
PATENT ELIGIBILITY OF NATURAL PRODUCTS: A GROWING PROBLEM

ABSTRACT

From the inception of the Constitution, the United States has protected inventions in the form of patent rights. For many years, innovation thrived and protections for patent rights continued to expand. However, beginning in 2012, the Supreme Court decisions of Mayo, Myriad, and Alice created a new barrier for what can be considered patent-eligible subject matter. These decisions completely undermined the patent system and made obtaining a patent an impossibility for several fields of invention.

By focusing on one type of technology—natural products—this Note examines the recent subject-matter eligibility decisions from the Supreme Court and the impact they have had on patent eligibility of natural products. This Note also discusses why those decisions were fundamentally made in error and proposes several solutions to the problem. While the problem the Supreme Court created is far more complicated than this Note could hope to address, it is apparent that Congress needs to intervene in order for the United States to remain competitive in the global economy by incentivizing advances in technology.

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I. INTRODUCTION

Improvements in technologies related to natural products are essential to any developed society. From human gene therapies in the field of medicine to genetically modified plants in the field of agriculture, we rely on our ever-expanding knowledge of the natural sciences. A robust patent system is a vital component of this process because patents incentivize innovation in these areas.¹ Without the possibility of receiving a patent in exchange for years of research and the associated costs, many would hesitate to invest in these technologies.² For many years, patent eligibility was not an issue.³ However, a handful of recent Supreme Court cases have made patent eligibility an independent obstacle—one which has become insurmountable in certain fields of invention.⁴

This Note will first discuss natural products and their scientific background in Part II and the history of patent eligibility regarding natural products in Part III.⁵ This Note next discusses recent Supreme Court decisions regarding patent eligibility in Part IV.⁶ This Note will then examine the impact of these cases in Part V,⁷ as well as the conflict these cases have created between the Supreme Court and the U.S. Court of Appeals for the Federal Circuit, and problems facing patent practitioners with regards to this conflict in Part VI.⁸ Finally, this Note will discuss the future of patent eligibility and possible solutions to the current problems facing patents directed towards natural products in Part VII.⁹

II. OVERVIEW OF NATURAL PRODUCTS

Before addressing patent eligibility of natural products, it is necessary to first explain how the U.S. Patent and Trademark Office (USPTO) defines

1. Kristina Lybecker, *How to Promote Innovation: The Economics of Incentives*, IPWATCHDOG (July 21, 2014), <http://www.ipwatchdog.com/2014/07/21/promote-innovation-the-economics-of-incentives/id=50428/>.

2. *Id.*

3. *See id.*

4. *See Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2352 (2014); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72–74 (2012).

5. *See infra* Parts II, III.

6. *See infra* Part IV.

7. *Infra* Part V.

8. *Infra* Part VI.

9. *Infra* Part VII.

“natural products.” In a recent Guidance,¹⁰ the USPTO stated that natural products include, but are not limited to, the following categories: chemicals derived from natural sources, foods, “metals and metallic compounds that exist in nature,” minerals, natural materials, nucleic acids, organisms, proteins and peptides, and other naturally occurring substances.¹¹ Of these categories, nucleic acids and organisms, which include plants, are most relevant to this Note.¹²

A. Brief Overview of Genetics

In order to understand why nucleic acids are important in the field of natural products, it is useful to review their biological structure and function. The central dogma of all biology is that “the coded genetic information hard-wired into DNA is transcribed into individual transportable cassettes, composed of messenger RNA (mRNA); each mRNA cassette contains the program for synthesis of a particular protein (or small number of proteins).”¹³ Expanding on that, segments of deoxyribonucleic acid (DNA) form genes, which are the base unit of genetics.¹⁴ Genes contain all of the information necessary to create proteins and ultimately the structure and function of living organisms.¹⁵ DNA is made of varying combinations of four different molecules called nucleotides.¹⁶ The four types of nucleotides are

10. The Commissioner for Patents issues Guidances in order to instruct patent examiners on legal issues. See *Patent Examination Policy*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/patent/laws-and-regulations/patent-examination-policy> (last visited Sept. 26, 2016).

11. Memorandum from Andrew H. Hirshfeld, Deputy Comm’r for Patent Examination Office, on 2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena, and/or Natural Products to Patent Examining Corps to Patent Examining Corps (Mar. 4, 2014), https://web.archive.org/web/20170704215708/https://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf [hereinafter Hirshfeld 2014 Memorandum].

12. See *id.*

13. HARVEY LODISH ET AL., *MOLECULAR CELL BIOLOGY* 5 (Sara Tenney et al. eds., 4th ed. 2000).

14. David N. Finegold, *Overview of Genetics*, MERCK MANUAL, <http://www.merckmanuals.com/professional/special-subjects/general-principles-of-medical-genetics/overview-of-genetics> (last updated June 2017).

15. *Id.*

16. *Deoxyribonucleic Acid (DNA)*, NAT’L HUM. GENOME RES. INST., <https://www.genome.gov/25520880/deoxyribonucleic-acid-dna-fact-sheet/> (last updated June 16, 2015).

adenine (A), thymine (T), cytosine (C), and guanine (G).¹⁷ These nucleotides are arranged in complimentary base pairs—A with T and C with G.¹⁸ Information is contained within the linear configuration of these nucleotides, similar to the lines of code used by computer programmers.¹⁹ Together, these structural factors result in two complementary strands of nucleotides arranged in a double-helix pattern.²⁰

The information in DNA then undergoes a process called transcription, where it is converted to ribonucleic acid (RNA).²¹ RNA also consists of a strand of nucleotides, though uracil (U) replaces the thymine (T).²² At the initiation of transcription, the double helix is separated and unwound.²³ The strands then become templates for the complementary RNA sequences, called messenger RNA (mRNA).²⁴ The mRNA is then transported to a different part of the cell, where protein synthesis can begin.²⁵

Translation is the process in which the constituent nucleotides of the mRNA strand are translated into amino acids, which are the building blocks of proteins.²⁶ The mRNA connects to a ribosome, which is the structure in which protein synthesis occurs.²⁷ Combinations of nucleotides within the mRNA code form different amino acids, which are recruited and linked as the mRNA passes through the ribosome.²⁸ The resulting chain of amino acids is a protein.²⁹ Thus, the nucleotide sequence of the DNA directly controls the resulting protein through the processes of transcription and

17. *Id.*

18. *Id.*

19. See Mike DeHaan, *Comparing the Genetic Code of DNA to Binary Code*, DECODED SCI. (Aug. 25, 2015), <https://www.decodedscience.org/comparing-genetic-code-dna-binary-code/55476>.

