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In Your Own Defense: The Importance of Immuno-Oncology and the Problem with Patenting Under the "Laws of Nature"

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IN YOUR OWN DEFENSE: THE IMPORTANCE OF IMMUNO-ONCOLOGY AND THE PROBLEM WITH PATENTING UNDER THE “LAWS OF NATURE”

Laura Schwartz

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I. INTRODUCTION

Advances in modern medicine and medical technology have led to tremendous success in treating formerly untreatable diseases, including many types of cancer.¹ This has resulted in the extension of patients’ lives for years, and sometimes even for decades.² The cornerstone behind these advances are treatments based on an understanding of the molecular basis of the diseases. For example, immuno-oncology, which uses the body’s own immune system to combat cancer, has proven to be a promising technique and has achieved great distinction over the last decade. In order to harness the power of immuno-oncology, scientists must be able to find the correct molecular targets located on the surface of the cancer cells in each individual patient.³ Diagnostic tests are used to find these molecular

1. This Note is dedicated to my mother, Dr. Anne Rybicki, who passed away in October 2019 from breast cancer.

2. See *Results from Clinical Trials with Keytruda: Metastatic Melanoma*, KEYTRUDA, <https://www.keytruda.com/melanoma/monotherapy-clinical-trial-results/> (last visited Oct. 26, 2021).

3. See Inês Martins, *About Immuno-Oncology*, IMMUNO-ONCOLOGY NEWS,

targets.⁴ However, the patents that protect these tests’ intellectual property, known as “diagnostic method patents,” are currently under attack due to a recent change in Supreme Court precedent.⁵ Beginning in 2012 with the Supreme Court’s decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the ability to patent diagnostic method claims⁶ has been diminished under a patent-eligibility exception called the “laws of nature.”⁷ This has often resulted in reductions in the commercial value of diagnostic tests and imposed a chilling effect on innovation. The adverse effects of this change in the patentability of diagnostic methods are felt by both the innovators in the biotechnology sector as well as the patients whose diseases would benefit from advances in immuno-oncology discoveries.

This Note argues that diagnostic method patent claims, which are at the forefront of molecular medicine, must be afforded proper legal protection by the United States court system. Part II of this Note discusses the central role of immuno-oncology in the development of life-saving therapeutics. Part III of this Note explains the critical link between advances in immuno-oncology and the patentability of diagnostic method patent claims. Part IV describes the issues related to securing diagnostic method patents under 35 U.S.C. § 101. Part V discusses the evolution of Supreme Court precedent regarding patent-eligibility under 35 U.S.C. § 101 and how lower courts have struggled to interpret § 101 under Supreme Court precedent. Part VI explores the different remedies stakeholders have taken in response to the Supreme Court precedent and its inconsistent interpretations by various tribunals. Part VII argues that in a world where rapid changes in medical technology can provide dramatic opportunities to meaningfully decrease patient morbidity and mortality—particularly in the

<https://immuno-oncologynews.com/immuno-oncology/> (last visited Nov. 17, 2021).

4. See Margarita Udall et al., *PD-L1 Diagnostic Tests: A Systematic Literature Review of Scoring Algorithms and Test-Validation Metrics*, *DIAGNOSTIC PATHOLOGY* (Feb. 2018), <https://diagnosticpathology.biomedcentral.com/articles/10.1186/s13000-018-0689-9>.

5. See discussion *infra* Part V.

6. A claim is the part of the patent that describes the invention.

7. See discussion *infra* Part V.

area of cancer therapeutics—it is necessary for the law and technology to collaborate in order to allow for the continued stimulation of innovation.

II. WHAT IS IMMUNO-ONCOLOGY & WHY IS IT IMPORTANT?

“Immuno-oncology is the study and development of treatments that take advantage of the body’s immune system to fight cancer.”⁸ These treatments, which are called immunotherapy, are important because they have the potential to revolutionize modern cancer care.⁹ Unlike the standard “cut, poison, burn” regimen that most people associate with combating cancer, immuno-oncology harnesses the power of the body’s best defense to fight against these diseases.

The immune system is comprised of a network of different organs, cells, and proteins that protect the body against foreign substances such as bacteria, viruses, fungi, and toxins.¹⁰ It does this by distinguishing unfamiliar “non-self” molecules from the body’s own “self” molecules based on the biological markers present on their surfaces, called antigens.¹¹ Once these “non-self” molecules are identified, an immune response is triggered, causing different actors within the immune system to attack, kill, and clear them away.¹² This is called immunosurveillance.¹³ However, issues arise when the immune system is unable to differentiate between “self” and “non-self” molecules.¹⁴ For example, during an allergic reaction, the body registers harmless allergens such as dust, pollen, or peanuts as threatening, and in response produces increased levels of “self” antibodies called Immunoglobulin E (IgE), which causes an overreaction by the immune system that results in

8. *Understanding the Role of Immuno-Oncology in Treating Cancer*, CANCERCARE 4 (2020) https://www.cancercare.org/publications/285-understanding_the_role_of_immuno-oncology_in_treating_cancer).

9. *See What Is Cancer Immunotherapy?*, CANCER RSCH. INST., <https://www.cancerresearch.org/immunotherapy/what-is-immunotherapy> (Oct. 2020).

10. *See How Does the Immune System Work?*, INST. FOR QUALITY & EFFICIENCY IN HEALTH CARE, <https://www.ncbi.nlm.nih.gov/books/NBK279364/> (Apr. 23, 2020).

11. Martins, *supra* note 3.

12. *Id.*

13. *See id.*

14. *Id.*

inflammation, and in severe cases anaphylaxis.¹⁵ Another example of when the immune system encounters confusion is when cancer develops. Cancer cells are “self” cells that have genetically mutated over time, turning them from healthy cells into malignant cells.¹⁶ These mutations can be due to genetic inheritance, old age, or exposure to something damaging in the environment, such as cigarette smoke or free radicals.¹⁷ After a cancer cell mutates, it begins to divide rapidly and form tumors throughout the body.¹⁸ Sometimes the immune system can detect this abnormal division and transmit an alert (i.e., inflammation in the underarm that is produced in response to cancer cells located in the lymph node). However, most of the time cancer cells can evade immunosurveillance by “[u]sing deceptive signaling” that makes them appear as “self” cells when they are anything but that.¹⁹ One way they do this is by expressing antigens similar to those found on normal cells, essentially blending in with their surroundings.²⁰ This causes the cancer cells to grow unchecked in the body because the immune system cannot identify the threat. Therefore, cancer is usually not discovered until treatment is already critical.

Both modern technology and scientific researchers’ understanding of the immune system have advanced tremendously over the past few decades, leading to new and powerful tools to combat cancer. Some of these tools include immunotherapy techniques such as chimeric antigen receptor T-cell (“CAR-T”) therapy, immune checkpoint inhibitors, oncolytic virotherapy, vaccines, and monoclonal antibody (“mAb”)

15. See *Allergic Reaction Defined*, AM. ACAD. OF ALLERGY ASTHMA & IMMUNOLOGY, <https://www.aaaai.org/tools-for-the-public/allergy,-asthma-immunology-glossary/allergic-reaction-defined> (last visited Nov. 18, 2021).

