

FUNK BROTHERS, MYRIAD, & PRODUCTS OF NATURE: HOW A LACK OF UNDERSTANDING SCIENTIFIC PRINCIPLES IS DAMAGING THE PATENT SYSTEM

I. INTRODUCTION

Ms. Urvashi Bhagat has devoted her professional career to treating disease utilizing nutrition.¹ In the mid-2000s, Ms. Bhagat focused her research on how certain lipids affect chronic illnesses.² Specifically, Ms. Bhagat researched the health effects of the omega-6 and omega-3 families of fatty acids—two types of lipids.³ Previous research indicated that high concentrations of omega-6 fatty acids had adverse health effects.⁴ Ms. Bhagat discovered that previous research was incomplete, and that higher concentrations of omega-6 fatty acids, in specific ratios with omega-3 fatty acids, had positive health effects.⁵ Eventually, Ms. Bhagat developed an ideal formulation comprised of omega-6 and omega-3 fatty acids and other vital components, which provided the benefit of overcoming adverse health conditions while minimizing the consumption of undesirable components normally consumed with omega-6 and omega-3 fatty acids.⁶ Regrettably, Ms. Bhagat was denied a patent despite her efforts.⁷

The United States patent system was designed to compensate inventors for their beneficial endeavors, and the scenario described above is an example of a person wrongly denied the benefits of the system. Ms. Bhagat

1. Urvashi Bhagat, LINKEDIN, <https://www.linkedin.com/in/urvashibhagat/> (last visited Dec. 26, 2019).

2. Lawrence H. Frank, *Where Is the Line Between Patentable Subject Matter and Non-Patentable Products of Nature?*, IPWATCHDOG (Sept. 7, 2018), <https://www.ipwatchdog.com/2018/09/07/patentable-subject-matter-non-patentable-products-of-nature/id=101134/>.

3. *Id.*

4. *Id.*

5. *Id.*

6. *Id.*

7. *Id.*

invested years of research and money to develop her invention, and therefore should be rewarded. Without the prospect of monetizing their investment, inventors like Ms. Bhagat would cease to innovate. This is exactly what the United States patent system seeks to avoid. Congress realized that “[t]o promote the Progress of Science,”⁸ inventors needed an incentive. Thus, Congress grants inventors a limited monopoly on their invention in return for disclosing their discovery to the public via the patent system.⁹

For the United States patent system to be effective, the patent community needs a clear understanding of the patentability requirements. Unfortunately, the Supreme Court’s recent decision in *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*¹⁰ has only added confusion to the patentability requirements.¹¹ Specifically, *Myriad* created ambiguity as to what qualifies as patent-ineligible product of nature because the holding conflicts with the Supreme Court’s holding in *Funk Bros. Seed v. Kalo Inoculant Co.*,¹² which was decided more than fifty years prior to *Myriad*. An analysis of the United States Patent and Trademark Office (USPTO) patent application rejections after *Myriad* indicates the patent community lacks a clear understanding as to what qualifies as patent-eligible subject matter given the increased frequency of rejections on the basis of subject matter eligibility.¹³ The Supreme Court needs to clarify the boundaries of patent eligible subject matter and restore consistency to the patent system in order to preserve the objectives the system was designed to achieve. Unless the Supreme Court reconciles the discrepancy created by *Myriad*, the biotechnology and life science communities will continue to suffer.¹⁴

Part II explains the purpose of the patent system and provides a general overview of the statutory requirements to obtain a patent. Additionally, Part II elaborates on the products of nature doctrine and explains the significance of this doctrine to the biotechnology and life science communities. Part III argues that the products of nature doctrine is frustrating the purpose of the

8. U.S. CONST. art. I, § 8, cl. 8.

9. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998).

10. 569 U.S. 576 (2013).

11. See, e.g., Peter Lee, *The Supreme Court’s Myriad Effects on Scientific Research: Definitional Fluidity and the Legal Construction of Nature*, 5 U.C. IRVINE L. REV. 1077, 1104-10 (2015).

12. 333 U.S. 127 (1948).

13. See James Cosgrove, § 101 Rejections in the Post-Alice Era, IPWATCHDOG (Mar. 7, 2017), <https://www.ipwatchdog.com/2017/03/07/101-rejections-post-alice-era/id=78635/>.

14. See Sherry Knowles, *Guest Post: Sherry Knowles Responds to USPTO Comments on New Myriad Guidelines*, MANAGING INTELL. PROP.: THE GLOBAL IP RESOURCE (Apr. 24, 2014), <http://www.managingip.com/Article/3334160/Guest-post-Sherry-Knowles-responds-to-USPTO-comments-on-new-Myriad-guidelines.html> (“The [*Myriad*] guidelines are . . . chilling any ability to attract venture capital and stripping the value of numerous emerging life science companies.”).

patent system due to conflicting Supreme Court holdings in *Funk Brothers* and *Myriad*. Part IV examines how Ms. Bhagat's Petition for Writ of Certiorari can serve as a model for future litigants to bring a case before the Supreme Court to resolve the conflicting holdings in *Funk Brothers* and *Myriad*. Part IV then utilizes Ms. Bhagat's case to propose how the Supreme Court should resolve the confusion caused by the *Myriad* holding. Part V summarizes and concludes.

