”) in their system. *Id.* By measuring the amount of metabolite (broken-down drug) in the patient, doctors are able to tell how much of the drug the patient has absorbed and can accordingly adjust the patient’s future dosage. *Id.* See generally Jennifer Le, *Drug Metabolism*, MERCK MANUAL: CONSUMER VERSION (Oct. 2020), <https://www.merckmanuals.com/home/drugs/administration-and-kinetics-of-drugs/drug-metabolism> [<https://perma.cc/A57Y-6U3X>] (“Genetic variations in how certain drugs (for example, statins) are transported into and out of the liver may increase a person’s risk of drug side effects or drug-related liver injury.”).

30. *Mayo*, 566 U.S. at 79–80.

31. See Jennifer Gordon, *The Impact of Myriad and Mayo: Will Advancements in the Biological Sciences Be Spurred or Disincentivized? (Or Was Biotech Patenting Not Complicated Enough?)*, COLD SPRING HARBOR PERSPS. MED., May 2015, at 10–11 (“The thinking in *Myriad* that isolated DNA is a patent-ineligible product of nature may well be extended to other purified natural substances.” (citing *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013))).

32. Charlotte Harrison, *Patent Watch*, 11 NATURE REVS. DRUG DISCOVERY 344, 344–45 (2012) (quoting patent attorney Warren Woessner, who characterized the ruling as “extremely negative for companies and institutions attempting to develop assays that will be the cornerstone of personalized medicine”).

of such tests include assays for prostate cancer,³³ potential early detection tests for Alzheimer's disease,³⁴ and other targeted cancer treatments, as “[p]atients with a variety of cancers routinely undergo molecular testing as part of patient care, enabling physicians to select treatments that improve chances of survival and reduce exposure to adverse effects.”³⁵

The lack of patent protection for these methods is concerning because diagnostic development requires significant up-front investment.³⁶ Companies can spend millions before they have any chance to bring a diagnostic product to market.³⁷ Without an ex ante guarantee of patent protection to ensure developers can recoup research and development costs, these developers may have little incentive or ability to develop diagnostics.³⁸

In light of *Mayo*, the pertinent question is how pharmaceutical companies can patent diagnostic methods and precision medicines, or more broadly, how pharmaceutical companies can be incentivized to even develop them in the first place. The Federal Circuit has tempered the Supreme Court's harsh stance taken in *Mayo*, handing down some decisions that bow to *Mayo*'s precedent and invalidate diagnostic patents, and some that seem to flagrantly push past it in an attempt to save them.³⁹ Altogether, the Supreme Court and Federal Circuit decisions have left § 101 jurisprudence in a state of “chaos.”⁴⁰

33. *Id.*; *Prostate-Specific Antigen (PSA) Test*, NIH: NAT'L CANCER INST. (Oct. 4, 2017), <https://www.cancer.gov/types/prostate/psa-fact-sheet> [<https://perma.cc/5P4N-MQTL>].

34. Jonathan Graff-Radford, *Alzheimer's Test: Detection at the Earliest Stages*, MAYO CLINIC (Apr. 20, 2019), <https://www.mayoclinic.org/diseases-conditions/alzheimers-disease/expert-answers/alzheimers-test/faq-20057850> [<https://perma.cc/R6XA-UM7N>].

35. *Precision Medicine*, *supra* note 12.

36. *See infra* Part I.B.

37. The cost is estimated to be between \$20 million and \$106 million. 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/NBC2-6PL3>].

38. *See* Gordon, *supra* note 31, at 10–11 (“The bottom line is that after *Mayo*, the USPTO will grant narrowly drafted claims of significantly less commercial value At some point, the narrowness of available claim scope from the USPTO will deter the patenting of these kinds of inventions, if not the vitally important research that underlies them.”).

39. *See infra* Part II.

40. Gene Quinn, *Why the Federal Circuit Is To Blame for the 101 Crisis*, IPWATCHDOG (Feb. 25, 2019), <https://www.ipwatchdog.com/2019/02/25/federal-circuit-blame-101-crisis> [<https://perma.cc/U32M-DY2S>].

Given the confusion and unworkability of the *Mayo* test,⁴¹ legislators have begun to take action, claiming that “[i]t’s time to restore America’s patent system” because current patent laws are “hostile to innovation.”⁴² Senators Chris Coons and Thom Tillis, then-leaders of the Senate Judiciary Subcommittee on Intellectual Property,⁴³ released a bipartisan draft bill that seeks to overhaul the patent eligibility standards in § 101.⁴⁴ The bill would abrogate the judicially created implicit exceptions in order to create a “clear legal framework for what types of innovations are patent eligible.”⁴⁵ However, this is not a problem that calls for a legislative sledgehammer, but a targeted, surgical intervention by the courts. Patent law, because it involves continuously evolving technologies and scientific advancements, requires dynamic and nuanced common law development, not a legislative override that could leave the patent statute in as much chaos as before.⁴⁶

This Note proceeds in three parts. Part I discusses the policy tensions at play in cases like *Sequenom* where companies seek to patent diagnostic methods and precision medicines. Part I also describes the current Supreme Court interpretation of § 101 under the *Mayo* test.

41. See David O. Taylor, *Amending Patent Eligibility*, 50 U.C. DAVIS L. REV. 2149, 2153–57 (2017) (“[A]ll the Court has to show for its efforts is considerable confusion, a test that lacks administrability, and a result that presents the significant risk of reduced incentive to invent.”).

42. Chris Coons & Thom Tillis, *It’s Time To Restore America’s Patent System*, HILL (June 10, 2019, 8:15 AM), <https://thehill.com/blogs/congress-blog/technology/447666-its-time-to-restore-americas-patent-system> [<https://perma.cc/J87P-CW3H>].

43. *Subcommittee on Intellectual Property*, COMM. JUDICIARY, <https://www.judiciary.senate.gov/about/subcommittees/subcommittee-on-intellectual-property> [<https://perma.cc/8HKW-TSVD>].

44. Press Release, Off. of 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) [hereinafter Tillis-Coons Press Release], <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/73TR-9NL6>]. The senators released their draft bill in May 2019 and the subcommittee held hearings on patent eligibility on June 4, 5, and 11, 2019. *Id.*; see also *infra* note 156. They plan to rework the draft bill before presenting it to the Senate. Tillis-Coons Press Release, *supra*. Senator Patrick Leahy has since replaced Coons as the Democratic chair of the subcommittee. Dani Kass, *AIA Namesake Leahy Takes Over Senate IP Subcommittee*, LAW360 (Feb. 16, 2021, 3:34 PM), <https://www.law360.com/articles/1355100> [<https://perma.cc/X2BW-CYVY>]. Tillis remains the ranking member of the subcommittee, *id.*, and has stated that “reforming eligibility jurisprudence is going to be one of [his] top priorities this Congress and [he] will use every opportunity [he has]—from the President-Elect’s USPTO nomination to amicus briefs before the Supreme Court—to achieve that goal.” @IanMichaelLopez, TWITTER (Jan. 19, 2021, 5:22 PM), <https://twitter.com/IanMichaelLopez/status/1351656290355974146> [<https://perma.cc/S7CR-28MV>].

45. Coons & Tillis, *supra* note 42.

46. See *infra* Part III.

Part II describes how the Federal Circuit has struggled to apply that test, resulting in confusion and a clear need for intervention. Finally, Part III argues that the judiciary is better suited to fix § 101 standards than Congress, evaluates a proposed legislative amendment to § 101, and suggests a more flexible second step of *Mayo* which could filter meritorious patent claims from “junk patents” while still enabling the patenting of diagnostic methods.

I. PATENT SUBJECT MATTER ELIGIBILITY AND INNOVATION IN DIAGNOSTICS

This Part surveys the statutory basis for patent subject matter eligibility and subsequent judicial interpretations of it. Then, it explores how eligibility is critical to the biopharmaceutical industry and the development of diagnostic methods. Finally, it explains the current test for determining patent subject matter eligibility, which has jeopardized the patentability of diagnostics.

A. *Section 101: The Statutory Threshold and Its Judicially Created Exceptions*

Patent protection under U.S. law stems from the Intellectual Property Clause of the Constitution, which grants Congress the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”⁴⁷ This clause provides the constitutional hook for the Patent Act, which enables the government to grant exclusive rights to an inventor if an invention qualifies for a patent under the various requirements set out by the Act.⁴⁸ Patent eligibility is a threshold validity determination governed by 35 U.S.C. § 101, which reads: “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.”⁴⁹ This broad language, which dates back to the Thomas Jefferson–authored Patent Act of 1793,⁵⁰ has been constrained over time by three judicially created

47. U.S. CONST. art. I, § 8, cl. 8.

48. 35 U.S.C. § 101 (2018).