16. See *How Cancer Starts, Grows and Spreads*, CAN. CANCER SOC’Y, <http://www.cancer.ca/en/cancer-information/cancer-101/what-is-cancer/how-cancer-starts-grows-and-spreads/?region=qc> (last visited Nov. 18, 2021).

17. See *id.*

18. See *id.*

19. CTCA, *How Does the Immune System Work? When It Comes to Cancer, It’s Complicated*, CANCER TREATMENT CTRS. OF AM. (Oct. 18, 2017), <https://www.cancercenter.com/community/blog/2017/10/how-does-the-immune-system-work-when-it-comes-to-cancer-its-complicated>.

20. See *Catch Me If You Can: Finding Cancer Cells that Hide in Plain Sight*, DANA-FARBER CANCER INST. (Aug. 8, 2018), <https://blog.dana-farber.org/insight/2017/06/catch-me-if-you-can-finding-cancer-cells-that-hide-in-plain-sight>.

therapy.²¹ Immunotherapy is increasingly important because it can “effectively treat cancer in a non-toxic way as compared to conventional treatment options.”²² For example, chemotherapy, which involves the administration of toxic drugs into the body, kills both healthy and malignant cells, subsequently causing immunosuppression and a multitude of unwanted side effects (e.g., hair loss, fatigue, and nausea).²³ Not only are these conventional methods poisonous, but they are also painful.²⁴ Radiation, which consists of burning away the cancer cells, and surgery, which requires the removal of the cancer cells from the affected organs, are uncomfortable and unreliable choices.²⁵ In contrast, “the immune system is the only natural and the least toxic tool for fighting any kind of disease within the body[.]” including cancer.²⁶

Additionally, immunotherapy has the power to transform cancer care due to how personalized it is.²⁷ In recent years, scientific research has shown that “no two patients’ cancers are exactly the same,” which has resulted in inconsistent response rates to traditional treatment options.²⁸ This is because every individual has a specific genetic makeup, and so the cancer cells that form within their body are unique to them.²⁹ Thus, the oversimplified model of chemotherapy, radiation, and surgery often leads to ineffective results.³⁰ Further, due to the complexity of cancer and its ability to mask itself and silently spread throughout the body in a process known as metastasis, the standard “cut, poison, burn” routine may soon prove to be a thing of the past.³¹ The ability to personalize a patient’s medical

21. *See Types of Cancer Immunotherapy*, CANCER RSCH. UK (Jan. 20, 2021), <https://www.cancerresearchuk.org/about-cancer/cancer-in-general/treatment/immunotherapy/types>.

22. Martins, *supra* note 3.

23. *See id.*

24. *See id.*

25. *See id.*

26. *Id.*

27. *See What Is Cancer Immunotherapy?*, *supra* note 9.

28. Paulina Krzyszczyk et al., *The Growing Role of Precision and Personalized Medicine for Cancer Treatment*, 6 TECHNOLOGY 79, 80 (2018).

29. *See What Is Cancer?*, NAT’L CANCER INST. (May 5, 2021), <https://www.cancer.gov/about-cancer/understanding/what-is-cancer>.

30. *See Krzyszczyk et al.*, *supra* note 28.

31. *See What Is Metastasis?*, CANCER.NET (Mar. 2019), <https://www.cancer.net/navigating-cancer-care/cancer-basics/what->

treatment based on the “specific characteristics of [an] individual[]” or “the genetic profile of an individual’s tumor” has already been recognized as a smarter, more efficient, and more precise method of oncological medicine, and has even received support from the FDA.³²

One example of an immuno-oncology success story is Keytruda. Keytruda is an FDA-approved mAb immunotherapy medicine that treats various cancers such as melanoma and non-small cell lung cancer (“NSCLC”) by helping the immune system detect and fight against cancer.³³ Instead of attacking cancer directly, Keytruda assists the body in distinguishing malignant “non-self” cells that have tried to trick the immune system by hiding behind a “self” cell disguise.³⁴ Specifically, Keytruda is an “anti-PD-1 inhibitor,”³⁵ meaning that it “blocks the activity of a molecule called PD-1,” (“[p]rogrammed cell death protein 1”³⁶), which some cancer cells exploit to avoid immunosurveillance.³⁷ PD-1 is a protein expressed on the surface of activated T-lymphocytes, which are one of the many actors within the immune system.³⁸ PD-1 naturally binds to PD-L1 (“programmed cell death receptor ligand 1”³⁹), a protein often expressed on healthy muscles and nerve cells, but sometimes on stealthy cancerous cells as well.⁴⁰ When PD-1 and PD-L1 bind, a signal is sent that inactivates the T-lymphocytes from destroying what

metastasis.

32. *Precision Medicine*, U.S. FDA (Sept. 27, 2018), <https://www.fda.gov/medical-devices/vitro-diagnostics/precision-medicine>.

33. See *Frequently Asked Questions About Keytruda*, KEYTRUDA, <https://www.keytruda.com/keytruda-faq/> (last visited Nov. 22, 2021).

34. See *id.*

35. *Pembrolizumab (Keytruda®)*, MELANOMA RSCH. ALL., <https://www.curemelanoma.org/patient-eng/melanoma-treatment/immunotherapy/pembrolizumab-keytruda/> (Aug. 2021).

36. Arlene H. Sharpe & Kristen E. Pauken, *The Diverse Functions of the PD1 Inhibitory Pathway*, 18 NATURE REV. IMMUNOLOGY 153, 153 (2018).

37. *Pembrolizumab (Keytruda®)*, *supra* note 35.

38. See Han Yao et al., *Cancer Cell-Intrinsic PD-1 and Implications in Combinatorial Immunotherapy*, FRONTIERS IN IMMUNOLOGY (July 30, 2018), <https://www.frontiersin.org/articles/10.3389/fimmu.2018.01774/full>.

39. Akintunde Akinleye & Zoab Rasool, *Immune Checkpoint Inhibitors of PD-L1 As Cancer Therapeutics*, 12 J. HEMATOLOGY & ONCOLOGY 1, 1 (2019).

40. See Erik Thunnissen & Egbert F. Smit, *Non-small-Cell Cancers of the Lung: Pathology and Genetics*, in ENCYCLOPEDIA OF CANCER (Paolo Boffetta & Pierre Hainaut, eds., 3d ed. 2019).

looks like a normal cell.⁴¹ This PD-1/PD-L1 interaction allows cancer cells to escape “immune detection and elimination.”⁴² Keytruda works to block this interaction.⁴³ By blocking PD-1 from binding to PD-L1, cancer cells become susceptible to attack by the immune system and die.⁴⁴ The use of Keytruda has reduced the risk of metastatic melanoma progression “by 43% compared to chemotherapy[,]”⁴⁵ and for NSCLC patients with high levels of PD-L1, Keytruda reduced the risk of death “by 58 percent.”⁴⁶ For biotechnology companies, scientific researchers, oncologists, cancer patients, and patients’ families, these results are “game-changing.”⁴⁷ Keytruda demonstrates the potential of immuno-oncology to extend the lives of cancer patients who previously had a poor prognosis, and the field is rapidly becoming recognized as a primary therapy for a variety of cancers.

