

PATENTABLE SUBJECT MATTER: A *MYRIAD* OF PROBLEMS

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I. INTRODUCTION

For decades, the federal courts have struggled to define “patentable subject matter.” The statutory authorization, § 101 of the Patent Act, seems simple enough: “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”¹ The statute appears to contemplate that if an invention falls into one of the four statutory categories, it is eligible for patent protection, provided it meets the other requirements of the Patent Act. However, the issue is not so simple. For years, the Supreme Court has explained that there are certain judicially created categories of unpatentable subject matter. These include “[l]aws of nature, natural phenomena, and abstract ideas,” but the Court has never specifically defined these categories.²

The result has left the U.S. Patent and Trademark Office (PTO), lower courts, inventors, and industry grappling to define the bounds of patentable subject matter. With no single, coherent direction, the various actors are often left to guess at whether an invention toes the line of patentable subject matter. The Federal Circuit recently issued its opinion in *Association for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad)*.³ The court’s fractured opinion in the case highlights many of the problems with the current framework for patentable subject matter.

This Note seeks to summarize the current framework, identify its weaknesses, and suggest the best approach for the Court to take to return

1. 35 U.S.C. § 101 (2006).

2. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012) (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).

3. 689 F.3d 1303 (Fed. Cir. 2012), *aff’d in part, rev’d in part sub nom.* *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

stability and predictability to the topic of patentable subject matter. The first Part of the Note gives a brief review of the principles of patent law, and specifically patentable subject matter. This Part also details some of the Court's most important decisions regarding products of nature and abstract ideas/mental processes. Next, the Note discusses the *Myriad* case and analyzes the three different opinions it generated in the most recent Federal Circuit opinion.⁴ Finally, the Note discusses the impact of this unpredictability, reviews solutions suggested by commentators, and proposes the Court employ a simple, yet effective, solution to clarify this confounding area of the law.

II. THE BASICS

Before addressing the implications of *Myriad*, it is helpful to put the decision into context. This portion of the Note provides a basic overview of patent law and the subject of patentable subject matter.

The authority to create patent laws derives directly from the Constitution of the United States: Congress has 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.”⁵ A patent is in essence a form of a limited monopoly.⁶ The current patent laws provide that a patentee, or his licensee, has the exclusive right to make, use, sell, offer to sell, or import the invention for a duration of twenty years.⁷

In some ways, the grant of even this limited monopoly is remarkable. At the time of founding, monopolies were greatly distrusted, and influential leaders such as Thomas Jefferson doubted their benefit.⁸ Nonetheless, the founders kept the constitutional basis for patent laws and left it to Congress and the courts to balance the competing policies. The primary justification for patent laws, as reflected in the Constitution, is to encourage industrial and technological development.⁹ The belief is that if an inventor can exclusively profit from his invention, he is more likely to invest his time

4. This Note considers the Federal Circuit's 2012 decision in *Association for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012). Although the Supreme Court has already issued an opinion in this case, 133 S. Ct. 2107 (2013), affirming in part and reversing in part the Federal Circuit's decision, the Court perpetuates the problem identified in this Note. Namely, the Court continued to apply its muddled jurisprudence on patentable subject matter without clarifying the parameters of the § 101 inquiry.

5. U.S. CONST. art. I, § 8, cl. 8.

6. JOHN GLADSTONE MILLS III ET AL., PATENT LAW BASICS § 1:6 (2012).

7. 35 U.S.C. §§ 154(a)(2), 271 (2006).

8. Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), available at http://press-pubs.uchicago.edu/founders/documents/a1_8_8s12.html.

9. ALAN L. DURHAM, PATENT LAW ESSENTIALS: A CONCISE GUIDE 2 (3d ed. 2009).

and resources into the endeavor.¹⁰ In addition, a patent may be viewed as a bargain, whereby a limited monopoly is the inventor's compensation for disclosing the details of his invention to the public.¹¹

The grant of a monopoly, however, is not without its drawbacks. If patents are granted too liberally, the result would be a stifling effect on further developments.¹² As the Supreme Court has observed, some concepts are simply "part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none."¹³ To that end, Congress has provided certain limitations on when inventions are eligible to receive patents.¹⁴

One of these limitations is known as patentable subject matter. Section 101 of the Patent Act defines patentable subject matter as "any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof . . ."¹⁵ As the Supreme Court noted, "Congress plainly contemplated that the patent laws would be given wide scope."¹⁶ This, however, does not mean that anything is patentable subject matter. The Supreme Court has long recognized three judicial exceptions to patentable subject matter: "Laws of nature, natural phenomena, and abstract ideas' are not patentable."¹⁷ The rationale for these exceptions is that they are the basic tools for innovation, and their monopolization might impede rather than promote further innovation.¹⁸

In the context of medical research and development, two subcategories of these exceptions are particularly important—products of nature and abstract ideas/mental processes.¹⁹ These two limitations restrict the types of medical discoveries that are eligible for patent protection in different ways. For example, a researcher who discovers an isolated gene may wish to patent the gene itself and a process that utilizes that gene to detect a certain disease. In claiming the isolated gene, the researcher may encounter assertions that the gene is merely an unpatentable product of nature.²⁰ On the other hand, a claim to a process for using the gene may have to be

10. *Id.*

11. *Id.* at 2–3.