20. *Id.*

21. BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 332 (Majorie Anderson et al. eds., 5th ed. 2008).

22. *Id.*

23. *Id.* at 333.

24. *Id.* at 333, 335.

25. *Id.* at 364.

26. GEOFFREY M. COOPER, *THE CELL: A MOLECULAR APPROACH* 273–74 (2d ed. 2000).

27. *Id.* at 273–75, 282–89.

28. *Id.* at 282–89.

29. *Id.*

translation.³⁰

Of course, there are many exceptions to the simplified “DNA-makes-RNA-makes-protein” relationship. For example, while there are numerous different types of cells in the body (bone, muscle, liver, etc.), the DNA sequences (stored in the form of separate chromosomes), as well as the genes contained therein, are essentially identical.³¹ This is possible because different sections of a DNA sequence (i.e., genes) are differentially expressed with respect to the timing (in the context of cellular development) and quantity of any given gene product expressed for each different cell type—a process controlled by the DNA sequence itself.³² Additionally, the process of alternative splicing results in proteins with different functions being derived from the same DNA sequence.³³ The DNA sequence contains sections that encode certain proteins, called exons, and intervening sections that do not encode proteins, called introns.³⁴ The DNA is transcribed and the intron sequences are spliced out, leaving an RNA model with only coding sequences for a particular gene product or protein.³⁵

RNA is far more important than a simple intermediary between DNA and protein, though.³⁶ One example is the formation of complimentary DNA (cDNA).³⁷ cDNA is a double-stranded DNA that is synthesized from a single-stranded RNA molecule.³⁸ The synthesis of cDNA begins with an RNA template and an enzyme called reverse transcriptase, which essentially reverses the normal process of transcription.³⁹ This cDNA can then be used to clone a gene that may not normally be present in high quantities in the

30. Finegold, *supra* note 14.

31. *See id.*; *see also* Katherine Barrington, *Why Do We Need Cells?*, BRIGHT HUB EDUC. (Apr. 7, 2015), www.brighthubeducation.com/science-homework-help/106593-types-of-cells-in-the-human-body/.

32. *See* Finegold, *supra* note 14.

33. Yevgeniy Grigoryev, *What Is Alternative Gene Splicing and Why Is It Important?*, BITESIZEBIO (Dec. 28, 2012), <http://bitesizebio.com/10148/what-is-alternative-splicing-and-why-is-it-important/>.

34. Finegold, *supra* note 14.

35. *Id.*

36. *See generally* *The RNA Revolution: Biology's Big Bang*, ECONOMIST (June 14, 2007), <http://www.economist.com/node/9339752> (discussing the growing importance of RNA in the field of biology).

37. *See cDNA (Complimentary DNA)*, HUMANGENES.ORG, <http://humangenes.org/cdna-complementary-dna> (last visited Oct. 5, 2017).

38. *Id.*

39. *Id.*

cell.⁴⁰

The basics of genetics can quickly become complicated beyond the topics covered here (e.g., post-translational modification of proteins and epigenetics). While it is not important to understand every minute detail of how gene expression works, it is the aforementioned principles that form the basis of biotechnology and genetic engineering.

B. Genetic Engineering of Plants

While the basic principles of genetic engineering apply to many species,⁴¹ this Note will focus on genetic modification of plants specifically. Genetic engineering is defined as “[t]he act of introducing one or several new genes into an organism.”⁴² The modification could be as simple as switching out one pair of nucleotides or as complicated as introducing an entirely new gene.⁴³ In plants, these modifications are commonly used to confer resistance to insects or herbicides.⁴⁴ Corn and soybeans are some of the most commonly modified food plants in the United States,⁴⁵ both of which are of immense importance here in Iowa.⁴⁶ In fact, genetically engineered corn accounted for 92 percent of all corn acreage in 2016,⁴⁷ and Iowa produces more corn than any other state.⁴⁸ As such, intellectual property protection is important for the continued success of this industry in Iowa and beyond.

40. *See id.*

41. *See generally* CHARLOTTE K. OMOTO & PAUL F. LURQUIN, GENES AND DNA: A BEGINNER’S GUIDE TO GENETICS AND ITS APPLICATIONS (2004) (giving many examples of genetic engineering, such as plants, animals, and humans).

42. *Id.* at 209.

43. *What Is Genetic Engineering?*, YOURGENOME, <http://www.yourgenome.org/facts/what-is-genetic-engineering> (last updated Feb. 17, 2017).

44. OMOTO & LURQUIN, *supra* note 41, at 80.

45. *Id.* at 86.

46. *Value-Added Agriculture*, IOWA AREA DEV. GROUP, <http://www.iadg.com/iowa-advantages/value-added-agriculture/> (last visited Jan. 10, 2017) (stating that Iowa leads the country in production of soybeans and corn).

47. *Recent Trends in GE Adoption*, U.S. DEP’T. AGRIC.: ECON. RES. SERV., <http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx> (last updated July 12, 2017).

48. *Corn Facts*, IOWA CORN, <https://www.iowacorn.org/media-page/corn-facts/> (last visited Oct. 29, 2017).

III. PATENTABILITY OF NATURAL PRODUCTS

A. *Expansion of Protection*

Many companies working in the field of genetic engineering rely on patents to protect their intellectual property.⁴⁹ The basis for this right comes from the text of the Constitution itself, which states its purpose is “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”⁵⁰ The Patent Act of 1952 later clarified the existing patent laws, and it provided: “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”⁵¹ Patents granted under § 101 (and subsequent sections) of the Act are considered utility patents, which grant the inventor an exclusive right to make, use, or sell the invention for a period of 20 years.⁵² Utility patents are the most commonly issued type of patent, accounting for approximately 90 percent of issuances.⁵³

Patents are also available specifically to plants under the Patent Act of 1952.⁵⁴ 35 U.S.C. § 161 states: “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”⁵⁵ Plant patents convey a “right to exclude others from asexually reproducing the plant” for a period of 20 years.⁵⁶ Asexual reproduction is defined as “the propagation of a plant without the use of fertilized seeds to assure an exact genetic copy of the plant being

49. See, e.g., *Delivering Innovative Seed Technologies*, SYNGENTA, http://www.syngentabiotech.com/bio_issuedpatents.aspx (last visited Nov. 18, 2016) (listing patents held by two major genetic-engineering companies); *Patents*, MONSANTO, <http://www.monsanto.com/newsviews/pages/patents.aspx> (last visited Nov. 18, 2016).