III. IMMUNO-ONCOLOGY & THE LINK TO DIAGNOSTIC METHOD PATENTS

Diagnostic tests are used to detect immune pathways such as PD1/PD-L1.⁴⁸ A diagnostic test is “[a] type of test used to help diagnose a disease or condition.”⁴⁹ With respect to immuno-oncology, diagnostic tests are used to locate certain antigens on the surface of cancer cells, called “cancer biomarkers.”⁵⁰

41. See *Understanding PD-L1*, GENENTECH (May 16, 2016), <https://www.gene.com/stories/understanding-pd-11>.

42. *Cancer Immunotherapy and the PD-1/PDL-1 Checkpoint Pathway*, ABCAM, <https://www.abcam.com/cancer/cancer-immunotherapy-and-the-pd1pd11-pathway> (last visited Nov. 24, 2021).

43. See *Pembrolizumab (Keytruda®)*, *supra* note 35.

44. See *id.*

45. *Results from Clinical Trials with Keytruda*, KEYTRUDA, <https://www.keytruda.com/melanoma/monotherapy-clinical-trial-results/#compare-chemotherapy> (last visited Nov. 24, 2021).

46. Jamie Reno, *Keytruda Performs Well in Latest Lung Cancer Clinical Trials*, HEALTHLINE (Apr. 27, 2018), <https://www.healthline.com/health-news/keytruda-performs-well-in-latest-lung-cancer-clinical-trials#1>.

47. *Id.*

48. See Udall et al., *supra* note 4.

49. *NCI Dictionary of Cancer Terms: Diagnostic Test*, NIH NAT’L CANCER INST., <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/diagnostic-test> (last visited Nov. 24, 2021).

50. Klervi Even-Desrumeaux, et al., *State of the Art in Tumor Antigen and Biomarker Discovery*, 3 *CANCERS (SPECIAL ISSUE)* 2554, 2555 (2011).

“[C]ancer biomarkers can be defined as markers produced either by the tumor itself or by other tissues, in response to the presence of cancer or other associated conditions, such as inflammation.”⁵¹ Once identified, these biomarkers can be used in a variety of ways, including to diagnose cancer, monitor a patient’s response to treatment, and create new and innovative immunotherapies based on a particular molecular pathway.⁵²

Another example of a cancer-related diagnostic test is the test for the BRCA1 and BRCA2 gene mutations.⁵³ These mutations are associated with breast cancer.⁵⁴ Although only roughly “0.25% of the population carry a mutated BRCA1 or BRCA2 gene[,]” women who carry the BRCA mutations have a significantly “higher lifetime risk” of developing breast cancer.⁵⁵ Studies show that “55–65% of women with the BRCA1 mutation will develop breast cancer before age 70” and “[a]pproximately 45% of women with the BRCA2 mutation will develop breast cancer by age 70.”⁵⁶ Moreover, “[a]bout 1 in 8 U.S. women . . . will develop . . . breast cancer over the course of her lifetime.”⁵⁷ The diagnostic test for BRCA1 and BRCA2 has significantly increased the lifespan of carriers of this deadly gene.

Due to the tremendous health benefits of identifying cancer biomarkers, the commercial value of diagnostic tests is significant. The promise of profitability, in turn, incentivizes biotechnology companies and other key scientific investigators to continue the search for additional tumor antigens, and thus creates the potential for new immunotherapy treatments. However, a recent change in Supreme Court precedent has thrown into disarray the patentability of such discoveries. In 2012, the Supreme Court handed down its unanimous ruling in

51. *Id.* at 2555.

52. *See id.*

53. *See Genetic Testing for Breast Cancer*, NAT’L BREAST CANCER FOUND., INC., <https://www.nationalbreastcancer.org/genetic-testing-for-breast-cancer> (last visited Nov. 25, 2021).

54. *See BRCA Gene Test for Breast and Ovarian Cancer Risk*, MAYO CLINIC (Aug. 12, 2021), <https://www.mayoclinic.org/tests-procedures/brca-gene-test/about/pac-20384815>.

55. *BRCA: The Breast Cancer Gene*, NAT’L BREAST CANCER FOUND., INC. (Apr. 15, 2020), <https://www.nationalbreastcancer.org/what-is-brca>.

56. *Id.*

57. *U.S. Breast Cancer Statistics*, BREASTCANCER.ORG, https://www.breastcancer.org/symptoms/understand_bc/statistics (Feb. 4, 2021).

Mayo Collaborative Services v. Prometheus Laboratories, Inc., holding that diagnostic methods for detecting cancer biomarkers were unpatentable under 35 U.S.C. § 101, the section of the law that determines the subject matter eligibility of patents.⁵⁸ The Court held that such diagnostic method patents are not patentable because they “effectively claim natural laws or natural phenomena” (i.e., seek to patent processes that occur effortlessly in nature).⁵⁹ This ruling, and several Supreme Court cases that followed it, have created new challenges for the scientists and companies that are developing therapies based on immuno-oncology.

IV. 35 U.S.C. § 101 AND THE “LAWS OF NATURE”

Under 35 U.S.C. § 101, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”⁶⁰ This statute, which was most recently revised in 2019, “limit[s] the subject matter that is eligible for patenting.”⁶¹ In order to successfully obtain a patent, the claimed invention must meet the United States Patent and Trademark Office’s (“USPTO”) two criteria for subject matter eligibility.⁶² According to the USPTO, the first criteria is that “the claimed invention must be to one of the four statutory categories . . . of invention that Congress deemed to be the appropriate subject matter of a patent: processes, machines, manufactures and compositions of matter.”⁶³ The second criteria is that “the claimed invention also must qualify as patent-eligible subject matter, i.e., the claim must not be directed to a judicial exception unless the claim as a whole includes additional limitations amounting to significantly more than the

58. See 566 U.S. 66, 73 (2012).

59. *Id.* at 76.

60. 35 U.S.C. § 101 (2019).

61. *35 USC § 101: Statutory Requirements and Four Categories of Invention*, U.S. PAT. & TRADEMARK OFF. (Aug. 2015), https://www.uspto.gov/sites/default/files/101_step1_refresher.pdf.

62. See *2106 Patent Subject Matter Eligibility*, U.S. PAT. & TRADEMARK OFF. (June 25, 2020, 6:21 PM), <https://www.uspto.gov/web/offices/pac/mpep/s2106.html#d0e197244>.

63. *Id.*

exception.”⁶⁴ Courts have interpreted judicial exceptions to include “abstract ideas, laws of nature, and natural phenomena (including products of nature).”⁶⁵ This is problematic for diagnostic method patents because these terms typically cover “the basic tools of scientific and technological work” such as scientific principles and naturally occurring phenomena.⁶⁶ For example, a diagnostic test that locates the presence of a naturally occurring antigen on the surface of a tumor is considered to claim a “law of nature,” or in other words, a judicially recognized exception.⁶⁷

The USPTO’s judicial exceptions are at the crux of diagnostic method claims patentability. Since malignant tumor antigens are a product of nature, and products of nature are unpatentable, the ability to secure a patent for a diagnostic test that tests for the presence (or absence) of specific cancer biomarkers has been thrown into disarray. Without the means to acquire a patent, the monetary value of diagnostic testing has diminished, and consequently, innovation has been hindered. Also, importantly, instead of disclosing these inventions to the public, as occurs in the quid pro quo of obtaining a patent,⁶⁸ biotechnology companies and other scientific researchers who have already found (and are continuing to find) new tumor targets will likely keep their diagnostic tests as trade secrets, preventing others from benefiting from those discoveries.⁶⁹

V. MAYO, MYRIAD, ALICE & THE LOWER COURTS’ APPLICATION

Mayo was the first of three Supreme Court cases that changed the rules of patent-eligibility for diagnostic method claims. In *Mayo*, plaintiff Prometheus Laboratories, Inc. (“Prometheus”), brought a claim for patent infringement against defendants Mayo Clinic Rochester and Mayo Collaboratives Services (collectively “Mayo”) after Mayo purchased

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.*

68. See Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 125 (2006).

69. See *What Is a Trade Secret?*, WORLD INTEL. PROP. ORG., <https://www.wipo.int/tradesecrets/en/> (last visited Nov. 25, 2021).