12. See James E. Bessen, *Patent Thickets: Strategic Patenting of Complex Technologies* (Mar. 2003), available at <http://www.researchoninnovation.org/thicket.pdf>.

13. *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

14. See, e.g., 35 U.S.C. §§ 101–103 (2006).

15. *Id.* § 101.

16. *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

17. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012) (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).

18. *Id.* (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

19. See *Myriad*, 689 F.3d 1303, 1324 (Fed. Cir. 2012), *aff'd in part, rev'd in part sub nom.* *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

20. *Id.* at 1325–26.

defended as more than just an unpatentable mental process or abstract idea.²¹ Although these concepts are related, the following two Subparts review each limitation independently.

A. *Products of Nature*

The restriction on patenting products of nature derives from the rule against patenting laws of nature.²² For example, one could not patent a new mineral discovered deep in the earth or a new plant discovered deep in the jungle.²³ However, if one discovers a new use for or a medication made from that mineral or plant, the new use or medication would potentially be patentable.²⁴ Thus, this distinction can sometimes be tricky to maintain. All compositions of matter, at some level, are products of nature.²⁵

This distinction may become even more challenging when dealing with living organisms as the product of nature. While not too long ago these were truly only products of nature, the technology to develop and modify organisms has recently developed to the point that this is no longer the case.²⁶

The seminal case addressing the patentability of living organisms is *Diamond v. Chakrabarty*.²⁷ In *Chakrabarty*, the applicant sought to patent a bacterium that was genetically engineered to break down crude oil.²⁸ This trait was not possessed by any naturally occurring bacteria and was said to have significant value in treating oil spills.²⁹ Although the Patent Office rejected Chakrabarty's claims to the bacterium, the majority of the Supreme Court held that it was patentable.³⁰ It explained that "[h]is claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'"³¹

To illustrate the point, the Court compared Chakrabarty's invention to the invention in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*³² In *Funk*, the inventor had discovered a way to mix certain strains of bacteria such

21. *Id.* at 1333–37.

22. DURHAM, *supra* note 9, at 26.

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

24. DURHAM, *supra* note 9, at 26.

25. *Myriad*, 689 F.3d 1303, 1325 (Fed. Cir. 2012), *aff'd in part, rev'd in part sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

26. DURHAM, *supra* note 9, at 27.

27. 447 U.S. 303.

28. *Id.* at 305.

29. *Id.*

30. *Id.* at 310.

31. *Id.* at 309–10 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

32. 333 U.S. 127 (1948).

that they would not inhibit each other.³³ Each strain inoculated different species of plants.³⁴ The result, therefore, was that this new culture with multiple strains of bacteria could inoculate a broader range of plants.³⁵ The Court held these “qualities [were] the work of nature,” and therefore, “free to all men and reserved exclusively to none.”³⁶ Importantly, this new culture produced no new bacteria; rather, each species was merely performing the same function it naturally performed.³⁷

In contrast, the *Chakrabarty* Court explained the Chakrabarty’s invention was “a new bacterium with markedly different characteristics from any found in nature”³⁸ This crucial difference made Chakrabarty’s invention patentable subject matter.³⁹ Thus, the distinction between an unpatentable product of nature and a patentable invention “turns on a change in the claimed composition’s identity compared with what exists in nature.”⁴⁰

B. *Abstract Ideas/Mental Processes*

The category of abstract ideas is the most general, yet hardest to define, type of unpatentable subject matter.⁴¹ The most basic statement of the rule is “[a]n idea of itself is not patentable.”⁴² Yet, this basic principle is unhelpful because at a certain level every invention is an idea. Somewhat more helpful, the Court has explained that, “[w]hile a scientific truth . . . is not [a] patentable invention, a novel and useful [application] created with the aid of knowledge of scientific truth may be.”⁴³ The question then becomes at what level of application does an abstract idea become patentable. Merely stating a law of nature and adding the words “apply it” is not enough.⁴⁴

In *Gottschalk v. Benson*, the Supreme Court considered an inventor’s claim to an algorithm for converting binary-coded decimal numbers into

33. *Id.* at 129–30.