II. THE UNITED STATES PATENT SYSTEM AND THE BIOLOGICAL SCIENCES

A. Patent System Principles

The United States patent system was designed to incentivize innovation in accordance with the United States Constitution.¹⁵ Article I, section 8, clause 8 of the Constitution provides: "Congress shall have [the] power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."¹⁶ The Framers understood that the public benefits from technological developments and Congress created the United States patent system to achieve that purpose.¹⁷

Accordingly, the patent system offers a monetary incentive for inventors to encourage such developments by granting inventors a limited monopoly on their invention.¹⁸ In exchange for the limited monopoly, the inventor is required to fully disclose his invention and make that disclosure available to the public.¹⁹ Hence, a patent is akin to a contract between the inventor and the public, where the inventor is granted the opportunity to exploit his invention free from competition in exchange for adding to the public's total wealth of knowledge.

The patent system, however, is a "two-edged sword."²⁰ Although the ability to exclude others from practicing one's invention provides an alluring incentive to invent, excessive protection can have an adverse effect.²¹ The exclusivity which seeks to incentivize innovation could impede technological advancements by obstructing the free flow of information.²² For example, a patent applicant was denied a patent on a novel process for making a known

15. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 6 (1966).

16. U.S. CONST. art. I, § 8, cl. 8.

17. *Graham*, 383 U.S. at 6.

18. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998).

19. 35 U.S.C. § 112 (2012).

20. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 92 (2012).

21. *Id.*

22. *Id.*

chemical compound because the applicant did not know the effects of the compound, and to grant a patent on the compound would “block off whole areas of scientific development, without compensating benefit to the public.”²³ The patent system is perpetually evolving to balance these competing considerations.²⁴

B. Statutory Requirements and Exceptions

An inventor must satisfy various statutory requirements to obtain a patent. The most notable sections of the patent statutory code are Sections 101,²⁵ 102,²⁶ and 103.²⁷ Section 101 mandates that the invention be patent eligible subject matter;²⁸ Section 102 requires the invention be “novel;”²⁹ and Section 103 requires the invention be “non-obvious.”³⁰ These statutory sections are referred to as “patentability” requirements.³¹

Section 101 states that an inventor may obtain a patent for “any new and useful process, machine, manufacture, or composition of matter.”³² Accordingly, Section 101 requires the invention be useful and be within the field the patent system was designed to protect, namely a process, machine, article of manufacture, or composition of matter.³³ In fact, the Supreme Court has stated, “anything under the sun that is made by man” has the potential to be patent eligible.³⁴

Section 102, “novelty,” requires the invention be new.³⁵ In other words, one cannot obtain a patent on technology already in existence. An invention that does not satisfy this requirement is said to be “anticipated.”³⁶ For an invention to be “anticipated,” the previous technology (referred to as “prior art”) must contain every element of the invention being claimed.³⁷

23. *Brenner v. Manson*, 383 U.S. 519, 534 (1966).

24. *Mayo*, 566 U.S. at 92.

25. 35 U.S.C. § 101 (2012).

26. *Id.* § 102.

27. *Id.* § 103.

28. *Id.* § 101.

29. *Id.* § 102.

30. *Id.* § 103.

31. *E.g.*, *United States v. Adams*, 383 U.S. 39, 48 (1966).

32. 35 U.S.C. § 101.

33. *Id.*

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

35. 35 U.S.C. § 102.

36. *Celeritas Techs. Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998).

37. *Id.*

Section 103 requires that the invention not be “obvious.”³⁸ An invention is “obvious” if a person of “ordinary skill”³⁹ in the relevant field of technology would think the claimed inventiveness was trivial. An “obviousness” analysis involves reviewing previous technology and deciding whether the claimed invention was “obvious” in light of the technologies.⁴⁰ The “non-obviousness” requirement is another safeguard to prevent the over-protection of technologies.

While Section 101 defines what qualifies as patent eligible subject matter, courts have created exceptions.⁴¹ A multitude of patent cases have been adjudicated which have resulted in the exclusion of various subject matter from Section 101.⁴² The exceptions to Section 101 include abstract ideas, natural laws, and products of nature.⁴³ “Thus, 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.”⁴⁴ This Note focuses on the products of nature exception.