Prometheus' diagnostic tests but then decided to sell a similar version of its own.⁷⁰ The diagnostic tests at issue were created by Prometheus and assessed the dosages of thiopurine drugs given to patients to treat autoimmune diseases such as ulcerative colitis.⁷¹ Through administration of the test, doctors were able to determine how a patient was metabolizing the thiopurine compounds and then adjust the given dose to make sure it was not too low or too high because if left unadjusted, it could either cause harm or ineffectiveness for the patient.⁷² For many years, Mayo bought and used these diagnostic tests.⁷³ However, "in 2004 Mayo announced that it intended to begin using and selling its own test—a test using somewhat higher metabolite levels to determine toxicity . . ."⁷⁴ Prometheus then brought a claim for patent infringement against Mayo.⁷⁵

The Supreme Court ultimately invalidated Prometheus' patents on the ground that they only "set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm."⁷⁶ Because the patents simply described those natural relations, and did not add anything more or apply them in any way, they were not eligible for patentability.⁷⁷ Prometheus' patents set forth a three-step process that doctors could take in order to gather data about a patient.⁷⁸ These steps, the Court held, were not "sufficient to transform the nature of the claim."⁷⁹ Unlike the Court of Appeals for the Federal Circuit ("CAFC"), who believed that this process passed under the "machine or transformation test," which would have brought the patents within the scope of § 101, the Court held that the steps were merely instructions that added "nothing specific to the laws of nature other than what [was] well-understood, routine, conventional activity, [and]

70. *See Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 75 (2012).

71. *See id.* at 73.

72. *See id.*

73. *See id.* at 75.

74. *Id.*

75. *See id.*

76. *Id.* at 77.

77. *See id.*

78. *Id.* at 78.

79. *Id.*

previously engaged in by those in the field.”⁸⁰ Further, the Court emphasized that “upholding [these] patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.”⁸¹

One year later, in *Association for Molecular Pathology v. Myriad, Genetics, Inc.*, the Supreme Court issued another unanimous decision “invalidating patent claims directed toward isolated DNA molecules derived from the human genome.”⁸² In *Myriad*, defendant Myriad Genetics, Inc. (“Myriad”) “discovered the precise location and sequence” of the BRCA1 and BRCA2 gene mutations and “obtained a number of patents based upon its discovery.”⁸³ As previously mentioned, these mutations are associated with a dramatically increased risk of developing breast cancer.⁸⁴ Myriad was able to identify “the exact location of the BRCA1 and BRCA2 genes” on two specific chromosomes, and from there, could determine the genes’ typical nucleotide sequence.⁸⁵ This information “enabled Myriad to develop medical tests that [were] useful for detecting mutations in a patient’s BRCA1 and BRCA2 genes and thereby assess[] whether the patient ha[d] an increased risk of cancer.”⁸⁶ By claiming patent rights over this DNA isolation, Myriad had “the exclusive right to isolate an individual’s BRCA1 and BRCA2 genes.”⁸⁷ When Myriad found out that other parties were offering genetic testing for the BRCA gene mutations, they sent these parties letters “asserting that the genetic testing infringed Myriad’s patents.”⁸⁸ These parties, which included doctors, medical laboratories, and advocacy groups, responded by filing suit “seeking a declaration that Myriad’s patents [were] invalid” under § 101.⁸⁹

80. *Id.* at 82.

81. *Id.* at 73.

82. Christopher M. Holman, Mayo, Myriad, and the Future of Innovation in Molecular Diagnostics and Personalized Medicine, 15 N.C. J.L. & TECH. 639, 640 (2014).

83. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 579–80 (2013).

84. *See id.* at 583.

85. *Id.*

86. *Id.*

87. *Id.* at 585.

88. *Id.*

89. *Id.* at 586.

Referencing its previous holding in *Mayo*, the Court again held that “laws of nature, natural phenomena, and abstract ideas are not patentable . . . Rather, ‘they are the basic tools of scientific and technological work’ that lie beyond the domain of patent protection.”⁹⁰ The Court reasoned that since Myriad “did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes” and because “[t]he location and order of the nucleotides existed in nature before Myriad found them,” the patents were invalid.⁹¹ In sum, “[a] naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated”⁹² As in *Mayo*, the Court determined that Myriad’s patents lacked an innovative method, were well understood by scientists at the time the patents were obtained, and did not involve any new application of the knowledge.⁹³ Although Myriad’s diagnostic test was agreed to be immensely important for human health, the Court held that without more, it was not enough to surpass the judicial exception of “the laws of nature.”⁹⁴

In *Alice Corporation Pty. v. CLS Bank International*, the Supreme Court was asked to determine whether certain patents disclosing a computer-implemented scheme for mitigating “settlement risk” were patent-eligible under § 101.⁹⁵ The defendant Alice Corporation (“Alice”) claimed the patents protected an invention that “facilitate[d] the exchange of financial obligations between two parties by using a computer system as a third-party intermediary.”⁹⁶ This was done through a computer system that instructed “financial institutions to carry out ‘permitted’ transactions” based on “‘shadow’ credit and debit records . . . that mirror[ed] the balances in the parties’ real-world accounts” at institutions such as banks.⁹⁷ Based on these “shadow” records, the intermediary was able to mitigate “the risk that only one party [would] perform the agreed-upon

90. *Id.* at 589.

91. *Id.* at 590.

92. *Id.* at 576.

93. *See id.* at 595–96.

94. *Id.*

95. 573 U.S. 208, 212 (2014).

96. *Id.* at 213.

97. *Id.*

exchange.”⁹⁸ Plaintiffs CLS Bank International and CLS Services Ltd. (collectively “CLS Bank”) operated “a global network that facilitate[d] currency transactions.”⁹⁹ CLS Bank filed suit against Alice, “seeking a declaratory judgment that the claims at issue [were] invalid, unenforceable, or not infringed.”¹⁰⁰ Alice counterclaimed, “alleging infringement.”¹⁰¹

The Court, in line with *Mayo* and *Myriad*, invalidated the patents under the judicially recognized exceptions to § 101, which exclude “[l]aws of nature, natural phenomena, and abstract ideas” from eligible subject matter.¹⁰² The Court held that the patent claims at issue were directed to an abstract idea, and thus were patent-ineligible.¹⁰³ The Court reasoned that the claims were drawn to “the concept of intermediated settlement” and this concept was “a fundamental economic practice long prevalent in our system of commerce.”¹⁰⁴ It was determined that the claims did nothing more than “recite the concept of intermediated settlement as performed by a generic computer.”¹⁰⁵ This, the Court held, was equivalent to claiming the “building blocks” of human ingenuity, which, if patentable, “would risk disproportionately tying up the use of the underlying’ ideas, and [were] therefore ineligible for patent protection.”¹⁰⁶ Because these patents merely claimed the “building blocks,” as opposed to integrating them into a new and useful inventive concept, they “fail[ed] to transform that abstract idea into a patent-eligible invention.”¹⁰⁷ Alice’s claims could not be protected under § 101.

