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Mayo v. Prometheus: Reorganizing the Toolbox for Patent Eligible Subject Matter and Uses of Natural Laws

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MAYO V. PROMETHEUS: REORGANIZING THE TOOLBOX FOR PATENT ELIGIBLE SUBJECT MATTER AND USES OF NATURAL LAWS

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I. INTRODUCTION

Advances in medical technology, in particular the development of new and improved medical methods, pose a unique problem for the United States patent system, in that some of these inventions exist at the fringe of patent eligible subject matter under 35 U.S.C. § 101. As a threshold requirement before consideration of utility, novelty, or non-obviousness, patent eligible subject matter requires that a new invention be of such a nature as to fall within an inventive category enumerated in the statute.[1] In revising the patent system in 1952, Congress intended for the subject matter eligibility requirement to be broad, encompassing "any new and useful process, machine, manufacture, or composition of matter . . . ."[2] Despite this broad intent, federal courts have long recognized an exception to patent eligible subject matter for attempts to patent laws of nature.[3] Since most inventions rely to some extent upon a law of nature, the question arises concerning in just what manner such inventions are permitted to rely on or incorporate these laws of nature.[4]

For the vast majority of patent applications, the subject matter of the invention fits snugly into one of the enumerated categories in § 101, and the demarcation of patent eligible subject matter need not be resolved with any definiteness. However, over the past forty years, technological advances in computer technology, software, medical treatment methods, and genetics have resulted in questions about where the boundary lies between a patentable and un-patentable use of a law of nature.[5] As

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1. 35 U.S.C. § 101 (2006); *see also In re* Bergy, 596 F.2d 952, 960 (C.C.P.A. 1979) (describing patent eligible subject matter as the first door through which an inventor must pass before matters of novelty and obviousness are even considered).

2. 35 U.S.C. § 101 (2006); Diamond v. Chakrabarty, 477 U.S. 303, 308 (1980).

3. *E.g.*, Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) ("He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.").

4. *See* Diamond v. Diehr, 450 U.S. 175, 187 (1981) ("Our earlier opinions lend support to our present conclusion that a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program, or digital computer.").

5. *Id.* at 175–88 (discussing the challenges with computer technology and software); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012) (addressing medical methods); Ass'n for Molecular Pathology v. United States PTO, 689 F.3d 1303 (Fed. Cir. 2012) (analyzing the

inventions come closer to this boundary between the broad statutory definition of patent eligible subject matter and the judicial exception for laws of nature, the distinction between permissible and impermissible use of a natural law is not easily discernable.

This lack of clarity over the boundary of patent eligible subject matter for laws of nature has broad implications for the rate of innovation in the United States. The rate of technological innovation has increased dramatically over the past thirty years, greatly improving the efficiency of gathering and collecting data about the physical world and opening up new fields of research. These new fields present new challenges to the patent system, in particular the concept of patent eligible subject matter. Genetics research presents the question of whether specific gene sequences, though naturally occurring, can be isolated and patented;[6] computer and data technology pose the question of whether data conversion operations and methods satisfy the requirements for eligible subject matter;[7] and medical methods research challenges the scope of patent eligible subject matter.[8]

Future developments in the legal standard for patent eligible subject matter will likely have a substantial impact on the medical research field, especially with respect to medical methods research. Health care spending represents more than 17% of the gross domestic product of the United States and continues to increase, and U.S. companies spend billions of dollars on medical research to capitalize on this market.[9] From 2007 through 2011, the United States Patent and Trademark Office (PTO) granted 30,035 patents in the technology class for pharmaceuticals and associated methods.[10] This total was the most of any technology class examined by the PTO and represents over 3% of the total number of patents granted.[11]

With medical methods in particular, many commentators theorize that

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subject matter eligibility in the field of genetics).

6. *Ass'n for Molecular Pathology*, 689 F.3d at 1303.

7. *Diehr*, 450 U.S. at 175.

8. *Mayo*, 132 S. Ct. at 1289.

9. Alex Wayne, *Health-Care Spending to Reach 20% of U.S. Economy by 2021*, BLOOMBERG NEWS, June 13, 2012 (reporting that spending on health care services rose 3.9% in 2011 to about 17.9% of the U.S. GDP); *$95 Billion a Year Spent on Medical Research*, ASSOCIATED PRESS, Sept. 20, 2005 ("Total U.S. spending on medical research has doubled in the past decade to nearly $95 billion a year" in 2005).