50. U.S. CONST. art. I, § 8, cl. 8.

51. 35 U.S.C. § 101 (2012).

52. *Types of Patents*, U.S. PAT. & TRADEMARK OFF. (Mar. 31, 2016), <https://www.uspto.gov/web/offices/ac/ido/oeip/taf/patdesc.htm>.

53. *Id.*

54. 35 U.S.C. § 161 (2012).

55. *Id.*

56. *General Information About 35 U.S.C. 161 Plant Patents*, U.S. PAT. & TRADEMARK OFF. (Aug. 14, 2014), <https://www.uspto.gov/patents-getting-started/patent-basics/types-patent-applications/general-information-about-35-usc-161>.

reproduced.”⁵⁷ Therefore, because asexual reproduction is a product of human intervention and not nature, it makes sense to allow a period of exclusive use similar to that of a utility patent.⁵⁸

Even with the enactment of 35 U.S.C. § 161, a gap existed in intellectual property protection because plant patents were not available for sexually reproducing plants or tubers, such as potatoes.⁵⁹ This defect was remedied with the introduction of the Plant Variety Protection Act (PVPA) of 1970.⁶⁰ The PVPA covers any new variety of seed or tuber, which extends to sexually reproducing plants.⁶¹ The term of protection is also similar to plant patents, with 20 years of protection for most varieties and 25 years for vines and trees.⁶²

However, there are drawbacks involved in using plant variety protection, which come in the form of three exemptions.⁶³ First, the PVPA provides for public interest in wide usage, which can eliminate coverage for plants if the U.S. Department of Agriculture declares it necessary to ensure “an adequate supply of fiber, food, or feed in this country and that the owner is unwilling or unable to supply the public needs for the variety at a price which may reasonably be deemed fair.”⁶⁴ Second, it is not considered infringement if a person saves seeds descended from protected plants.⁶⁵ Third, the “research exemption” makes bona fide research an exemption to infringement.⁶⁶ Overall, these three exemptions significantly limit the scope

57. *Id.*

58. *See id.*

59. *Id.*

60. 7 U.S.C. §§ 2321–2582 (2012) (§ 2325 repealed 1980, §§ 2463, 2502–03 repealed 1994).

61. *Id.*; *Plant Variety Protection*, U.S. DEP’T AGRIC., <https://www.ams.usda.gov/services/plant-variety-protection> (last visited Nov. 17, 2016).

62. *Plant Variety Protection*, *supra* note 61.

63. *See* 7 U.S.C. §§ 2404, 2543–44.

64. 7 U.S.C. § 2404.

65. 7 U.S.C. § 2543. Seed-saving is a problem because it allows farmers to purchase the proprietary seeds once and then replant the same variety in subsequent years, potentially even distributing the variety to other farmers. *See Why Does Monsanto Sue Farmers Who Save Seeds?*, MONSANTO (Apr. 11, 2017), <https://monsanto.com/company/media/statements/saving-seeds/>. This prevents the inventors from making any returns on their investment in developing new varieties. *See, e.g., id.* (discussing the rationale behind why Monsanto sues individuals who save seeds).

66. 7 U.S.C. § 2544. The statute does not provide a definition for “bona fide research,” however this can be understood as research that is done for the advancement of science and is publicly published. *Bona Fide Research*, MED. RES. COUNCIL,

of the plant breeder's exclusive right to the variety.

The scope of protection was increased, however, in 2001, when the Supreme Court confirmed that utility patents could be issued for sexually reproducing plants.⁶⁷ In *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, Pioneer held patents for hybrid corn seeds and licensed them under a provision prohibiting “the use of such seed or the progeny thereof for propagation or seed multiplication or for production or development of a hybrid or different variety of seed.”⁶⁸ J.E.M. Ag Supply purchased seeds under this license and then resold the bags, which directly violated the patent license.⁶⁹ Pioneer then brought an infringement suit, and J.E.M. Ag Supply brought a counterclaim that the patent was invalid, arguing sexually reproducing plants were not patentable subject matter under 35 U.S.C. § 101.⁷⁰ Nevertheless, the Supreme Court held plants could be protected under the PVP or a utility patent, as the requirements to obtain a utility patent are far more stringent.⁷¹ Because plants are eligible to receive utility patents, they are also implicated by the potential problems caused by the natural products doctrine.

B. Limitations on Protection

There have always been limitations on what can be patented. For example, “a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity.”⁷² In 1948, the Supreme Court held that “manifestations of laws of nature” are “part of the storehouse of knowledge . . . free to all men and reserved exclusively to none.”⁷³ These limitations were later clarified as the judicial exceptions to the four statutory categories of patentability.⁷⁴ The

<http://www.nshd.mrc.ac.uk/data/data-sharing/meta-data-repository/bona-fide-research/> (last visited Oct. 6, 2017).

67. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 145–46 (2001).

68. *Id.* at 128.

69. *Id.*

70. *Id.* at 128–29.

71. *Id.* at 142.

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

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

74. U.S. PATENT & TRADEMARK OFFICE, *THE MANUAL OF PATENT EXAMINING PROCEDURE* § 2106 (9th ed. 2015), <https://www.uspto.gov/web/offices/pac/mpep/s2106.html> (noting that the four statutory categories are: process, machine, manufacture,

exceptions were first defined in an early case, *Diamond v. Chakrabarty*, which questioned whether genetically modified microorganisms could be patented.⁷⁵ The microbe at issue was a bacterium that had been modified to break down crude oil.⁷⁶ The Court held that the microbe was indeed patent eligible but defined the exceptions to patentability, which are “laws of nature, physical phenomena, and abstract ideas.”⁷⁷

In the past, § 101 drew very little consideration, partly because of the broad language of the statute.⁷⁸ Patent eligibility applied to “anything under the sun that is made by man.”⁷⁹ As such, isolated DNA patents were routinely issued from the 1980s until very recently.⁸⁰ The rationale behind this practice was that the isolation of a gene product was, in effect, creating an entirely new composition.⁸¹

Even though [DNA] is found in nature, as is said, what the patent is granted on is not the form that’s found in nature, but, rather, for the isolated and purified form of that gene. The chemical composition of that gene or that gene fragment has never been known before, and the scientist who made that discovery, has made that invention, and is entitled to it because they have isolated and purified it.⁸²

The USPTO clearly agreed with that assessment, as it is estimated that as many as 40,000 DNA-related patents were issued by 2005.⁸³ Within the past decade, though, the Supreme Court has introduced ambiguity into the system, making patent eligibility uncertain for several different fields of

and composition of matter).