In light of these decisions, lower courts have attempted to clarify what *Mayo*, *Myriad*, and *Alice* actually mean. The CAFC, which has nationwide jurisdiction over patent suits, has struggled to provide consistent guidance on the application of § 101 to its sister circuits, the district courts, and to the makers of

98. *Id.* at 214.

99. *Id.*

100. *Id.*

101. *Id.*

102. *Id.* at 216.

103. *See id.* at 219.

104. *Id.* (quoting *Bilski v. Kappos*, 561 U.S. 593, 611 (2010)).

105. *Id.* at 225.

106. *Id.* at 217. (quoting *Mayo Collaborative Servs. v. Prometheus Lab’s, Inc.*, 566 U.S. 66, 73 (2012)).

107. *Id.* at 221.

diagnostic method patents.¹⁰⁸ For example, in 2016, the CAFC vacated and remanded the District Court's conclusion in *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*¹⁰⁹ In *CellzDirect*, the District Court granted summary judgment invalidating certain patents for being "directed to a patent-ineligible law of nature" under § 101.¹¹⁰ The invention at issue involved hepatocytes, which are a "type of liver cell that have a number of attributes useful for testing, diagnostic, and treatment purposes."¹¹¹ However, "fresh hepatocytes can only be obtained from liver resections or non-transplantable livers of organ donors, and their lifespan is short," making their supply limited and unpredictable.¹¹² In order to preserve the supply, they are often frozen at polar temperatures in a process called "cryopreservation."¹¹³ Yet scientists are well-aware that cryopreservation has its drawbacks; mainly because hepatocytes can only be frozen and thawed once before becoming too damaged for further use.¹¹⁴ That was until Rapid Litigation Management Ltd. ("IVT") discovered a way for hepatocytes to "surviv[e] multiple freeze-thaw cycles."¹¹⁵ Upon this discovery, IVT "developed an improved process of preserving hepatocytes" and claimed it in a patent.¹¹⁶ In short, the process involved thawing the hepatocytes, separating the viable from non-viable ones, and refreezing only the viable cells, which showed to exhibit "70% viability after the second thaw" upon later use.¹¹⁷ When CellzDirect, Inc. ("LTC") began employing this improved process in their own hepatocyte production, IVT sued for patent infringement.¹¹⁸ LTC responded by filing "a motion for summary judgment of invalidity under 35 U.S.C. §§ 101 and 112."¹¹⁹ The

108. *See Court Jurisdiction*, U.S. CT. OF APPEALS FOR THE FED. CIR. (Nov. 24, 2021, 9:09 PM), <http://www.cafc.uscourts.gov/the-court/court-jurisdiction>.

109. *Rapid Litig. Mgmt. v. CellzDirect, Inc.*, 827 F.3d 1042, 1044 (Fed. Cir. 2016).

110. *Id.*

111. *Id.* at 1045.

112. *Id.*

113. *Id.*

114. *See id.*

115. *Id.*

116. *Id.*

117. *Id.*

118. *See id.* at 1046.

119. *Id.*

District Court granted LTC’s motion on the ground that IVT’s patent was invalid based on the “Supreme Court’s two-step framework for determining patent eligibility.”¹²⁰ At step one, the patent was found to fall under the “law of nature” exception.¹²¹ At step two, the patent was found to lack “the requisite inventive concept” necessary to survive protection under § 101.¹²² IVT appealed to the CAFC.¹²³

Upon review, the CAFC vacated and remanded the District Court’s judgment. The CAFC disagreed with the District Court’s interpretation of what constitutes a “natural law” and, in doing so, held that IVT’s claim was patent-eligible. Under step one of the Supreme Court’s two-part test, the CAFC determined that the patent at issue was not merely directed to a natural discovery—the capability of the hepatocyte cells to survive multiple freeze-thaw cycles—but instead claimed a “new and improved way of preserving hepatocyte cells for later use.”¹²⁴ The CAFC went further to “immediately distinguish[]” this case from Supreme Court precedent, holding that the claimed invention involved an innovative method of “producing a tangible and useful result,” which falls outside of the “categories of inventions that are ‘directed to’ patent-ineligible concepts.”¹²⁵ Even if the claim did not survive step one, the CAFC held that it would still pass under step two because claims that “‘improve[] an existing technological process’ are sufficient to ‘transform[] the process into an inventive application’ of the patent-ineligible concept.”¹²⁶ Either way, IVT’s invention constituted patent-eligible subject matter under § 101.

This case was a huge sigh of relief for those who had still been reeling from the outcomes of *Mayo*, *Myriad*, and *Alice*. Even the former Commissioner for Patents at the USPTO, Robert Stoll, agreed that the holding in *CellzDirect* was “very heartening.”¹²⁷ Some considered the decision a “significant

120. *Id.*

121. *Id.*

122. *Id.*

123. *See id.*

124. *Id.* at 1048.

125. *Id.* at 1048, 1050.

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

127. Gene Quinn, *Federal Circuit Gives Patent Eligibility Relief to Life Sciences Sector*, IPWATCHDOG (July 5, 2016),

turning point” from the Supreme Court’s broad interpretation of patent-ineligible subject matter.¹²⁸ For the companies, scientists, and inventors interested in securing diagnostic method patents, *CellzDirect* was the beacon of hope they had been waiting for.

Those hopes were short-lived when, in 2019, the CAFC decided *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC*. Athena Diagnostics (“Athena”) was the exclusive licensee of a patent that covered methods for diagnosing rare neurological disorders, such as myasthenia gravis (“MG”), by detecting the binding of a patient’s autoantibodies to a protein called muscle-specific tyrosine kinase (“MuSK”).¹²⁹ Through a process of iodination and immunoprecipitation (which were undisputed as known techniques in the art at the time of the invention), a sample of a patient’s bodily fluid was tested for the binding of their autoantibodies to a MuSK epitope.¹³⁰ The sample was then tested for radioactivity, which was indicative of MG.¹³¹ After Mayo Collaborative Services, LLC (“Mayo”) “developed two or more competing tests that allegedly practice[d]” the steps in Athena’s patent, “Athena accused Mayo of patent infringement.”¹³² Mayo moved to dismiss, arguing that the claims in Athena’s patent were invalid under § 101.¹³³ The District Court, citing *Mayo*, granted the motion, and Athena appealed.¹³⁴

The CAFC affirmed the District Court’s conclusion that Athena’s patent claims were “directed to a law of nature.”¹³⁵ Since the claims focused on the interaction between autoantibodies in bodily fluid and a MuSK epitope, which was a relationship that occurred naturally for some people with MuSK-related neurological disorders, the CAFC, in a split decision, determined that the patent fell within a judicial

<https://www.ipwatchdog.com/2016/07/05/federal-circuit-patent-eligibility-life-sciences/id=70614/>.