Generally, the products of nature doctrine states that naturally occurring products are not patent eligible subject matter.⁴⁵ The difficulty of this doctrine is defining what constitutes a product of nature. A narrow interpretation of the doctrine could result in stifling innovation by allowing one to monopolize on a fundamental component of technology because the exceptions to the subject matter eligibility requirement can be seen as the basic tools of scientific and technological work.⁴⁶ A broad interpretation of the doctrine would make it substantially difficult for one to obtain a patent because “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.”⁴⁷ In the context of the natural products doctrine, the USPTO has explicitly mandated that for an

38. 35 U.S.C. § 103.

39. *Id.*

40. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17 (1966).

41. *See, e.g., Bilski v. Kappos*, 561 U.S. 593, 601-02 (2010); *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *In re Alappat*, 33 F.3d 1526, 1542-43 (Fed. Cir. 1994).

42. *See, e.g., Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Funk Bros. Seed v. Kalo Inoculant Co.*, 333 U.S. 127 (1948); *O'Reilly v. Morse*, 56 U.S. 62 (1853); *Le Roy v. Tatham*, 55 U.S. 156 (1852).

43. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1979).

44. *Id.*

45. John M. Conley, *Gene Patents and the Product of Nature Doctrine*, 84 CHI. KENT L. REV. 109, 113 (2008).

46. *Mayo Collaborative Serv. v. Prometheus Labs., Inc.*, 566 U.S. 66, 89 (2012).

47. *Id.* at 71.

invention to be patent eligible, it must be “markedly different” than a natural product.⁴⁸

C. The Products of Nature Doctrine and the Biological Sciences

The products of nature doctrine has special significance in the biotechnology and life science industries. Particularly, Section 101 contemplates that living organisms and multicellular animals are patent eligible subject matter.⁴⁹ The USPTO will issue patents for such organisms reasoning that they are compositions of matter or articles of manufacture.⁵⁰ Problems arise because current technology allows scientists to manipulate living organisms and natural products in ways that were not previously possible.⁵¹

The subject matter eligibility of living organisms was expressly addressed by the Supreme Court in *Diamond v. Chakrabarty*.⁵² There, the Supreme Court held that bacteria genetically engineered to degrade oil was patentable and did not fall under the products of nature exception.⁵³ Since *Chakrabarty*, the courts have continued to address the plethora of complications inherent in the patenting of inventions originated from natural products.⁵⁴

Recently, Section 101 jurisprudence has undergone substantial change in large part due to a line of cases starting with *Bilski v. Kappos*⁵⁵ in 2010 that includes *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*⁵⁶ in 2012, *Association for Molecular Pathology v. Myriad Genetics, Inc.*⁵⁷ in 2013, and *Alice Corp. v. CLS Bank International*⁵⁸ in 2014. Since *Bilski*, the number of rejections due to Section 101 has increased. According

48. See, e.g., MPEP § 2106.04(c) (2018).

49. See, e.g., *Chakrabarty*, 447 U.S. at 309.

50. See, e.g., *id.* at 314 n.9 (1980) (“In 1873, the Patent Office granted Louis Pasteur a patent on ‘yeast, free from organic germs of disease, as an article of manufacture.’ And in 1967 and 1968, immediately prior to the passage of the Plant Variety Protection Act, that Office granted two patents which, as the petitioner concedes, state claims for living micro-organisms.”).

51. See generally Ashish Swarup et al., *Biotechnology in the Realm of History*, 3(3) J. PHARMACY & BIOALLIED SCI. 321 (2011).

52. 447 U.S. 303 (1980).

53. *Id.* at 317.

54. E.g., *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013); *Mayo Collaborative Serv. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012); *Funk Bros. Seed v. Kalo Inoculant Co.*, 333 U.S. 127 (1948); *Rapid Litig. Mgmt. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).

55. 561 U.S. 593 (2010).

56. 566 U.S. 66.

57. 569 U.S. 576.

58. 573 U.S. 208.

to legal analyst James Cosgrove,⁵⁹ the number of Section 101 rejections in the molecular biology, microbiology, and immunology groups has seen an increase of roughly 5% pre-*Bilski* to 15% post-*Alice*.⁶⁰ *Mayo* and *Myriad* are the two cases dealing with the biological sciences.

This Note argues that the increased volume of 101 rejections is partly attributed to the *Myriad* holding contradicting an earlier Supreme Court decision in *Funk Brothers*. Both *Funk Brothers* and *Myriad* are Supreme Court decisions regarding the scope of the products of nature doctrine.