49. *Id.* (emphasis added).

50. The original language was “any new and useful art, machine, manufacture or composition of matter.” Patent Act of 1793, ch. 11, § 1, 1 Stat. 318, 319. “Art” was replaced with

exceptions: “laws of nature, natural phenomena, and abstract ideas” are not patent eligible.⁵¹ As the Supreme Court has explained, “While these exceptions are not required by the statutory text, they . . . have defined the reach of the statute as a matter of statutory *stare decisis* going back 150 years.”⁵²

These exceptions are primarily based on a preemption rationale, a concern that patent monopolies on “‘the basic tools of scientific and technological work’ . . . might tend to impede innovation more than it would tend to promote it.”⁵³ Patent protection of such foundational elements of research might preempt future discoveries, hence why “Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity.”⁵⁴ However, practical applications of laws of nature and abstract ideas “to a new and useful end” may be patent eligible.⁵⁵ The difficulty is in evaluating exactly what constitutes a law of nature, natural phenomenon, or abstract idea, absent a statutory definition for the terms, and what goes far enough to become a patentable practical application.⁵⁶ The courts have adjudicated these determinations on a case-by-case basis such that “the scope of patentable subject matter has waxed and waned over time, depending on the trends of recent judicial decisions.”⁵⁷ The most recent

the more modern term “process” in 1952, and “process” was defined as “process, art, or method.” Patent Act of 1952, Pub. L. No. 82-593, §§ 100–101, 66 Stat. 792, 797. This change did not alter the scope of § 101. See 1 DONALD S. CHISUM, *Overview: Historical Development of Patent Law*, at n.4, in CHISUM ON PATENTS (2020), <https://plus.lexis.com/api/permalink/063c39be-9e2d-42a1-8dea-87175b936f9b> [<https://perma.cc/3C8S-7NY9>] (“[As used in the 1793 Patent Act, t]he term ‘art’ meant process or method.”).

51. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

52. *Bilski v. Kappos*, 561 U.S. 593, 601–02 (2010) (citing *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 174–75 (1853)).

53. *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66, 71 (2012) (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)); see also *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014) (“We have described the concern that drives this exclusionary principle as one of pre-emption.”).

54. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

55. *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

56. See Daniel J. Klein, *The Integrity of Section 101: A “New and Useful” Test for Patentable Subject Matter*, 93 J. PAT. & TRADEMARK OFF. SOC’Y 287, 289 (2011) (describing the judicial exceptions as “metaphysically vague and extra-statutory,” resulting in judges applying an “‘I know it when I see it’ test” when evaluating whether or not a claimed invention is an “abstract idea”).

57. KEVIN J. HICKEY, CONG. RSCH. SERV., R45918, PATENT-ELIGIBLE SUBJECT MATTER REFORM IN THE 116TH CONGRESS 12 (2019), <https://fas.org/sgp/crs/misc/R45918.pdf> [<https://perma.cc/V8WY-ZEUY>].

Supreme Court decisions on the topic have only served to further muddy the waters, particularly in the realm of biotechnology patents.

These muddied waters are problematic for any party engaging in the patent system, including patent examiners, judges, and inventors. Patent examiners at the U.S. Patent and Trademark Office (“PTO”) must attempt to apply the confusing rule on eligibility consistently across different fields of technology, and all in the limited time they have to evaluate each patent application.⁵⁸ District court judges, themselves often not experts in patent law or technological sciences, must also apply the rule to varying bodies of technology and scientific invention. Further, the potential for invalidity under the unclear “law of nature” and “abstract idea” exceptions presents particular problems for biotechnology inventors whose inventions often involve “laws of nature” on some level and who require incentives to initiate the expensive research and development process in the first place.

B. Diagnostics Require Innovation Incentives

The patentability concerns implicated by the judicially created exceptions are pronounced in the area of diagnostic technology, where inventions focus on testing biomarkers or other biological processes that could be considered “laws of nature.” Diagnosis has been called “the foundation of medicine,” and while developing diagnostic methods and precision medicines “does not assure effective treatment, . . . it is unequivocally the place to start.”⁵⁹ A study of how diagnostics are used in medical practice shows that they are a crucial tool in patient management, and that developing “[n]ew markers should deliver actionable and medically relevant information[] to guide decision-making and foster improved patient outcomes.”⁶⁰ The COVID-19 pandemic made clear the importance of diagnostics: in the “greatest public health challenge of the 21st century,” the United States’ lack of “high-quality diagnostics . . . resulted in inaccurate patient identification and poor epidemiological characterization of

58. For a detailed discussion of how time allotment at the PTO affects patent issuance, see Michael D. Frakes & Melissa F. Wasserman, *Irrational Ignorance at the Patent Office*, 72 VAND. L. REV. 975, 982–87 (2019).

59. COMM. ON A FRAMEWORK FOR DEVELOPING A NEW TAXONOMY OF DISEASE, NAT’L RSCH. COUNCIL, TOWARD PRECISION MEDICINE: BUILDING A KNOWLEDGE NETWORK FOR BIOMEDICAL RESEARCH AND A NEW TAXONOMY OF DISEASE 79 (2011), https://www.ncbi.nlm.nih.gov/books/NBK91503/pdf/Bookshelf_NBK91503.pdf [<https://perma.cc/8M28-RM4S>].

60. Rohr et al., *supra* note 14, at 2.

viral spread,” which ultimately led to “fewer patients being tested and rapid spread of the virus.”⁶¹

Development of diagnostic tools is not cheap. One panel of experts estimates the average cost of developing and commercializing a diagnostic is between \$20 million and \$106 million.⁶² For precision medicines, which consist of a companion diagnostic paired with a treatment, the cost of developing the diagnostic must be added to the cost of developing the drug as well, which is estimated to be in the billions of dollars.⁶³ Furthermore, to be marketed to doctors for eventual patient use, most drugs and diagnostics must receive regulatory clearance from the Food and Drug Administration (“FDA”)—a process that comes with its own costs.⁶⁴ The economic incentive of patent protection for the treatment drug alone may not be sufficient to assure a drug developer that investment in a companion diagnostic will be worthwhile; whereas granting patent protection for the diagnostic as well as the treatment drug would provide a stronger incentive for the development of precision medicines.

Strong incentives are particularly vital to encourage research and development in the pharmaceutical and biotechnology industries, which encompass both drug and diagnostic development. Technologies and drugs in these industries are “very expensive to develop but relatively cheap to reproduce.”⁶⁵ Not only are drugs expensive to develop, but they can also take over thirty years to progress from the research and development stage to FDA approval.⁶⁶ Furthermore,

61. Chaarushena Deb, Osman Moneer & W. Nicholson Price II, *Covid-19, Single-Sourced Diagnostic Tests, and Innovation Policy*, J.L. & BIOSCIENCES, Jan.–June 2020, at 1–2.

62. Dolginow et al., *supra* note 37.

63. The average cost of developing a drug and obtaining FDA approval is roughly \$2.6 billion. Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 31 (2016).

64. *Development & Approval Process | Drugs*, FDA (Oct. 28, 2019), <https://www.fda.gov/drugs/development-approval-process-drugs> [<https://perma.cc/M5W7-2ZUE>]; *Overview of IVD Regulation*, FDA (Sept. 16, 2019), <https://www.fda.gov/medical-devices/ivd-regulatory-assistance/overview-ivd-regulation> [<https://perma.cc/MN98-7XQ4>].

65. Anatole Krattiger, *Promoting Access to Medical Innovation*, WIPO MAG. (Sept. 2013), https://www.wipo.int/wipo_magazine/en/2013/05/article_0002.html [<https://perma.cc/H5Y4-989T>].

66. The median time to develop a drug from initial research on novel drug targets to FDA approval is thirty-six years. Laura M. McNamee, Michael Jay Walsh & Fred D. Ledley, *Timelines of Translational Science: From Technology Initiation to FDA Approval*, PLOS ONE 1 (May 8, 2017), <https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0177371&type=printable> [<https://perma.cc/3PN8-DKUP>]; see also Fred D. Ledley, *30 Years Is Too Long To Wait for New Medicines*.

drug development is a risky endeavor—more than 90 percent of drug candidates fail before reaching the clinical testing phase,⁶⁷ and this comes after companies have already invested significant funds into developing them. Generic imitations, on the other hand, take significantly less time and money to develop once the novel drug has come to market, given that the patent describing the drug has already been published.⁶⁸ Thus, to remain financially viable, ex ante assurance of patent protection is necessary to incentivize companies to invest in research, development, and regulatory approval.