10. *Patenting by Geographic Region, Breakout by Technology Class*, USPTO (Mar. 27, 2012), http://www.uspto.gov (From the "Patent" menu select "Statistics," select "General Patent Statistics," and under patents select "Calendar Year Patent Statistics." From the table of contents, select "By Patented Technology" and then scroll down to the report named "clsstc/stc_cl_gd." Open reports by clicking on the hyperlink. Click on "all countries") (Technology class 424, "Drug, Bio-Affecting and Body Treating Compositions," also included technology class 514, which is the technology class of the patent at issue in *Mayo*).

11. *Id*.

a change in jurisprudence concerning patent eligible subject matter could have a drastic effect on future funding of medical research, if the change results in precluding an entire class of medical method claims from eligibility for patent protection. Even without a clear definition of what is patentable, the uncertainty makes it difficult for researchers to predict the value of certain types of research and estimate the possible return on the investment of research funds.

For the past thirty years, federal courts have tried a number of approaches to determine the eligibility of subject matter, but have not adequately defined the judicial exception to eligible subject matter for laws of nature. In the latest attempt in *Mayo Collaborative Services v. Prometheus Labs*, the United States Supreme Court invalidated a medical methods patent on the grounds that it was an attempt to patent a law of nature.[12] The Court attempted to illuminate a clear standard for determining the boundary of the judicial exception to patent eligible subject matter for laws of nature, but its efforts have fallen short. The Court only deepened the confusion by covering the issue of patent eligible subject matter with a patchwork quilt of past jurisprudence that adds very little to clarify the boundary of the appropriate use of a natural law in an invention.

This article seeks to evaluate the Supreme Court's decision in *Mayo*, to consider the decision's impact on future patent infringement cases, and to suggest alternative pathways to clarify the issue of patent eligible subject matter for medical methods. Part II provides an overview of the statutory subject matter requirement for patent eligibility and the development of the judicial exception for natural laws, abstract ideas, and natural phenomenon. Part III parses through the Court's decision in *Mayo* and examines the reaction to *Mayo* in the lower courts and among industry participants. Part IV critiques the Court's analysis in *Mayo*, proposes an alternative to the inventive concept method for evaluating subject matter eligibility, and suggests that Congress take action to examine the complex policy considerations surrounding eligible subject matter for medical methods and, if necessary, take action to clarify the standard.

II. PATENT ELIGIBLE SUBJECT MATTER AND THE DEVELOPMENT OF THE JUDICIAL EXCEPTION FOR NATURAL LAWS

Introduction to patent eligible subject matter begins with the Constitutional mandate to promote progress. Article I, Section 8, Clause 8 of the United States Constitution grants to Congress the power "[t]o

12. *Mayo*, 132 S. Ct. at 1305.

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."[13] In pursuit of this mandate, the first Congress of the United States established the patent system under the direction of Thomas Jefferson, the first Secretary of State.[14] As expressly stated in the "Progress Clause," the purpose of the patent system is to promote progress in the useful arts.[15] The intended result is to strengthen the economy by facilitating the introduction of new products into the market, which advances manufacturing and creates jobs.[16]

The patent system accomplishes this by conferring patent rights to an inventor in exchange for a complete disclosure of the invention. The patent rights granted to the inventor are negative property rights, meaning that the inventor is granted the right to exclude others from practicing the invention, but the inventor does not possess an unbounded right to use or practice the invention.[17] Therefore, a patent grants an inventor a right to exclude others from practicing the invention.[18] Representing a critical element of the patent, the claims of the patent distinctly define the boundaries of the inventor's exclusive rights.[19]

To be eligible for patent protection, the invention must meet the statutory requirements for patentability. Under 35 U.S.C. § 101, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[20] This section sets forth the first two patentability requirements. First, the invention must be useful, and second, the invention must be a process, machine, manufacture, or composition of matter.[21] The last phrase of the statute, "subject to the

13. U.S. CONST. art. I, § 8, cl. 8.

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

15. U.S. CONST. art. I, § 8, cl. 8.

16. Kewanee v. Bicron, 416 U.S. 470, 480 (1974) ("The productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.").

17. 35 U.S.C. § 154(a) (2006) ("Every patent shall contain . . . a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process . . . ."); *see also Kewanee*, 416 U.S. at 480.

18. *Id*.

19. JANICE M. MUELLER, PATENT LAW 65 (Aspen Publishing, 3d ed. 2009) (describing the function of patent claims).

20. 35 U.S.C. § 101 (2006).