III. *FUNK BROTHERS* AND *MYRIAD*: CASES IN CONFLICT

A. *Funk Bros. Seed v. Kalo Inoculant Co.*

The invention at issue in *Funk Brothers* was a mixed culture of different species of Rhizobia bacteria capable of inoculating a multitude of leguminous plant seeds.⁶¹ Rhizobium bacteria play a critical role in the agriculture of leguminous plants because these bacteria enable the plants to take nitrogen from the air and fix it in the plant for conversion to organic nitrogenous compounds by infecting the roots and forming nodules.⁶² However, only a specific strain of Rhizobium bacteria will infect a certain group of leguminous plants.⁶³ Moreover, when different species of Rhizobium bacteria are mixed, the mixture results in an inhibitory effect, thereby reducing the efficiency in which the bacteria form root nodules.⁶⁴

To avoid the inhibitory effect produced when mixing the bacteria together, inoculants were sold as a single strain of the bacteria.⁶⁵ Researchers at Kalo Inoculant discovered an ideal mixture of bacteria that would not have an inhibitive effect and could be used to inoculate a wide range of leguminous plants rather than requiring a single packaged inoculant for certain plant groups.⁶⁶ Kalo Inoculant obtained a patent on the mixture and filed suit against Funk Brothers claiming infringement when they began selling similar mixtures.⁶⁷

59. For credential information for James Cosgrove, see IPWATCHDOG, <https://www.ipwatchdog.com/author/jamescosgrove/> (last visited Dec. 25, 2019).

60. See James Cosgrove, § 101 Rejections in the Post-Alice Era, IPWATCHDOG (Mar. 7, 2017), <https://www.ipwatchdog.com/2017/03/07/101-rejections-post-alice-era/id=78635/>.

61. *Funk Bros. Seed v. Kalo Inoculant Co.*, 333 U.S. 127, 129 (1948).

62. *Id.* at 128-29.

63. *Id.*

64. *Id.* at 129-30.

65. *Id.*

66. *Id.* at 130.

67. See *id.* at 128.

Ultimately, the Court held that the Rhizobium bacteria mixture was not patent eligible subject matter.⁶⁸ The Court's analysis was centered around the contention that Kalo Inoculant was attempting to patent a "phenomena of nature" because the resultant combination did not produce a new property of the bacteria.⁶⁹ Significantly, the Court stated:

The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes.⁷⁰

Additionally, the Court placed significance on the principle that for a discovery to be patentable, "it must come from the application of the law of nature to a new and useful end."⁷¹

Here, the researchers at Kalo discovered a law of nature and the application was the mere packaging of the inoculants:

But once nature's secret of the non-inhibitive quality of certain strains of the species of Rhizobium was discovered, the state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention. There is no way in which we could call it such unless we borrowed invention from the discovery of the natural principle itself. That is to say, there is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention. But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed. All that remains, therefore, are advantages of the mixed inoculants themselves. They are not enough.⁷²

B. Association for Molecular Pathology v. Myriad Genetics, Inc.

Myriad was a case challenging the validity of Myriad's patents claiming the BRCA1 and BCRA2 genes.⁷³ The BRCA1 and BRCA2 genes are associated with women's breast and ovarian cancer, and knowledge of the genes' locations and nucleotide sequences provide insight into studying those cancers.⁷⁴ By identifying those genes, Myriad developed medical tests for

68. *Id.* at 132.

69. *Id.* at 130.

70. *Id.*

71. *Id.*

72. *Id.* at 132.

73. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 583 (2013).

74. *Id.*

detecting mutations in the genes and could evaluate the patient's risk of developing breast and ovarian cancer.⁷⁵

The Myriad patents themselves claim two types of deoxyribonucleic acid (DNA) sequences: isolated genomic DNA and complementary DNA (cDNA).⁷⁶ Isolated genomic DNA refers to the DNA scientists extract from cells using well known laboratory methods.⁷⁷ Isolated genomic DNA contains an identical nucleotide sequence as would be found *in vivo*.⁷⁸ cDNA requires a more comprehensive explanation.

DNA consists of biological compounds called nucleotides.⁷⁹ Certain sequences of nucleotides code for specific amino acids.⁸⁰ Amino acids are the basic building blocks which combine to form proteins.⁸¹ Proteins are the cellular structures that carry out biological functions.⁸² However, only some DNA nucleotide sequences code for amino acids.⁸³ Nucleotide sequences which code for amino acids are called “exons” and nucleotide sequences which do not code for amino acids are called “introns.”⁸⁴

The creation of proteins from DNA involves two biological processes, transcription and translation.⁸⁵ In transcription, DNA—consisting of two nucleotide stands—is separated into two single strands, and one strand is used to create complementary ribonucleic acid (RNA).⁸⁶ The resulting RNA strand, known as pre-RNA, is an intermediary molecule containing information of both the exons and introns from the single stranded DNA.⁸⁷ The pre-RNA then undergoes a process by which the introns are removed from the RNA molecule.⁸⁸ The resultant product, known as messenger RNA (mRNA), is an RNA molecule containing information solely of the exons of the corresponding DNA strand.⁸⁹

mRNA is the molecule that undergoes translation to produce amino acids.⁹⁰ In translation, cellular structures “read” codons in the mRNA and

75. *Id.*

76. *Id.* at 583-85.

