Akron Law Review

Volume 54
Issue 3 *Intellectual Property Issue*

Article 6

2021

Treating Diagnostics: Protecting *in Vitro* Diagnostic Testing in an Uncertain § 101 Landscape

Emily Iroz Rich

TREATING DIAGNOSTICS: PROTECTING *IN VITRO* DIAGNOSTIC TESTING IN AN UNCERTAIN § 101 LANDSCAPE

*By: Emily Iroz Rich**

* J.D., University of Akron School of Law, 2021. I am grateful to Aurelie and Alison Pahnke who inspired my research; to Patrick Gaughan for his mentorship throughout the writing process; and to my husband, Matthew Rich for his continued support and encouragement. Thank you also to the editors of the Akron Law Review for their thoughtful suggestions and editing. All errors and opinions are my own.

ABSTRACT

Beyond question, medical diagnostic tests, they save lives. The diagnostic tests also contribute to the overall health of the U.S. economy. However, the current state of subject-matter eligibility for patent protection does not incentivize the research and development of these life-saving tools. Previous legislative and judicial efforts to fix subject-matter eligibility have failed. This article proposes a diagnostic patent act to allow the protection of in vitro diagnostic tests. The proposed diagnostic patent act would include safeguards to allow adequate access to fundamental research while incentivizing the return of investment to the patent holder. Safeguards would include exceptions to patent infringement claims and compulsory licensing requirements under certain conditions. Exceptions, which limit infringement liability to third parties in specific situations, would be used for narrow experimental use and mandatory processes required to comply with federal regulations. Compulsory licensing, which requires patent holders to allow third parties to use a patent in certain circumstances in exchange for a determined fee, would be permitted when the patent holder acts in an anti-competitive way and for governmental or public health uses. The combination of these limitations on a patent holder's exclusive monopoly will ensure that access to research is available while patent holders are adequately incentivized to develop innovative diagnostic tests.

I. INTRODUCTION

In the Fall of 2009, Alison, a four-year old girl, was diagnosed with *myasthenia gravis*.[1] *Myasthenia gravis* (MG) is a chronic autoimmune neuromuscular disorder that causes varying degrees of weakness in the voluntary skeletal muscles.[2] In hindsight, Alison's symptoms were typical of MG, but at the time, Alison's symptoms weren't anything out of ordinary by themselves.[3] Alison stopped drinking from her sippy cup. She couldn't blow out her birthday candles. Sometimes she and her twin brother would laugh when milk came out of her nose. Her voice was quieter and her smile seemed wrong. When Alison couldn't drink her favorite treat, a Slurpee, out of a straw in light of her other symptoms, Alison's mom knew something was wrong and sought medical advice.[4]

At first, Alison's condition puzzled many doctors. Diagnosing MG is a difficult task and is often delayed months, or even years because MG has multiple mechanism types that exhibit an array of symptoms that can be confused with other diseases.[5] Diagnosing MG generally requires multiple tests to eliminate similar diseases that manifest similar symptoms.[6] After ruling out numerous conditions through various diagnostic testing, a neurologist hypothesized that Alison had MG.[7] In Alison's case, she underwent a variety of tests and treatments to confirm the MG hypothesis.

The next task was to determine how best to treat her.[8] At the time of Alison's diagnosis, medical professionals around the world disagreed with how to treat MG.[9] This, in part, is due to the complex mechanisms of the disease, the different antibodies involved in various types of MG, and the fluctuation of symptoms.

Typically, MG is characterized by the presence of antibodies that attack the acetylcholine (ACh) receptor, which in turn inhibits control of skeletal muscles. Approximately 85 percent of patients with MG test positive for ACh antibodies. An additional 5–7 percent of the patient

1. Telephone Interview with Aurelie Pahnke (Sept. 24, 2019).
2. *MG Quick Facts*, MYASTHENIA GRAVIS FOUND. OF AM., https://myasthenia.org/What-is-MG/MG-Quick-Facts [https://perma.cc/6EX7-W99W].
3. Telephone Interview with Aurelie Pahnke (Sept. 24, 2019).
4. *Id.*
5. *MG Quick Facts*, *supra* note 2.
6. *Id.*
7. Telephone Interview with Aurelie Pahnke (Sept. 24, 2019).
8. *Id.*
9. James F. Howard, Jr., *Clinical Overview of MG*, MYASTHENIA GRAVIS FOUND. OF AM., https://myasthenia.org/For-Professionals/Clinical-Overview-of-MG [https://perma.cc/2CF2-827K] (describing the three-year effort to develop guidelines that were published in 2016).

population has the presence of muscle specific tyrosine kinase (MuSK) antibodies. The remaining patient population of about 7–8 percent have neither antibody.[10] In order for doctors to make an informed decision for the best possible treatment, doctors needed to know what type of MG Alison had by confirming what type of antibody was present in her blood.[11]

Before 2001, the scientific community was aware of the connection between ACh antibodies and MG, but not of the connection between MG and the MuSK antibodies.[12] Then in 2001, Athena Diagnostics submitted a patent application for "neurotransmission disorders," disclosing a "method for diagnosing neurotransmission or developmental disorders . . . [by] detecting . . . the muscle specific tyrosine kinase (MuSK)."[13] Athena Diagnostics had discovered that MuSK was associated with MG. Athena Diagnostics subsequently developed a blood assay to detect the MuSK molecule allowing medical providers to more accurately diagnosis and treat patients with MG.[14] Prior to Athena Diagnostic's invention, no one had ever used MuSK to diagnose the 5–7 percent of the MG patient population. After six years of patent prosecution, U.S. Patent No. 7,267,820 was granted to Athena Diagnostics in 2007.[15]

Timing was on Alison's side. With the newly developed diagnostic test of MG, Alison's team was able to determine which antibodies were present or absent. In turn, her team created an individualized treatment plan.[16] Today, Alison is in remission and has no symptoms of MG.

The same diagnostic test that allowed Alison to receive the correct treatment was held to be subject-matter ineligible and subsequently invalidated by the courts in 2019.[17] This has not been the only diagnostic

10. *Id.*

11. *Autoimmune MG and Diagnostic Tests*, MYASTHENIA GRAVIS FOUND. OF AM., https://myasthenia.org/What-is-MG/MG-and-Related-Disorders/Autoimmune-MG-and-Diagnostic-Tests [https://perma.cc/Y596-Z5QB].

12. Brief of the Biotechnology Innovation Org., et al. as Amici Curiae Supporting Appellants' Petition for Rehearing *en banc* at 10, Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333 (Fed. Cir. 2019) (No. 17-2508), 2019 WL 1894542.

13. Neurotransmission Disorders, U.S. Patent No. 7,267,820 col. 1 l. 58–62 (filed June 15, 2001) (issued Sept. 11, 2007).

14. Telephone Interview with Aurelie Pahnke (Sept. 24, 2019).

15. '820 Patent.

16. Telephone Interview with Aurelie Pahnke (Sept. 24, 2019).

17. Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 275 F. Supp. 3d 306 (D. Mass. 2017), *aff'd* 915 F.3d 743, 746 (Fed. Cir. 2019), *en banc reh'g denied*, 927 F.3d 1333 (Fed. Cir. 2019).

test invalidated due to subject-matter ineligibility in recent years.[18] Since *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* in 2014, the courts have invalidated numerous life-saving diagnostic tests.[19] Every time a patent is invalidated, it negatively affects millions of people and burdens the international and national economy.[20]

In May 2019, the Senate Judiciary Committee IP Subcommittee released draft legislation with the objective to fix subject-matter eligibility, which affects the patent protection for diagnostic tests.[21] However, the draft legislation, which abrogated all judicial exceptions, did not find majority support among the various public opinions because of the vast breadth of subject-matter eligibility across diverse industries.[22] While there is a widespread outcry for a fix of the subject-matter eligibility as a whole, this note will focus on solutions for *in vitro* diagnostic (IVD) testing patents.[23]

---

18. *See Athena Diagnostics, Inc.*, 927 F.3d at 1352 (Moore, J., dissenting) ("Since Mayo, we have held every single diagnostic claim in every case before us ineligible."). *See also Athena Diagnostics, Inc.*, 915 F.3d 743 (invalidating method of diagnosing a neurological disorder); Roche Molecular Sys., Inc. v. Cepheid, 905 F.3d 1363 (Fed. Cir. 2018) (invalidating method for detecting pathogenic bacterium); Genetic Techs. Ltd. v. Merial L.L.C., 818 F.3d 1369 (Fed. Cir. 2016) (invalidating methods for detecting a coding region of DNA based on its relationship to non-coding regions); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1373 (Fed. Cir. 2015) (invalidating methods for detecting paternally inherited cffDNA in the blood or serum of a pregnant female); *In re* BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., 774 F.3d 755, 761 (Fed. Cir. 2014) (invalidating methods for screening for an altered BRCA1 gene).

19. The Supreme Court in *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012) (setting forth a two-step framework for determining subject-matter eligibility, the first being a requirement that the technology be patentable). *Athena Diagnostics, Inc.*, 927 F.3d at 1352 (Moore, J., dissenting) ("Since Mayo, we have held every single diagnostic claim in every case before us ineligible.").

20. *See infra* Part II.

21. Press Release, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Section 101 Patent Reform Framework, THOM TILLIS U.S. SENATOR FOR N.C. (Apr. 17, 2019) [hereinafter *101 Framework*], https://www.tillis.senate.gov/2019/4/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-section-101-patent-reform-framework [https://perma.cc/6NGW-X5M7].

22. Gene Quinn, *Time to Wake Up: Stakeholders Must Compromise to Save the U.S. Patent System*, IPWATCHDOG (Jan. 29, 2020), https://www.ipwatchdog.com/2020/01/29/time-wake-stakeholders-must-compromise-save-u-s-patent-system/id=118362/ [https://perma.cc/4KBG-5SVU].

23. Diagnostic testing comes in a variety of forms. *In vivo* testing occurs outside of the body. In contrast, *in vitro* testing which occurs inside the body. This note will focus on *in vitro* diagnostics, or diagnostics performed outside the body. *In vitro* tests are used for the examination of specimens derived from the human body to provide information for screening, diagnosis, or treatment monitoring purposes. *Laboratory and In Vitro Diagnostics*, WORLD HEALTH ORG., https://www.who.int/in-vitro-diagnostic/en/ [https://perma.cc/732S-XXZF]. Examples of *in vitro* testing includes, but is not limited to molecular diagnosis, point of care, and clinical chemistry. Molecular diagnosis refers to the detection of variants on DNA and genetic materials. S.A. TURNER & G.J. TSONGALIS, DIAGNOSTIC MOLECULAR PATHOLOGY: A GUIDE TO APPLIED MOLECULAR TESTING ch. 4 (Academic Press, 2016); Point of care testing refers to diagnostic testing that is done in minutes with the patient. *Point of Care*

To protect IVD patents, Congress must find legislative middle ground that preserves the spirit and objectives of the patent system. Congress must create separate special patentability requirements for IVD patents that balance return on investment against access to the tools necessary for scientific advancements.

To define an appropriate middle ground, this note will first provide an overview of the importance of IVD testing, and then a background of the current state of subject-matter eligibility through a review of the major Supreme Court cases that affect the patentability of IVD testing. Next, this note will discuss why Congress is in the best position to create legislation to protect IVD testing by reviewing the unsuccessful efforts of the USPTO, discussing the divide of the Federal Circuit, and reviewing the ill-conceived solution of the Senate IP Subcommittee of the Senate Judiciary Committee. Finally, this note will propose an alternative legislative framework for IVD patents that maintains the spirit and purpose of the patent system by balancing access to technologies with return on investment. In short, the proposed legislative framework will create a separate diagnostic patent act that imposes infringement exceptions and conditions of compulsory licensing for those granted an IVD patent. In the end, this note will show that Congress must carve out a separate diagnostic patent act to preserve the economic mechanism needed for diagnostics to develop and save the lives of millions of individuals.

II. THE IMPORTANCE OF DIAGNOSTIC TESTING

As the case of Alison shows, the importance of diagnostic testing cannot be understated.[24] "An accurate diagnosis is the first step to getting effective treatment."[25] About 66 percent of clinical decisions rely on IVD

Testing, ABBOTT, https://www.pointofcare.abbott/us/en/about-us/benefits-of-point-of-care-testing [https://perma.cc/R7T8-3WWS]; Clinical chemistry measures specific concentrations or activities of substances in the body. A common example would be drug testing, or glucose tests. *See* ROBERTA REED, LEARNING GUIDE: CLINICAL CHEMISTRY (Abbott 2020), https://www.corelaboratory.abbott/sal/learningGuide/ADD-00061345_ClinChem_Learning_Guide.pdf [https://perma.cc/CU86-XCY2].

24. *Laboratory and In Vitro Diagnostics*, *supra* note 23 ("IVDs are essential to improve health outcomes, and are critical tools both in everyday medical practice and in emergencies.").