As personalized medicine becomes the way of the future, patients will want to know more about their own disease susceptibility. Research into genetic markers of disease will continue to grow. However, if one can only obtain a patent on an actual treatment rather than on a diagnostic test, there will be little incentive for the biopharma industry to transform the basic genetic research into a diagnostic that doctors and patients can actually use.

C. *Striking a Balance Between Innovation Incentives and Preemption*

In determining patent eligibility, there is a risk of being both overinclusive and underinclusive; of granting too many patents to undeserving inventions or failing to protect deserving ones. To combat these extremes, the vital patent protections necessary to promote diagnostic development must be balanced with the primary concern underlying § 101: preemption. The lack of a proper test to sort between meritorious patent claims and claims wholly directed to laws of nature, natural phenomena, or abstract ideas creates a risk of tying up the “building blocks” of research and impeding future research.⁶⁹ Indeed,

There Are Ways To Speed Up Drug Development, STAT (June 6, 2018), <https://www.statnews.com/2018/06/06/drug-development-speed-new-medicines> [<https://perma.cc/HY6M-YGY8>].

67. See Helen Dowden & Jamie Munro, *Trends in Clinical Success Rates and Therapeutic Focus*, 18 NATURE REVS. DRUG DISCOVERY 495, 495 (2019); Michael Hay, David W. Thomas, John L. Craighead, Celia Economides & Jesse Rosenthal, *Clinical Development Success Rates for Investigational Drugs*, 32 NATURE BIOTECHNOLOGY 40, 41 (2014).

68. The median time for a generic to receive FDA approval was 296 days. FDA OFF. OF PLANNING, FY 2018 PERFORMANCE REPORT TO CONGRESS FOR THE GENERIC DRUG USER FEE AMENDMENTS 30 (n.d.), <https://www.fda.gov/media/130572/download> [<https://perma.cc/SUZ8-VPUY>].

69. *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014) (“We have ‘repeatedly emphasized this . . . concern that patent law not inhibit further discovery by improperly tying up the future use of’ these building blocks of human ingenuity.” (quoting *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66, 85 (2012))); *O’Reilly v. Morse*, 56 U.S. 62, 120–21 (1853)

§ 101 exists to “identify certain patents or categories of patents that should not be granted because their economic harms exceed their benefits.”⁷⁰ Thus, overbroad patents should be denied patent protection due to their chilling effect on downstream innovation.

In addition to chilling downstream innovation, a poorly formulated test risks blocking downstream innovation entirely by extending the power of patent protection to discoveries with little innovative value. Attempts to patent marginally innovative developments—a practice pejoratively deemed “evergreening”—can extend the life of brand-name drug patents, delaying the introduction of generics to market and driving up prescription drug costs.⁷¹ Critics of evergreening claim that “by obtaining later patents on improvements or ancillary aspects of a pharmaceutical, pharmaceutical manufacturers effectively extend patent protection beyond the term set by Congress, deterring follow-on competitors and keeping prices high,” and these later patents are often of “questionable value and validity.”⁷² An effective test would filter out these patents, too. Unfortunately, the current test established by the Supreme Court has not effectively navigated the space between innovation and preemption and instead has left the lower courts with a confusing standard, often inconsistently applied.

D. The Modern Framework: The Mayo Test

Beginning in 2010, the Supreme Court took a renewed interest in patent subject matter eligibility, handing down four decisions on the topic in five years.⁷³ Altogether, these cases yielded the current iteration of the *Mayo* two-step test for determining subject matter eligibility for process patents.⁷⁴ The Court first established the test in

(explaining that claiming more than what one has invented is forbidden because it “prevents others from attempting to improve upon the manner and process . . . described in [the] specification—and may deter the public from using it”).

70. HICKEY, *supra* note 57, at 25 (surveying rationales for § 101).

71. Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590, 596 (2018).

72. KEVIN J. HICKEY, ERIN H. WARD & WEN W. SHEN, CONG. RSCH. SERV., R45666, DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE 116TH CONGRESS 14 (2019), <https://crsreports.congress.gov/product/pdf/R/R45666> [<https://perma.cc/YMK5-M65U>].

73. The series began with *Bilski* in 2010, followed by *Mayo* in 2012, *Myriad* in 2013, and *Alice* in 2014.

74. Process claims “differ[] fundamentally from the other three classes (machine, manufacture, and composition of matter). A process is not a structural entity but rather an

the diagnostic context in *Mayo*, and then further developed it in *Alice Corp. v. CLS Bank International*,⁷⁵ which dealt with a software patent.⁷⁶ The first step of the test asks whether the patent claim is “directed to” a patent-ineligible concept.⁷⁷ For example, is the claim focused on measuring a natural correlation in the body, like the rate of absorption of a drug—something that could be deemed a “law of nature”? Or does it claim something clearly outside the judicially created exceptions of a law of nature, a natural phenomenon, or an abstract idea, like a novel method for artificially editing genes?⁷⁸ If the patent claim is *not* directed to an exception, then the invention is patent eligible. If it is directed to one of the judicial exceptions, then the analysis proceeds to the second step.

Mayo’s second step asks whether the claimed patent involves an “inventive concept” that transforms the claim into something *more* than a mere recitation of a law of nature or abstract idea.⁷⁹ At this step, the court “consider[s] the elements of each claim both individually and ‘as an ordered combination’ to determine whether the additional elements ‘transform the nature of the claim’ into a patent-eligible application.”⁸⁰ This “inventive concept” cannot be “well-understood, routine, conventional,” as such activity “is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.”⁸¹

operation or series of steps leading to a useful result.” CHISUM, *supra* note 50, § 1.03 (footnote omitted).

75. *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208 (2014).

76. The test is also known as the *Mayo/Alice* test.

77. *Alice*, 573 U.S. at 217 (citing *Mayo Collaborative Servs. v. Prometheus Lab’y, Inc.*, 566 U.S. 66, 77–78 (2012)).

78. CRISPR, a new research tool developed in 2012, allows scientists to precisely edit genes in the lab in a way that has revolutionized biological research. Heidi Ledford & Ewen Callaway, *Pioneers of Revolutionary CRISPR Gene Editing Win Chemistry Nobel*, NATURE (Oct. 7, 2020), <https://www.nature.com/articles/d41586-020-02765-9> [<https://perma.cc/GT34-RHBX>]. The scientists who developed CRISPR won the 2020 Nobel Prize in Chemistry for their work. *Id.* CRISPR is the subject of several patents and extensive patent litigation. See, e.g., Jon Cohen, *Surprise Patent Ruling Revives High-Stakes Dispute over the Genome Editor CRISPR*, SCI. (June 26, 2019, 1:45 PM), <https://www.sciencemag.org/news/2019/06/surprise-patent-ruling-revives-high-stakes-dispute-over-genome-editor-crispr> [<https://perma.cc/Y3HM-88VT>]; U.S. Patent No. 10,308,961 (filed July 11, 2018) (directed to “[m]ethods and compositions for RNA-directed target DNA modification and for RNA-directed modulation of transcription”).

79. *Alice*, 573 U.S. at 217–18 (quoting *Mayo*, 561 U.S. at 78).

80. *Id.* at 217 (quoting *Mayo*, 561 U.S. at 78–79).

81. *Mayo*, 561 U.S. at 79.

The patent directly at issue in *Mayo* involved a diagnostic method that correlated a patient's unique drug metabolism to a dosing scheme in an effort to optimize drug treatment for autoimmune diseases.⁸² If a test showed a patient had a certain concentration of broken-down drug in their blood, then the doctor should adjust their treatment accordingly to give a more precise, effective dose.⁸³ The Court held the claim to be patent ineligible because the correlation itself was a law of nature, and the additional step of adjusting the dose was the sort of "well-understood, routine, conventional activity . . . [that is normally] not sufficient to transform unpatentable natural correlations into patentable applications of those regularities."⁸⁴ Altogether, the method "amount[ed] to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients."⁸⁵

The *Mayo* decision was strong medicine, stronger than necessary to weed out the particular patent it evaluated. Though the patented method could be seen as only a marginal improvement—it "optimized" a test and dosing procedure that doctors already recognized and performed⁸⁶—the Court did not need to use such a sweeping test to eliminate it. The Patent Act lays out other requirements for obtaining a patent, like novelty or nonobviousness, which could have been used to invalidate the patent.⁸⁷ Instead, the Court unnecessarily left the patent bar with a controversial and confusing new test.⁸⁸

82. *Id.* at 73–74.

83. *Id.* at 74–75.

84. *Id.* at 79–80.

85. *Id.* at 79.

86. Dennis Crouch, *Mayo v. Prometheus: Medical Methods and Patentable Subject Matter at the Supreme Court*, PATENTLY-O (Oct. 28, 2009), <https://patentlyo.com/patent/2009/10/mayo-v-prometheus-medical-methods-and-patentable-subject-matter-at-the-supreme-court.html> [<https://perma.cc/MDC9-ZYTH>] ("[T]he general iterative process is well known, what makes the Prometheus claims novel is that they identify the particular thresholds that are important (e.g., 230 pmol).").