75. *Chakrabarty*, 447 U.S. at 305.

76. *Id.*

77. *Id.* at 309–10.

78. See 35 U.S.C. § 101 (2012) (stating there are no explicit limitations, just the implied judicial exceptions).

79. *Chakrabarty*, 447 U.S. at 309 (quoting S. REP. NO. 1979, at 5 (1952); H.R. REP. NO. 1923, at 6 (1952)).

80. John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part I)*, 85 J. PAT. & TRADEMARK OFF. SOC’Y 301, 304 (2003); see, e.g., U.S. Patent No. 5,747,282 (issued May 5, 1998) (entitled “17Q-linked Breast and Ovarian Cancer Susceptibility Gene”).

81. Symposium, *The Human Genome Project: DNA Science and the Law: The American Legal System’s Response to Breakthroughs in Genetic Science*, 51 AM. L. REV. 371, 377 (2002) (remarks of Todd Dickinson).

82. *Id.*

83. Eric J. Rodgers, Note, *Can You Patent Genes—Yes and No*, 93 J. PAT. & TRADEMARK OFF. SOC’Y 19, 19 (2011).

invention.⁸⁴

IV. RECENT TRENDS IN SUBJECT-MATTER ELIGIBILITY

A string of recent cases have made patent eligibility an actual, independent obstacle, rather than “merely a label to be applied when a claimed invention is found to be new and useful.”⁸⁵ The first was *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, which related to a medical test for determining a personalized dosage of a drug.⁸⁶ The claims involved administering the drug to a patient and measuring the level of a particular metabolite in the patient’s blood.⁸⁷ The measured metabolite levels, when compared to the optimal metabolite range, indicate whether to increase or decrease the drug dosage.⁸⁸ The Supreme Court unanimously ruled this method was not eligible for patent protection, claiming the correlation between drug dosage and metabolite levels was a law of nature, and the additional claimed steps were considered to be simply the routine activities of researchers.⁸⁹

The Supreme Court continued the trend of invalidating claims in *Association for Molecular Pathology v. Myriad Genetics, Inc.*⁹⁰ The patented technology at issue was a genetic test for two cancer-associated genes.⁹¹ The patents claimed segments of genomic DNA (gDNA), as well as cDNA.⁹² The pertinent difference between these types of molecules is that the gDNA can be extracted directly from cells, whereas cDNA is usually synthesized in a lab (i.e., not naturally occurring).⁹³ In another unanimous decision, the Supreme Court held that naturally occurring DNA segments are products of nature even when isolated from an organism’s genome and are therefore

84. Chris Coons, *A Few Thoughts on the Supreme Court’s Section 101 Jurisprudence*, IPWATCHDOG (Feb. 8, 2017), <http://www.ipwatchdog.com/2017/02/08/thoughts-supreme-courts-section-101-jurisprudence/id=78166/>.

85. Conley & Makowski, *supra* note 80, at 303.

86. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 74–75 (2012).

87. *Id.* at 74.

88. *Id.* at 75.

89. *Id.* at 79–80.

90. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013).

91. *Id.* at 2112–13.

92. *Id.*; see Dan L. Burk, *The Curious Incident of the Supreme Court in Myriad Genetics*, 90 NOTRE DAME L. REV. 505, 507–08 (2014).

93. See JAMES D. WATSON ET AL., *MOLECULAR BIOLOGY OF THE GENE* 749 (Beth Wilbur et al. eds., 6th ed. 2008).

patent-ineligible subject matter.⁹⁴ However, the Court did find that cDNA is patentable because it is not naturally occurring.⁹⁵

Nevertheless, there is a fundamental problem with Justice Clarence Thomas's reasoning in *Myriad*. The opinion reasons that gDNA is unpatentable because the nucleotide sequence contains the same coding sequence as the human chromosome, despite the fact that chemical composition would be changed.⁹⁶ On the flip side, the reasoning given for the patentability of cDNA is that there are structural differences between the molecule after going through reverse transcription and the molecule present in the human chromosome, because the introns have been removed.⁹⁷ The opinion glosses over the fact that the cDNA also has the same coding sequence as the naturally occurring genome.⁹⁸ Therefore, the Supreme Court created a situation where molecules that have the same coding information as a naturally occurring molecule are both patent-eligible and patent-ineligible subject matter, and molecules that have a different chemical structure are also both patent-eligible and patent-ineligible subject matter.⁹⁹

The USPTO issued a Guidance the day the *Myriad* decision came down, which merely instructed the examiners that “[a]s of today, naturally occurring nucleic acids are not patent eligible merely because they have been isolated.”¹⁰⁰ The narrow reading gave no guidance about the eligibility of other molecules.¹⁰¹ Still, practitioners at the time believed the consequences to biotechnology would be minimal, as cDNA is far more essential to the later stages of any biotech-related invention.¹⁰²

That belief was shattered when the *Alice Corp. Pty. Ltd. v. CLS Bank*

94. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2120.

95. *Id.* at 2119.

96. *Id.* at 2118.

97. *Id.* at 2119.

98. Burk, *supra* note 92, at 508.

99. *Id.*

100. Memorandum from Andrew W. Hirshfeld, Deputy Comm'r for Patent Examination Office, Supreme Court Decision in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* (June 13, 2013), https://www.uspto.gov/sites/default/files/patents/law/exam/myriad_20130613.pdf.

101. *See id.*

102. Jason Rantanen, *Myriad: Isolated DNA Out, cDNA In*, PATENTLYO (June 13, 2013), <http://patentlyo.com/patent/2013/06/myriad-isolated-dna-out-cdna-in.html>.