128. *Id.*

129. *See Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 746 (Fed. Cir. 2019).

130. *See id.* at 748.

131. *See id.*

132. *Id.* at 746.

133. *See id.* at 746.

134. *See id.* at 748.

135. *Id.*

exception to § 101.¹³⁶ In other words, the patent claims failed under the first step of the Supreme Court’s two-step test for patent-eligibility. Additionally, the CAFC held that Athena’s claims failed under step two of the test because they merely recited steps involving standard techniques in the art (iodination and immunoprecipitation) and thus “lacked an inventive concept.”¹³⁷ Athena argued that the claims did provide an inventive concept: “a new laboratory technique,” which consisted of a sequence of steps “us[ing] man-made molecules” to detect MuSK autoantibodies.¹³⁸ Athena contended that because there was no way to diagnose these rare neurological conditions prior to their invention, their diagnostic method claims were new, unobvious, and safe from patent-ineligibility.¹³⁹ However, the CAFC struck down these arguments as insufficient.¹⁴⁰ Distinguishing this case from *CellzDirect*, the CAFC held that Athena’s invention, unlike IVT’s, did not use an unconventional combination of steps, but instead performed “standard techniques in a standard way to observe a newly discovered natural law.”¹⁴¹ Without any technical improvement, the CAFC held that the patent claims at issue could not be afforded any protection under § 101.¹⁴² According to the CAFC, Athena had failed to transform its patent-ineligible diagnostic method into a patent-eligible invention. Athena subsequently requested a rehearing en banc.¹⁴³

The request was denied.¹⁴⁴ In an eighty-six-page order, which included “eight separate opinions” with four judges “concurring with the *en banc* denial and another four dissenting from the decision,” the conflicting opinions reflected that the

136. *See id.* at 748–49.

137. *Id.* at 748.

138. *Id.* at 750.

139. *See id.* at 754.

140. *See id.* at 752–53.

141. *Id.* at 754.

142. *See* Robert Stoll, *What Happens to Diagnostic Method Patents After Athena?*, IPWATCHDOG (Mar. 6, 2019), <https://www.ipwatchdog.com/2019/03/06/diagnostic-method-patents-athena/id=107058/>.

143. *See* Athena v. Mayo: A Splintered Federal Circuit Invites Supreme Court or Congress to Step Up on 101 Chaos, IPWATCHDOG (July 8, 2019), <https://www.ipwatchdog.com/2019/07/08/splintered-federal-circuit-invites-supreme-court-review-athena-v-mayo/id=111055/>.

144. *See id.*

CAFC was not “divided so much on the issue of the importance of Athena’s now invalidated patent claims but, rather, the application of the U.S. Supreme Court’s [§] 101 jurisprudence under *Mayo*.”¹⁴⁵ For example, some concurring judges approved of the *Mayo* subject matter framework, while others considered it “harder to apply consistently” than the previously decided patent-eligibility standards.¹⁴⁶ On the other hand, some dissenting judges considered *Mayo* to have been “mistakenly enlarged” by the CAFC, causing the holding to be extended much farther than it was intended to reach.¹⁴⁷ However, both the concurring and dissenting opinions agreed that it should be the Supreme Court, not the CAFC, that “clarif[ies] *Mayo*’s judicial exception to [the] laws of nature and its impact on patent claims covering medical diagnostics.”¹⁴⁸ Athena ultimately petitioned for a writ of certiorari.¹⁴⁹ Despite the CAFC’s cry for Supreme Court intervention on the subject, the Court denied the request, as further discussed below.

Why the apparent disconnect between the holding in *Athena* as opposed to the holding in its predecessor *CellzDirect*? Interestingly, the three Judges who decided *CellzDirect*, Chief Judge Prost, Judge Stoll, and Judge Moore, were not all in harmony on the issue presented in *Athena*. With Chief Judge Prost concurring with the en banc denial of *Athena*, and both Judge Stoll and Judge Moore dissenting from the denial of the request, it is clear that there is still disagreement on the interpretation of the *Mayo* framework, which is leading to ongoing, inconsistent, and confusing jurisprudence.¹⁵⁰

The implications of *Athena* rippled through the scientific community and dashed the hopes of many stakeholders. *Athena* was viewed by many as an inconsistent application of Supreme Court precedent regarding the eligibility of diagnostic method

145. *Id.*

146. *Id.*

147. *Id.*

148. *Athena Implores Supreme Court to Heed Federal Circuit’s ‘Unprecedented Cry for Help’*, IPWATCHDOG (Oct. 3, 2019), <https://www.ipwatchdog.com/2019/10/03/athena-implores-supreme-court-heed-federal-circuits-unprecedented-cry-help/id=114201/>.

149. See Petition for Writ of Certiorari, *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed. Cir. 2019) (No. 19-430).

150. See *Athena v. Mayo: A Splintered Federal Circuit Invites Supreme Court or Congress to Step Up on 101 Chaos*, *supra* note 143.

patent claims under 35 U.S.C. § 101. Without any consistent rules as to what is and is not patentable, the makers of diagnostic tests are left without any understanding as to which of their innovations are patentable, thereby leading to a disturbing effect on development. Noteworthy, in a footnote of the CAFC opinion, the *Athena* majority admitted that they felt compelled by the Supreme Court to render their decision in favor of patent-ineligibility (“[o]ur precedent leaves no room for a different outcome here”¹⁵¹), but “recognized that protection of diagnostic methods would be good for society.”¹⁵² The dissent in *Athena* noted that the CAFC’s “decisions on the patent-ineligibility of diagnostic methods are not consistent, and . . . exacerbate the judge-made disincentives to development of new diagnostic methods, with no public benefit.”¹⁵³ For the millions of people who could live better and healthier lives with the help of these diagnostic tests, including the roughly 1.8 million Americans who were diagnosed with cancer in 2019, innovation is essential.¹⁵⁴ Therefore, it is imperative that the courts provide inventors and the other stakeholders of diagnostic method patents with clarity and consistency on what is patent-eligible.

VI. WHERE DOES THAT LEAVE US?

In the wake of *Athena*, many members of the intellectual property community have come forward to express their discontentment with the CAFC’s decision, and to ask the Supreme Court for clarification on when diagnostic tests can be patentable.¹⁵⁵ For example, the Biotechnology Innovation Organization (“BIO”), which is the principal trade association representing the biotechnology industry both domestically and abroad, issued a statement in August 2018 asking the Supreme

151. *Athena Diagnostics, Inc.*, 915 F.3d at 764 n.4.

152. Stoll, *supra* note 142.

153. *Athena Diagnostics, Inc.*, 915 F.3d at 757 (Newman, J., dissenting).

154. See *Cancer Facts & Figures 2019*, AM. CANCER SOC’Y, <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2019.html> (last visited Nov. 25, 2021).

155. See Tiffany Hu, *Ex-Fed. Circ. Judge Decries ‘Fundamental Rift’ Over Eligibility*, LAW360 (Nov. 1, 2019, 9:35 PM), https://www.law360.com/ip/articles/1216107?utm_source=shared-articles&utm_medium=email&utm_campaign=shared-articles.