87. 35 U.S.C. § 102 (2018) (codifying the novelty requirement); *id.* § 103 (codifying the nonobviousness requirement).

88. Compare Gene Quinn, *Killing Industry: The Supreme Court Blows Mayo v. Prometheus*, IPWATCHDOG (Mar. 20, 2012), <https://www.ipwatchdog.com/2012/03/20/supreme-court-mayo-v-prometheus> [<https://perma.cc/3A82-ALWU>] (arguing that the *Mayo* framework conflates patent eligibility with novelty and nonobviousness), with Julie Samuels, *The Supreme Court Gets It Right: No Patents on Laws of Nature*, ELEC. FRONTIER FOUND. (Mar. 21, 2012), <https://www EFF.org/deepinks/2012/03/supreme-court-gets-it-right-no-patents-laws-nature> [<https://perma.cc/J79N-EM3S>] (arguing that *Mayo* correctly reaffirms that "laws of nature . . . are not patentable").

With the decision came concerns that the new test would render diagnostics and other precision medicines nonpatentable, since many are based on biological correlations. The Biotechnology Industry Organization, the world's largest trade association representing biotechnology companies and institutions worldwide, released a statement decrying the ruling and criticizing the Court for "fail[ing] to appropriately recognize the importance of personalized medicine, and of the research and investment incentives needed to develop new individualized therapies for untreated diseases."⁸⁹

Others saw it as a victory for patients and medical research, confirming that "[m]edical innovations that provide insight into natural human biology must remain freely accessible and widely disseminated."⁹⁰ The American Medical Association released a statement in support, saying that *Mayo* protected physicians' ability to "consider[] all relevant scientific information when reviewing diagnostic test results" without fear of "encounter[ing] a vast thicket of exclusive rights" that would have precluded them.⁹¹ But it is not clear that such a sweeping standard was required to prevent that result. Indeed, the patent at issue in *Mayo* was not particularly new or useful and could have been invalidated on novelty or utility grounds, rather than on subject matter eligibility grounds. The patent took an already existing practice and merely made it more precise. By establishing such a broad test—which the Federal Circuit has subsequently struggled to apply—to invalidate it, the Court created what a former PTO director and the former chief judge of the Federal Circuit have called an "uncertain patent climate [that] has a chilling effect on innovation in biosciences to the detriment of public health."⁹²

Notably absent from the decision were any guiding criteria for determining inventiveness under the second step, leading some

89. Hans Sauer, *Mayo v. Prometheus: BIO Statement on Supreme Court Decision*, BIOTECHNOW (Mar. 20, 2012), <https://dev.bio.org/blogs/mayo-v-prometheus-bio-statement-supreme-court-decision> [<https://perma.cc/7WX2-GFTE>].

90. Press Release, Robert M. Wah, Am. Med. Ass'n, *AMA Welcomes Supreme Court Decision To Invalidate Prometheus Patents* (Mar. 20, 2012), <https://web.archive.org/web/20120322204224/http://www.ama-assn.org/ama/pub/news/news/2012-03-20-supreme-court-decision-prometheus-patents.page>.

91. *Id.*

92. David J. Kappos & Paul R. Michel, *Supreme Court Patent Decisions Are Stifling Health Care Innovation*, MORNING CONSULT (Oct. 29, 2018, 5:00 AM), <https://morningconsult.com/opinions/supreme-court-patent-decisions-stifling-health-care-innovation> [<https://perma.cc/4FV7-TW7M>].

commentators to predict that the decision’s “fairly unclear language” leaves wriggle room for the Federal Circuit to apply the test at varying levels of discretion.⁹³ Some worried that patent examiners and lower courts would “struggle to consistently and rationally implement” the “new and confusing” test.⁹⁴ This was prescient, as the subsequent case law has borne out. Exactly what kind of steps are sufficiently “inventive” to be transformative is still unclear, as the Federal Circuit has applied the test in a dizzying variety of ways, sometimes saving diagnostic patents and sometimes casting them aside.

II. *MAYO*’S FAILURE: THE FIGHT TO SAVE DIAGNOSTICS AT THE FEDERAL CIRCUIT

The Federal Circuit, limited by *Mayo* but recognizing the value in diagnostics, has “signaled a willingness to find valid diagnostic method claims,” increasingly pushing the *Mayo* boundary over time.⁹⁵ This Part explores four Federal Circuit cases post-*Mayo* that evaluated the eligibility of biotechnology process patents and came to drastically different conclusions, demonstrating the need for clarification of § 101.

A. *Mayo Over-Filters*: *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*

Fears about the *Mayo* test over-filtering patents were realized at the Federal Circuit in 2015, when application of the test resulted in the invalidation of a legitimately useful discovery. The patent at issue in *Sequenom* claimed a novel, noninvasive method of prenatal testing using fetal DNA found in maternal plasma or serum, materials that had previously been routinely discarded.⁹⁶ The new method allowed patients to avoid the risks of the commonly used, invasive prenatal testing techniques that took samples from the fetus or the placenta.⁹⁷ Nonetheless, the court found the test patent ineligible because it was directed at the natural phenomenon of fetal DNA, and because the subsequent steps of amplifying and detecting the DNA were routine

93. Harrison, *supra* note 32, at 344–45 (quoting Hank Greely, director of the Center for Law and the Biosciences at Stanford University).

94. Sauer, *supra* note 89.

95. Adil Moghal & Gaby L. Longworth, *INSIGHT: The Latest in Patenting Diagnostic Methods*, BLOOMBERG L.: IPL NEWS (Sept. 24, 2018, 7:01 AM), <https://news.bloomberglaw.com/ip-law/insight-the-latest-in-patenting-diagnostic-methods> [https://perma.cc/AA6B-W7CR].

96. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373, 1376 (Fed. Cir. 2015).

97. *Id.* at 1373.

and conventional at the time the patent was issued.⁹⁸ Ultimately, the court reasoned that the method “amount[ed] to a general instruction to doctors to apply routine, conventional techniques when seeking to detect [fetal] cffDNA,” and therefore was “not new and useful.”⁹⁹ The only new and useful part of the claim was the discovery of the fetal DNA in the maternal plasma, which, standing alone, could not be patented.¹⁰⁰

In an early pushback to the Supreme Court’s § 101 jurisprudence, Judge Richard Linn concurred in the opinion but wrote separately to emphasize that he did so only because he was “bound by the sweeping language of the test set out in *Mayo*.”¹⁰¹ He took issue with *Mayo*’s overly broad second step requiring sufficient inventiveness, explaining that *Sequenom* “represent[ed] the consequence . . . in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain.”¹⁰² He thought that *Mayo* had wrongly “discounted, seemingly without qualification, any ‘[p]ost-solution activity that is purely conventional or obvious,’” which standing alone might not warrant protection, but, taken together in combination, might constitute a novel process that did merit patent protection.¹⁰³ The post-solution activity in *Mayo*, the dosage adjustment, was already being performed by doctors at the time; the patent merely made the adjustment more precise.¹⁰⁴ In *Sequenom*, *no one* had been amplifying and detecting the fetal DNA in maternal plasma—the steps, though conventional, were a new use “deserving of patent protection.”¹⁰⁵

98. *Id.* at 1377.

99. *Id.*

100. *Id.*

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

102. *Id.*

103. *Id.* (alteration in original) (quoting *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66, 82 (2012)).

104. *Id.* at 1380–81.

105. *Id.* at 1381. *Sequenom*, which had pioneered the technology and brought it to market, lost its patent while attempting to assert it against competitors that had quickly brought similar noninvasive prenatal tests to market. This had created a competitive environment in a growing market. Michael Gibney, *Diagnostics: Illumina, Ariosa and Sequenom*, FIERCE BIOTECH (Oct. 21, 2014, 8:10 AM), <https://www.fiercebiotech.com/special-report/diagnostics-illumina-ariosa-and-sequenom> [<https://perma.cc/RU4K-FTJL>]. After some financial struggles, *Sequenom* was acquired by *LabCorp*, through which doctors can now order the test, along with other competitors. Frank Vinluan, *LabCorp Boosts Prenatal Testing Presence with \$371M Sequenom*

Judge Linn was not alone: upon denial of a rehearing en banc, other Federal Circuit judges expressed a similar concern about *Mayo*'s restrictive nature but agreed that they must bow to precedent.¹⁰⁶ Many thought *Sequenom* was the ideal vehicle for the Supreme Court to grant certiorari and clarify their patent eligibility jurisprudence.¹⁰⁷ The Court declined, and so the Federal Circuit resorted to more extreme measures.