34. *Id.*

35. *Id.*

36. *Id.* at 130.

37. *Id.* at 131.

38. 447 U.S. at 310 (1980).

39. *Id.*

40. *Myriad*, 689 F.3d 1303, 1327–28 (Fed. Cir. 2012), *aff’d in part, rev’d in part sub nom.* Ass’n for Molecular Pathology v. *Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

41. DURHAM, *supra* note 9, at 24.

42. *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) (quoting *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. 498, 507 (1874)).

43. *Id.* (alteration in original) (quoting *Mackay Co. v. Radio Corp.*, 306 U.S. 86, 94 (1939)).

44. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012).

pure binary numbers.⁴⁵ As claimed, the process was not tied to any particular machines and could even be performed mentally.⁴⁶ Moreover, the Court noted that the claim was “so abstract and sweeping as to cover both known and unknown uses” of the conversion.⁴⁷ Because the process was not tied to any particular machine, the Court considered whether the process transformed or reduced an article “to a different state or thing,” which it stated was a clue to the patentability of a process.⁴⁸ Given the breadth of the claim, the Court held that the claimed process was unpatentable.⁴⁹ Of particular concern was the fear that allowing the patent on the algorithm would “wholly pre-empt the mathematical formula.”⁵⁰

Although not specifically addressed by the Court in *Benson*, the Court’s opinion suggests that processes which can be performed entirely within the human mind counsel special concern. Since then, the Federal Circuit has observed that mental processes are unpatentable as a subcategory of abstract ideas.⁵¹ For example, in *Cybersource Corp. v. Retail Decisions, Inc.*, the Federal Circuit addressed whether a claim to a process for validating credit card transactions was patentable subject matter.⁵² The claim was so broad that it would have covered an individual visually comparing two lists of credit card transaction data.⁵³ The court held that the claim covered unpatentable subject matter because processes “which can be performed *entirely* in the human mind are the types of methods that embody the ‘basic tools of scientific and technological work’ that are free to all men and reserved exclusively to none.”⁵⁴

Most recently, the Supreme Court addressed the category of unpatentable abstract ideas in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*⁵⁵ In that case, the patent claims concerned a method to administer thiopurine drugs.⁵⁶ These drugs can be especially challenging to administer because individual responses to the drugs vary widely, but the researchers had correlated the effectiveness of the drugs with levels of

45. 409 U.S. at 64.

46. *Id.* at 67.

47. *Id.* at 68.

48. *Id.* at 70. The Federal Circuit later adopted this statement, referred to as the machine-or-transformation test, as the exclusive test for the patentability of processes. See *In re Bilski*, 545 F.3d 943, 959 (Fed. Cir. 2008). This test, however, has been rejected by the Supreme Court as the exclusive test of patentability; instead, it is only “a useful and important clue.” *Bilski v. Kappos*, 130 S. Ct. 3218, 3227 (2010).

49. *Benson*, 409 U.S. at 72.

50. *Id.*

51. *Cybersource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1371 (Fed. Cir. 2011).

52. *Id.* at 1370.

53. *Id.* at 1372–73.

54. *Id.* at 1373 (quoting *Benson*, 409 U.S. at 67).

55. 132 S. Ct. 1289 (2012).

56. *Id.* at 1294–95.

certain metabolites found in the blood stream.⁵⁷ A typical claim described a process in which a patient would be administered a thiopurine drug, the concentration of certain metabolites in the patient's bloodstream would be measured, and the drug dosage would be adjusted based on the metabolite levels as defined in the claims.⁵⁸ Thus, the claims essentially embodied the researchers' findings on the correlations.

The Federal Circuit, applying the machine-or-transformation test, concluded that the administering and measuring steps satisfied the transformative prong and were not token post-solution activity.⁵⁹ The Supreme Court, however, disagreed and held the claims were invalid because they were claims to unpatentable natural laws.⁶⁰ The Court explained that the correlation was a principle of nature and that the remaining steps were "well-understood, routine, conventional activity" that "add[ed] nothing significant beyond the sum of their parts taken separately."⁶¹

The Court's approach represents a somewhat new tack to patentable subject matter. Rather than address the claims as a whole, the Court chose to dissect the claim elements and assess them individually.⁶² The central inquiry appeared to be whether the claims added "enough" to the natural laws to be eligible for patent protection.⁶³ This new approach greatly expanded the scope of the unpatentable laws of nature exception to § 101.⁶⁴

III. THE *MYRIAD* DECISION

The Federal Circuit's recent decision in the *Myriad* case demonstrates the lack of coherence in the area of patentable subject matter and the shortcomings of the Supreme Court's piecemeal, reactive approach. This Part begins by reviewing the background and context of the case. Then, this Part dissects the court's decision, which produced three widely divergent opinions.