25. Press Release, World Health Org., First-Ever WHO List of Essential Diagnostic Tests to Improve Diagnosis and Treatment Outcomes (May 15, 2018) [hereinafter *Essential diagnostics*], https://www.who.int/news-room/detail/15-05-2018-first-ever-who-list-of-essential-diagnostic-tests-to-improve-diagnosis-and-treatment-outcomes [https://perma.cc/7CYE-3YJ2].

tests according to a 2016 report.[26] IVD tests are the tools in which clinicians in all areas of medicine examine specimens from the body to provide information for screening, diagnosis, or treatment monitoring purposes. IVD tests include simple cotton swaps, testing blood or tissue to sequencing DNA to identify mutations. With an accurate diagnosis, patients receive correct treatments and are protected from incorrect, potentially harmful treatments and unnecessary healthcare costs associated with erroneous treatments.[27]

Early detection of chronic diseases with IVD tests produces better patient outcomes, saves lives, and saves costs at a later, more expensive stage of care.[28] For example, in the U.S., 90 percent of 3.5 trillion in annual health care expenditures are for people with chronic or mental health conditions.[29] The World Health Organization ("WHO") estimates that 46 percent of adults with type 2 diabetes worldwide are undiagnosed.[30] In the U.S., more that 30 million Americans have diabetes, and another 84 million adults have prediabetes, a risk factor for type 2 diabetes.[31] Diabetes in turn leads to higher costs for health complications and long-term care.[32] The Center for Disease Control estimates that diabetes alone costs the U.S. health care system and employers $327 billion every year.[33] Diagnostic testing can mitigate those costs on the economy and provide better quality of life for individuals.

Dr. Tedros Adhanom Ghebreyesus, the Director-General of WHO said, "No one should suffer or die because of a lack of diagnostic services, or because the right tests were not available."[34] Yet since 2014, the courts are invalidating IVD tests as subject-matter ineligible.[35] The diagnostic test that allowed Alison to receive the correct treatment was invalidated

26. Sanjeev Mahanta, *Patent Eligibility of Medical Diagnostic Inventions: Where Are We Now, and Where Are We Headed?*, IPWATCHDOG (Apr. 14, 2019), https://www.ipwatchdog.com/2019/04/14/patent-eligibility-of-medical-diagnostics-inventions-where-are-we-now-and-where-is-there-to-go/id=108263/ [https://perma.cc/C3B6-ZX4V]; *Laboratory and In Vitro Diagnostics*, *supra* note 23.

27. *Essential diagnostics*, *supra* note 25.

28. *Laboratory and In Vitro Diagnostics*, *supra* note 23.

29. *Health and Economic Costs of Chronic Diseases*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/chronicdisease/about/costs/index.htm [https://perma.cc/FR45-ALXL].

30. *Essential diagnostics*, *supra* note 25.

31. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 29.

32. *Id.* ("Diabetes can cause heart disease, kidney failure, and blindness . . . .").

33. *Id.*

34. *Essential diagnostics*, *supra* note 25.

35. Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1352 (Moore, J., dissenting) ("Since Mayo, we have held every single diagnostic claim in every case before us ineligible.").

by the courts in 2019.[36] A test assessing the risk of cardiovascular disease and early diagnosis was invalidated in 2014.[37] Cardiovascular disease accounts for one-third of all deaths in the U.S. every year and costs the healthcare system $214 billion per year and $138 billion in lost productivity on the job.[38] A diagnostic test screening for altered genes, linked to hereditary breast and ovarian cancers, was invalidated in 2014.[39] Cancer causes almost 600,000 deaths every year and is estimated to cost 174 billion by 2020.[40] A test for detecting tuberculosis was invalidated in 2018.[41] Tuberculosis affects around 10 million worldwide; 1.5 million people die from tuberculosis annually.[42]

While diagnostic testing is critical for the health of individuals and the economy, the current state of patent law has created obstacles in protecting and accessing capital in the industry.[43] Globally, the IVD industry was worth about 40–45 billion dollars in 2018.[44] In the United States, the diagnostic industry is estimated to be worth 19 billion dollars.[45] The global diagnostic industry is expected to grow 5.2 percent from 2019 to 2024.[46]

The patent system was meant to incentivize investments for the commercialization of new technologies by allowing a limited monopoly

36. Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 275 F. Supp.3d 306 (D. Mass. 2017), *aff'd* 915 F.3d 743, 746 (Fed. Cir. 2019), *and en banc reh'g denied,* 927 F.3d 1333 (Fed. Cir. 2019).

37. Cleveland Clinic Found. v. True Health Diagnostics LLC, 859 F.3d 1352, 1355 (Fed. Cir. 2017).

38. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 29.

39. *In re* BRCA1-& BRACA2-Based Hereditary Cancer Test Patent Litig., 774 F.3d 755 (Fed. Cir. 2014).

40. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 29.

41. Roche Molecular Sys., Inc. v. Cepheid, 905 F.3d 1363, 1365 (Fed. Cir. 2018).

42. *Tuberculosis,* WORLD HEALTH ORG. (Oct. 17, 2019), https://www.who.int/news-room/fact-sheets/detail/tuberculosis [https://perma.cc/SV7Y-3B4E].

43. *The State of Patent Eligibility in America: Part I Before the Sen. Subcomm. on Intellectual Prop. of the Sen. Comm. on the Judiciary,* 116th Cong. 1 (2019) [hereinafter *Patent Eligibility in America, Part I*] (questions for the record for Mr. Robert A. Armitage from Senator Blumenthal, Consultant, IP Strategy and Consultant).

44. THE EUROPEAN OBSERVATORY ON HEALTH SYSTEMS AND POLICIES, ENSURING INNOVATION IN DIAGNOSTICS FOR BACTERIAL INFECTION 13 (Chantal Morel et al. eds., 2016).

45. *Id.* Europe, Japan, and the United States account for 80 percent of the diagnostic market. Europe contributes 14 billion annually, while Japan's market is valued at 4 billion annually.

46. Press Release, MarketWatch, Clinical Diagnostic Market 2019 Global Industry; Trends, Share, Size, Demand, Growth Opportunities, Industry Revenue, Future and Business Analysis by Forecast - 2023 (July 11, 2019), https://www.marketwatch.com/press-release/clinical-diagnostic-market-2019-global-industry-trends-share-size-demand-growth-opportunities-industry-revenue-future-and-business-analysis-by-forecast-2023-2019-07-11 [https://perma.cc/4AJV-V2QQ].

for a limited term.[47] Without an objective, predictable patent system, the industry will not receive the adequate investments necessary to allow growth in the IVD industry, and ultimately create the life-saving technologies that are desperately needed.[48]

The development and commercialization of a single diagnostic test costs between $20.1 million to $106 million dollars and often takes around 10 years.[49] Many times, research encounters a dead end before market-ready technology is fully developed.[50] Without investments, advancements in technologies will be slowed.[51] Investors are reluctant to invest when the patent system, charged with giving a return on investment, is riddled with uncertainty. Henry Hadad, President of the Intellectual Property Owners Association, testified that "[c]onfusion about what is patent-eligible discourages inventors from pursuing work in certain [R&D intensive] technology areas, including discovering new genetic biomarkers and developing diagnostic . . . technologies. For businesses, uncertainty disincentivizes the enormous investment in research and development . . . ."[52]

III. THE DEVELOPMENT OF SUBJECT-MATTER ELIGIBILITY FOR DIAGNOSTIC TESTING

The Constitution confers upon Congress the power to "promote the Progress of Science . . . by securing for limited Times to . . . Inventors the

47. *Patent Eligibility in America, Part I*, *supra* note 44 (questions for the record for Mr. Robert A. Armitage from Senator Blumenthal, Consultant, IP Strategy and Consultant) ("The prime justification for the patent system is that it provides incentives that are essential for securing investments required to develop and commercialize new technology.").

48. *The State of Patent Eligibility in America: Part II Before the Sen. Subcomm. on Intellectual Prop. of the Sen. Comm. on the Judiciary,* 116th Cong. (2019) [hereinafter *Patent Eligibility in America, Part II*], (questions from Senator Tillis for Rick Brandon representing the Association of American Universities); David O. Taylor, *Patent Eligibility and Investment*, 41 CARDOZO L. REV. 2019, 2028 (2019) (finding that "the elimination of patents would either somewhat decrease or strongly decrease their firms' investments in the biotechnology . . . medical device[s] . . . and pharmaceutical industries . . . .").

49. Peter Keeling, *Mystery Solved! What is the Cost to Develop and Launch a Diagnostic?* DIACEUTICS (Jan. 15, 2013), https://www.diaceutics.com/?expert-insight=mystery-solved-what-is-the-cost-to-develop-and-launch-a-diagnostic [https://perma.cc/892E-GAPJ]; Athena Diagnostics, Inc. v. Mayo Collaborative Serv., LLC, 927 F.3d 1333, 1355 (Moore, J., dissenting).

50. *The State of Patent Eligibility in America: Part III Before the Sen. Subcomm. on Intellectual Prop. of the Sen. Comm. on the Judiciary,* 116th Cong. (2019) [hereinafter *Patent Eligibility in America Part III*] (questions for the record for Laurie Hill, Ph.D., J.D., Vice President, Intellectual Property, Genentech, Inc.).

51. *Patent Eligibility in America Part I*, *supra* note 44 (testimony of Patrick Kilbride, Senior Vice President of Global Innovation Policy Center, U.S. Chamber of Commerce).

52. *Patent Eligibility in America, Part II*, *supra* note 49 (questions for Henry Hadad, President, Intellectual Property Owners Association).

exclusive Right to their . . . Discoveries."[53] The first Congress enacted the original Patent Act in 1790 to incentivize innovation by rewarding limited monopolies that could bring in financial gain.[54] In exchange, the invention would be disclosed to the public domain as a resource for further scientific advancements.[55] The system was designed to "ensure that while inventors receive the direct benefit of their inventions in terms of capturing the market, the research that they have done is available to others as a resource or building block for future inventions."[56]

The Patent Act sets out the criteria necessary to obtain a patent.[57] The first criteria, laid out in 35 U.S.C. § 101, 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 . . . ."[58] Today's language for the § 101 patentability requirement is nearly identical to that passed in 1790.[59] However, the Supreme Court has long recognized limitations to subject-matter eligibility beyond those explicitly set out in § 101.[60] These judicially-created limitations stemmed from the disfavor of undue preemption.[61] Undue preemption occurs when "a patent . . . claims a natural principle itself or claims such a broad application of the natural principle that there is no way to use the natural principle itself without infringing upon the patent."[62] In essence, undue preemption ties up future applications and stunts scientific progress until the patent expires. Diagnostics, by definition, is "the procedure through which the nature of a phenomenon, such as a disease, is determined."[63] Because IVDs are based on natural principles, the judicially-created exceptions sow the

53. U.S. CONST. art. I, § 8, cl. 8.

54. Patent Act of 1790, 1 Stat. 109–112 (April 10, 1790); *Patent Eligible Subject Matter: Report on Views and Recommendations from the Public*, USPTO (July 2017) https://www.uspto.gov/sites/default/files/documents/101-Report_FINAL.pdf [https://perma.cc/4CMB-68WX].

55. *Id.*

56. Alexa Johnson, Note, *A Crisis of Patent Law and Medical Innovation: The Category of Diagnostic Claims in the Wake of* Ariosa v. Sequenom, 27 HEALTH MATRIX 423, 440 (2017).

57. Patent Act of 1790, ch. 7, 1 Stat. 109 (1790).

58. 35 U.S.C. § 101 (2018).

59. *In re* Bilski, 545 F.3d 943, 966 (Fed. Cir. 2008) (Dyk, J., concurring) ("The criteria for patentability established by the 1793 Act remained essentially unchanged until 1952, when Congress amended § 101 by replacing the word 'art' with 'process' and proving in § 100(b) a definition of the term 'process.'").

60. USPTO, *supra* note 54.

61. Johnson, *supra* note 57, at 440.

62. *Id.*

63. *Diagnosis*, NATURE RES., https://www.nature.com/subjects/diagnosis [https://perma.cc/2VSK-B3KZ].

seeds that contribute to the current problems with the unpatentability of diagnostic testing.

A. Early Supreme Court Jurisprudence

As early as the mid-1800s, the Supreme Court began creating judicial exceptions to subject-matter eligibility.[64] In 1852, the Court stated that "[a] principle, in the abstract, is a fundamental truth" and "cannot be patented" unless the principle effectuated a practical result.[65] The Supreme Court reasoned that patenting principles would "prohibit all other persons from making the same thing by any means whatsoever."[66] "This, by creating monopolies, would discourage arts and manufactures, against the avowed police of the patent laws."[67] The Supreme Court held that patents could not be obtained for new power like steam or electricity.[68] In the 1853 case of *O'Reilly v. Morse*, the Court held that Morse was unable to patent electromagnetism because the claims were too broad.[69] The Court expressed their worry for preemption:

> For aught that we now know some future inventor, in the onward march of science, may discover a [different] mode of writing or printing at a distance by means of the electric or galvanic current . . . . But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.[70]

64. USPTO, *supra* note 54.

65. Le Roy v. Tatham, 55 U.S. 156, 175 (1852) ("A principle, in the abstract, is a fundamental truth; and original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right. . . . In all such cases, the processes used to extract, modify, and concentrate natural agencies, constitute the invention. The elements of the power exist; the invention is not in discovering them, but in applying them to useful objects.").

66. *Id.* ("A patent is not good for an effect, or the result of a certain process, as that would prohibit all other persons from making the same thing by any means whatsoever. This, by creating monopolies, would discourage arts and manufactures, against the avowed policy of the patent laws.").