B. Carving out Safe Harbors: Rapid Litigation Management Ltd. v. CellzDirect, Inc. and Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals International Ltd.

One year later, the Federal Circuit took the opposite tack in demonstrating *Mayo*'s weaknesses: it held valid a method patent that, facially, did not seem particularly “inventive” at all. The patent at issue in *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*¹⁰⁸ described a method of extending the lifespan of cryopreserved hepatocytes, a type of liver cell.¹⁰⁹ Prior to the inventors' discovery, it was thought that the cells could only survive one freeze–thaw cycle.¹¹⁰ The inventors subjected the cells to a second freeze–thaw cycle, found that the cells were still viable, and thus claimed their refreezing method.¹¹¹

Deal, XCONOMY (July 27, 2016), <https://xconomy.com/raleigh-durham/2016/07/27/labcorp-boosts-prenatal-testing-presence-with-371m-sequenom-deal> [<https://perma.cc/H73F-92XZ>].

106. *Ariosa Diagnostics, Inc. v. Sequenom Inc.*, 809 F.3d 1282, 1284, 1287 (Fed. Cir. 2015) (Lourie, J., concurring in the denial of reh'g en banc).

107. *E.g.*, Paul Cole, *Ariosa v Sequenom—A Path to the Supreme Court?*, PATENT DOCS (Dec. 14, 2015), <https://www.patentdocs.org/2015/12/guest-post-ariosa-v-sequenom-a-path-to-the-supreme-court.html> [<https://perma.cc/S2AW-K3ZL>] (summarizing the arguments of amici from industry, academia, research institutions, and arguing for grant of certiorari); Bart Eppenauer, *Section 101 – Pivotal Moment for Clarity on Patent Subject Matter Eligibility*, PATENTLY-O (Apr. 21, 2016), <https://patentlyo.com/patent/2016/04/section-subject-eligibility.html> [<https://perma.cc/HE9U-Z65Q>] (“[T]he Supreme Court should agree to hear the *Sequenom* case and clarify (or revise) its *Mayo/Alice* test to ensure that meritorious inventions in life sciences and software remain patentable.”); Gene Quinn, *SCOTUS Blog Founder Asks Supreme Court To Reconsider Mayo Ruling in Sequenom v. Ariosa*, IPWATCHDOG (Mar. 21, 2016), <https://www.ipwatchdog.com/2016/03/21/scotus-supreme-court-reconsider-mayo-sequenom-ariosa> [<https://perma.cc/HSC2-VUE8>] (“It is time for the Supreme Court to stand up and face the music. If they did not intent [sic] to render groundbreaking medical innovations patent ineligible they must take this case and they must place real, consequential limits on *Mayo*.”).

108. *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016).

109. *Id.* at 1045.

110. *Id.*

111. *Id.*

The Federal Circuit held that the method passed *Mayo*'s first step because it was *not* directed to a patent-ineligible judicial exception, but rather “to a new and useful laboratory technique”: “a ‘method of producing a desired preparation of multi-cryopreserved hepatocytes.’”¹¹² So, it was more than a mere unpatentable observation of the “natural law” of “the cells’ capability of surviving multiple freeze-thaw cycles.”¹¹³ Therefore, this claim satisfied the first step. But even if it had failed, the court reasoned that the patent would have been eligible under the second step because it “improve[d] an existing technological process.”¹¹⁴

So, by artfully claiming the technique as a “method of *producing*,” rather than merely “optimizing” (as in the *Mayo* patent)¹¹⁵ or “detecting” (as in the *Sequenom* patent),¹¹⁶ the patentee successfully avoided *Mayo*'s § 101 filter. It is unsettling that clever manipulations of claim language could allow the facially basic process of putting cells back in the freezer to be patent eligible, whereas a method that brought about a “global transformation of prenatal care” was left by the wayside.¹¹⁷ However, the Federal Circuit has continued to use these linguistic hooks as tools to evade *Mayo*.

In continuing its quest to refine *Mayo*'s filtering function and further push the Supreme Court's reasoning, the Federal Circuit then essentially flipped its result in *Sequenom* and held a similar diagnostic method patent eligible. In *Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals International Ltd.*,¹¹⁸ the court found eligible a patent claim for a “method for treating” schizophrenia that determined a patient's genotype, which correlated with their ability to metabolize a schizophrenia drug, and then instructed the physician to dose the patient accordingly.¹¹⁹ The court distinguished it from *Mayo* by pointing to the explicit instruction in the *Vanda* patent to “internally administer[]” the drug in certain amounts, which meant the patent was directed to a “method of treatment” and a “new way of using an

112. *Id.* at 1048 (quoting U.S. Patent No. 7,604,929 col. 19 l. 56 (filed Apr. 21, 2005)).

113. *Id.*

114. *Id.* at 1050 (quoting *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 223 (2014)).

115. U.S. Patent No. 6,355,623 col. 10, l. 10 (filed Apr. 8, 1999).

116. U.S. Patent No. 6,258,540 col. 23, l. 61 (filed Mar. 4, 1998).

117. See *Bianchi & Chiu*, *supra* note 5, at 464 (discussing how sequence analysis of cell-free DNA fragments in pregnant women has changed prenatal clinical care).

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

119. *Id.* at 1121.

existing drug.”¹²⁰ It was an “application of [the] relationship” between the patient’s genotype, drug metabolism, and treatment, rather than an observation of that relationship.¹²¹ Therefore, the patent satisfied the first step: taken altogether, the patent constituted a “method of treatment,” rather than a “diagnostic method” that indicated a need to change dosage, and, therefore, the court did not need to continue to the second step.¹²² Again, by relying on an insubstantial linguistic distinction, the court carved out a safe harbor for so-called “method of treatment” patents.¹²³

Commentators agree that this seems like a distinction without a difference and that, in reality, *Mayo* and *Vanda* are “both . . . diagnostic and treatment oriented.”¹²⁴ It appears that having had their invitation to grant certiorari in *Sequenom* refused, the Federal Circuit tried to force the Supreme Court’s hand through *Vanda*. Indeed, one law professor said that a denial of rehearing en banc in *Vanda* would be “a high flaunting of Supreme Court precedent.”¹²⁵ Regardless, the Federal Circuit proceeded to deny the en banc rehearing.¹²⁶ The Solicitor General’s office, invited by the Supreme Court to file a brief on whether or not to grant certiorari in

120. *Id.* at 1134–35.

121. *Id.* at 1135.

122. *Id.* at 1134–35.

123. From a claim-drafting standpoint, these linguistic distinctions—a pro forma additional “now apply!” step—could be seen as narrowing the claims. However, from the standpoint of an ordinary scientist or a nonspecialist jurist, they appear to be a textual workaround for *Mayo*. The drafters have taken a biological correlation and added an insubstantial instruction to apply the correlation to a treatment, magically transforming the diagnostic into a patentable invention. District court judges and Supreme Court Justices who are not steeped in the details of claim drafting would likely see the essence of the claims as no different from one case to another—yet one is patentable under *Mayo* and the other fails. A general patent-eligibility standard should be accessible to all district court judges, not just patent claim drafters, so they can more easily apply it to such claims.

124. Dennis Crouch, *Vanda on Rehearing: Will the Federal Circuit Defy SCOTUS?*, PATENTLY-O (June 27, 2018), <https://patentlyo.com/patent/2018/06/rehearing-federal-circuit.html> [<https://perma.cc/HCE3-CWCH>]; Stephanie Sivinski, *Vanda v. West-Ward: This Time, Dosage Adjustment Claims Are Patent Eligible Subject Matter*, IPWATCHDOG (May 16, 2018), <https://www.ipwatchdog.com/2018/05/16/vanda-v-west-ward-dosage-adjustment-claims-patent-eligible> [<https://perma.cc/N3CF-JQVC>] (“While the subject matter-eligibility inquiry inherently requires some line-drawing, the court relied on a very thin line to distinguish *Vanda*’s claims from *Mayo*’s ineligible ones.”).

125. Crouch, *supra* note 124.

126. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1284 (Fed. Cir. 2015) (per curiam) (denying reh’g en banc).