57. *Id.*

58. *Id.*

59. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1355–57 (Fed. Cir. 2010).

60. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. at 1297–98.

61. *Id.* at 1298.

62. Michael J. Malecek & Kenneth M. Maikish, *The Prometheus Effect on Software Patents*, 24 INTELL. PROP. & TECH. L.J. 3, 6 (2012).

63. *Id.* at 6–7.

64. *Id.* at 3; *see also Myriad*, 689 F.3d 1303, 1343 (Fed. Cir. 2012) (Moore, J., concurring) ("The scope of the law of nature/manifestation of nature exception was certainly enlarged" by *Mayo.*), *aff'd in part, rev'd in part sub nom. Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

A. Background

Myriad, the defendant in the case, owns patents on certain compositions that are derived from human DNA and method claims used to compare a patient's DNA to the discovered DNA sequences.⁶⁵ As analyzed by the court, there were three distinct groups into which the claims fell for the purposes of its patentable subject matter analysis. The first group was composition claims that covered "isolated" human genes (isolated DNA) of varying length and certain mutations in this DNA.⁶⁶ The second group included all but one of the method claims, each describing a process in which a patient's DNA sequence was to be compared to the normal sequence to identify a predisposition to certain cancers.⁶⁷ Finally, the third group consisted of a single method claim that disclosed a process to screen potential cancer therapeutics.⁶⁸

The plaintiffs in the case included various organizations and individuals who had either performed or wished to be able to perform genetic testing that was covered by Myriad's patents.⁶⁹ In 2009, these plaintiffs collectively brought an action for declaratory judgment in the Southern District Court of New York, seeking a declaration that Myriad's patents were invalid and unenforceable.⁷⁰ Initially, Myriad challenged the standing of the plaintiffs to bring suit under the Declaratory Judgment Act, but the district court concluded the plaintiffs had standing to challenge the validity of Myriad's patents.⁷¹ Both parties then moved for summary judgment on the validity of Myriad's claims.⁷² The district court granted the plaintiffs' summary judgment, finding that both the composition claims and method claims were invalid under § 101.⁷³

Myriad then filed an appeal in the Federal Circuit, challenging the district court's ruling on both grounds. In 2011, the Federal Circuit issued its initial opinion affirming in part and reversing in part the decision of the district court.⁷⁴ The court reversed the district court's finding that Myriad's composition claims and the single method claim for screening potential cancer therapeutics covered unpatentable subject matter.⁷⁵ The court, however, agreed with the district court that the remaining method claims

65. 689 F.3d at 1309 (majority opinion).

66. *Id.*

67. *Id.* at 1309–10.

68. *Id.* at 1310.

69. *See id.* at 1314–16.

70. *Ass'n for Molecular Pathology v. U.S.P.T.O.*, 669 F. Supp. 2d 365, 380 (S.D.N.Y. 2009).

71. *Id.* at 385–93.

72. *Ass'n for Molecular Pathology v. U.S.P.T.O.*, 702 F. Supp. 2d 181, 186 (S.D.N.Y. 2010).

73. *Id.* at 232, 236–37.

74. *Ass'n for Molecular Pathology v. U.S.P.T.O.*, 653 F.3d 1329, 1333–34 (Fed. Cir. 2011).

75. *Id.*

were drawn to unpatentable subject matter.⁷⁶ Judge Moore filed a concurring opinion in which she concurred with most of the court's opinion but concurred in the judgment only with respect to the validity of the composition claims.⁷⁷ Judge Bryson also filed a separate opinion, which dissented from part of the court's judgment regarding the composition claims.⁷⁸

Following the Federal Circuit's decision, a petition for certiorari was filed with the Supreme Court. In March 2012, the Supreme Court granted the petition, vacated the Federal Circuit's judgment, and remanded the case for further consideration in light of *Mayo*.⁷⁹ The case, thus, returned to the Federal Circuit and generated the most recent opinion.

B. *The Federal Circuit's Decision*

In large part, the Federal Circuit's second decision mirrored its first. The panel reached the same conclusions as before, with the individual judges parting ways over the same issues.⁸⁰ Judge Lourie again wrote the opinion for the court, with Judge Moore concurring in part and Judge Bryson concurring in part and dissenting in part.