67. *Id.*

68. *Id.* ("Through the agency of machinery a new steam power may be said to have been generated. But no one can appropriate this power exclusively to himself, under the patent laws. The same may be said of electricity, and of any other power in nature, which is alike open to all, and may be applied to useful purposes by the use of machinery.").

69. O'Reilly v. Morse, 56 U.S. 62, 113 (1853) ("If this claim can be maintained, it matters not by what process or machinery the result is accomplished. For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth . . . . But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.").

70. *Id.*

However, the Court allowed the narrower claims tied directly to the invention.[71] These cases were the foundation of the Court's prohibition of natural principles.[72]

In 1873, the Supreme Court held that "a pulp suitable for the manufacture paper, made from wood or other vegetable substances" was unpatentable.[73] The Court reasoned that "[t]here are many things well known and valuable in medicine or in the arts which may be extracted from divers[e] substances. But the extract is the same, no matter from what it is has been taken. . . . [B]ut the thing itself when obtained cannot be called a new manufacture."[74] In 1876, the Supreme Court first considered patent eligibility for processes, holding that process patents can be obtained when the process was new and useful.[75] In *The Telephone Cases*, the Supreme Court found Alexander Bell's inventions patentable because Bell did not claim electricity in its natural state.[76]

Entering into the 20th century, it was well established that natural phenomena, laws of nature, and abstract ideas were not patentable.[77] However, diagnostic testing was in a primitive stage.[78] American physicians were deeply skeptical of medical science, experimentation, and

71. *Id.* at 117 ("[F]or the particular method or process thus discovered, he is entitled to a patent.").

72. USPTO, *supra* note 54.

73. Am. Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. 566, 594 (1874) (explaining that an extraction is not eligible, but the process of the extraction could be patented).

74. *Id.*

75. Cochrane v. Deener, 94 U.S. 780, 788 (1876) ("A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state of thing. If new and useful, it is just as patentable as a piece of machinery. . . . [T]he process itself may be altogether new, and produce an entirely new result.").

76. Dolbear v. Am. Bell. Tel. Co. (*The Telephone Cases*), 126 U.S. 1, 534 (1888) ("In the present case the claim is not for the use of a current of electricity in its natural state as it comes from the battery, but for putting continuous current, in a closed circuit, into a certain specified condition suited to the transmission of vocal and other sounds, and using it in that condition for that purpose.").

77. Rubber-Tip Pencil Co. v. Howard, 87 U.S. 498, 505 (1874) (rejecting a patent for a rubber head "to be attached to a pencil or something else of like character.").

78. The beginning of modern physical diagnostic techniques began in 1761 with the discovery of percussion, the act of tapping body parts with fingers, hands or small instruments while listening to particular sounds within the chest cavity. In 1816, the stethoscope was invented in France. In 1871, the thermometer was invented in Germany. *See generally* H. KENNETH WALKER, W. DALLAS HALL, & J. WILLIS HURST, CLINICAL METHODS: THE HISTORY, PHYSICAL, AND LABORATORY EXAMINATIONS ch. 1 (3rd ed. 1990) (detailing the history of diagnostic testing); Darlene Berger, *A brief history of medical diagnosis and the birth of the clinical laboratory: Part I – Ancient times through the 19th century,* AM. SOC'Y FOR CLINICAL LABORATORY SCI.–PA., https://www.ascls-pa.org/uploads/2/4/2/1/24211033/meddiagandlab.pdf [https://perma.cc/ZK47-LG53] ("The advancement of medicine . . . was more theoretical than practical [in the 18th century].").

laboratory sciences and disregarded these diagnostic tools.[79] It wasn't until the late 1800s that American physicians began to put importance on researching diagnostics with the hope of better treatment of diseases.[80]

B. Refinements of the 20th Century

The Supreme Court continued to define the limits on subject-matter eligibility into the 20th century. In two cases from 1931 and 1948, the Supreme Court held that natural products that did not produce a new or distinctive property or quality were not patent eligible.[81] In *American Fruit Growers, Inc v. Brogdex Co.*, the Supreme Court held ineligible a patent for treating citrus fruit with borax to make the fruit mold resistant. The Court reasoned that the addition of the borax to the "fruit does not produce from the raw material an article for use which possess a new or distinctive form, quality, or property."[82]

The second case was *Funk Bros. Seed Co. v. Kalo Inoculant Co.*[83] The Court held ineligible a combination of different bacteria strains that increased nitrogen fixation in plants. The Court reasoned that the combination of the two bacteria did not create something new with distinct effects. The Court stated, "The bacteria perform[ed] in their natural way[s]" and "[was] no more than the discovery of some of the handiwork of nature . . . ."[84] The handiwork of nature is "part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none."[85]

79. WALKER et al., *supra* note 78, at 18 ("One estimate is that 110,000 Union soldiers died from wounds and 225,000 from disease; 50,000 Confederate soldiers died from wounds and 150,000 from disease! Percussion was performed by only a small portion of physicians. Very few used the thermometer. Stethoscopes were rarely used. . . . The U.S. government finally required that each physician entering the army or navy pass a compulsory examination: barely 25% passed.").

80. *See generally id.* The change came after the Civil War. American physicians travelled to Europe to train in medicine. Upon their return, they realized the inadequacies of American medical training. Harvard, Pennsylvania, Michigan, and Johns Hopkins put emphasis on research and teaching with the hope to develop diagnostic techniques that would influence better outcomes.

81. *See* Am. Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1 (1931) (holding the patent ineligible because there was no change in the appearance or general characteristics of the fruit that made it new or distinctive); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948) (explaining that the discovery of bacteria inhibition properties was "no more than the discovery of some of the handiwork of nature" and was not patentable.).

82. Am. Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11 (1931).

83. *Funk Bros. Seed Co.*, 333 U.S. 127.

84. *Id.* at 131.

85. *Id.* at 130.

Likewise, the Supreme Court prohibited subject-matter involving mathematical formulas.[86] The Court explained that natural principles, such as mathematical formulas, "cannot support a patent unless there is some other inventive concept."[87] If the inventive concept was intertwined with the mathematical formula to create a structure that was novel and useful, the patent could be eligible.[88] This translated to diagnostic testing in 1989 when the Federal Circuit first addressed the eligibility of diagnostic testing in *In re Grams*.[89] The claims in *In re Grams* were directed to "[a] method of diagnosing an abnormal condition in an individual" by performing various laboratory tests and referencing them to a range of normal parameters.[90] The Federal Circuit held that the claim was directed to non-statutory subject-matter because the novelty of the invention was centered around a mathematical algorithm and was held to be ineligible.[91]

In the 1980 case, *Diamond v. Chakrabarty*, the Court held that if an invention relies on a natural phenomenon, the invention must have, "markedly different characteristics from any found in nature and one having the potential for significant utility."[92] Likewise in 1981, *Diamond v. Diehr*, the Court held that to be subject-matter eligible, the claimed process must, "[transform] the article . . . into a different state or thing . . . ."[93] During the Court's analysis of the claimed invention, the Court stressed the importance of evaluating the invention as a whole and that it was not appropriate to dissect claims into old and new elements.[94]

86. Gottschalk v. Benson, 409 U.S. 63 (1972) (holding that a method for converting binary-coded decimal signals to pure binary signals is not eligible because it is "so abstract and sweeping"); Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 94 (1939) ("While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.").

87. Parker v. Flook, 437 U.S. 584, 595 (1978).

88. Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 94 (1939) ("While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be."). *See also Parker*, 437 U.S. at 595 (explaining a mathematical formula cannot be patented unless it is accompanied by an inventive concept).

89. *In re* Grams, 888 F.2d 835 (Fed. Cir. 1989).

90. *Id.* at 836–37.

91. *Id.* at 836.

92. Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (holding a genetically engineered bacterium used for oil spills patent eligible).

93. Diamond v. Diehr, 450 US 175, 184 (1981) (recognizing that the Arrhenius's equation alone is ineligible but the application of the Arrhenius's equation to a process for molded synthetic rubber was eligible).

94. *Id.*

These cases signify the Court holding ineligible subject-matter that was closely tied to a judicial exception, such as a natural product or natural phenomenon. IVDs assess the natural relationships between diseases and their signs or symptoms through physical examination and laboratory techniques.[95] The Court's holdings effectively eliminated any protections for new biological discoveries and their connections to natural phenomena, which are essential for diagnostic testing. Following these cases, the Supreme Court was silent on subject-matter eligibility for almost 30 years.

C. Recent Supreme Court Decisions

Beginning in 2010, the Supreme Court issued a number of decisions that radically shifted the limits of subject-matter eligibility: *Bilski v. Kappos*,[96] *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,[97] *Association for Molecular Pathology v. Myriad Genetics, Inc.*,[98] and *Alice v. CLS Bank International*. [99] These four Supreme Court cases changed the contours of the subject-matter eligibility test for natural phenomena, natural products, and abstract ideas. In particular, *Mayo* and *Myriad* address biological patents that changed the eligibility for natural products. These four cases greatly impacted the subject-matter eligibility landscape today, but caused great confusion in the legal field due to the various interpretations of the decisions.

The first of the decisions was *Bilski v. Kappos* which involved a business method for hedging risk.[100] The Court of Appeals for the Federal Circuit used the machine-or-transformation test as an exclusive test in evaluating the eligibility of a process.[101] The machine-or-transformation test would allow the invention to be patent eligible when: 1) the invention was tied to a particular machine or apparatus; and 2) the invention transforms a particular article into a different state or thing.[102] The Supreme Court rejected the Federal Circuit's machine-or-transformation

95. *Diagnosis*, NATURE RES., https://www.nature.com/subjects/diagnosis [https://perma.cc/2VSK-B3KZ].

96. Bilski v. Kappos, 561 U.S. 593, 599 (2010).

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

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

99. Alice Corp. v. CLS Bank Int'l, 573 U.S. 208 (2014); USPTO, *supra* note 54.

100. *Bilski*, 561 U.S. at 599 (explaining the claimed invention as a way to hedge against risk of price changes in the energy market).

101. *Id.*

102. *Id.* at 603 (describing the machine-or-transformation test).

test as the primary factor of determining subject-matter eligibility.[103] The Court reasoned "[s]ection 101 is a 'dynamic provision designed to encompass new and unforeseen inventions.'"[104] The Court continued by explaining that "[t]echnology and other innovations progress in unexpected way[s]," and a rigid rule would "deny patent protection for 'inventions in areas not contemplated by Congress . . . frustrat[ing] the purposes of the patent law."[105]

Furthermore, the Court foresaw that the machine-or-transformation test would be insufficient for inventions in the Information Age, including inventions of advanced diagnostic medicine techniques.[106] Following *Bilski*, whether diagnostic methods were patentable subject-matter remained uncertain.[107] The Supreme Court had implied advanced diagnostic medical techniques might be patented if they were not overly broad preemptive claims pertaining to laws of nature.[108]

In 2012, two years after *Bilski*,[109] the Supreme Court heard *Mayo*.[110] This landmark case changed the way subject-matter eligibility is analyzed. The framework set out in *Mayo* is how subject-matter eligibility is determined today for natural phenomena and natural products.[111] The patents at issue in the case claimed a process that allowed doctors to

103. *See id.* at 603 ("Technology and other innovations progress in unexpected way" and a rigid rule would "deny patent protection for 'inventions in areas not contemplated by Congress . . . frustrat[ing] the purposes of the patent law. . . . [T]he machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101.").

104. *Id.* at 605 (quoting J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001)).

105. *Id.* (quoting Diamond v. Chakrabarty, 447 U.S. 303, 315 (1980)).

106. *Id.*

107. *See* JOHN R. THOMAS, CONG. RESEARCH SERV., R42815, MAYO V. PROMETHEUS: IMPLICATIONS FOR PATENTS, BIOTECHNOLOGY, AND PERSONALIZED MEDICINE (2012).

108. THOMAS, *supra* note 108.

109. The day after *Bilski*, the Supreme Court granted certiorari for two cases: *Classen Immunotherapies, Inc. v. Biogen IDEC*, 304 Fed. App'x. 866 (Fed. Cir. 2008), and *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009). In both cases, the Supreme Court immediately vacated the Federal Circuit decisions and remanded for reconsideration based on *Bilski*. *Prometheus Laboratories, Inc. v. Mayo Collaborative Services* subsequently was granted certiorari for the second time.

110. Prometheus sued Mayo Collaborative Services when they developed a similar diagnostic test. The district court granted summary judgment for Mayo holding that the claims were directed at natural laws or phenomena and therefore unpatentable. On appeal, the Federal Circuit reversed, reasoning that the claimed processes were involved in the "transformation of the human body or of blood taken from the body." Petition for certiorari was granted resulting in remand in light of *Bilski* which eliminated the machine-or-transformation test. The Federal Circuit again reaffirmed patent eligibility and certiorari was granted for a second time. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 76 (2012).

111. *Id.*

identify metabolite levels associated with drug administration and adjust for metabolic differences between patients.[112] The invention allowed doctors to deliver the correct dosage of drug to each person.[113]

In building an analytical framework, the Court sought to balance the objectives of the patent system: creating limited monopolies while promoting science.[114] Such framework "must distinguish between patents that claim the 'buildin[g] block[s]' of human ingenuity and those that integrate the building blocks into something more, thereby 'transform[ing]' them into a patent-eligible invention."[115] The Court did this by creating a two-step framework now referred to as the *Alice/Mayo* test.[116] Step one requires a determination of whether the claimed invention is directed to a law of nature, a natural phenomenon or product of nature, or an abstract idea.[117] If the invention is directed towards a judicial exception, then the question is whether the claims do "significantly more than simply describe . . . natural relations."[118] If the claims do "significantly more," the claims are eligible.