21. *Id*.

conditions and requirements of this title," refers to the additional patentability requirements of novelty, obviousness, and adequacy of disclosure.[22] The patent eligible subject matter requirement is a threshold requirement that must be determined before moving on to the novelty and non-obviousness requirements.[23]

The discussion of patent eligible subject matter begins in § 101 with the requirement that the invention be a "process, machine, manufacture, or composition of matter."[24] Analyzing the statutory construction of § 101, the Supreme Court reasoned that Congress intended for § 101 to have a wide scope, because of the expansive language used in drafting the statute.[25] In addition, Congressional reports preceding passage of the 1952 Patent Act indicated a desire to "include anything under the sun that is made by man."[26]

Although Congress intended for § 101 to be broad, courts have long recognized a judicial exception to patent eligible subject matter for laws of nature, physical phenomenon, abstract ideas, unapplied mathematical algorithms, and products of nature.[27] This exception is based on the idea that certain information is a manifestation of nature and should be free to all persons.[28] The demarcation of what is and what is not such a manifestation of nature is more difficult to determine, and the courts have repeatedly attempted to define this boundary. The motivation behind the exception is to make sure that patents do not preclude the use of natural laws in further innovation.[29] Though patent protection is intended to motivate innovation by providing a financial incentive for

22. 35 U.S.C. § 101 (2006); 35 U.S.C. § 102 (2006) (novelty requirement); 35 U.S.C. § 103 (2006) (non-obviousness requirement); 35 U.S.C. § 112 (2006) (sufficiency of disclosure requirements).

23. Parker v. Flook, 437 U.S. 584, 593 (1978) ("The obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious.").

24. 35 U.S.C. § 101 (2006).

25. Diamond v. Chakrabarty, 477 U.S. 303, 308 (1980).

26. S. REP. NO. 1979, 82d Cong., 2d Sess., at 5 (1952); H.R. REP. NO. 1923, 82d Cong., 2d Sess., at 6 (1952).

27. O'Reilly v. Morse, 56 U.S. 62, 112–20 (1854) (holding claim 8 of the Morse Patent to be un-patentable subject matter as an attempt to patent the use of electromagnetism to transmit characters over a distance; discussing *Nielson v. Hartford*, a case from the English Court of Exchequer that first discussed the issue of patentable subject matter in relation to a patent granted for the first blast furnace); LeRoy v. Tatham, 55 U.S. 156, 175 (1853) (laws of nature are not eligible for patent protection); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130–31 (1948) (discoveries of natural phenomena are not eligible for patent protection); Bilski v. Kappos, 130 S. Ct. 3218, 3229–30 (2010) (abstract ideas are not patent eligible subject matter); Gottschalk v. Benson, 409 U.S. 63, 67–72 (1972) (applying the judicial exception to unapplied mathematical algorithms); Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (discussing the judicial exception to patent eligible subject matter for products of nature).

28. *Funk Bros.*, 333 U.S. at 130.

29. *See Gottschalk*, 409 U.S. at 67 ("Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.").

research and development, claims that are too broad, such that they foreclose the tools of science from use by others, can have a negative effect on innovation.[30]

Although the judicial exception for laws of nature seems straightforward, the Supreme Court has struggled to develop a workable standard that provides adequate notice to inventors.[31] The Court has favored two approaches to deciding the question of patent eligible subject matter. First, the Court has employed an "inventive concept" analysis, wherein the Court examines the patent claims to determine if they include an inventive concept beyond the expression of the natural law.[32] In response to an attempt to patent a mathematical algorithm, the Court stated, "[i]f there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end."[33] In essence, the "inventive concept" approach looks to see if the claimed invention is a practical application of the law of nature. Concerned that a skilled claim draftsperson could circumvent the patent eligible subject matter requirement through the crafty choice of language, the Court enhanced the standard by requiring more than adding insubstantial post-solution activity to a natural law in order to make the claim patentable subject matter.[34] Stated another way, adding insignificant steps to the natural law is not enough to make it patentable. In addition, the Court has also held that confining the applicability of a natural law to a narrow and specific field of endeavor is also insufficient to make the claim to a natural law patentable subject matter.[35]

Second, the Supreme Court and lower courts have looked to the "machine or transformation test" to decide the patent eligibility of process patent claims.[36] Under the machine or transformation test, a process is patent eligible subject matter only "if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article

30. *See id*. at 71–72.

31. From now on, the article will refer to the judicial exception for natural laws and will leave off abstract ideas, mathematical algorithms and natural phenomenon for the sake of efficiency.