Vanda, recommended denying certiorari, agreeing with the Federal Circuit’s holding on “methods of medical treatment” and pointing out that “[h]istorically, such methods were well understood to be patent-eligible.”¹²⁷ However, the solicitor general acknowledged that the Supreme Court’s § 101 decisions—and *Mayo* in particular—“have fostered substantial uncertainty” and recommended the Court instead look at a case that has generated the most significant discord at the Federal Circuit: *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*.¹²⁸

C. *A Cry for Help: Athena Diagnostics, Inc. v. Mayo Collaborative Services*

No clearer are the fault lines in the Federal Circuit than those presented in the recent fractured decision in *Athena*. There, the court invalidated a patent on a new method for diagnosing myasthenia gravis, a neurological disorder, by detecting certain antibodies.¹²⁹ Reluctantly, the court held the claim was not patent eligible under *Mayo*. Instead, it was directed to the detection of a natural law—the correlation between the antibodies and myasthenia gravis—and because it did not include a treatment element, it lacked any sufficiently inventive further step.¹³⁰ Upon denial of rehearing en banc, it became clear that all of the judges of the Federal Circuit agreed that the claims *should* be patent eligible—they only disagreed whether *Mayo* required them to declare the claims patent *ineligible*.¹³¹

The denial of rehearing en banc produced eight different opinions: four concurring in the denial and four dissenting.¹³² Many of the opinions expressed either frustration with the *Mayo* test, frustration with the Federal Circuit’s inability to overrule it (especially given the

127. Brief for the United States as Amicus Curiae at 1, 8, *Hikma Pharms. USA Inc. v. Vanda Pharms. Inc.*, 140 S. Ct. 911 (2020) (mem.) (No. 18-817).

128. *Id.* at 8, 22 (citing *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333 (Fed. Cir. 2019) (per curiam)).

129. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 746–47 (Fed. Cir.), *reh’g en banc denied*, 927 F.3d 1333 (Fed. Cir. 2019) (per curiam).

130. *Athena Diagnostics*, 915 F.3d at 750, 753–57.

131. *Athena v. Mayo: A Splintered Federal Circuit Invites Supreme Court or Congress To Step Up on 101 Chaos*, IPWATCHDOG (July 8, 2019), <https://www.ipwatchdog.com/2019/07/08/splintered-federal-circuit-invites-supreme-court-review-athena-v-mayo> [<https://perma.cc/A944-4CMM>].

132. *Athena Diagnostics*, 927 F.3d at 1334.

resulting treatment of diagnostic patents), or both.¹³³ The judges encouraged the Supreme Court to intervene and clarify its interpretation of § 101.¹³⁴ Notably, Judge Todd Hughes queried whether congressional action may be necessary: “[F]urther explication of eligibility standards in the area of diagnostics patents . . . might come from Congress, with its distinctive role in making the factual and policy determinations relevant to setting the proper balance of innovation incentives under patent law.”¹³⁵ Judge Kathleen O’Malley actively encouraged Congress to step in and fix the judiciary’s mistakes by amending the Patent Act to clarify that there was no “inventive concept” requirement.¹³⁶ Despite the solicitor general and the Federal Circuit’s respective pleas, the Supreme Court denied cert in *Athena*, *Vanda*, and all other § 101 cases of the 2019 Term.¹³⁷

The Federal Circuit judges are well aware of the policy justifications and need for patents on diagnostics, and they believe *Mayo* either obstructs innovation in the field or, at the very least, is too broad and unworkable in its current form to effectively differentiate bad patents from meritorious ones. Though this unworkability

133. *Id.* at 1337 (Hughes, J., concurring in the denial of reh’g en banc) (“I also agree . . . that the bottom line for diagnostics patents is problematic. But this is not a problem that we can solve. As an inferior appellate court, we are bound by the Supreme Court.”); *id.* at 1339 (Dyk, J., concurring in the denial of reh’g en banc) (“I share the concerns expressed by my dissenting colleagues that the *Mayo* test for patent eligibility should leave room for sufficiently specific diagnostic patents. But it is the Supreme Court, not this court, that must reconsider the breadth of *Mayo*.”); *id.* at 1354 (Moore, J., dissenting from the denial of reh’g en banc) (“We have turned *Mayo* into a per se rule that diagnostic kits and techniques are ineligible. That per se rule is ‘too broad an interpretation of this exclusionary principle [which] could eviscerate patent law.’” (alteration in original) (quoting *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66, 71 (2012))).

134. Judge Hughes noted that

further explication of eligibility standards in the area of diagnostics patents . . . 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. Such an explication might come from the Supreme Court.

Id. at 1337 (Hughes, J., concurring in the denial of reh’g en banc); *see also id.* at 1343–44 (Dyk, J., concurring in the denial of reh’g en banc) (“[T]his case could provide the Supreme Court with the opportunity to refine the *Mayo* framework as to diagnostic patents.”); *id.* at 1344 (Chen, J., concurring in the denial of reh’g en banc) (same).

135. *Id.* at 1337 (Hughes, J., concurring in the denial of reh’g en banc).

136. *Id.* at 1371–72 (O’Malley, J., dissenting from the denial of reh’g en banc).

137. *See* Eileen McDermott, *It’s Official: SCOTUS Will Not Unravel Section 101 Web*, IPWATCHDOG (Jan. 13, 2020), <https://www.ipwatchdog.com/2020/01/13/scotus-will-not-unravel-section-101-web> [https://perma.cc/25WM-XLTK] (discussing the denials of certiorari and the solicitor general’s request for the Supreme Court to grant certiorari in *Athena*).

admittedly came from the courts, it should nevertheless be the courts who remedy it through a targeted intervention, rather than the legislative sledgehammer that Congress might wield.

III. SAVING § 101 THROUGH JUDICIAL DEVELOPMENT RATHER THAN LEGISLATIVE OVERRIDE

This Part first discusses how the current *Mayo* standard for determining patent eligibility cannot continue. It then argues that, compared to the blunt instrument that is congressional legislation, courts are best suited to remedy that standard, and it suggests one way the doctrine could be adjusted to allow for diagnostic patents.

A. *The Current Mayo Test Is Unworkable*

The *Mayo* test's overbroad language is unworkable, as evidenced by the Federal Circuit's struggles to apply it and reach results they consider just. It is confusing¹³⁸ and vague, leading some decisions to turn merely on clever claim drafting.¹³⁹ Because almost every biotechnological invention is based at some point on a law of nature or natural phenomena to some extent, the test's first step automatically casts doubt on every attempt to patent a diagnostic method.¹⁴⁰ This would not be so problematic if the second step of *Mayo* were better tailored to evaluate the inventiveness of a claimed method. Unfortunately, the Supreme Court's lack of guidance on the second step has led to confusingly disparate treatment of similar diagnostic or treatment claims,¹⁴¹ depending on a judge's willingness to squint at the claim and work to find patentability.

The uncertain standards of the test are also unworkable for the public and the industry at large. Without assurance that their efforts will actually be protected by a patent and provide a return on investment, companies will be unwilling to pursue the lengthy and

138. See David O. Taylor, *Confusing Patent Eligibility*, 84 TENN. L. REV. 157, 158–59 (2016) (discussing the confusion caused by the current test for patent eligibility).

139. See *supra* Part II.B.

140. *Athena Diagnostics*, 927 F.3d at 1354 (Moore, J., dissenting from the denial of reh'g en banc) (“We have turned *Mayo* into a per se rule that diagnostic kits and techniques are ineligible. That per se rule is ‘too broad an interpretation of this exclusionary principle [which] could eviscerate patent law.’” (alteration in original) (quoting *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 71 (2012))).

141. See *supra* Part II.

expensive research process necessary to develop the diagnostics.¹⁴² Though it may seem like the standard is so flawed that a legislative override is the best option for solving this unworkability, the nature of patent law and the dynamic landscape that lies beneath it counsel otherwise.

B. The Judiciary Is Better Suited to Fixing § 101 than Congress

Patent law has long been one of the few areas of federal common law for a reason—patents, because they often deal with technology and science, are a fast-developing and ever-changing area.¹⁴³ Through common law development, it is easier for judges to nimbly respond and surgically intervene in such areas than it is for Congress, who must deal with the legislative process and its many stalling points.¹⁴⁴ Generally, administrative agencies fill this role,¹⁴⁵ but given that the PTO currently lacks substantive rulemaking authority,¹⁴⁶ either Congress or the courts must shape patent law.

Courts are well versed in developing laws over time. Patent law, like other areas of federal common law, is governed by a common law “enabling” statute that authorizes the courts to make and develop the

142. WRITTEN TESTIMONY OF SHERRY M. KNOWLES, PRINCIPAL, KNOWLES INTELLECTUAL PROPERTY STRATEGIES, LLC, BEFORE THE UNITED STATES SENATE COMMITTEE ON THE JUDICIARY SUBCOMMITTEE ON INTELLECTUAL PROPERTY, ON “THE STATE OF PATENT ELIGIBILITY IN AMERICA, PART I” 28 (2019), <https://www.judiciary.senate.gov/imo/media/doc/Knowles%20Testimony.pdf> [<https://perma.cc/M7FQ-7J8L>].