The Court concluded through the two-step analysis that the claims were unpatentable because they claimed a natural law, the relationship between metabolite levels and drug toxicity, without anything more.[119] If

112. *Id.*

113. Prometheus held patents for the use of certain drugs to treat autoimmune diseases such as Crohn's disease and ulcerative colitis. Due to the metabolic differences between patients, the effectiveness of the drug at delivery varied tremendously causing ineffectiveness or serious toxicity. The claims allowed doctors to identify metabolic levels and adjust an individual's drug dosage. *Id.*

114. *Id.* at 71, 85, 92 ("Patent protection is . . . a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. . . . The Court has recognized, however, that too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas. . . . The Court has repeatedly emphasized . . . a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature.").

115. Alice Corp. v. CSL Bank Int'l, 573 U.S. 208, 217 (2014) (quoting *Mayo*, 566 U.S. at 72, 89).

116. *Mayo* was the first case to set out the new two-step analysis to natural laws or natural phenomena. Two years later in *Alice Corp. v. CSL Bank Int'l*, 573 U.S. 208, the Court confirmed its holding. The technology in question in Alice was a computer-implemented process for mitigating settlement risk. The Court extended the two-step framework to abstract ideas. However, instead of determining whether the claims simply described the natural relation, the Courts searched for an "inventive step." The Court held the patent to be ineligible. Today, *Alice* is typically talked about in the context of software and AI; however, it is common nomenclature to use the Alice/Mayo test to describe § 101 eligibility.

117. *Mayo Collaborative Servs.*, 566 U.S. at 72.

118. *Id.* at 77.

119. *Id.* at 71 ("Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972))).

the patent were granted, the Court reasoned that "monopolization of [these basic] tools through the grant of a patent might tend to impede innovation more than it would tend to promote it."[120] Furthermore, the Court reasoned that patents addressing the body's natural responses should not be granted because it would limit physicians' access to diagnostics.[121]

Myriad in 2013 had claimed isolated natural DNA associated with increased risk of breast cancer, and synthetic DNA created from RNA.[122] The Court held that while genes fell within the law of nature exception, the question of eligibility was dependent on "markedly different characteristics from any found in nature"[123] or if the claims added "significantly more" as laid out in *Mayo*.[124] In *Myriad*, the Court reiterated its concern with "t[ying] up" the use of basic tools and thereby "inhibit[ing] future innovation premised upon them."[125] The Court held the natural isolated DNA was not subject-matter eligible because "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."[126] Furthermore, there was nothing more than the natural DNA.[127] The synthesized DNA, on the other hand, differed from naturally occurring DNA, and was therefore patent eligible.[128] The Court explicitly stated that innovative methods of manipulating the genes could have resulted in a valid patent.[129]

120. *Id.* ("And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.").

121. *Id.* at 91 (stating that if "claims to exclusive rights over the body's natural responses to illness and medical treatment are permitted to stand, the result will be a vast thicket of exclusive rights over the use of critical scientific data that must remain widely available if physicians are to provide sound medical care." (quoting Brief for Am. Coll. of Med. Genetics et al. as Amici Curiae Supporting Petitioners at 7, *Mayo Collaborative Servs.*, 566 U.S. 66 (No. 10-1150), 2011 WL 4071917).

122. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 582 (2013).

123. *Id.* at 577 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980)).

124. *Mayo Collaborative Servs.*, 566 U.S. at 77.

125. *Ass'n for Molecular Pathology,* 569 U.S. at 589 (quoting *Mayo Collaborative Servs.*, 566 U.S. at 86) (stating that the Court has long held that laws of nature, natural phenomena, and natural ideas are not patentable because "they are the basic tools of scientific and technological work" and allowing patentability would "inhibit future innovation premised upon them." (quoting Gottschalk v. Benson 409 U.S. 63, 67 (1972)).

126. *Id.* at 591.

127. *Id.*

128. *Id.* at 594.

129. *Id.* at 595.

IV. THE CURRENT STATE OF CHAOS

A. The Aftermath of the Mayo

The Court's decision in *Mayo* and *Myriad* elicited a variety of responses. Some scholars praised the opinions as protecting "patient care and innovative medical research."[130] Some in the biotechnology industry claimed that "potentially every patent in biotechnology is not valid because most use 'natural processes'"[131] and that the decisions "called into doubt innumerable biotech patents."[132] Others criticized the Court for not providing more guidance on what a patentable natural law looked like and predicted the uncertainty would discourage investment and progress in diagnostics.[133]

Former Chief Judge Paul R. Michel of the Federal Circuit characterized the effects of the *Alice/Mayo* framework as "unending chaos" that has created "[u]ncertainty, unpredictability, [and] inconsistent results and undue and harmful exclusions of new technologies . . . ."[134] He was right. From July 2014 to June 2019, 838 patent claims were brought in the federal courts.[135] Sixty-two percent were found to be ineligible under § 101.[136]

Mayo and the subsequent confirmation in *Alice*, was understood to be applicable to natural phenomena, natural laws, and abstract ideas.[137]

---

130. *AMA Welcomes Supreme Court Decision to Throw Out Prometheus Patents*, HEALTH NEWS DIG. (Mar. 20, 2012) http://www.healthnewsdigest.com/news/Legal_370/AMA_Welcomes_Supreme_Court_Decision_to_Throw_Out_Prometheus_Patents_printer.shtml [https://perma.cc/J9ME-E627].

131. THOMAS, *supra* note 108, at 9 (quoting Jeffrey L. Fox, *Industry Reels as Prometheus Falls and Myriad Faces Further Reviews*, 30 NATURE BIOTECHNOLOGY 373, 373 (2012)).

132. Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1369 (Fed. Cir. 2019) (Newman, J., dissenting) (quoting Brief for Biotechnology Innovation Org. et al. as Amici Curiae Supporting Appellants at 3, *Athena Diagnostics, Inc.*, 927 F.3d 1333 (Fed. Cir. 2019) (No. 2017-2508)).

133. THOMAS, *supra* note 108 (citing Jeffrey L. Fox, *Industry Reels as Prometheus Falls and Myriad Faces Further Reviews*, 30 NATURE BIOTECHNOLOGY 373, 373 (2012)).

134. *Patent Eligibility in America, Part I*, *supra* note 44 (statement of former Chief Justice Paul Michel, Federal Circuit).

135. Robert Sachs, Alice*: Benevolent Despot or Tyrant? Analyzing Five Years of Case Law Since* Alice v. CLS Bank*: Part I*, IPWATCHDOG (Aug. 29, 2019), https://www.ipwatchdog.com/2019/08/29/alice-benevolent-despot-or-tyrant-analyzing-five-years-of-case-law-since-alice-v-cls-bank-part-i/id=112722/ [https://perma.cc/2ENR-6ZSU].

136. *Id.*

137. *Id.*; Kevin Madagan & Adam Mossoff, *Five Years Later, the U.S. Patent System is Still Turning Gold to Lead*, IPWATCHDOG (Dec. 15, 2019), https://www.ipwatchdog.com/2019/12/15/five-years-later-the-us-patent-system-is-still-turning-gold-to-lead/id=116984/ [https://perma.cc/8TUP-DVKD] ("Under the *Alice/Mayo* framework, courts continue to invalidate patents securing the fruits of inventive labors in medical diagnostic tests, medical treatment methods,

The four categories listed in 35 U.S.C. § 101: processes, machines, manufacturing, and compositions of matter, have historically been held eligible.[138] However, the uncertainty of § 101 has leaked into these areas.[139] For example, the Federal Circuit ruled a garage door opener operated by a wireless transmitter to be abstract and ineligible.[140] The Federal Circuit held that the software-based method of operating an oil-drilling rig is an abstract idea.[141] In October 2019, the Federal Circuit shocked the patent community when it held ineligible a "method for manufacturing driveline propeller shafts[142] with liners that are designed to 'attenuat[e] . . . vibrations transmitted through a shaft assembly'" because it was directed to a natural law.[143]

The various interpretations of the *Mayo* framework have caused uncertainty to the biotech industry and the diagnostic field. Healthcare related technologies including diagnostic testing bear the brunt of the consequences.[144] Since *Mayo*, the Court of Appeals for the Federal Circuit has not held a single diagnostic test to be subject-matter eligible.[145] District Courts are following the Federal Circuit's lead.[146] Indeed, the

medical devices, and in high-tech inventions. . . . But the patent ineligibility contagion is spreading . . . .").

138. 35 U.S.C. § 101 (2018).

139. Madigan & Mossoff, *supra* note 137 ("Courts have invalidated patents covering methods of using garage door openers and operating oil derricks as allegedly claiming abstract ideas or laws o[f] nature.").

140. Chamberlain Grp. v. Techtronic Indus., 935 F.3d 1341, 1344 (Fed. Cir. 2019) ("[W]e conclude that [the patent] are directed to an abstract idea and therefore patent-ineligible.").

141. TDE Petroleum Data Sols, Inc. v. AKM Enters, Inc., 657 F. App'x 991, 992 (Fed. Cir. 2016).

142. Propeller shafts ("propshafts") are used to transmit rotary power in a driveline. *See* Am. Axle & Mfg. v. Neapco Holdings, 939 F.3d 1355, 1358 (Fed. Cir. 2019).

143. *Id. (*quoting U.S. Patent No. 7,774,911) (holding that the invention ineligible because it claimed an application of the laws of thermodynamics). *See* Madigan & Mossoff, *supra* note 137.

144. Madigan & Mossoff, *supra* note 137.

145. Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1352 (Fed. Cir. 2019) (Moore, J., dissenting) ("Since Mayo, we have held every single diagnostic claim in every case before us ineligible.").

146. *Id.* at n.1 (Moore, J., dissenting) (citing the district courts who are holding diagnostic tests to be ineligible). See, e.g., Illumina, Inc. v. Ariosa Diagnostics, Inc., 356 F. Supp. 3d 925 (N.D. Cal. 2018); Genetic Veterinary Scis., Inc. v. LABOklin GmbH & Co., 314 F. Supp. 3d 727 (E.D. Va. 2018); Mallinckrodt Hosp. Prods. IP Ltd. v. Praxair Distribution., No. 15-170-GMS, 2017 WL 3867649 (D. Del. Sept. 5, 2017); Esoterix Genetic Labs. LLC v. Qiagen Inc., No. 14-cv-13228-ADB, 2016 WL 4555613 (D. Mass. Aug. 31, 2016); Esoterix Genetic Labs. LLC v. Qiagen Inc., 133 F. Supp. 3d 349 (D. Mass. 2015); Genetic Veterinary Scis., Inc. v. Canine EIC Genetics, LLC, 101 F. Supp. 3d 833 (D. Minn. 2015).

critics of *Mayo* correctly predicted the *per se* ineligibility rule of diagnostic tests that would proceed from the Supreme Court's holding.[147]

The consequences of a *per se* ineligibility rule for diagnostics is spiraling. Paul Michel, former Chief Judge of the Federal Circuit, and David Kappos, former Director of the USPTO wrote:

> This uncertain patent climate has a chilling effect on innovation in biosciences to the detriment of public health. . . . [I]nvestors are less interested in funding costly new biomarker diagnostic research. As a result, diseases will go undiagnosed, and patients will suffer the consequences. . . . Investment in diagnostics goes to the core of containing spiraling health care costs, improving patient outcomes and treating illnesses before they become debilitating to suffering Americans.[148]

Reform of § 101 is vital to the future of U.S. innovation and health care. In an article, Kevin Madigan and Adam Mossoff emphasized the impacts will be felt for a long time because "Section 101 confusion . . . affects investment decisions made in long time-horizon R&D programs . . . . These R&D programs are measured in decades." [149] With the IVD industry, that has a significant impact on individuals, public health, the economy, and costs of healthcare, it is imperative to find alternative legal solutions to protect these life-saving technologies.[150]

However, the efforts of the USPTO, alongside a divided Federal Circuit have not yielded change. Congress is in the best position to change the law and assure the overarching policies are met.[151] But the Senate Judiciary Committee Subcommittee on Intellectual Property proposed draft legislation that could not reach a consensus across the industries affected. Therefore, for IVDs to be patentable, Congress needs an alternative legislative solution that finds balance between access and return on investment.

---

147. *Athena Diagnostics, Inc.*, 927 F.3d at 1354 (Moore, J., dissenting) ("We have turned *Mayo* into a per se rule that diagnostic kits and techniques are ineligible.").

148. David J. Kappos & Paul R. Michel, *Supreme Court Patent Decisions are Stifling Health Care Innovation*, MORNING CONSULT (Oct. 29, 2018, 5:00 AM ET), https://morningconsult.com/opinions/supreme-court-patent-decisions-stifling-health-care-innovation/ [https://perma.cc/Y6D5-XRYE].

149. Madigan & Mossoff, *supra* note 137.

150. Kappos & Michel, *supra* note 147.

151. Andrew Berks & Gene Quinn, *How Misaligned Incentives Are Now Killing Us,* IPWATCHDOG (Apr. 1, 2020), https://www.ipwatchdog.com/2020/04/01/how-misaligned-incentives-are-now-killing-us/id=120312/ [https://perma.cc/PRJ3-5CX8] ("[T]he courts are really not in a position to determine overarching policy, although they have certainly tried in this area—and failed. . . . Policy arguments frequently fail to persuade courts. That is why the Constitution gives Congress the power to enact legislation where the courts go astray.").