32. Parker v. Flook, 437 U.S. 584, 594 (1978) (holding the patent for recalculating an alarm limit invalid because the claims included no other inventive concept other than using an algorithm to calculate a new alarm limit and then storing that alarm limit in computer memory).

33. *Gottschalk*, 409 U.S. at 67.

34. *Flook*, 437 U.S. at 590–91 (outlining the principle that post-solution activity must establish some additional inventive concept in order to transform a law of nature/mathematical algorithm into patent eligible subject matter).

35. *See id.* at 592–96.

36. *Gottschalk*, 409 U.S. at 70–71 (discussing prior precedents favoring the machine or transformation test but declining to make it the exclusive test for patent eligibility for process claims); *see also* Bilski v. Kappos, 545 F.3d 945, 954 (Fed. Cir. 2008) [hereinafter *Bilski I*] (claiming the machine or transformation test to be the exclusive test for patent eligible subject matter for process claims), *overruled by*, Bilski v. Kappos, 130 S. Ct. 3218 (2010) [hereinafter *Bilski II*].

into a different state or thing."[37] In other words, a process claim based on a law of nature would not preempt the use of that law of nature if the process was confined to the use of a particular machine or transformed materials in a particular way.[38] Prior to *Bilski II*, decided in 2010, the Federal Circuit favored the machine or transformation test for determine patent eligibility for process patents, but in *Bilski II*, the Supreme Court held that the machine or transformation test was only one consideration and not the exclusive test to determine the patent eligible subject matter for process claims.[39]

While these are the two primary methods used by the Court to determine patent eligible subject matter under § 101, other methods have also been used. One method suggested in *Flook* was to treat a law of nature as an invention already existing, and therefore not novel, and then seeing if anything else was left that was patentable.[40] Functionally, this method is similar to the "inventive concept" method. Another consideration is the extent to which the claims involving the natural law preempt future use of the natural law.[41] None of these approaches have been adequate to resolve the confusion and doubt surrounding the question of patent eligible subject matter for inventions that make use of laws of nature.

The Supreme Court has not been the only entity responsible for making changes to the scope of patent eligible subject matter. In the past, Congress has clarified and changed the scope of patent eligible subject matter by passing legislation to alter patent eligibility for certain types of technology. To promote innovation in plant breeding, Congress enacted the Plant Patent Act in 1930 to extend patent eligibility to asexually reproduced plants, which had formerly been considered by courts to be unpatentable as products of nature.[42] Congress also added a separate patent provision for design patents to cover new ornamental designs for articles of manufacture.[43] As part of the America Invents Act of 2011, Congress enacted a provision declaring that "no patent may issue on a claim directed to or encompassing a human organism," thereby removing human organisms from patent eligible subject matter.[44] In the past, Congress has intervened to define patent eligible

37. *Bilski I*, 545 F.3d at 954.

38. *Id*.

39. *Bilski II*, 130 S. Ct. at 3227.

40. Parker v. Flook, 437 U.S. 584, 591–92 (1978).

41. *Gottschalk*, 409 U.S. at 71–72 (stating that upholding the claims to the mathematical algorithm would pre-empt the use of that algorithm in any use).

42. 35 U.S.C. § 161 (2006); JANICE M. MUELLER, PATENT LAW 288 (Aspen Publishing, 3d ed. 2009).

43. 35 U.S.C. § 171 (2006).

44. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33, 125 Stat. 284, 340 (enacted

subject matter in certain fields of endeavor. Congress has not addressed the patent eligible subject matter issue for medical methods or computer software applications, and because of this, the Court continues to struggle, as shown by its extensive discourse in *Mayo*.

III. *MAYO COLLABORATIVE SERVICES V. PROMETHEUS LABS, INC.*

For over thirty years, the Court has employed a variety of considerations in determining whether process claims based on natural laws or abstract ideas are patent eligible subject matter. With this kaleidoscope backdrop of methods, the Court approached *Mayo* intending to set forth a clear standard for determining statutory subject matter eligibility for processes involving natural laws. This Casenote looks first at the Court's decision in *Mayo* and its attempt to clarify the issue of patent eligible subject matter and then examines the response in the lower courts in cases that have arisen since *Mayo*.