International decision came down.¹⁰³ *Alice* is different because it involved a computer-implemented business method rather than a life sciences technology.¹⁰⁴ The patent in this case claimed a method for exchanging financial obligations, a computer used to perform the method, and software that instructed the computer to perform the method.¹⁰⁵ The Supreme Court once again unanimously ruled that the technology was not eligible for patent protection since it was simply an abstract idea implemented.¹⁰⁶

Alice's legacy is the two-part test the Supreme Court applies in invalidating claims.¹⁰⁷ First, the Court determines whether the claim is directed to a patent-ineligible concept.¹⁰⁸ If it is, the Court then moves on to the second step, which is an analysis of "whether the additional elements 'transform the nature of the claim' into a patent-eligible application."¹⁰⁹ The analysis hinges on separating "patents that claim the 'buildin[g] block[s]' of human ingenuity and those that integrate the building blocks into something more."¹¹⁰

Alice is relevant to the biotech industry because it was quickly cited in a Federal Circuit case in which additional *Myriad* genetic-testing patents were invalidated.¹¹¹ These patents claimed primers derived from genomic DNA, as well as methods for comparing a patient's DNA sequence for a particular gene to the naturally occurring sequence.¹¹² The court found that primers were simply isolated DNA segments which are patent-ineligible subject matter under *Myriad*.¹¹³ The court then used the *Alice* test to find that the method claims were patent ineligible because the court held that the comparison of a patient's DNA to a reference sequence is an abstract mental step.¹¹⁴

103. *Alice Corp. Pty. Ltd., v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014).

104. *Id.* at 2352.

105. *Id.*

106. *Id.* at 2360.

107. *Id.* at 2355.

108. *Id.* (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)).

109. *Id.* at 2355 (quoting *Mayo Collaborative Servs.*, 566 U.S. at 78).

110. *Id.* at 2354 (alterations in original) (quoting *Mayo Collaborative Servs.*, 566 U.S. at 89).

111. *BRCA1 v. Ambry Genetics Corp.*, 774 F.3d 755, 763 (Fed. Cir. 2014).

112. *Id.* at 758–59.

113. *Id.* at 761.

114. *Id.* at 764.

V. IMPACT ON NATURAL PRODUCTS

The *Mayo*, *Myriad*, and *Alice* line of cases have majorly impacted many areas of technology, and not in a good way. It is particularly easy to see the effect of these cases by examining the number of § 101 rejections patent examiners issue for patent applications.¹¹⁵ In January of 2012, zero percent of plant-related applications received eligibility rejections.¹¹⁶ However, by October of the same year, approximately 67 percent of plant-related applications were rejected on subject-matter eligibility grounds.¹¹⁷ So what happened in between those two time periods that could transform a virtually untouched technology into an ineligible application? The *Mayo* decision came down on March 20, 2012.¹¹⁸

Things seemed to settle down once the March 2014 Guidance was issued.¹¹⁹ From July 2014 to April 2015, the § 101 rejection rate was back down to zero percent for plant-related patent applications.¹²⁰ In that Guidance, the Deputy Commissioner stated, “There is *no change* to examination of claims reciting an abstract idea, which should continue to be analyzed for subject-matter eligibility using the existing Guidance in MPEP § 2106(II)[,]” which seemed to signify a return to the well-known policy of years before.¹²¹ However, the rejection rate jumped back up to 50 percent in May 2015, “likely a result again of the USPTO’s Interim Guidance which essentially instructed examiners to reject any claim that included any form of a natural product.”¹²²

However, the Supreme Court’s interpretation in *Mayo*, *Myriad*, and *Alice* as applied to plant-related applications directly contradicts congressional intent regarding this technology.

Legislative history, such as the House and Senate Reports accompanying the Plant Patent Act of 1930, expresses Congress’s understanding that the patent laws have always applied “both to the acts

115. Robert R. Sachs, *The One Year Anniversary: The Aftermath of #Alicestorm*, BILSKIBLOG (June 20, 2015), <http://www.bilskiblog.com/blog/2015/06/the-one-year-anniversary-the-aftermath-of-alicestorm.html>.

116. *Id.*

117. *Id.*

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

119. See Hirshfeld 2014 Memorandum, *supra* note 11.

120. Sachs, *supra* note 115.

121. Hirshfeld 2014 Memorandum, *supra* note 11.

122. Sachs, *supra* note 115.

of inventing and discovery.”

Furthermore, the intent to protect *conventional* applications of new discoveries was incorporated directly into § 101 of the 1952 Act. The legislative history of the Plant Patent Act shows that Congress defined routine and conventional applications of new discoveries as patent-eligible subject matter under § 101’s predecessor statute, R.S. § 4886. And the legislative history of the 1952 Act shows that Congress intended to carry forward that standard of patent-eligibility in § 101.¹²³

Thus, there is no indication that Congress intended for an “inventive application” requirement, and the Supreme Court misinterpreted both legislative and case law history in deciding the *Mayo*, *Myriad*, and *Alice* cases.¹²⁴ As a result, many plant-related technologies have been declared unpatentable.¹²⁵

VI. CURRENT CONFUSION

The Supreme Court in *Alice* states: “In applying the [35 U.S.C.S.] § 101 exception, [the] Court must distinguish patents that claim the ‘buildin[g] block[s]’ of human ingenuity, . . . from those that integrate the building blocks into something more, . . . thereby ‘transform[ing]’ them into a patent-eligible invention.”¹²⁶ The problem is that the Court provided no guidance on what qualifies as “something more.”¹²⁷

At first, *Alice* was thought to be a minor case with limited applicability. The Court stated that it “tread[s] carefully in construing this exclusionary

123. Jason Rantanen, *Patent Protection for Scientific Discoveries: Sequenom, Mayo, and the Meaning of § 101*, PATENTLYO (Apr. 22, 2016), <https://patentlyo.com/patent/2016/04/protection-scientific-discoveries.html>.

124. See Peter S. Menell & Jeffrey A. Lefstin, *Restoring the Legislative Framework for Patenting Applications of Scientific Discoveries 2* (U.C. Berkeley Pub. Law Research Paper No. 2767904, 2016), <https://ssrn.com/abstract=2767904>.

125. See Sachs, *supra* note 115.

126. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2350 (2014) (third, fourth, and fifth alterations in original).