Court for guidance on the eligibility of nature-based products.¹⁵⁶ BIO's main concern was that ever since the *Mayo* decision was rendered, "increasing uncertainty exists about the patent-eligibility of biotechnological products that incorporate naturally-occurring substances, and of methods using such products in therapeutic [and] diagnostic . . . processes."¹⁵⁷ This "unstable state of patent-eligibility jurisprudence" subsequently affects modern biotechnologies "[a]s the developers of, and investors in . . . [the] technologies" cannot predict the rules of patent-eligibility for the claimed inventions.¹⁵⁸ In other words, with much risk and without the guarantee of reward, investment in biotechnological innovation is inhibited due to the unavailability of patent protection.¹⁵⁹ Therefore, it is highly important for biotechnology stakeholders to obtain clarification regarding patent-eligibility for naturally occurring products (such as diagnostic tests used to diagnose and treat cancer) under 35 U.S.C. § 101.

In addition to the biotechnology stakeholders, even the former CAFC Chief Judge Paul Michel, has publicly urged the Supreme Court to grant certiorari to "clear up the 'fundamental rift' within the" CAFC, which had caused "disharmony, disagreement, and inconsistency" on the issue of patent-eligibility.¹⁶⁰ In his amicus brief, which was filed in support of Athena's petition for certiorari, Judge Michel went further to say that the CAFC's misinterpretation of Supreme Court precedent has "created an unbounded and detrimental uncertainty in biotechnology innovation" and the law now needs "correction."¹⁶¹ Eleven other stakeholders, including "intellectual property or patent law associations," law professors, and "biotechnological, pharmaceutical or medical disease associations," also filed amicus briefs in support of Athena.¹⁶² Nevertheless, on January

156. See Letter from Hans Sauer, Deputy Gen. Couns., VP for Intell. Prop., for Biotechnology Innovation Org., to Hon. Andrei Iancu, Director of the U.S. Pat. & Trademark Off. (Aug. 20, 2018) (on file with the USPTO).

157. *Id.*

158. *Id.*

159. *See id.*

160. Hu, *supra* note 155.

161. *Id.*

162. Leslie Kushner, *Patenting Diagnostic Tests: Can We Expect Changes?*, LAW J. NEWSLS. (Jan. 2020) <http://www.lawjournalnewsletters.com/2020/01/01/patenting-diagnostic-tests->

13, 2020, the Supreme Court denied certiorari.¹⁶³

By denying certiorari the Supreme Court has left it up to Congress to determine whether a change in § 101 should be fixed by legislation.¹⁶⁴ The Court solidified its stance on January 27, 2020, when it denied certiorari from three other petitioners who were seeking a more “cohesive understanding” of § 101.¹⁶⁵ Several CAFC Judges are in agreement with the idea of legislative reform.¹⁶⁶ For instance, Judge Kathleen O’Malley has stated “I encourage Congress to amend the Patent Act once more . . .” to clarify the § 101 standard.¹⁶⁷ Under the congressional action approach, “a bicameral, bipartisan group for Congress, initiated by Senators Coon (D-DE) and Tillis (R-NC) [has] released a draft bill to reform § 101 of the Patent Act.”¹⁶⁸ This draft includes “new text for § 101” and creates “a ‘practical exception’ test to ensure that” patent-ineligible categories are narrowly construed.¹⁶⁹ Another important feature of this draft is its “default position on eligibility.”¹⁷⁰ Simply put, “to address a concern that courts will seek to interpret the new statutory language to salvage many of the existing judicial exceptions” the bill has an “Additional Legislative Provisions” section that “explicitly states that the ‘provisions of [§] 101 shall be construed in favor of eligibility.’”¹⁷¹ This could be significant for reducing the “challenges to patents under § 101.”¹⁷² Although the draft is still “open to discussion,”¹⁷³ it has “already been the subject of hearing before the Intellectual Property Sub-Committee of the

can-we-expect-changes/.

163. See *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 140 S. Ct. 855 (2020) (mem.) (No. 19-430).

164. See Kushner, *supra* note 162.

165. Dani Kass, *Justices Reject 3 More Cases Challenging Alice*, LAW360 (Jan. 27, 2020, 3:12 PM), <https://www.law360.com/articles/1236828>.

166. See Kushner, *supra* note 162.

167. *Id.*

168. *Id.*

169. Christopher P. King, *Patent Eligibility Reform in Congress: Updates on the Coons/Tillis Proposal*, FENWICK: BILSKI BLOG (June 4, 2019), <https://www.bilskiblog.com/2019/06/patent-eligibility-reform-in-congress-updates-on-the-coons-tillis-proposal/#more-3974>.

170. *Id.*

171. *Id.*

172. *Id.*

173. *Id.*

Senate Judiciary Committee.”¹⁷⁴ However, legislation is a slow-moving process, so it may be some time before the draft bill, if ever, evolves into law.

If a legislative fix is attempted, guidance may be available by looking at other countries’ guidelines on diagnostic method patent-eligibility. For example, the European Patent Office (“EPO”), which is responsible for grants of European patents for the Contracting States to the European Patent Convention, has some significant differences from the USPTO with regard to the discovery and patentability of natural phenomenon that American diagnostic method patent reform could benefit from.¹⁷⁵ The USPTO and EPO are alike in that “the discovery of a natural phenomenon is not patent eligible,” but the EPO differentiates from the USPTO in that “a patentable invention can derive from a practical use of that discovery . . . such as its use in a method of diagnosis.”¹⁷⁶ This means that “the discovery of a naturally occurring correlation between a biomarker and a disease can be put to a practical use in the form of a method for diagnosing the disease” and thus be transformed into a patentable invention.¹⁷⁷ For diagnostic tests that use this same pattern, such as those that test for specific biomarkers on tumor cells in order to diagnose different kinds of cancer, the EPO’s perspective on patent-eligibility is ideal. This is because although these claims are objectionable under current USPTO standards, they are patentable by EPO standards. By altering the USPTO’s subject matter eligibility requirements to more closely mirror Europe’s approach, American diagnostic method patent claims may have more success under § 101.

Change is likely inescapable, but how far and wide that change may reach is what remains to be seen. With a growing demand for medical innovation, particularly related to the development of immuno-oncology therapies for cancer treatments, patent protection for diagnostic testing methods is more necessary now than ever. These tests, which require a

174. Kushner, *supra* note 162.

175. See Hazel Ford, *Patentability of Diagnostic Methods in Europe*, FINNEGAN (Jan. 4, 2018), <https://www.finnegan.com/en/insights/blogs/european-ip-blog/patentability-of-medical-methods-in-Europe-copy.html>.

176. *Id.*

177. *Id.*

large monetary investment (the average cost to develop a diagnostic test in the United States “is \$50 to \$75 million”¹⁷⁸), are invaluable to the patients who can benefit from them. Therefore, it is crucial to incentivize investment in these life-saving diagnostic testing methods. In the absence of such motivation, society could face “significant costs in human health, lives, and medical care.”¹⁷⁹ Immuno-oncology and the future of modern cancer care may very well depend on the coming changes to the subject matter eligibility analysis under 35 U.S.C. § 101.