A. The U.S. Supreme Court's Decision in Mayo

Mayo involved an action against Mayo Collaborative Services for infringement of two patents covering methods of administering thiopurine drugs for the treatment of immune-mediated gastrointestinal disorders.[45] In March of 2002, the United States Patent and Trademark Office (USPTO) issued the 6,355,623 ('623) Patent for a "[m]ethod of treating IBD/Crohn's disease and related conditions wherein drug metabolite levels in host blood cells determine subsequent dosage."[46] Almost two years later, the USPTO granted a second patent, the 6,680,302 ('302) Patent, to the same entity for a similar method for optimizing the effectiveness of drug doses in treating immune-mediated gastrointestinal disorders.[47]

The claims represented in the '623 Patent follow a standard format and include an administration step, in which the thiopurine drug is administered to a patient, and a determination step, in which the blood concentrations of the metabolites arising from administration of the drug are measured. The third step is a wherein step, in which the result of the determination step is compared to an experimentally determined correlation between the concentration of the metabolites and the effective dosage of the administered drug. Below a certain concentration, the results suggest that the dosage may be ineffective, and

Sept. 16, 2011).

45. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1295–96 (2012).

46. U.S. Patent No. 6,355,623 (filed Apr. 8, 1999).

47. U.S. Patent No. 6,680,302 (filed Dec. 27, 2001).

above a higher concentration, the results suggest that the dosage may result in harmful side effects.[48]

Prometheus Labs became the exclusive license holder of both the '623 and '302 Patents and marketed and sold the medical method described therein to Mayo Collaborative Services and Mayo Rochester, who used the diagnostic method to treat patients.[49] After several years of purchasing the diagnostic test from Prometheus, Mayo planned to develop and sell its own medical method for determining the effectiveness of dosing levels for administering thiopurine drugs to treat immune-mediated gastrointestinal disorders.[50] The only substantial difference in the Mayo test was a slightly higher threshold metabolite concentration for the toxicity limit.[51] As the sole exclusive license holder, Prometheus Labs brought a claim for infringement of the '623 and '302 Patents.[52]

The procedural posture of *Mayo* demonstrates the confusion and differences of opinion regarding the treatment of patent eligible subject matter for medical methods. The district court found infringement because the difference in the two tests was not significant, but declared the patent invalid because the patent was an attempt to patent a law of nature. In so holding, the district court applied an analysis similar to *Morse* and *Gottshalk*, in which the attempt to patent a law of nature was held invalid for precluding use of the natural law for future innovation. On appeal, the Federal Circuit reversed the district court's finding of invalidity. The Federal Circuit employed the machine or transformation test and found that the administration of the drug to the patient caused a transformation to the patient and that measurement of the concentration of metabolites in the blood effected a transformation of the sample of blood, which the court viewed as a tangible article.[53] Upon granting a writ of certiorari, the Supreme Court summarily vacated the Federal Circuit's decision and remanded the case for reconsideration in light of the Supreme Court's ruling in *Bilski II*, which held that the machine or transformation test was a consideration in determining eligible subject matter but was not the only consideration.[54] On remand, the Federal

48. *Mayo*, 132 S. Ct. at 1295. *See also* Nathan A. Reed, Note, *A New Metric To Determine Patent Eligible Subject Matter for Medical Methods*, 16 MICH. ST. J. MED. & LAW 321, 332–36 (2012) (describing in detail the treatment of autoimmune diseases with thiopurine drugs and the operation of the medical method in patent number '623).

49. *Mayo*, 132 S. Ct. at 1295–96.

50. *Id*. at 1296.

51. For the metabolite 6-TG, the toxicity limit in the Prometheus patent method was 400 pmol per 8x108. The Mayo test had an upper toxicity limit for 6-TG of 450 pmol per 8x108. *Id*.

52. *Id*.

53. *Id*.

54. *Id*.

Circuit affirmed its prior decision, finding its analysis under the machine or transformation test to be compelling despite its consideration of *Bilski II*.[55] The case returned to the Supreme Court on another grant of certiorari.[56] In a unanimous decision, the Court again reversed the Federal Circuit decision and held the patent claims to be invalid as an attempt to effectively claim a patent on a law of nature.[57]

The Supreme Court began its substantive opinion with a declaration that the claims of the '623 and '302 Patents included laws of nature, namely the relationship between the level of metabolites in the patient's blood and the effectiveness of the drug.[58] The Court stated that the correlation is a law of nature because the "relation itself exists in principle apart from any human action," even though resulting from the initial action of injecting the drug.[59] The Court determined that the correlation in the wherein step in the '623 Patent claims was a law of nature, because the relationship between the concentration of metabolites and the effectiveness of the drug existed with no further human interaction beyond the initial injection of the drug.[60] Since the correlation was a law of nature, the question before the Court became whether or not the claims of the patent did more than just describe the law of nature.[61]