Judge Lourie first addressed whether the composition claims were drawn to patentable subject matter. Explaining that *Mayo* had not changed the framework for composition claims, he turned to *Chakrabarty* and *Funk* for the applicable principles.⁸¹ The important line, he explained, was "between compositions that, even if arrayed in useful combinations or harnessed to exploit newly discovered properties, have similar characteristics as in nature, and compositions that human intervention has given 'markedly different,' or 'distinctive,' characteristics."⁸² Under this test, Judge Lourie explained that the isolated DNA was patentable subject matter because it was "markedly different" from what is found in nature.⁸³ He explained that this process by which the DNA was isolated was more than simple purification: it "results from human intervention to cleave or synthesize a discrete portion of a native chromosomal DNA, imparting on that isolated DNA a distinctive chemical identity."⁸⁴ This was true of all the

76. *Id.*

77. *Id.* at 1358 (Moore, J., concurring).

78. *Id.* at 1373 (Bryson, J., dissenting in part).

79. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012).

80. *Myriad*, 689 F.3d 1303, 1308–09 (Fed. Cir. 2012) (majority opinion), *aff'd in part, rev'd in part sub nom.* *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

81. *Id.* at 1326–27.

82. *Id.* at 1328 (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)).

83. *Id.*

84. *Id.*

composition claims to isolated DNA, but Judge Lourie took care to note that the claims to cDNA⁸⁵ were “especially distinctive” and “even more the result of human intervention.”⁸⁶

Turning to the method claims, the court concluded that all but one of the claims amounted to only unpatentable mental processes.⁸⁷ It explained that the claims amounted to “nothing more than the abstract mental steps necessary to compare two different nucleotide sequences.”⁸⁸ These claims were even more abstract than those found insufficient in *Mayo*, as those claims also included an administering and determining step prior to the comparison.⁸⁹

The court, however, concluded that the method claim for screening potential cancer therapeutics was patentable subject matter.⁹⁰ Part of the claimed method is to grow host cells that have been transformed with an altered gene, making the cells man-made.⁹¹ Echoing principles of the machine-or-transformation test, the court explained that this method did more than recite a law of nature and state “apply it”: “The transformed, man-made nature of the underlying subject matter in [the claim] makes the claim patent-eligible.”⁹² The court further explained, “[O]nce one has determined that a claimed composition of matter is patent-eligible subject matter, applying various known types of procedures to it is not merely applying conventional steps to a law of nature.”⁹³

Judge Moore joined the opinion of the court with respect to the method claims and composition claims relating to cDNA but concurred in the judgment of the court only with respect to the remaining isolated DNA sequences.⁹⁴ She disagreed with Judge Lourie that the chemical differences between the naturally occurring and isolated DNA were sufficient to hold that the claims were patentable.⁹⁵ Looking for another ground upon which to hold them patentable, she observed that the claims covered sequences that ranged from the whole gene to lengths of only fifteen nucleotides.⁹⁶ To

85. cDNA is a type of synthetic DNA molecule called “complementary DNA.” cDNA is synthesized using mRNA (messenger RNA), which mirrors a DNA sequence but includes only the exon sequences. Exon sequences are those that actually code for a protein. Thus, cDNA derives from the naturally occurring DNA but includes only the protein-producing sequences. See *id.* at 1310–14 for a further explanation of the types of materials involved in the Myriad patents.

86. *Id.* at 1329.

87. *Id.* at 1333–34.

88. *Id.* at 1334.

89. *Id.* at 1335.

90. *Id.* at 1335–36.

91. *Id.* at 1336.

92. *Id.*

93. *Id.*

94. *Id.* at 1337 (Moore, J., concurring).

95. *Id.* at 1341.

96. *Id.*

her, the shorter sequences would be patentable because they can be used in ways in which naturally occurring DNA cannot be used,⁹⁷ but this justification was insufficient because the claims reached sequences that were too long to be of any new use.⁹⁸ Without having a new utility, the chemical change to the longer DNA strands was not enough for Judge Moore to conclude they were patentable subject matter.⁹⁹

Nevertheless, Judge Moore concluded the isolated DNA sequences were patentable. Although she appeared to be persuaded the claims did not cover patentable subject matter, her conclusion was driven by “both [the] settled expectations and extensive property rights . . . involved.”¹⁰⁰ In particular, she feared destroying the expectations of businesses and inventors that had heavily invested resources in their intellectual property rights, stating that any change should come from Congress.¹⁰¹ She noted that there was a difference between allowing patent protection where none previously existed and denying protection where it was currently recognized.¹⁰² The latter act is one not particularly well-suited to the judiciary.¹⁰³

Finally, Judge Bryson joined the same parts of the opinion as Judge Moore, but he dissented from the court’s opinion that the remaining isolated DNA sequences were patentable.¹⁰⁴ As he framed the issue, the question was “whether the process of isolating genetic material from a human DNA molecule makes the isolated genetic material a patentable invention.”¹⁰⁵ Judge Bryson likened this process to that of extracting a newly discovered mineral from the earth: although the process of extraction may be extremely difficult, “merely isolating the products of nature by extracting them from their natural location and making those alterations that are attendant to their extraction does not give the extractor the right to patent the products themselves.”¹⁰⁶

Turning to the case law, Judge Bryson believed that what is claimed and what is found in nature must be compared in two respects: their structure and their utility.¹⁰⁷ The claimed material failed to differ in any

97. For example, these shorter sequences have utility in diagnostic screening. They can serve as primers to assist in detecting gene mutations. *Id.*

98. *Id.* at 1343.