B. USPTO Efforts

The United States Trademark and Patent Office (USPTO), promulgates the Constitution's words by "promot[ing] the Progress of Science and useful Arts, by securing for a limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[152] The USPTO's statutory mandate allows for the "[establishment of] regulations" to "facilitate and expedite the processing of patent[s]."[153]

The USPTO has expressed major concerns with the current state of § 101 subject-matter eligibility. It has been difficult to "[p]roperly apply[] the *Alice/Mayo* test in a consistent manner."[154] The inconsistency has caused "unique challenges for the USPTO, which must ensure that its more than 8500 patent examiners and administrative patent judges apply the *Alice/Mayo* test in a manner that produces reasonably consistent and predictable results across applications, art units and technology fields."[155] Furthermore, "it has become difficult in some cases for inventors, businesses, and other patent stakeholders to reliably and predictably determine what subject-matter is patent-eligible."[156]

To alleviate the inconsistencies and unpredictability in subject-matter eligibility, the USPTO periodically releases revised guidelines based on new precedent from the courts for determining subject-matter eligibility.[157] The USPTO released guidelines related to subject-matter eligibility in January 2019 and October 2019, with the goal to "improve the clarity, consistency, and predictability of actions across the USPTO."[158]

The "2019 Revised Patent Subject-Matter Eligibility Guidance" primarily focus on the proper scope and application of the abstract idea exception particularly in the realm of software and artificial

152. U.S. CONST. art. I, §8, cl. 8. *See also* U.S. PATENT & TRADEMARK OFFICE, FY 2018 PERFORMANCE AND ACCOUNTABILITY REPORT (2018), https://www.uspto.gov/sites/default/files/documents/USPTOFY18PAR.pdf [https://perma.cc/HR8A-HKJ7].

153. 35 U.S.C. § 2(b)(2)(C) (2018).

154. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019).

155. *Id.*

156. *Id.*

157. *See* October 2019 Patent Eligibility Guidance Update, 84 Fed. Reg. 55,942 (Oct. 18, 2019) [https://perma.cc/358N-D4J3]; 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50; May 2016 Subject Matter Eligibility Update, 81 Fed. Reg. 27,381 (May 6, 2016) [https://perma.cc/6VMY-7MPU]; July 2015 Update on Subject Matter Eligibility, 80 Fed. Reg. 45,429 (July 20, 2015) [https://perma.cc/VPF6-Y7YJ]; 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618 (Dec. 16, 2014) [https://perma.cc/8LGX-ZS8F].

158. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50; October 2019 Patent Eligibility Guidance Update, 84 Fed. Reg. 55,942.

intelligence.[159] However, because natural laws and abstract ideas both rely on the *Alice/Mayo* framework, these guidelines also apply to claims directed to natural laws or phenomenon of nature.[160] The 2019 Guidelines made two changes to examination: 1) dividing abstract ideas into subcategories, and 2) "clarifying that a claim is not 'directed to' a judicial exception if the judicial exception is integrated into a practical application of that exception."[161] In the October 2019 supplement to the revised guidance, the USPTO released a list of examples illustrating the new examination procedures and major eligibility cases from the Supreme Court and the Federal Circuit.[162]

The efforts of the USPTO to create consistency are ineffective for diagnostic testing for two reasons. First, "[t]he backbone of diagnostics is the recognition of a relationship between a biomarker, a level of a chemical, etc., and a disease state, efficacy, etc."[163] The ability to transform this relationship into a novel application or method is difficult because "[n]ew diagnostics are often the product of a new understanding . . . not necessarily dependent on new test methods."[164] Therefore, the revision of examiner guidelines does not alleviate the underlying "flawed and confusing jurisprudence and analytic[al] frameworks."[165]

Second, the Federal Circuit disregards guidance from the USPTO and the USPTO lacks "substantive rule-making authority" leaving patentability up to chance in subsequent legal battles.[166] During the process of discovery, "[i]nnovators track closely any guidance or direction from the USPTO with respect to what products are eligible for patents."[167] For example, the Cleveland Clinic, in developing a diagnostic test for cardiovascular disease, carefully followed the 2016 examination

159. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 ("In particular, stakeholders have expressed concern with the proper scope and application of the 'abstract idea' exception.").

160. *See supra* Part III(C).

161. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50.

162. October 2019 Patent Eligibility Guidance Update, 84 Fed. Reg. 55,942.

163. Brian R. Dorn, Mayo v. Prometheus*: A Year Later,* 4 ACS MEDICINAL CHEMISTRY LETTERS 572, 572 (2013).

164. *Id.* at 573.

165. *Patent Eligibility in America, Part I*, *supra* note 44, at 30 (statement of Q. Todd Dickinson, Former USPTO Director).

166. *Id.*

167. *Patent Eligibility in America, Part III*, *supra* note 50 (statement of Peter O'Neill, Executive Director, Cleveland Clinic Innovations) ("[T]he USPTO is the federal entity that provides guidance on patentable subject matter and issues patents. Innovators track closely any guidance or direction from the USPTO with respect to what products are eligible for patents.").

guidelines to obtain patent protection.[168] In 2019, these patents that complied with the USPTO guidelines were later challenged and invalidated by the Federal Circuit.[169] The Federal Circuit in its opinion stated:

> While we greatly respect the [US]PTO's expertise on all matters relating to patentability, including patent eligibility, *we are not bound by its guidance*. And, especially regarding the issue of patent eligibility and the efforts of the courts to determine the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws, we are mindful of the need for consistent application of our case law.[170]

However, there is not consistency in the application of the case law in the Federal Circuit or between the USPTO and the Federal Circuit. Rather than an issued patent "represent[ing] the approval of the federal government that a product meets the standards of the federal statute, [it is] the beginning of a protracted legal battle."[171] The inconsistency creates confusion for patent holders and investors in technologies and stifles research and development of life-saving technologies.[172] As long as the courts continue to give no standing to the USPTO, the unpredictability and inconsistency will continue.[173] Congress needs to step in to resolve the dissonance between the USPTO and the courts.

168. *Id.*

169. Cleveland Clinic Found. v. True Health Diagnostics LLC, 760 Fed. App'x 1013, 1020 (Fed. Cir. 2019).

170. *Id.* (emphasis added).

171. *Patent Eligibility in America, Part III*, *supra* note 50 (statement of Peter O'Neill, Executive Director, Cleveland Clinic Innovations) ("A patent issued by USPTO should represent the approval of the federal government that a product meets the standards of the federal statute, not the beginning of a protracted legal battle.").

172. *Id.* (statement of Peter O'Neill, Executive Director, Cleveland Clinic Innovations) ("The resources for [bringing a new health care product to market] generally come from outside . . . working with the investment community. That investment community takes into account a number of factors when deciding whether to support commercialization – including whether a product is likely to be able to acquire intellectual property protections, like patents.").

173. *Id.* (statement of Peter O'Neill, Executive Director, Cleveland Clinic Innovations) ("These questions about patents hurt the ability of . . . innovators to bring new products to market that involve the life sciences. . . . [The Cleveland Clinic] ha[s] an established process to assess inventions, based on their likelihood to be able to be developed into commercial products. Ability to get protectable intellectual property . . . is the first, and most influential factor . . . . If an invention can't get intellectual property protection, usually that is a fatal flaw and the invention is abandoned at that point.").

C. A Split Federal Circuit

Following the *Alice/Mayo* framework, the general consensus was that the courts would clarify subject-matter eligibility.[174] In particular, the Federal Circuit was in the best position to clarify the *Alice/Mayo* framework due to its nationwide jurisdiction on patent law.[175] Between July 2014 and June 2018, the federal courts issued 692 decisions applying the *Alice/Mayo* framework.[176] The district courts invalidated these patents on 101 grounds 60.8 percent of the time.[177] The Federal Circuit invalidated 87.5 percent of its cases.[178] The Federal Circuit judges are increasingly criticizing the § 101 framework. One Federal Circuit judge called the patent eligibility law "incoherent" and explained that, "[t]he law . . . renders it near impossible to know with any certainty whether the invention is or is not patent eligible."[179]

The uncertainty regarding patent eligibility, particularly in the biotechnology and diagnostic fields, can be seen through splits in the Federal Circuit.[180] This deep divide was recently illustrated in the denial of an *en banc* rehearing of *Athena Diagnostics, Inc. v. Mayo Collaborative Services* in July 2019.[181] The 7-5 order denying the rehearing was approximately 82 pages, consisting of four separate concurrences and four separate dissents.[182] The length and number of opinions itself exhibits the rift in § 101 law and the need for clarification.[183]

174. *Patent Eligibility in America, Part I*, *supra* note 44, at 4 (statement of Q. Todd Dickinson, Former USPTO Director).

175. *Court Jurisdiction*, U.S. CT. OF APPEALS FOR THE FED. CIR., http://www.cafc.uscourts.gov/the-court/court-jurisdiction [https://perma.cc/R973-HHTB] ("As of FY 2018, the [Federal Circuit's] jurisdiction consists of administrative law cases (20%), intellectual property cases (67%), and cases involving money damages against the United States government (13%). . . . Nearly all of the intellectual property cases involve patents originating from the U.S. Patent and Trademark Office and all U.S. District Courts.").

176. *Patent Eligibility in America, Part I*, *supra* note 44, at 5 (statement of Adam Mossoff, Professor of Law, Antonin Scalia Law School, George Mason University).

177. *Id.* (statement of Adam Mossoff, Professor of Law, Antonin Scalia Law School, George Mason University).

178. *Id.* (statement of Adam Mossoff, Professor of Law, Antonin Scalia Law School, George Mason University).

179. Interval Licensing v. AOL, Inc., 896 F.3d 1335, 1348 (Fed. Cir. 2018) (Plager, J., dissenting).

180. *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1353, (Fed. Cir. 2019); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1373 (Fed. Cir. 2015).

181. Athena Diagnostics, Inc., 927 F.3d at 1353.

182. *Id.*

183. *Id.*

Athena v. Mayo dealt with the diagnostic test that confirms MG, as it did for Alison.[184] The majority wished to "write on a clean slate," but felt bound by *Mayo*.[185] The minority believed the case was distinguishable from *Mayo.*[186] The dissent expressed concerns that the overbroad interpretation of *Mayo* created a per se ineligibility rule for diagnostic testing that stunts research and development of life-saving technologies.[187]

All 12 judges agreed that the current framework was "problematic" for diagnostic patents and denied patent protection for "essential life saving inventions."[188] The judges "welcome[d] further explication of eligibility standards in the area of diagnostic patents," either by the Supreme Court or Congress.[189] Acknowledging that § 101 issues cannot be fixed by the Federal Circuit, the judges called for "clarification by [a] higher authority, perhaps by Congress" to address § 101 issues that lay "beyond the power of [the Federal Circuit]."[190]

D. A Sleeping Supreme Court

In January 2020, the Supreme Court denied the petition for certiorari for *Athena v. Mayo* against the pleas of the Solicitor General, Federal Circuit, and numerous amici.[191] The Supreme Court also denied four other petitions relating to patent eligibility, bringing the overall count of denied petitions on subject-matter eligibility to over 48 since *Alice* in 2014.[192] With the inaction of the Supreme Court, a fix of § 101 rests squarely on the shoulders of Congress.

---

184. *Id.*

185. *Id.* at 1335 (Lourie, J., concurring).

186. *Id.* at 1352 (Moore, J., dissenting).

187. *Id*. at 1354.

188. *Id.* at 1337 (Hughes, J., concurring).

189. *Id.*

190. Berkheimer v. HP, Inc., 890 F.3d 1369, 1374 (Fed. Cir. 2018) (mem.) (Lourie, J., concurring) ("However, I believe the law needs clarification by higher authority, perhaps by Congress, to work its way out of what so many in the innovation field consider are § 101 problems. . . . Section 101 issues certainly require attention beyond the power of this court."). *See also Patent Eligibility in America, Part I*, *supra* note 44, at 30 (statement of Q. Todd Dickinson, Former USPTO Director).

191. Sherry Knowles, *Reflections on Denial of Cert in* Athena Diagnostics, IPWATCHDOG (Jan. 20, 2020), https://www.ipwatchdog.com/2020/01/20/reflections-denial-cert-athena-diagnostics/id=118025/ [https://perma.cc/ZW3C-JMAJ].

192. Gene Quinn, *The Supreme Court is More Interested in Being Right Than Shedding Light on 101*, IPWATCHDOG (Jan. 14, 2020), https://www.ipwatchdog.com/2020/01/14/supreme-court-interested-right-shedding-light-101/id=117822/ [https://perma.cc/YMH6-H44R].