143. See Craig Allen Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L. REV. 51, 53, 55 (2010) (“[T]he common law has been the dominant legal force in the development of U.S. patent law for over two hundred years . . . [P]atent law has and must continue to adapt to a changing world of technological innovation.”).

144. For a discussion of these “vetogates” and their effect on delegating lawmaking and law-laborating authority to agencies and the courts, see generally William N. Eskridge, Jr., *Vetogates*, Chevron, *Preemption*, 83 NOTRE DAME L. REV. 1441 (2008).

145. As Professor Jonathan Masur notes,

Agency attempts to regulate industries and markets characterized by rapid advancements with permanent regulations—and permanent regulations that operate on the vanguard of technology—thus hold the possibility of catalyzing significant error costs if the regulatory terrain shifts quickly. Yet these are precisely the circumstances under which an agency’s expertise is of greatest value, and in which agencies have the greatest institutional advantages vis à vis other decisionmaking bodies.

Jonathan Masur, *Judicial Deference and the Credibility of Agency Commitments*, 60 VAND. L. REV. 1021, 1071 (2007).

146. See Jonathan S. Masur, *Regulating Patents*, 2010 SUP. CT. REV. 275, 279 (arguing that the PTO should be given substantive rulemaking authority in line with other agencies who must deal with developing technology, like the EPA).

law.¹⁴⁷ These statutes “effectively empower[] courts to act like agencies do.”¹⁴⁸ However, “[c]ourts develop the law in the context of specific cases and controversies rather than via generally applicable regulations.”¹⁴⁹ These congressional delegations of lawmaking power to courts and agencies require “an interpretive approach that is both flexible and sensitive to policy.”¹⁵⁰ In interpreting these common law statutes, courts apply a “relaxed” version of statutory stare decisis, allowing them to adjust their interpretations of statutes and overrule past interpretations over time.¹⁵¹

Congress, on the other hand, is not well-equipped to do the kind of fine-tuning and continual interpretation that common law statutes and dynamic areas of the law require. Even when Congress intends to make small changes, larger effects result. It is difficult for Congress to surgically intervene and make small tweaks to statutes because courts draw conclusions about what is *not* changed when Congress takes limited action. If Congress makes a minute amendment, courts then draw the negative inference that because Congress did *not* change *another* related provision, it has “acquiesced” to the previous interpretation of that provision and means to lock it in.¹⁵² The resulting

147. Antitrust is a similar area of federal common law, where the Sherman Act provides the statutory backbone and “offer[s] only broad, vague legal standards to the courts . . . [who] view[] these open-ended statutes as a legislative delegation to the judiciary.” Note, *Antitrust Federalism, Preemption, and Judge-Made Law*, 133 HARV. L. REV. 2557, 2569 (2020); see also Nard, *supra* note 143, at 53 (“[T]he patent code, much like the Sherman Act, is a common law enabling statute, leaving ample room for courts to fill in the interstices or to create doctrine emanating solely from Article III’s province.” (footnotes omitted)).

148. Margaret H. Lemos, *Interpretive Methodology and Delegations to Courts: Are “Common-Law Statutes” Different?*, in INTELLECTUAL PROPERTY AND THE COMMON LAW 89, 93 (Shyamkrishna Balganesh ed., 2013) (footnote omitted).

149. *Id.*

150. *Id.*

151. *Id.*

152. See, e.g., *Apex Hosiery Co. v. Leader*, 310 U.S. 469, 488 (1940) (“The long time failure of Congress to alter the [Sherman] Act after it had been judicially construed, and the enactment by Congress of legislation which implicitly recognizes the judicial construction as effective, is persuasive of legislative recognition that the judicial construction is the correct one.”); Deborah A. Widiss, *Shadow Precedents and the Separation of Powers: Statutory Interpretation of Congressional Overrides*, 84 NOTRE DAME L. REV. 511, 546–51 (2009) (explaining how Congress’s neglecting to amend other discrimination-related statutes like the Americans with Disabilities Act and Age Discrimination in Employment Act when it amended Title VII was interpreted by the Court as a signal that Congress intended the language in those other statutes to be governed by the prior, “overridden” judicial interpretation).

statute is then more “static” and less capable of evolution, as courts work to maintain its locked-in interpretation.

Though a legislative override could be well-intentioned and might successfully allow for the patenting of diagnostic methods *now*, it risks keeping other parts of the patent statute in stasis, a result not conducive to dealing with developing technology and science in the future. Furthermore, it faces the same problem of being subject to subsequent judicial interpretations of statutory language, which, as the next Section demonstrates, may revert back to the old standard anyway.

C. A Legislative Override Is Still Subject to Judicial Interpretation

As the situation at the Federal Circuit has grown more dire, an increasing number of parties have called for either the Supreme Court or Congress to step in and address the mess that is § 101.¹⁵³ Legislators have begun to take action, claiming that “[i]t’s time to restore America’s patent system” because current patent laws are “hostile to innovation.”¹⁵⁴ Senators Coons and Tillis have released a draft bill¹⁵⁵ that seeks to overhaul the patent eligibility standards in § 101 and have held hearings before the Senate Judiciary Subcommittee on Intellectual Property soliciting feedback on the drafted language.¹⁵⁶ Representatives from industry, academia, trade groups, bar

153. Steven Lundberg, *Dave Kappos Calls for Abolition of Section 101*, NAT’L L. REV. (Apr. 14, 2016), <https://www.natlawreview.com/article/dave-kappos-calls-abolition-section-101> [<https://perma.cc/FG72-RG8D>] (detailing a former USPTO director’s call to eliminate § 101 entirely). Bart Eppenaer, a former chief patent counsel at Microsoft, notes,

While I don’t believe it is yet time to take legislative action, recent calls for the abolition of Section 101 entirely and dissatisfaction with application of the *Mayo/Alice* test is reaching a critical level. [*Sequenom*] offer[s] a significant opportunity to establish much-needed clarifications. Should this opportunity be missed, it is hard to see how Congressional action can be avoided.

Eppenaer, *supra* note 107; *see also supra* note 134 and accompanying text.

154. Coons & Tillis, *supra* note 42.

155. Tillis-Coons Press Release, *supra* note 44.

156. Videos and transcripts of testimony can be found on the Senate Judiciary Committee’s website. *See The State of Patent Eligibility in America: Part I*, COMM. JUDICIARY (June 4, 2019, 2:30 PM), <https://www.judiciary.senate.gov/meetings/the-state-of-patent-eligibility-in-america-part-i> [<https://perma.cc/M9WJ-SSFD>]; *The State of Patent Eligibility in America: Part II*, COMM. JUDICIARY (June 5, 2019, 2:30 PM), <https://www.judiciary.senate.gov/meetings/the-state-of-patent-eligibility-in-america-part-ii> [<https://perma.cc/URG3-CUEE>]; *The State of Patent Eligibility in America: Part III*, COMM. JUDICIARY (June 11, 2019, 2:30 PM), <https://www.judiciary.senate.gov/meetings/the-state-of-patent-eligibility-in-america-part-iii> [<https://perma.cc/4FQL-4F7V>].

associations, former Federal Circuit judges, PTO officers, and other stakeholders testified.¹⁵⁷

The proposed bill is an example of what a legislative override of patent eligibility might look like. It adds a new definition of “useful” to § 100, the definition section of the patent statute, and overhauls § 101:

Section 100:

(k) The term “useful” means any invention or discovery that provides specific and practical utility in any field of technology through human intervention.

Section 101:

(a) Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.¹⁵⁸

The bill completely abrogates the judicially created exceptions and two centuries of case law¹⁵⁹ in order to create a “clear legal framework for what types of innovations are patent eligible.”¹⁶⁰ However, like any legislative override, the language of the new draft bill would still be left to courts to interpret. The “framework” may not be so clear to the judges who must interpret it, especially when it comes to applying it to new inventions in a variety of fields. And while the language of this specific bill may succeed in securing patents for diagnostics, eliminating the exceptions wholesale threatens to create a new, clear path to evergreening for pharmaceutical companies.¹⁶¹ Instead of over-filtering, the new § 101 could under-filter, allowing for

157. For a detailed summary of the testimony, see Stuart P. Meyer, *Still No Shortage of Viewpoints as Eligibility Debate Moves to the Hill*, FENWICK: BILSKI BLOG (June 27, 2019), <https://www.bilskiblog.com/2019/06/still-no-shortage-of-viewpoints-as-eligibility-debate-moves-to-the-hill> [<https://perma.cc/BKT3-BTVZ>].

158. Tillis-Coons Press Release, *supra* note 44.

159. *See id.* (“No implicit or other judicially created exceptions to subject matter eligibility, including ‘abstract ideas,’ ‘laws of nature,’ or ‘natural phenomena,’ shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated.”).