To answer this question, the Court engaged in three separate approaches to demonstrate that the claims did no more than describe the law of nature and, as such, were not patent eligible subject matter: (1) a step-by-step inventive concept analysis; (2) a guidepost analysis based on prior precedents; and (3) a determination of scope and preemptive effect of that scope.[62] First, the Court analyzed each step of the method claims to determine if the claims included more than the law of nature itself.[63] The Court stated that a claim to a process that includes a law of nature is not patentable unless the claim has "additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself."[64] The Court focused on the need for additional elements in a claim beyond the law of nature and referenced the *Flook* Court's viewpoint that a law of nature cannot

55. *Id*.
56. *Id*.
57. *Id*. at 1305.
58. *Id*. at 1296.
59. *Id*. at 1297.
60. *Id*.
61. *Id*.
62. *Id*. at 1297–1302.
63. *Id*. at 1297–98.
64. *Id*. at 1297.

support a patent unless there is some other inventive concept.[65]

Using the principle of inventive concept, the Court analyzed the three general process steps in the '623 Patent. The 'wherein' step, which set forth the correlation between the blood concentrations of metabolite and the effectiveness of the drug, was the embodiment of the law of nature at issue. Therefore, the Court analyzed the other two steps in the method claims to see if those steps added inventive concept independent of the law of nature. The first step of administering the drug to a patient with an autoimmune disease worked to confine the invention to a particular class of patients.[66] Relying on its decision in *Bilski II*, the Court held that this narrowing of the use of the correlation to a specific field of endeavor did not turn the claim into patent eligible subject matter.[67] The Court held that the second step of determining the level of metabolites constituted pre-solution activity.[68] Because methods of measuring the level of the metabolites in the patient were well-documented in the field of medicine, the Court classified the determination step as "well understood, routine, conventional activity previously engaged in by scientists who work in the field," which was not enough to make the claims patent eligible according to the Court's prior decisions in *Bilski II* and *Flook*.[69] Conventional or obvious pre- or post-solution activity is not sufficient to make a claim to a law of nature patent eligible.[70] Last, the Court looked at all three steps as a whole and determined that the combination added nothing to the claims that did not exist in each of the three steps taken independently.[71] The Court's first approach, based on analyzing each step of the claim for an inventive concept separate from the law of nature itself, resulted in a finding of invalidity.

In its second approach, the Court employed a guidepost analysis, in which the Court compared *Mayo* to its two prior decisions in *Diehr* and *Flook*, two decisions that resulted in opposing opinions.[72] *Diehr* involved a rubber molding process that utilized a mathematical equation to calculate estimated residence times based on temperature measurements inside the mold.[73] Because the process claim included the additional steps of adding rubber to the mold, closing the mold, measuring the mold temperature, comparing the calculated value against

65. *Id*. at 1297; *see also* Parker v. Flook, 437 U.S. 584, 594 (1978).
66. *Mayo*, 132 S. Ct. at 1297.
67. *Id*.
68. *Id*. at 1298.
69. *Id*. at 1297–98.
70. *Id*. at 1298.
71. *Id*.
72. *Id*. at 1298.
73. *Id*.

the actual elapsed time in the mold, and opening the mold when the elapsed time equaled the calculated time, the Court found the *Diehr* claims did not seek to preempt the use of the equation by others and, therefore, were patent eligible.[74] Comparing *Mayo* to *Diehr*, the Court determined that the claims in the '623 Patent were weaker than the process claims in *Diehr*.

In contrast, the claims in *Flook* included far fewer process steps and amounted to an attempt to patent a mathematical algorithm.[75] The patent at issue in *Flook* involved a method for changing alarm limits in a process control system that consisted of continuously measuring the process variables, recalculating the alarm limits using a novel mathematical algorithm, and storing the new alarm limit value.[76] The *Flook* Court determined that the process steps of measuring the process variables and storing the new alarm limit were well-known steps in the industry and that no inventive concept existed outside of the novel mathematical algorithm used to perform the calculation.[77] Comparing *Mayo* to *Flook*, the Court found the '623 Patent claims to be no stronger than the claims found to be un-patentable in *Flook*.[78] Based on this guidepost analysis, the Court found the '623 and '302 Patent claims to be at the *Flook* end of the *Flook–Diehr* eligibility spectrum and thus not patent eligible subject matter.[79]

In the third approach to patent eligible subject matter, the Court examined the scope of the claims and decided that the claims would pre-empt any future use of the natural law.[80] The Court began the analysis by reviewing additional prior decisions supporting the precedent "that simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable."[81] Referencing *Morse*, the Court recounted the discussion of the *Nielsen* case, where an English court found a method for adding warm air to a furnace to be patent eligible because the method involved non-conventional steps in addition to the natural law that adding warm air to a furnace improves efficiency.[82] Moving to *Bilski II*, the Court reiterated its holding that narrowing the application of a natural law to a