77. *Id.* at 582.

78. *Id.* at 596 (Scalia, J., concurring).

79. *Id.* at 581.

80. *Id.* at 581-82.

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.* at 581.

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.*

89. *Id.*

90. *Id.* at 581-82.

synthesize amino acids to create a protein.⁹¹ The cellular structures which read the mRNA are known as ribosomes.⁹² Codons are a set of three nucleotides which tell the ribosome to either synthesize a particular amino acid or to stop production of amino acids.⁹³

The biological processes which convert DNA to proteins occur naturally in the cell.⁹⁴ Using established laboratory methods, scientists are capable of extracting DNA from the cells which is then utilized for further study or to be used in a particular manner.⁹⁵ Additionally, scientists are capable of synthesizing DNA using equally routine methods as extracting natural DNA.⁹⁶ One method of creating synthetic DNA utilizes the bonding properties of the nucleotides contained in mRNA to create a corresponding DNA molecule.⁹⁷ Significantly, the resultant DNA molecule contains only exon nucleotide sequences because the mRNA utilized to create synthetic DNA does not contain the corresponding intron information.⁹⁸ This laboratory created synthetic DNA is referred to as cDNA.⁹⁹ cDNA provides scientists with an additional tool to study genetic sequences.¹⁰⁰

The *Myriad* Court began its analysis by focusing on the isolated genomic DNA. First, the Court discussed *Chakrabarty*, noting that the bacterium from that case was patentable because it had “markedly different characteristics from any found in nature,” placing importance on the genetic components added to the bacterium to provide it with the ability to degrade oil.¹⁰¹ The Court concluded that Myriad, however, did not create anything; Myriad found a gene, and separating it “from its surrounding genetic material is not an act of invention.”¹⁰²

After the Court’s discussion of *Chakrabarty*, the Court reaffirmed the holding in *Funk Brothers* and analogized the BRCA claims to the *Funk Brothers* claims.¹⁰³ The *Myriad* Court reasserted its conclusion from *Funk Brothers* that it was no act of invention to discover a property of bacteria and

91. *Id.*

92. *Id.* at 581.

93. *Id.* at 581-82.

94. *Id.* at 582.

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.*

99. *Id.*

100. *See id.*

101. *Id.* at 590-91 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)).

102. *Id.* at 591.

103. *Id.*

package the results.¹⁰⁴ Using the logic from *Funk Brothers*, the Court reasoned it was no act of invention for Myriad to locate the BRCA genes and separate the genes from its surrounding material.¹⁰⁵ It was a mere act of discovery insufficient to render the composition of matter patent eligible.¹⁰⁶ Thus, just like the claims in *Funk Brothers*, Myriad's claims "fell squarely within the law of nature exception."¹⁰⁷

In addition to discussing precedent, the Court held the isolating process itself does not remove the isolated DNA segment from the law of nature exception.¹⁰⁸ Specifically, the fact that the isolating process results in severed chemical bonds thereby creating a product that does not occur in nature is insufficient to find the product patentable subject matter.¹⁰⁹ The Court reasoned that Myriad was concerned with the genetic information rather than the structural characteristics.¹¹⁰ If this were held to be sufficient, a "would-be infringer" could merely isolate the entire BRCA1 and BRCA2 genes with an additional nucleotide to avoid infringement.¹¹¹ In doing so, the DNA segment would technically be a different structure, but the genetic information encoded in the DNA would be identical.¹¹² Thus, *de minimis* structural changes could not yield the isolated DNA patent eligible.¹¹³

Following the discussion of isolated DNA, the Court proceeded to discuss the patent claims directed at cDNA.¹¹⁴ The Court held cDNA was patent eligible under Section 101.¹¹⁵ The Court stated, "the lab technician unquestionably creates something new when cDNA is made."¹¹⁶ However, the Court clarified that cDNA that was merely a "short series of DNA" with "no intervening introns to remove" when synthesizing the cDNA is not patentable because the cDNA would be "indistinguishable from natural DNA."¹¹⁷ Thus, cDNA escaped the products of nature exception.¹¹⁸

104. *Id.*

105. *Id.* at 591-93.

106. *Id.* at 591.

107. *Id.*

108. *Id.* at 593.

109. *Id.*

110. *Id.*

111. *Id.*

112. *See id.*

113. *See id.*

114. *Id.* at 594-95.

115. *Id.* at 595.