160. Coons & Tillis, *supra* note 42.

161. *See supra* Part I.C.

an influx of questionable patents that may also threaten downstream innovation.¹⁶²

For example, under the language of the proposed new bill, an invention must provide utility *in any field of technology*. What counts as a field of technology? An artful patent prosecutor could easily search for ways to use the term “technology” to obtain patents on concepts not currently considered patentable. For example, it is well recognized that Einstein’s equation for mass-energy equivalence, $E=mc^2$, is not patentable.¹⁶³ Under the Tillis-Coons standard, could a method of using a calculator (a field of technology) that is programmed to take inputs from a human (human intervention) and apply them to the equation be patented? And would that then prevent others from using a calculator to compute applications of the equation in the future? Of course, this would almost certainly not pass other patent requirements, but it is not immediately clear that it would fail at the Tillis-Coons § 101 stage. This goes to show how any legislative solution will necessitate judicial interpretation and elaboration—what counts as a field of technology, and how rigorously should that distinction be applied? By abrogating the current § 101 wholesale, the courts will have to start from an entirely blank slate in attempting to corral a chaotic technological landscape. Broad language like that of the Tillis-Coons bill would offer minimal guidance.

Furthermore, in a phenomenon that Professor Deborah Widiss has termed “shadow precedent,” “the Supreme Court and lower courts often narrowly construe the significance of congressional overrides and instead rely on the prior judicial interpretation of statutes as expressed in overridden precedents.”¹⁶⁴ Though Widiss focuses on the phenomenon as it applied to interpretations of Title VII and

162. E.g., Othman Laraki, *Proposed Patent Legislation Would Block Research, Stifle Innovation, and Harm Patients*, STAT (June 6, 2019), <https://www.statnews.com/2019/06/06/proposed-patent-legislation-stifle-innovation-harm-patients> [<https://perma.cc/54P5-M8K7>]; Alex Moss, *The Tillis-Coons Patent Bill Will Be a Disaster for Innovation*, ELEC. FRONTIER FOUND. (Apr. 24, 2019), <https://www.eff.org/deeplinks/2019/04/tillis-coons-patent-bill-will-be-disaster-innovation> [<https://perma.cc/QHR2-TJWW>]; Alex Moss, *A Terrible Patent Bill Is On the Way*, ELEC. FRONTIER FOUND. (May 29, 2019), <https://www.eff.org/deeplinks/2019/05/terrible-patent-bill-way> [<https://perma.cc/99H8-WAMG>].

163. See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (explaining that like “a new mineral discovered in the earth or a new plant found in the wild,” such an equation is a “manifestation[] of . . . nature, free to all men and reserved exclusively to none” (quoting *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948))).

164. Widiss, *supra* note 152, at 512.

discrimination law,¹⁶⁵ this phenomenon has occurred in patent law as well, following the enactment of the Leahy-Smith America Invents Act (“AIA”)—major legislation that overhauled the U.S. patent system in 2011.¹⁶⁶ Despite the amendment and addition of new language to the patent statute, the Supreme Court held that a common law rule about secret sales that predated the AIA survived its enactment.¹⁶⁷ In doing so, they dismissed a plain text reading that indicated that the new language should change the rule.¹⁶⁸

Here, future courts may rely on the “shadow precedent” of *Mayo* to construe newly enacted § 101 language in a similar manner to the previous iteration of § 101. Absent any new guidance on how to interpret the new § 101 statute, courts may fall back on using the old common law judicial exceptions, recreating them anew and bringing the inquiry back to square one: How should these judicially created exceptions be interpreted and applied?

D. A Refined Two-Step Test Can Save Diagnostics and § 101

Rather than waiting for congressional action and continuing to allow the Federal Circuit to muddle its way through *Mayo*, the Supreme Court should grant certiorari in a patent subject matter eligibility case and clarify that the *Mayo* test need not be applied so rigorously. As Judge Linn suggested in his concurrence in *Sequenom*, the Court should limit *Mayo* to its facts and emphasize that the second step should not categorically dismiss a patent with *any* “conventional

165. *Id.* at 536–60.

166. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended in scattered sections of 35 U.S.C.).

167. Prior to the enactment of the AIA, an inventor’s secret commercial sale of an invention to a third party made the invention “prior art” such that it could no longer be patented. *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 139 S. Ct. 628, 633 (2019). The AIA changed the language of the governing provision slightly. *Id.* at 631–32. It now precludes a person from obtaining a patent on an invention that was “in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.” 35 U.S.C. § 102(a)(1) (2018) (emphasis added). The words “on sale” had been in the statute before the AIA, but the phrase “or otherwise available to the public” was a new addition, with little to no legislative history to explain it. *Helsinn Healthcare S.A.*, 139 S. Ct. at 633. Justice Clarence Thomas, writing for the Court, held that the reenactment of the words “on sale” was enough to justify importing the prior secret sale rule from before the AIA was enacted, *id.* at 634, even though “otherwise available to the public” could be interpreted as limiting “on sale” to instances where an invention is on sale to the public, not just in secret.

168. See *Helsinn Healthcare S.A.*, 139 S. Ct. at 634 (rejecting the argument that the added language constrained the meaning of “on sale”).

or obvious” activity, but it should rather look to see if that activity, in combination with all the other steps claimed in the process, still yields something new and useful that goes beyond a mere “abstract idea” or “law of nature.”¹⁶⁹

The Supreme Court itself, in a previous § 101 process patent case—which ostensibly still holds force—has emphasized that a patent’s claims must be “considered as a whole” because a combination of steps might still be patentable even if its individual constituents were already known and used before being combined.¹⁷⁰ In applying that language to the patent in *Mayo*, the Court did not find the combination sufficient for patentability since “the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.”¹⁷¹ Though that may have been appropriate for that specific patent, lower courts have read the case to mean that any similar diagnostic with “conventional” steps should be ineligible for a patent.¹⁷² This is a case of bad facts creating bad law, and it is time the Court step in and clarify the standard—conventional activities at the second step do not warrant a per se invalidation, even in the diagnostic context; rather, the second step should be an holistic evaluation of the claims in context.

This standard would filter out *Mayo*’s patent while still making Sequenom’s MaterniT21 method patent eligible. Though the steps of isolating and amplifying fetal DNA may be conventional, isolating and amplifying fetal DNA *noninvasively*, from a material that was previously considered *disposable garbage* is certainly innovative. The patent at issue in *Athena* would also be patent eligible. Though it is directed to a “law of nature”—the interaction between the biomarker antibody and the testing molecule the inventors use to detect it—and the subsequent steps of detecting and evaluating the biomarker are conventional in the field, using this system to detect this *particular* biomarker *was* groundbreaking.¹⁷³ Furthermore, it enabled doctors to determine the cause of myasthenia gravis in the 20 percent of patients whose etiology had previously been unknown.¹⁷⁴

169. *Mayo Collaborative Servs. v. Prometheus Lab’s, Inc.*, 566 U.S. 66, 79 (2012); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1380 (Fed. Cir. 2015) (Linn, J., concurring).

170. *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

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

172. *See supra* Part II.A.

173. Petition for Writ of Certiorari at 8, *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 140 S. Ct. 855 (2020) (mem.) (No. 19-430).

174. *Id.* at 5–6.

This flexible, holistic version of *Mayo*'s second step allows diagnostics to be patent eligible while still filtering out completely conventional and noninnovative patents at the § 101 stage. The Federal Circuit, with its greater subject matter expertise in patent law and emerging technologies, could further refine the test as more cases percolate through the system. This will provide guidance to the lower courts, examiners, and inventors, and it will assure the biopharmaceutical industry that patent protection is available for successful investments in research and development. Those worried that it sets too low a bar for eligibility can rest assured that other requirements of the patent statute, namely novelty and nonobviousness, can still play a filtering role.

IV. CONCLUSION

The current state of § 101 cannot continue—it is unworkable for the lower courts, resulting in inconsistent applications that leave actors in the patent system in flux and unsure of how to evaluate new inventions. This is especially so in the biotechnology field, where many new developments rely on the “laws of nature” implicit in the functioning of the human body. By raising doubts about patents for these developments, the current *Mayo* test also raises doubts for those potential investors who might fund the research necessary to bring new diagnostics and precision medicines to patients. By reworking the *Mayo* test to more holistically evaluate diagnostic patents, the Supreme Court could effectively balance innovation and preemption concerns to ensure that meritorious diagnostics are patent eligible. A judicial refinement of the patent-eligibility test also acknowledges that because the inventions and technology that patents cover are ever evolving, judicial interpretations of the patent statute must be as well. A legislative override, while well-meaning, could lead to widespread and unintended effects in an area of the law that should remain federal common law.