74. *Id*. at 1298–99.
75. *Id*. at 1299.
76. *Id*.
77. *Id*.
78. *Id*.
79. *Id*.
80. *Id*. at 1300–02.
81. *Id*. at 1300.
82. *Id*.

specific field of endeavor did not make the natural law patent eligible.[83] And finally, the Court referenced *Gottschalk*'s holding that without a practical application of the natural law the claims would be overbroad.[84]

After reviewing these past precedents, the Court expressed the concern that the continued enforcement of the claims would prevent further use of the correlation in research.[85] In *Morse*, the claims at issue foreclosed the use of electro-magnetism for any future innovation in the area of transmitting letters or characters over a distance, regardless of the devices invented.[86] Similarly in *Gottschalk*, the claims precluded the use of the algorithm for converting of binary coded numbers to pure binary numbers in any future application.[87] Likewise, the Court found that the general language employed by the '623 and '302 Patent claims would likely preclude the use of the correlation in any future medical research, even though the correlation is a narrow natural law applicable only to a specific treatment with a specific drug.[88] The Court found that the claims would interfere with too much future use of the law of nature and that this confirmed its decision to find the claims patent ineligible.[89]

After discussing the scope of the claims, the Court rebutted arguments made in favor of the patentability of the claims.[90] Regarding the Federal Circuit's application of the machine or transformation test, the Court stated that the test is only a clue and does not trump the judicial exception to patentability for laws of nature.[91] In response to Prometheus's argument that the natural law itself is narrow and specific, the Court responded that the scope of the natural law is irrelevant to the question of patentability.[92] In its amicus brief, the government argued that any step added to a natural law should make the subject matter patentable, because if the added step is routine in the art, then the claims will fail the novelty and nonobvious requirements.[93] The Court thought the government's view would do away completely with the patentable subject matter inquiry altogether, which is inconsistent with past precedents.[94] Last, Prometheus argued that invalidating the patent would have a chilling effect on research, because the patent incentive is

83. *Id.* at 1300–01.
84. *Id.* at 1301.
85. *Id.* at 1301–02.
86. *Id.* at 1301.
87. *Id.*
88. *Id.* at 1302.
89. *Id.*
90. *Id.* at 1302–05.
91. *Id.* at 1303.
92. *Id.*
93. *Id.*
94. *Id.*

critical to continued funding of medical research.[95] The Court responded by referencing opinions from the medical community in opposition to this position.[96]

At the conclusion of the opinion, the Court addressed the scope of its ruling. The Court stated that it hesitated to make any significant changes to the standard for determining patentable subject matter for fear that such a declaration may have unintended consequences in other fields of endeavor outside of medical methods.[97] The Court recognized that Congress too has a role in clarifying any exceptions to the patentable subject matter requirement.[98] In deciding *Mayo*, the Court set forth a fact-intensive, three-pronged approach for analyzing patent eligible subject matter but added very little substantive clarity to the uses of natural laws that are patent eligible.

B. Response to the Mayo *Decision*

In the months immediately following the *Mayo* decision, several lower courts found cause to interpret and apply the ruling in similar cases involving challenges to subject matter eligibility. In *Association for Molecular Pathology v. United States PTO* (*Myriad II*), the Federal Circuit upheld its initial decision that claims to an isolated DNA sequence and a method for screening potential cancer therapeutics were patent eligible subject matter, but the claim to a method for analyzing DNA sequences was not patent eligible.[99] In doing so, the majority employed pieces and parts of the *Mayo* decision depending on the situation. In regards to the claims to the isolated sequences of DNA, the majority opinion held that *Mayo* did not apply because a composition of matter was not a law of nature.[100] The majority then used a guidepost-type analysis, based on *Chakrabarty*[101] and *Funk Brothers*,[102] to show that the claims to isolated DNA sequences were indeed patentable

95. *Id*. at 1304.

96. *Id*. at 1304–05.

97. *Id*. at 1305.

98. *Id*.

99. Ass'n for Molecular Pathology v. United States PTO, 689 F.3d 1303, 1309 (Fed. Cir. 2012). Following the Federal Circuit decision in *Myriad I* in July 2011, the U.S. Supreme Court granted certiorari, vacated the Federal Circuit's decision and remanded the case to the Federal Circuit for reconsideration in light of the decision in *Mayo*. *Id*. at 1308. The case before remand is commonly referred to as *Myriad I*, and the case after remand, *Myriad II*.