127. See *Eclipse IP LLC v. McKinley Equip. Corp.*, No. SACV 14-154-GW(AJWx), 2014 WL 4407592, at *3 (C.D. Cal. Sept. 4, 2014) (“So, the two-step test may be more like a one step test evocative of Justice Stewart’s most famous phrase. See *Jacobellis v. State of Ohio*, 378 U.S. 184, 197 (1964) (Stewart, J., concurring) (‘I shall not today attempt further to define the kinds of material I understand to be embraced within that shorthand description; and perhaps I could never succeed in intelligibly doing so. But I know it when I see it’)).”)

principle lest it swallow all of patent law. . . . At some level, ‘all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.’”¹²⁸ However, in the two years following *Alice*, the Federal Circuit invalidated 95 percent of the claims in 40 cases involving subject-matter eligibility, which of course means the lower courts applied *Alice* far more broadly than the Supreme Court anticipated.¹²⁹

A simple explanation for the problem is that the technical nature of many patents far exceeds the scientific knowledge of the Justices. For example, in *Myriad*, Justice Antonin Scalia wrote his concurring opinion to explain that he did not understand the science involved in the case.¹³⁰ Thus, part of the current conflict between § 101 jurisprudence and the tech and biotech industries could be explained by the Justices not truly understanding the patents that they are ruling on.¹³¹

Another problem is that the Supreme Court seems to have conflated the requirements of 35 U.S.C. § 103 in determining patent eligibility.¹³² Section 103 provides that an invention will not receive a patent “if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious.”¹³³ In other words, an invention cannot be patented if it merely combines elements of prior art in a predictable manner.¹³⁴ Therefore, when the Court invalidates a patent because it does not add “something more” to an abstract idea, it seems as though the Court is applying obviousness or inventiveness rationales, rather than genuine issues of subject-matter eligibility.¹³⁵

128. *Alice*, 134 S. Ct. at 2354 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012)).

129. Robert R. Sachs, *Two Years After Alice: A Survey of the Impact of a “Minor Case” (Part I)*, BILSKI BLOG, (June 16, 2016), <http://www.bilskiblog.com/blog/2016/06/two-years-after-alice-a-survey-of-the-impact-of-a-minor-case.html>.

130. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2120 (2013) (Scalia, J., concurring in part and concurring in the judgment).

131. See Ron Katznelson, *Can the Supreme Court’s Erosion of Patent Rights Be Reversed?*, IPWATCHDOG (March 2, 2017), <http://www.ipwatchdog.com/2017/03/02/supreme-courts-erosion-patent-rights-reversed/id=78992/> (citing “the Justices’ lack of science and technology experience, never having been closely involved in discovery and invention” as a cause for criticism).

132. 35 U.S.C. § 103 (2012).

133. *Id.*

134. See U.S. PATENT AND TRADEMARK OFFICE, *supra* note 74, § 2143 (listing rationales that support a conclusion of obviousness).

135. See *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014) (quoting

For instance, in *Myriad*, Justice Thomas relied on *Funk Bros. Seed Co. v. Kalo Inoculant Co.* in invalidating the genetic sequence patents.¹³⁶ In *Funk Bros.*, the patent at issue claimed a mixture of several bacterial species used to help certain crops grow.¹³⁷ However, those bacteria were already being sold separately for the same purpose; it was simply believed that mixing the species prior to inoculating the soil would render them ineffective.¹³⁸ The Court invalidated the patent because it would have been obvious to provide a more convenient packaging of the bacterial species that were already being used for the same purpose.¹³⁹ Thus, even though *Funk Bros.* was a decision about obviousness and inventiveness, the holding in *Myriad* relies on the premise that the *Funk Bros.* was direct precedent on the patentability of natural products.¹⁴⁰

A. Inconsistency at the Federal Circuit

Considering the flaws inherent in the *Alice* test, it is unsurprising that the Federal Circuit has had trouble applying this subject-matter eligibility standard. In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the patent claimed a method for genetic testing of fetuses by using paternally inherited, cell-free fetal DNA (cffDNA) in maternal blood.¹⁴¹ The claims involved detecting the cffDNA and then amplifying it in order to do genetic tests in a far less invasive manner than what was previously available.¹⁴² The Federal Circuit invalidated the patent because cffDNA is naturally occurring (i.e., natural phenomena) and because using methods like polymerase chain reaction to amplify the DNA were well understood and routine in the art, thus not transforming the natural phenomena into a patent-eligible application.¹⁴³

Judge Richard Linn's concurring opinion was of particular interest, as it showed how the Federal Circuit did not particularly like the test it had to

Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71, 85 (2012)).

136. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013).

137. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 128–29 (1948).

138. *Id.* at 129.

139. *Id.* at 131.

140. Ass'n for Molecular Pathology, 133 S. Ct. at 2117; *Funk Bros. Seed Co.*, 333 U.S. at 131.

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

142. *Id.*

143. *Id.* at 1376–78.

apply following *Mayo* and *Alice*, but was forced to apply it regardless.¹⁴⁴

The Supreme Court's blanket dismissal of conventional post-solution steps leaves no room to distinguish *Mayo* from this case, even though here *no one* was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers. Indeed, the maternal plasma used to be "routinely discarded," . . . because, as Dr. Evans testified, "nobody thought that fetal cell-free DNA would be present."¹⁴⁵

He also stated: "This case represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain."¹⁴⁶

Sequenom got a lot of attention because the discovery of cffDNA was massively important.¹⁴⁷ Many people thought *Sequenom* was the case for the Supreme Court to clarify the *Alice* test to make it more workable.¹⁴⁸ Many in the life sciences industry were hopeful that a Supreme Court ruling in *Sequenom* would revise the existing test and reopen patent eligibility for diagnostic and life-saving inventions.¹⁴⁹ Particularly, as previously discussed, the *Alice* holding was premised on a fundamental error.¹⁵⁰

Thus, it was surprising when the Supreme Court denied certiorari on June 27, 2016.¹⁵¹ The denial was a signal that practitioners would have to consider other ways to lessen the impact of § 101, such as congressional intervention.¹⁵² In the absence of such action, though, "the industry will

144. *See id.* at 1380 (Linn, J., concurring).

145. *Id.* at 1381 (citation omitted).

146. *Id.* at 1380.

147. *See id.* at 1381 (describing cffDNA as "truly meritorious" and a "breakthrough invention").

148. *See, e.g.,* Jason Rantanen, *Section 101—Pivotal Moment for Clarity on Patent Subject Matter Eligibility*, PATENTLYO (Apr. 21, 2016), <https://patentlyo.com/patent/2016/04/section-subject-eligibility.html>.

149. *See, e.g., id.*

150. *See* Menell & Lefstin, *supra* note 124, at 18.

151. *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 136 S. Ct. 2511, 2511 (2016).