99. *Id.*

100. *Id.*

101. *Id.* at 1344, 1346.

102. *Id.* at 1345.

103. *Id.* at 1346–47.

104. *Id.* at 1348 (Bryson, J., dissenting in part).

105. *Id.*

106. *Id.* at 1350.

107. *Id.* at 1354.

meaningful way from the structure and utility found in nature.¹⁰⁸ Judge Bryson also turned to *Mayo* for the principle that when a patent involves a product of nature, the question becomes “whether the applicant has done ‘enough’ to distinguish his alleged invention.”¹⁰⁹ Myriad’s claims to isolated DNA fell short of this mark. Judge Bryson concluded by observing that the PTO’s practices should not be entitled to significant weight and that the court “should not shy away from deciding [] issues of law.”¹¹⁰

IV. THE AFTERMATH OF THE *MYRIAD* DECISION

Myriad is nothing new in the realm of patentable subject matter. Rather, it is endemic of the problem—the Supreme Court’s failure to articulate a useful and meaningful guide on the limits of patentable subject matter.¹¹¹ This shortcoming has important consequences. Showcasing the various problems, three Federal Circuit judges, experts in patentable subject matter jurisprudence, reached widely divergent conclusions in *Myriad*. Two appeared to agree that Myriad’s claims to isolated DNA sequences were not patentable under the Supreme Court’s murky framework. But one weighed this lack of clarity with settled expectations and concluded that any change must come from Congress, not the courts. The court thus allowed the claims to stand and passed the ball to the Supreme Court or Congress.

With the immense number of already issued patents, this concern is not surprising. In 2005, it was estimated that more than 40,000 DNA-related patents had been issued by the Patent Office, and this number has obviously grown.¹¹² In such circumstances, courts are understandably loath to create uncertainty or upheaval in industries heavily invested in intellectual property.¹¹³

However, the court’s opinion in *Myriad* did little to comfort inventors and businesses. Far from reassuring those holding and seeking patents of the value of their property rights, a majority of the court suggested isolated DNA is unpatentable. Although they dodged that bullet, they are left to wonder whether the Supreme Court or Congress may be less friendly. Indeed, if the Supreme Court’s most recent decision in *Mayo* is any

108. *Id.*

109. *Id.* at 1355.

110. *Id.* at 1357–58.

111. Rebecca S. Eisenberg, *Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods after In re Bilski*, 3 CASE W. RES. J.L. TECH. & INTERNET 1, 7 (2012).

112. Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. PAT. & TRADEMARK OFF. SOC’Y 19, 19 (2011).

113. *See, e.g., Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002) (“[C]ourts must be cautious before adopting changes that disrupt the settled expectations of the inventing community.”).

indicator, the Court seems willing to expand the scope of unpatentable subject matter.¹¹⁴

Moreover, decisions like *Myriad* create a feedback loop whereby the bounds of patentable subject matter are constantly pushed outward. Without any clear guidance from Congress or the courts, speculators are encouraged to gamble on the prospect of patent protection.¹¹⁵ This in turn encourages mainstream industry to invest in patent acquisition to protect their intellectual property.¹¹⁶ Now, with skin in the game, industry has incentive to maximize the value of its patent rights by ensuring their validity and will exert its influence on the various branches of government to protect its rights.¹¹⁷ As courts are unwilling to upset these expectations, this ultimately reinforces the behavior.¹¹⁸ In the words of one commentator:

Thus, the lack of a clear roadmap for determining the boundaries of patentability, the Supreme Court's reluctance to weigh in on these questions in a timely manner, the Federal Circuit's inclination toward expansive patentable subject matter, the incoherence and vagueness of the Supreme Court's opinions, and the constitutional and political impediments to legislative action on patent reform have inclined the system reflexively toward expansive patentable subject matter whether or not it comports with good policy or constitutional, jurisprudential, and statutory limits.¹¹⁹

It is therefore no surprise that commentators have grappled with the proper role and articulation for patentable subject matter and in the process produced widely divergent proposals for the courts and Congress to follow.¹²⁰ Proposals range from the most simple, including relying on other statutory provisions to limit patent scope¹²¹ or limiting the § 101 inquiry to only whether an invention is “new and useful,”¹²² to much more

114. See *Myriad*, 689 F.3d 1303, 1343 (Fed. Cir. 2012) (Moore, J., concurring), *aff'd in part, rev'd in part sub nom.* Ass'n for Molecular Pathology v. *Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

115. Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land: Bilski's Superficial Textualism and the Missed Opportunity to Return Patent Law to Its Technology Mooring*, 63 STAN. L. REV. 1289, 1305 (2011).