E. The Proposed Congressional Fix: Eliminate Everything

In February of 2019, the Senate Judiciary Committee Subcommittee on Intellectual Property was revived for the first time since 2007 because of a "need to reform our nation's complicated patent process . . . ."[193] The first priority for the subcommittee was to search for a solution for § 101 patent eligibility issues.[194] In April 2019, the subcommittee released a § 101 patent reform framework.[195] In May 2019, the subcommittee released the draft legislation of a revised § 101 of the Patent Act.[196]

One of the provisions stated, "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."[197] At first glance, the draft legislation was a win for IVD testing. The abrogation of laws of nature and natural phenomena broadened patentable subject-matter, opening a door for IVD testing to be patented.[198] However, the abrogation would also erase nearly 200 years of Supreme Court precedent.[199] With the broadening of patentable subject-matter, safeguards against abuse of the system would be replaced by patent thickets to shield competition and the building blocks needed for scientific advancements would be monopolized.[200]

---

193. Eileen McDermott & Gene Quinn, *As Momentum for a 101 Fix Builds on Capitol Hill, A Look at the Revived Senate IP Subcommittee's Leadership*, IPWATCHDOG (Feb. 26, 2019), https://www.ipwatchdog.com/2019/02/26/momentum-101-fix-builds-capitol-hill-look-revived-senate-ip-subcommittees-leadership/id=106690/ [https://perma.cc/TZP6-2Z27]; *101 Framework*, *supra* note 21 ("Senator Coons and I requested to reinstate the Senate Judiciary Subcommittee on IP because we saw a need to reform our nation's complicated patent process, starting with section 101.").

194. *101 Framework*, *supra* note 21 ("Senator Coons and I requested to reinstate the Senate Judiciary Subcommittee on IP because we saw a need to reform our nation's complicated patent process, starting with section 101.").

195. *Id.*

196. Press Release, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act, THOM TILLIS U.S. SENATOR FOR N.C. (May 22, 2019) [hereinafter Draft Bill Text], 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/XQN3-BPYY].

197. *Id.*

198. *Patent Eligibility in America, Part I*, *supra* note 44 (questions for the Record for Professor Mark A. Lemley).

199. *Id.* (questions for the Record for Professor Mark A. Lemley).

200. *Patent Eligibility in America, Part II*, *supra* note 49 (responses from Jeffrey K. Francer, Senior Vice President and General Counsel, Association for Accessible Medicines at 3, 5) (explaining that abuses of the system could include creating patent thickets, shielding brand-name drugs from generic and biosimilar competition, and increasing cost of healthcare for patients and the public);

In June 2019, the subcommittee held three days of hearings to, "solicit additional stakeholder feedback and to hear from a diverse set of witnesses on the problems different industries are facing with our nation's patent eligibility laws."[201] While the majority of stakeholders expressed a need for change to the eligibility framework, no consensus was met.[202] On one extreme, stakeholders lobbied for the elimination of all exceptions.[203] On the other extreme, stakeholders lobbied for Congress to leave the exceptions alone.[204]

Senator Tillis in an interview in January 2020 said:

> Given the reasonable concerns that have been expressed about the draft as well as the practical realities of the difficulty of passing legislation, absent stakeholder consensus I don't see a path forward for producing a bill—much less steering it to passage—in this Congress . . . . If we're going to get anything done on this issue, everyone will have to compromise. Anything less than that is dead on arrival.[205]

The way forward for a workable patent system for IVD testing must find a middle ground that balances a limited monopoly that produces a return on investment without stifling access to scientific building blocks needed to make medical advancements.

V. CARVING OUT MIDDLE GROUND: A DIAGNOSTIC TEST PATENT ACT

Congress needs to develop patentability standards that would "permit patenting of essential life saving inventions [like IVDs] based on natural laws."[206] These standards would need to use reasonable and measured safeguards to balance the monetary benefits of monopolies against access to the medical science needed to advance life-saving diagnostics.

To achieve this balance, Congress should create a diagnostic patent act to allow the patentability of IVD tests. The proposed diagnostic patent act would allow products of nature or natural phenomenon to be patented

---

Patent Eligibility in America, Part I, *supra* note 44 (Questions for the Record for Mr. Robert A. Armitage).

201. Draft Bill Text, *supra* note 195.

202. Eileen McDermott, *U.S. Companies and Groups to Congress: The Section 101 Reform Draft is Good and Genes are Safe,* IPWATCHDOG (June 26, 2019), https://www.ipwatchdog.com/2019/06/26/us-companies-groups-congress-101-draft-good-genes-safe/id=110717/ [https://perma.cc/RY3X-TJQ6].

203. *Id.*

204. *Id.*

205. Quinn, *supra* note 22.

206. Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1337 (Fed. Cir. 2019) (Hughes, J., concurring).

but would include safeguards to allow adequate access to fundamental research while incentivizing return on investment to the patent holder. Safeguards to prevent tying up future inventions and negatively impacting patient care would be included as exceptions to patent infringement claims and compulsory licensing requirements under certain conditions. Exceptions, which limit infringement liability to third parties in specific situations, would be used for narrow experimental use and mandatory processes required to comply with federal regulations. Compulsory licensing, which requires patent holders to allow third parties to use a patent in certain circumstances in exchange for a determined fee, would be permitted when a patent holder acts in an anti-competitive way to restrict access and for governmental or public health uses. The combination of these limitations on a patent holder's exclusive monopoly will ensure that access to research is available while patent holders are adequately incentivized to develop IVDs.

A. Creating special eligibility standards for diagnostic testing

Historically, products of nature and natural phenomena have never been patent eligible.[207] However, in 1930, Congress passed the Plant Patent Act (PPA), which gave patent protection to new plants variations, a product of nature. Prior to the passing the PPA, the general consensus was that plants were ineligible under 35 U.S.C. § 101 as products of nature.[208] The PPA bypassed the § 101 requirements by allowing patentability under certain conditions.[209] The Supreme Court explained in *Diamond v. Chakrabarty*,

> Prior to 1930, two factors were thought to remove plants from patent protection. The first was the belief that plants, even those artificially bred, were products of nature for purposes of the patent law . . . . In enacting the Plant Patent Act, Congress . . . explained at length its belief that the work of the plant breeder 'in aid of nature' was patentable invention.[210]

207. *See supra* Part III.

208. U.S. CONGRESS, OFFICE OF TECH. ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE – SPECIAL REPORT 71 (1989) https://ota.fas.org/reports/8924.pdf [https://perma.cc/R3RL-R7L2].

209. 35 U.S.C. § 161 (2018) ("Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.").

210. Diamond v. Chakrabarty, 447 U.S. 303, 311–12 (1980).

Congress should likewise create a separate patent act for IVD testing that would allow patent protection for those products of nature or natural phenomenon that are made artificially or with the assistance of science. The other requirements of novelty, anticipation, and written description that apply to utility patents would be applied as normal.

The challenges causing Congress to carve out separate eligibility standards for plants are similar to the challenges that IVD testing faces today. Plant varieties play an important role in the development of agriculture.[211] Historical events and the growing agricultural industry demanded "new disease-resistant, cold-tolerant, drought-tolerant, or medicinal varieties."[212] Yet, plant breeders and nurseries could not legally protect their inventions and discoveries.[213] Furthermore, "financial incentives . . . to develop new varieties were inadequate to recover research and development costs and earn a sufficient profit."[214] Plant breeders could not "capture legal and economic control over 'their' [inventions and discoveries]."[215]

Likewise, diagnostic testing plays an important role in the economy and public health.[216] Diagnostic testing contributes to the economy, has the potential to decrease chronic disease; allows for earlier interventions; and most importantly saves lives.[217] Although there is a need for new, efficient diagnostic testing for novel and preexisting illnesses, the current patent system has not provided adequate incentive to invent IVDs.[218] By excepting diagnostic patents from the judicially made subject-matter eligibility requirements, a diagnostic testing patent law can balance incentivization with access while addressing the concerns specific to the diagnostic industry.

B. Creating infringement limitations on the owner's monopoly to promote further medical research and advancements

Patent schemes can allow third parties to use patented technology without the authorization of the patent holder in specific scenarios.[219]

211. CONGRESS, *supra* note 207.
212. *Id.*
213. *Id.*
214. *Id.*
215. Cary Fowler, *The Plant Patent Act of 1930: A Sociological History of Its Creation,* 82 J. PAT. & TRADEMARK OFF. SOC'Y 621, 640 (2000).
216. *See supra* Part II.
217. *See supra* Part II.
218. *See supra* Part II.
219. Carlos M. Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* 7 (Inst. for Agric. & Trade Policy, Trade-Related Agenda, Dev.

These exceptions are limited circumstances in which the exclusive rights of the patent holder may be narrowed.[220] When circumstances are met, use of a patented invention is automatically granted to a third party without the authorization of the patent holder.[221] The third party technically infringes on the patent but the law does not afford remedies to the patent holder in these situations.[222] Examples of exceptions that limit infringement liability include: experimental or education use; prior use; acts for non-commercial or non-profit making purposes; preparations of prescribed drugs; compliance with federal regulations; and medical treatment exceptions to name a few.[223]

Exceptions are important to include in a diagnostic patent act to address the concerns with access to diagnostic tools, cost for general public, and public health. Exceptions mitigate the liability of accessing the patents in certain circumstances, allowing research to move forward and competition that influences the cost to the general public and quality of tests available.

Because exceptions limit the a patent holder's exclusive rights granted by the patent, exceptions must be reasonable and measured.[224] Article 30 of the Agreement of Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets out a "three-step test" for determining the validity of an exceptions: (1) be limited in scope, (2) not "unreasonably conflict with the normal exploitation of the patent," and (3) not "unreasonably prejudice the legitimate interest of the patent owner, taking account of the legitimate interests of third parties."[225]

The World Trade Organization (WTO) has defined limited scope as "one which makes only a small diminution of the rights in question" or narrowly binds the unauthorized use of the patent.[226] The limited scope

and Equity (T.R.A.D.E.) Working Paper No. 5, 1999) (Apr. 25, 2000) https://www.iatp.org/documents/intellectual-property-rights-and-the-use-of-compulsory-licenses-options-for-developing-cou [https://perma.cc/QX5P-WYXB].

220. *Id.*

221. *Id.*

222. *Id.*

223. Standing Comm. on the Law of Patents, *Experts Study on Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights*, Annex I at 29–30, WIPO doc. SCP/15/3 (Sept. 2, 2010) [hereinafter *Study of Exclusions and Exceptions*, Annex I].

224. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 30, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization Annex 1C, 1867 U.N.T.S. 299 [hereinafter TRIPS Agreement].

225. The TRIPS agreement governs intellectual property rights of Member States of the World Trade Organization. *Id.*

226. *Study of Exclusions and Exceptions*, Annex I, *supra* note 222, at 37 (quoting Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, ¶¶ 7.30, 7.44, WTO Doc. WT/DS 114/R (adopted Mar. 17, 2000)).

analysis is not based on the economic impact of the exception nor the number of rights infringed upon, but the impact on the exclusive rights itself.[227] For example, a Canadian "stockpile exception" which allowed manufacturing of a drug prior to the expiration of a patent was not considered limiting because it "abrogated the patentee's rights to make and use the invention entirely during the [last] six months."[228]

When determining the second-step of "unreasonable conflict" with "normal exploitation", WTO looks at how the patent holder would extract economic value from the patent in its commercial industry.[229] Finally, in determining the legitimate interests of the patent owner and third parties, WTO looks not at the legal interests, but the justifiable interests of the patent holder and third parties supported by "public polic[y] or other social norms."[230]

Using the TRIPS "three-step test," two exceptions should be included in a diagnostic testing act: (1) the Bolar exception that allows for earlier approval of IVDs by federal regulatory agencies to occur without the risk of an infringement action; and (2) a narrow experimental use exception that provides limited access to the IVD patent.

1. The Bolar Exception

Section 271(e)(1) of the Hatch-Waxman Act states:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . .[231]

This limitation of liability is referred to as the Bolar exemption.[232] The Bolar exception allows for unauthorized use of a patent in order to obtain regulatory approval. This exception is commonly used by generic drug companies wanting to put a competing product on the market once the patent covering the brand drug expires. However, in order to commercialize a drug, Federal Drug Administration (FDA) approval requires trials to be done with the patented drug to show

227. *Id.*
228. *Id.* (citing WT/DS 114/R, ¶¶ 7.30, 7.44).
229. *Id.* at 38.
230. *Id.* (quoting WT/DS 114/R, ¶ 7.69).
231. 35 U.S.C. § 271(e)(1) (2018).
232. Anthony Tridico, Jeffrey Jacobstein & Leythem Wall, *Facilitating Generic Drug Manufacturing: Bolar Exemptions Worldwide*, WIPO MAG., June 2014, at 17–20.

bioequivalence.[233] If the process started as soon as the patent expired, no competition would exist until approval was granted which could be years, effectively giving the patent holder a longer monopoly on the product. The Bolar exception corrects this abuse by allowing use in relation to federal regulations.

IVDs, like pharmaceuticals, are also subject to FDA approval.[234] Therefore, to ensure the monopoly a patented IVD is terminated at expiration, a Bolar exception must be included in a diagnostic patent act. This exception would encourage competition and likewise benefit the general public with access and options to a variety of diagnostic tests.

2. Experimental Use Exceptions

"The purpose of an experimental use exception should be to protect the patentee's ability to recoup her research and development investment while preventing her from using her exclusive rights to exercise unwarranted control over subsequent innovation."[235] In other words, an experimental use exception allows the non-patent holder to experiment with the patent in order to understand the science and mechanism and invent subsequent improvements without infringement liability. An experimental use exception provides the scientific community access to build upon.