152. Gene Quinn, *Supreme Court Denies Cert. in Sequenom v. Ariosa Diagnostics*, IPWATCHDOG (June 27, 2016), <http://www.ipwatchdog.com/2016/06/27/70409/id=70409/> ("For innovative companies in the life sciences space the only possible short-term relief will come from Congress if they choose to amend 35 U.S.C. § 101 to undo the damage done in recent years by the Supreme Court.").

continue to suffer the consequences of the Supreme Court's ignorance on the issue of patent eligibility."¹⁵³

Practitioners in the biotech industry were further surprised when the Federal Circuit later upheld a patent that applied a natural law.¹⁵⁴ The technology at issue in *Rapid Litigation Management v. CellzDirect, Inc.* involved freezing hepatocytes (liver cells) and then selecting the cells that remained viable, resulting in isolated cells that were able to withstand multiple freeze–thaw cycles.¹⁵⁵ The court held that the inventors merely claimed a particular application of a discovery, and thus the claims were not directed to a natural law.¹⁵⁶ They went on to state that even if the claims were directed to a natural law, there were enough additional steps to transform the application into an inventive process.¹⁵⁷

Given the incongruity between *Sequenom* and *CellzDirect*, some thought that the decision was a retaliation by the Federal Circuit in response to the Supreme Court denying certiorari in *Sequenom*.¹⁵⁸

With the Supreme Court recently denying *certiorari* in *Sequenom*, perhaps at least some of the Judges on the Federal Circuit believe enough is enough and it is time for them to start to apply their own independent judgment and not blindly follow the extraordinarily overbroad language of the Supreme Court that has led to truly bizarre rulings on patent eligibility in the life sciences sector—where groundbreaking innovations have been ruled patent ineligible despite everyone agreeing the innovation was of extreme importance.¹⁵⁹

After the *CellzDirect* decision came down, the USPTO issued a new memorandum that tried to reconcile the apparent conflict between *CellzDirect* and *Sequenom*.¹⁶⁰ The Guidance essentially stated that the two

153. *Id.*

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

155. *Id.* at 1045.

156. *Id.* at 1049.

157. *Id.* at 1050–51.

158. Gene Quinn, *Federal Circuit Gives Patent Eligibility Relief to Life Sciences Sector*, IPWATCHDOG (July 5, 2016), <http://www.ipwatchdog.com/2016/07/05/federal-circuit-patent-eligibility-life-sciences/id=70614/>.

159. *Id.*

160. Memorandum from Robert W. Bahr, Deputy Comm'r for Patent Examination Policy, on Recent Subject Matter Eligibility Rulings (*Rapid Litigation Management v. CellzDirect* and *Sequenom v. Ariosa*) to Patent Examining Corps 1 (July 14, 2016), https://www.uspto.gov/sites/default/files/documents/memo_rlm-sequenom.pdf.

decisions were consistent with the previous Guidance and that nothing needed to be changed.¹⁶¹ Therefore, despite a life sciences patent receiving a favorable outcome in the Federal Circuit, there was no change to patent eligibility at the USPTO.¹⁶²

Furthermore, there is no change on the horizon in terms of the Supreme Court providing clarity on the *Myriad*, *Mayo*, and *Alice* decisions, as the Court denied certiorari in all pending subject-matter eligibility cases.¹⁶³

VII. THE FUTURE OF § 101

The recent trends in § 101 jurisprudence are troubling because entire fields of industry are essentially being declared unpatentable. This directly contradicts the policy behind patents, which is to encourage invention by incentivizing discovery.¹⁶⁴ There is no doubt that the field of biotechnology is massively important for agriculture, biological research, and human health, and this should be reflected in the ability to obtain patents on these discoveries.

A. Potential Solutions

There are a number of different solutions to the problems created by the Supreme Court's intervention into subject-matter eligibility. Some patent practitioners have suggested eliminating § 101 entirely.¹⁶⁵ David Kappos, director of the USPTO from 2009 to 2013, recently called for Congress to repeal § 101.¹⁶⁶ To support his reasoning, he stated that:

When you look overseas, to China and Europe, they don't have

161. *Id.*

162. *See id.*

163. Dennis Crouch, *Not Eligible: Supreme Court Denies All Pending Subject Matter Eligibility Petitions*, PATENTLYO (Oct. 3, 2016), <http://patentlyo.com/patent/2016/10/eligible-eligibility-petitions.html>.

164. *See* U.S. CONST. art. I, § 8, cl. 8 (“To promote the Progress of Science . . .”).

165. *See, e.g.*, Daniel Cole, *Should Section 101 of the Patent Act Be Removed*, IPWATCHDOG (June 23, 2016), <http://www.ipwatchdog.com/2016/06/23/section-101-patent-act-removed/id=70230/> (“Removing 101 is a radical action. Such a radical action requires a radical need. The mess the Supreme Court has made of 101 supplies this radical need.”).

166. Ryan Davis, *Kappos Calls for Abolition of Section 101 of Patent Act*, LAW360 (Apr. 12, 2016), <http://www.law360.com/articles/783604/kappos-calls-for-abolition-of-section-101-of-patent-act>.

anything analogous to Section 101, and are they having problems? No, they are doing quite fine. You make an important software or biotech invention, and it's more likely you'll be able to get that protected in China or Europe as a patented invention than in the U.S. That is an important policy question that Congress needs to address.¹⁶⁷

Most foreign jurisdictions do not have a statutory patent eligibility requirement, and instead have an “inventive step” requirement.¹⁶⁸ The United States has the “novelty” requirement, § 103,¹⁶⁹ but the requirement is less stringent than its foreign counterpart.¹⁷⁰ Therefore, § 101 could plausibly be removed if § 103 were amended to more closely mirror its foreign counterparts.

While eliminating § 101 entirely may be a drastic option, Congress could certainly amend the statute to make it more workable. For example, the Intellectual Property Owners Association (IPO) recently proposed a new amendment to § 101.¹⁷¹ The amendment reads as follows:

101(a) ELIGIBLE SUBJECT MATTER: Whoever invents or discovers, and claims as an invention, any ~~[new and]~~ useful process, machine, manufacture, or composition of matter, or any ~~[new and]~~ useful improvement ~~[thereof]~~ thereto, ~~[may obtain]~~ shall be entitled to a patent for a claimed invention thereof ~~[therefor]~~, subject *only* to the exceptions and conditions, [and requirements] set forth in this Title [of this title].

101(b) SOLE EXCEPTION TO SUBJECT MATTER ELIGIBILITY: A claimed invention is ineligible under subsection (a) if and only if the claim as a whole, as understood by a person having ordinary skill in the art to which the claimed invention pertains, exists in nature

167. Andrew Chung, *Q&A: David Kappos on the “Mess” of Section 101 in Patent Law*, REUTERS (May 31, 2016), <http://www.reuters.com/article/ip-qa-kappos/qa-david-kappos-on-the-mess-of-section-101-in-patent-law-idUSL1N18S09N>.