116. *Id.*

117. *Id.*

118. *Id.*

C. *Funk Brothers* and *Myriad* in Conflict

The holding from *Myriad* that cDNA is patent eligible subject matter conflicts with the holding from *Funk Brothers*. The Court in *Myriad* reasoned cDNA was patent eligible because “the lab technician unquestionably creates something new.”¹¹⁹ This statement was in reference to a synthetic DNA molecule having a different molecular structure than its natural counterpart.¹²⁰ However, as the Court noted, the genetic information contained on cDNA is identical to the genetic information on its natural counterpart, and it is that genetic information *Myriad* is concerned with, not the nucleotide sequence itself.¹²¹ The Court in *Myriad* is contradicting itself. The *Myriad* decision stated structural changes were insufficient to render isolated DNA patent eligible because *Myriad* was concerned with the genetic information rather than the DNA segment’s structure.¹²² Despite this, cDNA was found to be patent eligible simply because it is not found in nature.¹²³

Applying this reasoning, the mixture of bacteria in *Funk Brothers* should be found to be patent eligible subject matter. The inventor in *Funk Brothers* discovered an ideal combination of bacteria—a combination of bacteria not found in nature—which was capable of inoculating a wide variety of leguminous plant seeds.¹²⁴ Although mixing the various strains of bacteria did not produce a different capability already possessed by the individual strains of bacteria,¹²⁵ the resultant combination was “something new,” which was the standard used to find the subject matter in *Myriad* patent eligible.¹²⁶

Correspondingly, if the Court in *Myriad* were to apply the reasoning from *Funk Brothers* to its cDNA analysis, cDNA would be held to be patent ineligible subject matter. In *Funk Brothers*, the court held the combination of bacteria was not patent eligible because merely packaging the mixture was not an “application of the law of nature to a new and useful end,” and “fell short of invention.”¹²⁷ Moreover, the mere packaging of the mixed inoculant was a “simple step” due to “the state of the art.”¹²⁸

119. *Id.*

120. *Id.* at 594-95.

121. *Id.* at 593.

122. *Id.*

123. *Id.* at 594-95.

124. *Funk Bros. Seed v. Kalo Inoculant Co.*, 333 U.S. 127, 128-30 (1948).

125. *See id.* at 130-31.

126. *Myriad*, 569 U.S. at 595.

127. 333 U.S. at 130-31.

128. *Id.* at 132.

Myriad's discovery of the BRCA genes and creating cDNA counterparts¹²⁹ is analogous to the inventor in *Funk Brothers* discovering the ideal combination of bacteria and packaging that combination.¹³⁰ Just like packaging the bacterial mixture was a "simple step"¹³¹ short of invention; synthesizing cDNA with knowledge of the natural DNA's genomic location is a "simple step" given the advances in the field of genetics.¹³² Therefore, it was no act of inventiveness for Myriad to produce BRCA1 and BRCA2 cDNA and thus, under the logic of *Funk Brothers*, should have been held to be patent ineligible.

Patent attorney Warren Woessner elegantly elucidated this argument by substituting the *Myriad* language into the *Funk Brothers* analysis:

But once nature's secret of the non-inhibitive quality of certain strains of the species *Rhizobium* [or the DNA sequence of an isolated BRCA gene] was discovered, the state of the art made the production of a mixed inoculant [or the production of cDNA] a simple step . . . All that remains [to support the mixture of strains being a product of invention] . . . are advantages of the mixture of inoculants [or the cDNA molecules] themselves. They are not enough.¹³³

It seems clear that had the Court in *Myriad* adhered to the principle of *stare decisis*, the patent community would have been spared additional confusion to the already convoluted Section 101 jurisprudence. The following section examines a writ of certiorari representative of the problem created by the Court's conflicting holdings to urge similar litigants to persist through the appeals process in an effort to resolve the *Funk Brothers-Myriad* tension.

IV. RESOLVING THE *FUNK BROTHERS-MYRIAD* TENSION

A. *Ms. Bhagat's Petition for Writ of Certiorari*

U.S. Patent Application No. 12/426,034¹³⁴ illustrates the problem created by *Funk Brothers* and *Myriad* and would have been ideal for the United States Supreme Court to accept for certiorari. Ms. Bhagat claimed a formulation comprising a dosage of specific amounts of omega-6 and omega-

129. *Myriad*, 569 U.S. at 582-83.

130. *See Funk Bros.*, 333 U.S. at 130-31.

131. *Id.* at 132.

132. *See Myriad*, 569 U.S. at 582.

133. Warren Woessner, *Bhagat v. Iancu—Did the Myriad Decision Overrule Funk Bros.?*, PATENTS4LIFE (Sept. 10, 2018), <http://www.patents4life.com/2018/09/bhagat-v-iancu-myriad-decision-overrule-funk-bros/>.