A narrow experimental use exception for diagnostic patents should be included in a legislative framework. Three contours define the scope of the exception: 1) the meaning of "experimental," 2) whether the use extends to use "with" or "on" the patented invention, and 3) whether the experimental use can be used for commercial activity.[236]

The meaning of "experimental" needs to be "very narrow and strictly limited."[237] Experimental use would not include commercial use or "furtherance of the alleged infringer's legitimate business" for two

233. *Id.*

234. The Supreme Court in *Merck KGaA v. Integra Lifesciences Ltd.*, interpreted § 271(e)(1) broadly, allowing use of a patented technology, not just pharmaceuticals, to develop and submit to the FDA. Merck KGaA v. Integra Lifesciences Ltd., 545 U.S. 193, 206–07 (2005).

235. Katherine Strandburg, *What does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 100.

236. *Study of Exclusions and Exceptions*, Annex I, *supra* note 222, at 39.

237. Madey v. Duke Univ., 307 F.3d 1351, 1361 (Fed. Cir. 2002). The Federal Circuit held in 2002 that the experimental use exception for patents is restricted to non-commercial use. *Id.* at 1362. The patent owner sued Duke University for using equipment that he held the patent to. *Id.* at 1352–53. The Federal Circuit reasoned that because Duke University had a commercial interest tied to its reputation as a research facility the experimental exception did not apply. *Id.* at 1362–63.

reasons.[238] First, the interests of a patent holder is to exploit IVD patent commercially to make a gain on investment. Without restricting experimental use exception to non-commercial purposes, third parties could use the experiment use exception as a guise to commercialize the IVD patent. This would unreasonably conflict with the patent holder's commercialization and return on investment, thereby destroying the patent holder's exclusivity of the rights and significantly undermine the expected return on investment for the patent holder.

Second, higher education institutions, which are often included in experimental use exceptions, are incubators for commercialized biotechnology and would undermine return on investment. Universities and their laboratories are increasingly partnered with biotech companies who "collaborate with universities by building laboratories, conducting research, and obtaining licenses to the patents obtained.[239] Companies look to research universities as "sources of new technologies."[240] "In 2017 alone, America's universities were granted more than 6800 patents, created over 1000 startup companies, produced many new medical breakthroughs, and generated millions of dollars of economic benefit for the country."[241] Therefore, by allowing commercial use without infringement liability, the patent holder would not receive adequate return on investment.

Additionally, the scope of the experimental use exception would need to be limited to experiments *on* the patented IVD rather than *with* the patented IVD. To experiment *on* an IVD patent would be to examine the invention itself through recreation. To experiment *with* an IVD patent would be to use it as a research tool without compensation to the patent holder. If research tools, such as diagnostic test patents, were allowed to be experimented *with* without payment a patentee would have no incentive to invest it its creation.[242] Furthermore, allowing experimentation or research *with* would "greatly ease the ability of competitors to 'design around' the invention or develop competing technologies" which would also strip the return on investment from

238. *Id.* at 1362.

239. Ruth E. Freeburg, *No Safe Harbor and No Experimental Use: Is it Time for Compulsory Licensing of Biotech Tools*, 53 BUFF. L. REV. 351, 404–05 (2005).

240. *Id.*

241. *Patent Eligibility in America, Part II, supra* note 49 (questions from Senator Tillis for Rick Brandon representing the Association of American Universities).

242. *Study of Exclusions and Exceptions*, Annex I, *supra* note 222, at 39.

research and development from the patent holder and discourage future investment.[243]

Opponents of a narrow experimental use exception generally argue that an overly restrictive exception "might conceivably depress technological advancement by decreasing the ability of researchers to experiment with the state-of-the-art technology."[244] This is true for diagnostic tools; life science research is often cumulative and the results of collaboration.[245] Without access to the patented invention, further research and development that could lead to medical treatments and other advancements could be stifled.[246] Therefore, in a legislative framework for diagnostic test patents, it is imperative that authorization for experimental use *with* the patent for commercial activities be subject to compulsory licensing.

C. Protecting Return on Investment and Granting Access through Compulsory Licensing

Like exceptions, compulsory licenses limit the exclusive rights of patent owners.[247] The difference is that "a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself."[248] Compulsory licensing can be used "as a legal measure against patent abuse and public health problems . . . ."[249] "The provision of compulsory licenses" is a crucial element in a health-sensitive patent law—such licenses may constitute "an important tool to promote competition . . . while ensuring that the patent owner obtains compensation for the use of the invention."[250]

243. JOHN R. THOMAS, CONG. RESEARCH SERV., RL32651, SCIENTIFIC RESEARCH AND THE EXPERIMENTAL USE PRIVILEGE IN PATENT LAW 9–10 (2004).

244. *Id.* at 2 (citing Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 UNIV. CHI. L. REV. 1017 (1989)).

245. Alexis K. Juergens & Leslie P. Francis, *Protecting essential information about genetic variants as trade secrets: A problem for public policy?*, 5 J.L. & BIOSCIENCES 682 (2018).

246. *Id.*

247. CARLOS CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES 93 (South Centre ed. 2000).

248. *Compulsory licensing of pharmaceuticals and TRIPS,* WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm [https://perma.cc/YXT4-DNAF].

249. Kyung-Bok Son, *Importance of the intellectual property system in attempting compulsory licensing of pharmaceuticals: A cross-sectional analysis*, GLOBAL HEALTH 15, no. 42, 2019, at 2.

250. CORREA, *supra* note 247, at 93.

Compulsory licensing significantly affects the right of the patent holder to decide who to license to and under what terms.[251] Therefore, it generally occurs under exceptional circumstances.[252] The TRIPS Agreement, Article 31, does not limit the uses of compulsory licenses but recommends that compulsory licensing be used for emergency situations, anti-competitive practices, public non-commercial use, and dependent patents.[253] To be used in other circumstances, Article 31 of the TRIPS Agreement provides a set of conditions to consider including: prior requests, non-exclusive character of the licenses, the stipulation of compensation based on the economic value of the license, and the conditions for termination of the authorization.[254] These standards help maintain a reasonable balance between the limited monopoly of the patented invention and the promotion of science for the public good.

For example, compulsory licensing is most frequently used in the pharmaceutical industry to promote competition and decrease drug prices.[255] In the context of the HIV pandemic, Thailand used compulsory licensing to enable the manufacturing of HIV drugs by third parties in order improve accessibility and cost for the public good.[256]

---

251. Esther van Zimmeren & Geertrui Van Overwalle, *A Paper Tiger? Compulsory License Regimes for Public Health in Europe*, 42 INT'L REV. INTELL. PROP. & COMPETITION L. 1, 13 (Jan. 2011).

252. *Id.* at 16.

253. Correa, *supra* note 218, at 8.

254. *Id.*; TRIPS Agreement, *supra* note 223; Standing Comm. on the Law of Patents, *Experts Study on Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights,* Annex V at 5, WIPO doc. SCP/15/3 (Sept. 2, 2010) [hereinafter *Study of Exclusions and Exceptions*, Annex V] ("There are certain common requirements: *(a)* the authorization of such use must be considered on its individual merits; *(b)* such use may be permitted only if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions, which efforts have not been successful within a reasonable time; *(c)* the scope and duration of such use must be limited to the purpose for which it was authorized, *(d)* such use must be non-exclusive; *(e)* such use must be non-assignable, except with that part of the enterprise or goodwill which enjoys such use; *(f)* any such use must be authorized predominantly for the supply of the domestic market of the Member authorizing such use; *(g)* authorization for such use must be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority must have the authority to review, upon motivated request, the continued existence of these circumstances; *(h)* the right holder must be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; *(i)* the legal validity of any decision relating to the authorization of such use must be subject to judicial review, or other independent review by a distinct higher authority in that Member; and any decision relating to the remuneration provided in respect of such use must be subject to judicial review, or other independent review by a distinct higher authority in that Member.").

255. *See Study of Exclusions and Exceptions*, Annex V, *supra* note 254.

256. *Id.* at 22.

1. Compulsory licensing for diagnostic testing

Compulsory licensing is not currently used in relation to diagnostic testing in the United States; however, compulsory licensing is suitable for diagnostic testing.[257] Compulsory licensing is especially useful for diagnostic test patents for two reasons. First, the public policy objectives of compulsory licensing are to "safeguard the interest of the general public . . . [and] 'protect the general public from the disadvantages of the monopoly position of a patent proprietor.'"[258] Because diagnostic testing plays such a fundamental part in both the effectiveness of the public health system and the advancement of public health, it cannot be completely monopolized.[259]

When patent holders refuse to grant accessibility to a life-saving technology, compulsory licensing can be used to limit a patent owner's rights under those extreme circumstances.[260] Compulsory licensing can pressure companies into engaging into licenses on their own terms before being compelled to by the courts or an agency.[261] For example, in 2001 during the anthrax scare, the U.S. threatened to impose compulsory licensing requirements for a drug to treat anthrax.[262] Companies responded with price discounts and access to supplies of the drug.[263]

Second, compulsory licensing "strik[es] a balance between the interests of patentee on the one hand and of third parties and/or public interest and/or society on the other hand."[264] The current structure of the patent system is unbalanced in relation to IVD diagnostics. By rewarding exclusive control over a diagnostic patent for 20 years, advancements and development by others may be prohibited and the public interest is harmed. Therefore, balancing the exclusive rights of the patentee with access to the technology through compulsory licensing is vital for a healthy diagnostic system. Compulsory licensing gives access to others while still rewarding the patent owner with a return on their investment for research and development.

Opponents argue that compulsory licensing is too aggressive towards the patentee's rights, that compulsory licensing will "diminish[] or

257. Correa, *supra* note 218, at 7.

258. Standing Comm. on the Law of Patents, *Draft Reference document on the Exception Regarding Compulsory Licensing*, Annex at 4, WIPO doc. SCP/30/3 (May 21, 2019) [hereinafter *Exception Regarding Compulsory Licensing*].

259. *See supra* Part II.

260. *Cf.* Zimmeren, *supra* note 251.

261. *Id.* at 27.

262. *Exception Regarding Compulsory Licensing*, *supra* note 258, at 56.

263. *Id.*

264. *Id.* at 5.

destroy[] the incentives to undertake R&D by patent holders."[265] Furthermore, that compulsory licensing "diminish[es] the purpose of the patent system by reducing inventors' incentive to develop new technologies [by] encouraging inventors to keep inventions secret."[266] However, studies have shown that there is no negative effect on R&D.[267] Contrary to common misconceptions, companies subject to compulsory licensing had a significant rise in investment because "spend[ing] large sums of money on efforts to 'invent around' the patents of their competitors . . . would be unnecessary . . . ."[268]

Opponents also argue that "compulsory licensing does not allow [a company] to recoup any investment incurred through research and development . . . to make a sufficient profit for them to remain in the business" and "diminish[es] the incentives for innovati[on]."[269] Forcing a patent holder to license his patented invention that grant him exclusive rights to that inventions for a limited time "usurp[s] traditional patent systems" and are "sometimes diametrically opposed to the patent system."[270]

While compulsory licensing does limit the patent holder's exclusive rights, "compulsory licensing positively influence[s] the survival of certain patents . . . because compulsory licens[es] [are] granted as an alternative to the abolition of patents."[271] Diagnostic testing patents are the perfect example of compulsory licensing saving a patent as an alternative to no patent at all. As § 101 stands currently, diagnostic testing is *per se* ineligible.[272] All diagnostic tests have been invalidated at the Federal Circuit level.[273] As of now, there is little to no incentive to invent diagnostic tests because they are being invalidated. Without intervention, diagnostic patents will die, alongside the people that these patents could

265. Correa, *supra* note 218, at 17.

266. Joseph A. Yosick, Note, *Compulsory Patent Licensing for Efficient Use of Inventions*, U. ILL. L. REV. 1275, 1291 (2001).

267. Correa, *supra* note 218, at 17; Dora Kripapuri, Comment, *Reasoned Compulsory Licensing: Applying U.S. Antitrust "Rule of Reason" to TRIP's Compulsory Licensing Provision*, 26 NEW ENG. L. REV. 669 (2002).

268. Correa, *supra* note 218, at 17 (citing Pankaj Tandon, *Optimal patents with compulsory licensing*, 90 J. POLITICAL ECON. 470, 485 (1982)); Kripapuri, *supra* note 267.

269. Kyung-Bok Son, *supra* note 249, at 2.

270. *Id.*

271. *Id.*

272. *See* Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1353 (Fed. Cir. 2019) (Moore, J. dissenting).

273. *Id.* ("Since *Mayo*, we have held every single diagnostic claim in every single case before us ineligible.").

save. Compulsory licensing creates an incentive while still protecting rights and access to further medical advancements.

2. Conditions for Granting Compulsory Licensing

Compulsory licenses are granted by a court or administration under specific circumstances.[274] Compensation is then paid to the patent owner.[275] Compulsory licensing is a tool to grant access to scientific research and tools where otherwise there would be no access. [276] Allowing access to life-saving technologies lead to further medical research, prevent anti-competitive practices, and incentivize the further medical research.[277]

Because of the aggressive way in which compulsory licensing limits a patent holder's exclusive rights, conditions for granting compulsory licensing should be measured and reasonable against the overall objectives of using compulsory licensing. Compulsory licenses should not be granted as a fishing expedition to gain access to any patent. Therefore, to prevent compulsory licensing from being abused, third parties applying for a compulsory license should be qualified, motivated, and have the required means to exploit the patent.[278]

a. Anti-competitive practices

Creating compulsory licensing for anti-competitive practices with diagnostic testing would not be something new. The use of compulsory licenses to prohibit monopolies is commonly used by the Federal Trade Commission (FTC).[279] For example, in 1997 the merger that created Novartis, a biotech company, the FTC compelled licensing of a number of healthcare related inventions to any interested party at a certain rate.[280] Extending compulsory licensing to diagnostic testing under a diagnostic patent act would ensure that healthy competition and access to life-saving technologies need to advance medicine.