168. Patent Cooperation Treaty art. 33, June 19, 1970, <http://www.wipo.int/export/sites/www/pct/en/texts/pdf/pct.pdf> (requiring patentable inventions to have an “inventive step” and “industrial applicability,” as adopted by the World Intellectual Property Organization).

169. 35 U.S.C. § 103 (2012).

170. See Patent Cooperation Treaty, *supra* note 168, art. 33.

171. INTELLECTUAL PROP. OWNERS ASS'N, PROPOSED AMENDMENTS TO PATENT ELIGIBLE SUBJECT MATTER UNDER 35 U.S.C. § 101, at 1 (2017), http://ipo.org/wp-content/uploads/2017/02/20170207_IPO-101-TF-Proposed-Amendments-and-Report.pdf.

independently of and prior to any human activity, or that exists solely in the human mind.

101(c) SOLE ELIGIBILITY STANDARD: The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard as to the requirements or conditions of sections 102, 103, and 112 of this Title, or the manner in which the claimed invention was made or discovered, or the claimed invention's inventive concept.¹⁷²

This proposal would eliminate judicial exceptions and make utility the only basis for patent eligibility.¹⁷³ The proposed amendment also strives to prevent examiners from considering other criteria, such as novelty or obviousness, in their § 101 analyses.¹⁷⁴

Another solution would be to import other considerations into the analysis of § 101. This would not be the first instance of using secondary considerations in analyzing patentability; secondary indicia of nonobviousness are already used in § 103 analyses.¹⁷⁵ “Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.”¹⁷⁶ In considering these indicia, the argument is that because there was a long-felt-but-unsolved need, for example, then the invention must not have been obvious or somebody else would have already done it.¹⁷⁷

Utilizing secondary considerations in determining patent eligibility under § 101 would give practitioners another way to show that the inventions should be patentable instead of being rejected for fitting the broad category of being directed to a law of nature. The considerations could even mirror those of § 103, such as long-felt need and commercial success.¹⁷⁸ Because the current test conflates the requirements of § 101 and § 103, practitioners should also be able to use the same kind of evidence as proof of validity.¹⁷⁹ For example, one could argue that if the claimed elements as ordered have achieved commercial success, then the claimed invention must not have been

172. *Id.* at 27–36 (emphasis added).

173. *Id.* at 27–29.

174. *Id.*

175. 35 U.S.C. § 103 (2012).

176. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

177. *Id.*

178. *See id.*

179. *See* 35 U.S.C. §§ 101, 103.

routine or conventional in the art; therefore, there should be a presumption of patent eligibility.

In a recent Supreme Court petition, DataTreasury makes a similar argument, asking whether it is necessary for a court to consider secondary indicia of invention in analyzing patent eligibility.¹⁸⁰ This is clearly the logical conclusion if the courts continue on their current path.¹⁸¹

Finally, the problem of Supreme Court overreach in patent decisions could be solved by simply not allowing the Supreme Court to hear patent cases. This is not a new solution, as many have previously criticized the Supreme Court's ability to create patent doctrine.¹⁸² Some Justices may actually prefer this solution, as Justice Scalia once remarked that he found patent cases "difficult, dull and insignificant,"¹⁸³ a sentiment likely shared by many others. Moreover, as previously discussed, the Justices do not have the requisite scientific or technical knowledge to make informed decisions about these types of cases.¹⁸⁴ In fact, the Supreme Court would presumably have little wisdom to impart once a case has already been heard at the Federal Circuit, which is the sole court that can hear patent appeals.¹⁸⁵ Thus, it seems as though patent doctrine could benefit from the Supreme Court keeping its hands off.

VIII. CONCLUSION

For most of the history of § 101, patent practitioners did not consider

180. Petition for a Writ of Certiorari at i, *DataTreasury Corp. v. Fid. Nat'l Info. Servs., Inc.*, 137 S. Ct. 1338 (2017) (No. 16–883), 2017 WL 167318, at *i.

181. See Dennis Crouch, *Supreme Court Update: Are Secondary Indicia of Invention Relevant to Eligibility?*, PATENTLYO (Feb. 8, 2017), <http://patentlyo.com/patent/2017/02/secondary-invention-eligibility.html> ("If we are going to include a 103 analysis as part of the eligibility doctrine then let[']s go whole hog.").

182. For example, Donald Chisum has remarked that the reasoning by the Supreme Court is "extraordinarily weak, illogical, ambiguous, or inconsistent" when it comes to deciding patent cases. Donald S. Chisum, *The Supreme Court and Patent Law: Does Shallow Reasoning Lead to Thin Law?*, 3 MARQ. INTELL. PROP. L. REV. 1, 4 (1999).

183. Gene Quinn, *Musings on Justice Scalia and the Hard, Dull Patent Cases*, IPWATCHDOG (July 26, 2012), <http://www.ipwatchdog.com/2012/07/26/musings-on-justice-scalia-and-the-hard-dull-patent-cases/id=26808/>.

184. See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2120 (2013) (Scalia, J., concurring) ("I am unable to affirm those details on my own knowledge or even my own belief.").

185. See John M. Golden, *The Supreme Court as "Prime Percolator": A Prescription for Appellate Review of Questions in Patent Law*, 56 UCLA L. REV. 657, 672–700 (2009).

subject-matter eligibility to be an obstacle to receiving a patent.¹⁸⁶ The biotech industry thrived under a robust patent system, and thousands of patents related to nucleic acids were issued in the years leading up to 2012.¹⁸⁷ The industry was completely upturned, however, after the *Mayo*, *Myriad*, and *Alice* decisions.¹⁸⁸

The test laid out in these cases has proven to be unworkable, and the biotech industry has been thrown into a state of turmoil as a result. In order for industries related to the life sciences to thrive, the current view of the natural products doctrine must be narrowed so that entire fields of invention are not completely wiped out.¹⁸⁹ If we are to return to a healthy patent system that encourages innovation, we must reinterpret the *Alice* test,¹⁹⁰ eliminate § 101 entirely,¹⁹¹ or introduce other considerations into analyzing patent-eligible subject matter.¹⁹²

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186. *See supra* Part III.B.

187. *See supra* Part V.

188. *See supra* Part V.

189. *See supra* Part V.

190. *See supra* Part VI.

191. *See supra* Part VII.

192. *See supra* Part IV.

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