116. *Id.*

117. *Id.* at 1306.

118. *Id.*

119. *Id.* at 1307.

120. Eisenberg, *supra* note 111, at 42.

121. Sam S. Han, *Analyzing the Patentability of "Intangible" Yet "Physical" Subject Matter*, 3 COLUM. SCI. & TECH. L. REV. 1, 5 (2002).

122. Daniel J. Klein, *The Integrity of Section 101: A "New and Useful" Test for Patentable Subject Matter*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 287, 312 (2011) (internal quotation marks omitted).

complicated approaches, such as employing detailed and elaborate decision trees¹²³ or assigning an administrative agency the task of applying a utilitarian analysis to determine what areas merit patent protection.¹²⁴ Certainly, the most appealing solution would be for Congress to step in and clarify the scope of patentable subject matter. However, as Congress has recently overhauled the patent statutes but left § 101 unchanged, it seems likely that Congress is unwilling to, believes it to be unnecessary to, or is unsure how to more clearly define patentable subject matter.¹²⁵

The Supreme Court has recently regranted certiorari in the *Myriad* case, asking the parties to brief a simple, yet loaded, question: Are human genes patentable?¹²⁶ I propose that the Court use this case, or a similar case, to clarify and simplify its patentable subject matter jurisprudence. The ideal approach would be a simple, bright-line test to classify subject matter. Two examples of such approaches have been proposed.¹²⁷ Both begin with a threshold inquiry of whether an invention is “new,” in other words whether it is man-made.¹²⁸ This inquiry is a rough test, with most inventions likely passing this test. In the first approach, the bulk of the screening is done by the proposed second step in the test: whether the identified use for the invention derives from what makes it a human invention.¹²⁹ On the other hand, the other approach proposes leaving § 112’s written description requirement to do the heavy lifting.¹³⁰

The approach I propose is a slight variation of these tests. I agree with the initial inquiry being that a court should first ask whether the invention is human-made. Indeed, this broad interpretation finds support both in the text of the statute, which contemplates four broad categories of patentable subject matter,¹³¹ and in the legislative history, where it was explained that it was to “include anything under the sun that is made by man.”¹³² However, I believe the remainder of filtering patentable subject matter should be left to the nonobviousness inquiry of § 103. When determining whether an invention is obvious, courts ask whether the invention or

123. Eftimios Parasidis, *A Uniform Framework for Patent Eligibility*, 85 TUL. L. REV. 323, 329 (2010).

124. David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMP. L. REV. 181, 185 (2009).

125. See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

126. Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 694 (2012); Petition for Writ of Certiorari, *Myriad*, 133 S. Ct. 694 (No. 12-398).

127. Klein, *supra* note 122, at 312; Han, *supra* note 121, at 5.

128. Klein, *supra* note 122, at 312; Han, *supra* note 121, at 5.

129. Klein, *supra* note 122, at 312.

130. Han, *supra* note 121, at 5.

131. 35 U.S.C. § 101 (2006).

132. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 82-1979, at 5 (1952)) (internal quotation marks omitted).

improvement would have been obvious to a person having ordinary skill in the prior art.¹³³ If the Court means what it says, then laws of nature, physical phenomena, and abstract ideas are “part of the storehouse of knowledge of all men.”¹³⁴ This storehouse of knowledge is available to one skilled in the art. Thus, if a method differs no more from what one can accomplish in one’s mind, or if a new composition simply derives from a naturally occurring substance with little change, such an invention would be unpatentable as obvious to one skilled in the art.

A few examples show how such an approach would work, and that it would achieve significantly the same results as the current framework. First, consider *Myriad*’s claims to isolated DNA, which the Supreme Court unanimously held unpatentable on appeal from the Federal Circuit.¹³⁵ Such a claim would not pass the first inquiry, whether it is human-made. Much like a precious metal that is extracted from the earth, the particular genetic sequence extracted by *Myriad* existed in nature before its isolation and is therefore not human-made. Next, consider the claim made in *Chakrabarty* to a genetically modified bacterium, which was held patentable by the Court.¹³⁶ Such a bacterium was not found in nature and is thus human-made under the first inquiry. Turning to the second inquiry, a court would ask whether this new bacterium would be obvious to one skilled in the art. The Court did not consider obviousness in its opinion, so the conclusion is not entirely clear. However, the Court’s opinion indicated that the bacterium possessed characteristics which were unknown in nature. These characteristics would seem to not be part of the storehouse of knowledge and imparting them on the bacterium at least appears to be nonobvious to one skilled in the art.