134. U.S. Patent Application No. 12/426,034 (filed Apr. 17, 2009).

3 fatty acids.¹³⁵ Ms. Bhagat’s claimed formulation is representative of the conflict created by *Myriad* and *Funk Brothers* because it contains a combination of natural products, as in *Funk Brothers*, and has claim limitations which provide structural characteristics that distinguish the formulation from a natural product, as in *Myriad*. The combination of natural products are fatty acids and the claim limitations which distinguish the formulation from fatty acid combinations found in nature are the claim elements “dosage” and “casings providing controlled delivery.”¹³⁶ The relevant claim at issue is reproduced below:

65. A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, contained in one or more complementing casings providing controlled delivery of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources, and wherein

(1) omega-6 fatty acids are 4-75% by weight of total lipids and omega-3 fatty acids are 0.1-30% by weight of total lipids; or

(2) omega-6 fatty acids are not more than 40 grams.¹³⁷

The Federal Circuit affirmed the Patent Trial and Appeal Board’s (the “Board”) rejections of the claims as being anticipated and patent ineligible subject matter under Section 101.¹³⁸ Only the Section 101 rejection analysis will be discussed as this is the pertinent aspect of the opinion to this Note.

The Board held the claims were not patent eligible subject matter under Section 101 because the patent examiner determined Ms. Bhagat’s claimed mixture occurs naturally in walnut oil and olive oil and the additional limitations in the claims (e.g., “dosage” and “casings providing controlled delivery”) did not change the characteristics of the fatty acid mixture nor did it “add ‘significantly more’ to the claims.”¹³⁹

The Board’s Section 101 rejection is flawed for a number of reasons. As an initial matter, the claim limitations should remove the claim from the scope of the products of nature doctrine because the claim limitations are not found in nature. Under *Myriad*, cDNA was held to be patent eligible merely because it was not found in nature.¹⁴⁰ It was not a requirement that cDNA be “significantly more” than its natural counterpart. In fact, the genetic information stored in the cDNA is identical to DNA extracted from a cell. It would be nonsensical to argue cDNA is “significantly more” than DNA

135. *Id.*

136. *In re Bhagat*, 726 Fed. App’x 772, 773-74 (Fed. Cir. 2018).

137. *Id.*

138. *Id.* at 774, 779.

139. *Id.* at 777.

140. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 594-95 (2013).

found in nature. Therefore, the mere fact the claim requires a “dosage” in “casings” should render the claim patent eligible subject matter because a dosage of such a formulation in a casing is certainly not found in nature. Whether or not Ms. Bhagat’s invention is significantly more is immaterial under the *Myriad* analysis.

However, the *Myriad* analysis conflicts with a *Funk Brothers* analysis. In *Funk Brothers*, the bacteria combination was held patent ineligible because the resultant combination did not create a new characteristic of the bacteria found in nature.¹⁴¹ The Board could reject the claims on the basis that the claim limitations do not create a new characteristic of the lipids found in natural sources.¹⁴² In fact, the Board stated, “that the Applicant has not shown that the claimed mixtures are a ‘transformation’ of the natural products, or that the claimed mixtures have properties not possessed by these products in nature.”¹⁴³ Nevertheless, the Board’s statement ignores *Myriad*. Specifically, the Board overlooks that *Myriad* did not require “the claimed . . . [invention] have properties not possessed” by its natural counterpart to be patent eligible.¹⁴⁴

Ms. Bhagat argues in her petition for writ of certiorari that “the degree of difference between what the court considers natural products and the claimed formulations is not an issue in determining whether subject matter is a natural product, *contrary to the reasoning in Funk Bros.*”¹⁴⁵ Furthermore, the application claims “non-naturally occurring *combinations . . . in non-naturally occurring casings . . . that constitute a non-naturally occurring dosage of certain fatty acids.*”¹⁴⁶

Although Ms. Bhagat’s claims could be rejected under *Funk Brothers*,¹⁴⁷ the claims should be patent eligible subject matter under *Myriad*. It is imperative the Supreme Court resolves the *Funk Brothers-Myriad* tension to help restore consistency to Section 101.

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

142. *See id.*

143. *In re Bhagat*, 726 Fed. App’x at 779.

144. *Id.*

145. Petition for Writ of Certiorari, *Bhagat v. Iancu*, 139 S. Ct. 430 (2018) (mem.) (No. 18-277).

146. *Id.*

147. However, I would disagree with a rejection under *Funk Brothers* because Ms. Bhagat provides numerous reasons to suggest her formulation produces new properties not found in nature. *See id.* These points are not discussed in this Note because the focus of this Note is that *Funk Brothers* should not be followed under Section 101 and thus should not have to be discussed.

B. The Supreme Court Should Overrule *Funk Brothers*

To reconcile the discrepancy between the *Funk Brothers* holding and the *Myriad* holding and restore consistency as to what qualifies as patent eligible subject matter, the Supreme Court should expressly overrule *Funk Brothers* under *Myriad*. The patent eligibility principles delineated from *Funk Brothers* are antiquated. In particular, the principle that an invention has to be more than a “simple step” from its natural derivation to be patent eligible is no longer applicable to subject matter eligibility. The “simple step” requirement is more akin to an obviousness analysis rather than a subject matter eligibility analysis. In *Funk Brothers*, the Court was reasoning that once the anticompetitive effects of the various strains of bacteria were discovered,¹⁴⁸ it would follow that it would be trivial—or obvious—for one skilled in the art to combine said bacteria.