Additionally, other countries, particularly European countries have used compulsory licensing to combat anti-competitive practices in the IVD testing area. Specifically, many European countries changed their laws in response to Myriad's restrictive licensing of the BRCA genes.[281]

274. Correa, *supra* note 218, at 8.
275. *Id.*
276. *Id.*
277. *Id.*
278. Zimmeren, *supra* note 251, at 26.
279. Correa, *supra* note 218, at 16.
280. *Id.*
281. Zimmeren, *supra* note 251, at 21.

Myriad Genetics, a leading diagnostic company, held patents for the BRCA1 and BRCA2 genes which are indicators for hereditary breast and ovarian cancers.[282] They were the "sole distributors of the genetic test" and collector of the data from the genetic testing.[283] Myriad exclusively licensed the gene sequences to other laboratories for a select set of mutations of the gene.[284] To obtain full analysis, Myriad would have to carry out the sequence analysis for a steep fee.[285] Because of the limited data, patients were not obtaining accurate results and advancements to science, including possible treatments, were stunted.[286]

European countries have amended their laws to prevent monopolization of important diagnostic testing.[287] France allows for *ex-officio* licensing but does not include diagnostics specifically.[288] Switzerland has specific text allowing for compulsory licensing of diagnostic products and processes.[289] The United States banned genetic testing patents.[290]

A patent owner*'*s refusal to deal, failure to work, and dependency patents *"*may be anti-competitive when this allows a patentee to block follow-on research, particularly if the initial patent is overly broad*"* or the patentee has created a patent thicket around the technology.[291] Therefore, under these circumstances and others that restrict access to the technology, compulsory licensing should be available.

b. Refusal to deal

The patent owner by virtue of holding the patent can refuse to license with a third party.[292] However, when a patent holder "refuses to grant a voluntary license which was requested on reasonable commercial terms," compulsory licensing should be used.[293] Refusal to deal is often considered in light of other factors, such as when "the availability of the

282. Juergens, *supra* note 245, at 686.
283. *Id.* at 688.
284. Zimmeren, *supra* note 251, at 9.
285. *Id.*
286. *Id.*
287. *Id.* at 22.
288. *Id.* at 23. *Ex officio* licensing is a mechanism that allows third parties to bypass authorization for the patent owner and compels the owner to grant right to use the patented invention in the interest of the public good.
289. *Id.*
290. *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).
291. Correa, *supra* note 218, at 10.
292. *Id*.
293. CORREA, *supra* note 247, at 98.

patented product is negatively affected . . . , or the development of a commercial activity [is] jeopardized" a compulsory license should be granted.[294] Myriad's restrictive licensing practice is an example of when compulsory licensing would have been useful to prevent the monopolization of a specific diagnostic test.[295] Under a compulsory licensing regime, Myriad would have had to license its diagnostic test under its own terms or been forced to license under the reasonable terms of a court or administration. As a result, the public health interest would have benefited because patients would receive full genetic results regarding the risk of hereditary breast and ovarian cancer and take the appropriate steps.[296]

c. Failure to work and inadequate supply

Currently, U.S. case law dictates that a patent owner has no obligation to use, license, or commercialize their patent.[297] However, this is harmful to the biotech industry and consequently American lives. Companies, especially pharmaceuticals, patent technologies for strategic and anticompetitive behavior to "deliberately suppress products or processes from the market to benefit financially."[298] These strategies abuse the system and undermine the purpose of the patent system.[299] These abuses significantly affect biotech research because it is collaborative and interconnected.[300] In terms of protecting diagnostic test patents, it is vital that patents are not suppressed to block future research.[301]

Failure to work describes circumstances when the patent holder does not sufficiently exploit a patent.[302] This can occur in many ways, such as: the invention is only partially implemented; the demand for the patented product is not being adequately met; the product is not available to the public at a reasonable price or does not fulfill the reasonable requirements of the public; or the quality of the product is not acceptable.[303]

294. *Study of Exclusions and Exceptions*, Annex V, *supra* note 254, at 13.
295. Juergens, *supra* note 245, at 688.
296. *Id.*
297. *See* Hartford-Empire Co. v. United States, 324 U.S. 570 (1945).
298. Neil S. Tyler, *Patent Nonuse and Technology Suppression: The Use of Compulsory Licensing to Promote Progress*, 162 U. PENN. L. REV. 451, 458 (2014).
299. *Id.*
300. *Id.*
301. *Id.*
302. Zimmeren, *supra* note 251, at 17.
303. *Study of Exclusions and Exceptions*, Annex V, *supra* note 254, at 13.

Compulsory licensing would curb these abuses by companies patenting technologies for the sole purpose of blocking others from using it.

The failure to work condition should be included in the diagnostic patent act to allow access when the patent is not being worked adequately. Allowing licensing would give others the opportunity to manufacture the IVD test for the public good. The scope of failure to work should be legislated with safeguards as to balance the interests of the patent holder with the interests of a third party's use of the invention as a public good. First, failure to work can be defined narrowly.[304] For example, in France, Belgium, and Switzerland, licensing to others for production is sufficient to satisfy the working requirement and compulsory licensing cannot be used.[305] In other countries, "non-working" or "insufficient working" refers to an inadequate supply of product for the domestic market or unreasonable prices.[306] Second, a time limitation should be included to allow the patent holder sufficient time to properly exploit the patent.[307] Placing a time limit would protect the patent holder's rights in a practical manner. Third, failure to work may provide evidentiary value to a court reviewing a compulsory licensing motion. For example, failure to obtain FDA approval may evince failure to work; however, if obtaining FDA approval for a diagnostic test is impossible, the courts could deny the compulsory license.[308] By allowing compulsory licensing for failure to work, medical advancements could move forward for the betterment of public health.

d. Dependent patents

Patents often build off each other in biotechnology.[309] For example, ABC Co. has an IVD patent to diagnose an illness. XYZ Inc. has discovered that ABC's patent plus component B allows the diagnostic test to be performed faster. However, without a license from ABC, XYZ cannot commercialize its invention of component B without infringing ABC's patent. If ABC refuses to license, this faster technology will never benefit the public. This is the problem of dependent patents.[310]

304. Zimmeren, *supra* note 251, at 17.

305. *Id.*

306. *Exception Regarding Compulsory Licensing*, *supra* note 258, at 27 (referencing responses to a questionnaire from Burkina Faso, China, Hong Kong, Greece, Israel, Poland, South Korea, Spain, Dominican Republic, India, and Morocco).

307. Zimmeren, *supra* note 251, at 17.

308. *Id.*

309. Ralf D. Kirsch, Claus Becker & Thomas Westphal, *Dependent patent in biotechnology*, 7 EURO BIOTECH NEWS 43 (2008).

310. *Id.*

Dependency occurs when the use of one invention is not possible without the infringement of another invention.[311] This typically occurs when "the owner of a patent covering an improvement on an invention that has already been patented by someone else may not practice its invention without the authorization by the first patentee.[312]

In diagnostic testing, patent dependency could essentially block out a competitor from an entire field of study. This in turn would harm the public interest. Therefore, the legislative framework should allow for compulsory licenses to be granted when dependency occurs and the original patentee is unwilling to negotiate reasonable terms.

e. Governmental Use or Public Health Interests

Compulsory licensing for government use occurs when the government wants to exploit a technology of another.[313] Through eminent domain, the government can use the patented technology in exchange for reasonable compensation.[314] A common example is the licensing of patents for national defense purposes.

The U.S. also has created compulsory licenses when the public interest is at stake. For example, the U.S. was going through an energy crisis in 1973. To become energy dependent, the Federal Non-Nuclear Energy Research and Development Act (ERDA) in 1974 allowed for recommendations on related technology that should be compelled to be licensed.[315]

In many jurisdictions, public health is considered to be a strong public interest. Art. 8 of the TRIPS agreement states that Member States should "adopt measures to protect public health . . . ."[316] The World Health Organization published a list on "essential diagnostic tests" that improve public health in 2018.[317] Additionally, some countries consider access to IVD tests vital to public health.[318] Belgium and Switzerland use compulsory licensing to access genetic diagnostic testing, which they consider a public health interest.[319]

311. Correa, *supra* note 218, at 13.
312. Zimmeren, *supra* note 251, at 17.
313. Correa, *supra* note 218, at 14.
314. *Id.*
315. *Id.*
316. TRIPS Agreement, *supra* note 223.
317. *Essential Diagnostics*, *supra* note 25.
318. Zimmeren, *supra* note 251, at 24.
319. *Id.*

Because "public health" can be a broad swath of circumstances, it is important to define the scope of "public health," what conditions must be fulfilled, and the geographical effects in order to use compulsory licensing under a public health reason.[320] Europe gives examples of how public health is defined for compulsory licensing.[321] France defines a public health interest to be triggered when the quality or quantity is insufficient, when the price is abnormally high, if the patent is being exploited contrary to public health interests, or if a patent is being used for anti-competitive practices.[322] Switzerland's public health interest is triggered when "inventions regarding diagnostic products or processes has engaged in anti-competitive practices . . . ."[323] This includes insufficient testing facilities or high prices that are detrimental to patient care.[324]

Like the European countries, a legislative framework for a diagnostic patent act should include conditions for public health interests. The public health definition should include circumstances of a public health crisis, inadequate product, or when the patent is being exploits contrary to public health interests. By allowing these circumstances, the interests of the public as a whole are protected. The individuals who need access to new technologies to be accurately diagnosed would have access in the case of a public health emergency while the patent holder is being compensated.

IV. CONCLUSION

"The public interest is poorly served by adding disincentive to the development of new diagnostic methods."[325] Yet, the patent system and judicially-made exceptions have disincentivized the research and development of diagnostic tools to the detriment of the public interest. This is not only harming medical advancements but killing people. In 2020, the world experienced a global pandemic of COVID-19. The United States struggled to supply diagnostics tests to gauge the severity of the outbreak, make public health decision, and manage scarce resources within hospitals.[326] On March 12, 2020, the FDA authorized a series of

320. *Id.*
321. *Id.*
322. *Id.*
323. *Id.* at 25.
324. *Id.* at 24.
325. Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1353 (Fed. Cir. 2019) (Moore, J., dissenting).
326. Robert P. Baird, *Why Widespread Coronavirus Testing Isn't Coming Anytime Soon*, NEW YORKER (Mar. 24, 2020) https://www.newyorker.com/news/news-desk/why-widespread-coronavirus-testing-isnt-coming-anytime-soon [https://perma.cc/3GGN-QYH2] ("The ability to test at scale appears to have been a crucial – though far from the only – means by which China, South

Emergency Use Authorizations for commercial test companies to manufacture and distribute tests. It was in the middle of a global pandemic that commercial diagnostic companies had the incentive to develop these life-saving tests.[327] The lack of tests and the race to develop tests is a wake-up call for the patent system. These important life-saving tests need to be incentivized and patent protected. The patent system for IVD tests needs to be reformed.

The current draft legislation does not properly balance the incentive to develop IVD patents with the appropriate access as to not stunt scientific advancements. Congress needs a middle-ground reform for IVDs. A separate diagnostic patent act is the balance. The proposed legislation outlined here allows for diagnostics to be patented. However, the proposed scheme does not allow for a free for all. It limits infringement to allow access under certain circumstances. On the other hand, it creates a compulsory licensing to give access to the scientific community when needed while compensating the patent holder. The proposed scheme allows for a return on investment and incentives to develop without locking down fundamental building blocks.

The diagnostic industry cannot stop. The proposed scheme would allow it to continue and flourish. Diagnostic testing is too important and impacts too many people to not protect it.

Korea, Singapore, and other countries have been able to control their epidemics . . . a comprehensive testing program that would, ideally, allow for a more targeted strategy of contact tracing, isolation, and quarantine."); Michael D. Shear, Abby Goodnough, Sheila Kaplan, Sheri Fink, Katie Thomas & Noah Weiland, *The Lost Month: How a Failure to Test Blinded the U.S. to Covid-19*, N.Y. TIMES (last updated Apr. 1, 2020) https://www.nytimes.com/2020/03/28/us/testing-coronavirus-pandemic.html [https://perma.cc/5BJ7-RNWS].

327. Megha Satyanarayana, *Companies are racing to develop COVID-19 test for the U.S. Will they help?*, CHEMICAL AND ENGINEERING NEWS (Apr. 1, 2020) https://cen.acs.org/analytical-chemistry/diagnostics/Companies-racing-develop-COVID-19/98/i14 [https://perma.cc/NGR8-EUED] ("While countries like Germany and South Korea have flattened the curve of the COVID-19 pandemic through widespread testing, the US has seen cases surge. Many blame that meteoric rise, in part, on bottlenecks in diagnosing the novel coronavirus. To try to break this logjam, some companies and academic groups are developing tests that exploit a variety of technologies and platforms.").