This contrasts with the analysis that would be applied to the claim to a mixture of naturally occurring bacteria that was made in *Funk Brothers*.¹³⁷ The Supreme Court held the mixture to be an unpatentable law of nature. Under the proposed framework for patentability, the mixture would likely pass the first inquiry. Although the mixture was composed of entirely natural substances, that precise mixture does not appear to have been naturally occurring but instead was human-made. Under the second inquiry, however, the mixture would probably not be patentable because it is obvious. In fact, much of the language used by the Court in classifying it as a law of nature suggests that such a mixture would be obvious to one skilled in the art: “once nature’s secret of the non-inhibitive quality of

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

134. *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)) (internal quotation marks omitted).

135. *Ass’n for Molecular Pathology v. U.S.P.T.O.*, 133 S. Ct. 2107 (2013).

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

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

certain strains of [bacteria] was discovered, the state of the art made the production of a mixed inoculant a simple step.”¹³⁸ In other words, once the non-inhibitive characteristic of the bacteria was known—once it was part of the storehouse of knowledge—it would have been obvious to one skilled in the art to combine the various bacteria. This analysis seems more intellectually honest. The mixture is unpatentable not because it merely employs a law of nature (the non-inhibitive characteristic) but because the mixture applies a law of nature in an obvious way.

Such an approach (or either of the simpler approaches upon which it is modeled) would have a number of advantages over the other more complicated alternatives. First, while taking a utilitarian approach would be more true to the spirit of patent law, courts are particularly ill-equipped to make policy decisions necessary to effectuate such an approach.¹³⁹ Such an approach would require courts to address questions like

(1) Would this type of innovation occur at sufficient levels without a patent grant? (2) Would granting a patent right for this type of innovation cause more loss to society than gain? (3) If society would not benefit from granting patentability to the particular type of innovation, can sufficiently clear lines be drawn between this subject matter and other subject matter that does need the protection of patentability?¹⁴⁰

Answering questions like these is not the typical role of federal courts. Instead, courts seek to resolve concrete disputes between two adverse parties.¹⁴¹ Even assuming it is desirable that federal courts answer these sorts of questions, courts would require far more parties than those before it to answer these questions. Moreover, until a particular issue is resolved at the Supreme Court or Federal Circuit level, what is patentable in one district court would not necessarily be patentable in another. If such an approach is to be adopted, it is for Congress to allocate the necessary decision-making power.¹⁴²

Additionally, such an approach would have the advantage of being far clearer and more predictable, benefiting the PTO, lower courts, inventors, and industry. Courts already engage in an analysis of the obviousness of the invention. And while this analysis can be challenging, courts have other

138. *Id.* at 132.

139. *See* Olson, *supra* note 124, at 237.

140. *Id.* at 184.

141. RICHARD H. FALLON, JR., DANIEL J. MELTZER & DAVID L. SHAPIRO, HART AND WECHSLER'S THE FEDERAL COURTS AND THE FEDERAL SYSTEM 67 n.2 (6th ed. 2009).

142. *See* Olson, *supra* note 124, at 237–38 (explaining that the best choice would be for Congress to delegate such a role to an administrative agency).

ways to cope with the challenge of this inquiry, such as identifying secondary considerations.¹⁴³ Moreover, such an approach is technology-agnostic. This means that as technology and inventions are driven into new, possibly unknown, fields, courts will not be left attempting to define what are the laws and products of nature. Instead, based on the applicable principles, courts will only be required to judge the obviousness of such an advancement. While this is no easy task, it is certainly simpler than attempting to assign subject matter into one of the metaphysical categories that the Supreme Court has defined.

Finally, adopting such a clear, definitive statement may be the impetus for Congress to change or further develop that subject of patentable subject matter. This new test for patentable subject matter would certainly be more inclusive than the current approach. Arguably, though, Congress contemplated this wide inclusion.¹⁴⁴ If Congress did not mean what it said, both in § 101 and its legislative history, then the ball would be in Congress's court to redefine patentable subject matter. Indeed, it would seem consistent with the constitutional directive that Congress, or an administrative agency, more precisely define in what areas patents are necessary to promote the useful arts.

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143. See *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (2006).

144. See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (“Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’” (quoting S. REP. NO. 82-1979, at 5 (1952))).

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