In hindsight, the Supreme Court in *Funk Brothers* appeared to conflate a subject matter eligibility analysis with an obviousness analysis because the law governing the patentability requirements has developed substantially between the time *Funk Brothers* was decided and the time *Myriad* was decided. *Funk Brothers* was decided before the obviousness standard was first codified in Section 103 of the 1952 Patent Act. Prior to the Patent Act of 1952, most of the patentability requirements were outlined in one section of the Revised Statutes of 1874 which only required novelty and utility for patentability.¹⁴⁹ The non-obviousness requirement was developed through case law before it was codified in the Patent Act of 1952.¹⁵⁰ Before the current “non-obviousness” standard of Section 103,¹⁵¹ patentable subject matter had to display “invention,”¹⁵² a standard that vaguely required the subject matter to exceed previous technology by a substantial amount to be worthy of a patent.

Given the historical context, it becomes clear that when the Court stated, “the state of the art made the production of a mixed inoculant a simple step” and “[e]ven though it may have been the product of skill, it certainly was not the product of invention,”¹⁵³ the Court improperly merged non-obviousness into the products of nature doctrine. Hence, when the Court in *Myriad* discussed *Funk Brothers* stating it was not an act of invention to discover a

148. *Funk Bros. Seed v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948).

149. Rev. Stat. §§ 4886, 4892 (1874).

150. Patent Act of 1952, § 103, ch. 950, 66 Stat. 792, 798 (codified as amended at 35 U.S.C. § 103 (2012)).

151. 35 U.S.C. § 103 (2012).

152. *See, e.g., Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 11-12 (1966).

153. *Funk Bros.*, 333 U.S. at 132.

property of bacteria and package the results,¹⁵⁴ and therefore the bacteria claims “fell squarely within the law of nature exception,”¹⁵⁵ *Funk Brothers* imputed its improper characterization of the products of nature doctrine into the *Myriad* holding, resulting in confusion to the patent community.

Thus, to resolve the mischaracterization originating from *Funk Brothers*, the Supreme Court needs to accept a “products of nature” case for certiorari and clearly hold inventions which exhibit properties possessed by the product from which it is derived do not, *ipso facto*, fall under the products of nature exception, thereby overruling *Funk Brothers*. Such a holding would not disturb the subject matter eligibility principles from *Myriad* and alleviate the *Funk Brothers-Myriad* tension. As a result, Ms. Bhagat’s invention would then clearly be patent eligible. At a minimum, the subject matter would be patent eligible because the claimed combination does not occur in nature.¹⁵⁶ Then the USPTO could proceed to evaluate the invention for novelty and obviousness and provide a clear rationale for rejecting the application, giving the applicant a reasonable opportunity to correct any errors. Therefore, overruling *Funk Brothers* would be beneficial to the patent community as a whole.

V. CONCLUSION

A patent system is a valuable device to promote the progress of technological advancements for the benefit of society. However, the patent system must be closely monitored to ensure the system is achieving the objective it was designed to attain. Such a delicate system could have adverse effects if not properly employed. Recently, there are indications that the system is not working properly, particularly for the life sciences and biotechnology sectors. Part of the problem is due to the *Myriad* holding.

The *Myriad* holding has caused confusion as to the scope of the products of nature doctrine and consequently what constitutes patent eligible subject matter. The *Funk Brothers* holding requires the claimed subject matter to produce a new property not possessed by its natural counterpart. This conflicts with *Myriad*’s holding which suggests the subject matter only be structurally different compared to its natural counterpart. Such confusion has caused inventors to invest time and money into research only to be denied a patent for a flawed rationale. The patent community deserves better.

Ms. Bhagat’s case would have been ideal for the Supreme Court to adjudicate and likely would have clarified what constitutes patent-ineligible

154. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 591 (2013).

155. *Id.*

156. *See In re Bhagat*, 726 Fed. App’x 772, 773-74 (Fed. Cir. 2018).

products of nature. Ms. Bhagat's confusion as to why her patent was subject matter ineligible should have been alleviated by the Supreme Court by expressly overruling *Funk Brothers* under *Myriad*.

Although Ms. Bhagat's petition for writ of certiorari was denied by the Supreme Court, her efforts should not be viewed as a loss. Through the arduous appeals process, Ms. Bhagat has developed a case that can serve as a model for other injured members of the patent community to craft a strategy to bring their own case before the Supreme Court. Hopefully, this Note inspires another party to bring a case before the courts to argue for a resolution to the confusion elicited by the *Myriad* decision and thus preserve the patent system's constitutional purpose.

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