VII. THE NEED FOR LAW & MODERN TECHNOLOGY TO CO-EXIST

The law is backward-looking; it focuses on case precedent and prior judicial interpretation to establish principles and maintain synonymy. On the other hand, science and technology are forward-looking; they are constantly evolving and going through cycles of revision as new information develops or comes to the forefront. Put differently, science and modern technology are quick to embrace change, while the law is much slower to accept it. But the law, science, and modern technology inevitably intersect, so they must find a way to exist together.

The Supreme Court initially sent shockwaves through the intellectual property community in 2012 with its unanimous decision in *Mayo*, where it narrowly interpreted patent-eligible subject matter under 35 U.S.C. § 101. Eight years later, after a fragmented application of Supreme Court precedent by the CAFC, stakeholders in the biotechnology community are still trying to understand the new patent-eligibility requirements. With the Supreme Court’s January 2020 denial of Athena’s recent petition for a writ of certiorari, it is clear that clarification will likely not be coming from the judiciary. Instead, it may be up to Congress to either amend or draft new legislation that will provide biotechnology stakeholders with proper guidance on what can and cannot be patented. With the rapid advances in technology that are offering revolutionary new treatments for the diseases in which there were few options only a short time ago, it is important that a legislative fix comes sooner rather

178. Kushner, *supra* note 162.

179. *Id.*

than later.

One of the most important groups of stakeholders who are particularly anxious to see a change in USPTO patent-eligibility under § 101 are the cancer patients themselves. As discussed in this Note, immunotherapy has proven to “extend and save the lives of many cancer patients” and “holds the potential to become more precise, more personalized, and more effective than current cancer treatments.”¹⁸⁰ In a world where people are forced to fight cancer every day, immunotherapy is the breakthrough that patients, their families, their doctors, and society as a whole has been hoping for. With immuno-oncology’s power to transform modern cancer care, it is imperative that the law finds a way to co-exist and indeed foster innovation in this technology.

VIII. ADDENDUM (WRITTEN APRIL 2020)

In light of the novel coronavirus (“COVID-19”) outbreak, a highly contagious flu-like respiratory illness which was officially declared a global pandemic by the World Health Organization on March 11, 2020, the need for scientific innovation and new medical discoveries (e.g., diagnostic tests, antiviral therapies, and a vaccine) are absolutely crucial for the health of society.¹⁸¹ With over 1.8 million people diagnosed around the globe (over 500,000 in the United States alone) in the first five months,¹⁸² this contagion has caused the world to stop and “social distance” until an effective remedy becomes available.¹⁸³ This is yet another, and even more pressing, example of why clarification under 35 U.S.C. § 101 is necessary.

On March 23, 2020, the Naples Roundtable made one of the first major pushes for a further explanation on subject matter

180. *What Is Cancer Immunotherapy?*, *supra* note 9.

181. *See Coronavirus Disease 2019 (COVID-19) Situation Summary*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html> (Feb. 25, 2020).

182. *See COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE)*, JOHNS HOPKINS U. & MED., <https://coronavirus.jhu.edu/map.html> (last visited Nov. 26, 2021).

183. Nell Greenfieldboyce, *New Analysis Suggests Months of Social Distancing May Be Needed to Stop Virus*, NPR (Mar. 17, 2020, 4:03 PM), <https://www.npr.org/sections/health-shots/2020/03/17/817214311/new-analysis-suggests-months-of-social-distancing-may-be-needed-to-stop-virus>.

patent-eligibility since the COVID-19 pandemic first exploded out of its epicenter in Wuhan, China.¹⁸⁴ In a letter written to Andrei Iancu, the Director of the USPTO, the Naples Roundtable asked Iancu “to designate two Patent Trial and Appeal Board opinions dealing with the patent eligibility of medical inventions as precedential” because the COVID-19 pandemic undoubtedly “highlights the need for clarity.”¹⁸⁵ In both opinions, medical invention patent applications were found to be patent-eligible under § 101.¹⁸⁶ According to the Naples Roundtable, this was significant, as “[t]he need for ongoing medical discovery and innovation in the life sciences” is critical in the face of the public health crisis that is the COVID-19 pandemic.¹⁸⁷ As stated in the letter to Iancu, the pandemic “will require innovation that should not be inhibited by a misapplication” of § 101.¹⁸⁸ In order to promote and incentivize this innovation, “[d]esignating these decisions as precedential will reduce the likelihood that [§] 101 will be misapplied and, in turn, will . . . encourage a robust response” to the crisis.¹⁸⁹ As the world grapples with COVID-19, anxiously waiting for fast-acting diagnostic testing kits, effective antiviral treatments, and ultimately an FDA-approved vaccine, it is in the hands of the USPTO to give the American people the relief they have been desperately waiting for.

Additionally, the COVID-19 pandemic should further motivate different groups of stakeholders to push harder for legislative reform. As argued in this Note, with the Supreme Court unwilling to grant certiorari to refine its previous interpretations of *Mayo*, *Myriad*, and *Alice*, it is more likely that Congress will be the vessel to provide the much-needed and more unified understanding of what constitutes patent-eligible subject matter under § 101. As the COVID-19 pandemic pushes individual Americans and their families (including many on Capitol Hill), the overall healthcare system, and the entire

184. See Dani Kass, *Kappos Says Pandemic Calls for New Medical IP Precedent*, LAW360 (Mar. 23, 2020, 8:07 PM), <https://www.law360.com/articles/1255666/kappos-says-pandemic-calls-for-new-medical-ip-precedent>.

185. *Id.*

186. *See id.*

187. *Id.*

188. *Id.*

189. *Id.*

global economy to its limits, this is the time for stakeholders to push the legislative branch to act. Reform under § 101 of the Patent Act is past due.

In conclusion, the world is currently facing very uncertain and unprecedented times, as the COVID-19 pandemic continues to sweep from its original outbreak in China to almost every country on Earth.¹⁹⁰ Due to the highly contagious nature of the virus, paired with its zero-immunity tolerance level, it has become immensely important for medical advances and scientific innovation to have the proper flexibility to patent new findings, targets, and therapies under 35 U.S.C. § 101. For example, the ability to diagnostically test for the novel coronavirus was one of the many hurdles recently faced in the race to contain the pandemic.¹⁹¹ Further, when moving forward to create a vaccine, one of the first steps will involve finding how the virus initially enters the cell (subsequently infecting the host and making it sick).¹⁹² Without the certainty of patent protection under § 101 for the inventions required to address this plague, stakeholders from both the public and private sectors may be reluctant to invest in the innovation necessary to fully address the pandemic. There has never been a more urgent need to incentivize American innovation to solve this global problem and save countless lives. The COVID-19 pandemic has shone a spotlight on the need to address the subject matter eligibility of these inventions and hopefully will stimulate a rapid and thoughtful legislative response.

190. See *Global COVID-19: For Non-U.S. Settings*, CDC (Jan. 20, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/world-map.html>.

191. See Sam Baker, *The Problems with Our Coronavirus Testing Are Worse Than You Think*, AXIOS (Mar. 16, 2020), <https://www.axios.com/coronavirus-outbreak-testing-delays-60a25ce6-f08d-438f-b294-358e0c300d95.html>.

192. See Stephanie Pappas, *Scientists Figure Out How New Coronavirus Breaks into Human Cells*, LIVESCI. (Mar. 11, 2020), <https://www.livescience.com/how-coronavirus-infects-cells.html>.