100. *Id*. at 1331.

101. Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (holding that a human engineered bacterium capable of consuming petroleum was patent eligible subject matter).

102. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130–31 (1948) (holding that a mixed culture of bacteria for inoculating seeds was not patentable subject matter because the bacteria were unchanged from their natural state and, therefore, a phenomenon of nature).

subject matter.[103] For the two method claims, the majority used a step-by-step analysis similar to the first approach used by the *Mayo* Court, except the majority focused on whether the added steps were transformative under the machine or transformation test.[104]

The concurring opinion in *Myriad II* disagreed with the majority that the *Mayo* decision applied strictly to method claims. The two concurring judges felt that *Mayo's* discussion of laws of nature "ought to apply equally to manifestations of nature."[105] Despite the difference of opinion on the scope of *Mayo*, the concurring judges agreed with the majority that the claims directed to isolated DNA sequences were patentable because the isolated sequences did not exist in exactly the same chemical or physical form in nature.[106] The dissenting opinion in *Myriad II* argued that the claims to isolated DNA sequences were not patentable subject matter because the claims would preempt further efforts to isolate larger DNA sequences or whole DNA sequences.[107] Not only did the judges disagree on the applicable scope of the *Mayo* decision, but each of the three opinions used different parts of the *Mayo* opinion to make its arguments.

On remand from the Federal Circuit, the District Court for the Northern District of Maryland, in *Classen Immunotherapies*, found patent eligible claims setting forth a method for choosing an immunization schedule for infants.[108] The claims as issue in *Classen* were similar to the claims in *Mayo* except that the *Classen* claims required the added application step of selecting the appropriate immunization schedule.[109] The court used the step-by-step method from *Mayo* to show that the additional application requirement was sufficient, without further evidence, to demonstrate that the patent claims constituted patentable subject matter.[110] The Federal Circuit case that remanded *Classen* case back to the District Court is currently under consideration for certiorari on the issue of patent eligible subject matter under § 101.[111]

In *SmartGene*, the District Court for the District of Columbia

103. *Myriad II*, 689 F.3d at 1326–31.

104. *Id*. at 1333–37.

105. *Id*. at 1340 (Moore, J., concurring).

106. *Id*. at 1340–41.

107. *Id*. at 1349 (Bryson, J., dissenting).

108. Classen Immunotherapies, Inc. v. Biogen IDEC, No. WDG-04-2607, 2012 U.S. Dist. LEXIS 112280, at *2–4 (N.D. Md. Aug. 9, 2012), *on remand from*, Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1037 (Fed. Cir. 2011). The Federal Circuit case is currently under consideration for certiorari on the issue of patentable subject matter.

109. *Id*. at *17–19.

110. *Id*.

111. *Id*. at *4–5.

followed the *Mayo* roadmap nearly verbatim in finding claims to a method of selecting a treatment regimen using a computer program to be non-patentable subject matter.[112] Using the *Mayo* template as a guide, the district court first engaged in a guidepost analysis based on *Diehr*, *Flook*, *Gottschalk*, *Bilski*, and *Mayo* and then engaged in a step-by-step analysis of each claim.[113] Unlike *Mayo*, the district court went a step further and added an analysis of the machine or transformation test to make sure that it left no stone unturned.[114]

In response to the *Mayo* decision, the USPTO revised the Manual of Patent Examining Procedure to incorporate a three-prong inquiry to determine if a process or method involving the use of a natural law is patent eligible subject matter.[115] The USPTO method first asks whether the claims set forth a process or method consisting of a series of steps.[116] The second inquiry asks whether the claim focuses on the use of a natural law.[117] Further guiding the second inquiry, the USPTO reframes the question into whether or not the natural law is a limiting element of the claim.[118] In other words, if the natural law imposes a limitation on the scope of the claims, then the claim may focus on the natural law. An affirmative answer to the second inquiry prompts the examiner to proceed to the third inquiry, which asks if the claim introduces additional elements or steps to integrate the natural law into the invention.[119] The additional elements must be sufficient to show that the invention is a practical application of the natural law.[120]

IV. DISCUSSION

The *Mayo* Court's decision resulted in confusion about the scope of the decision and in varied application in the lower courts, which prompted an outcry from certain sectors of the medical research community. The fuss is for the most part unwarranted, but the confusion is not. The Court consolidated all of its prior precedents into an extensive three-approach method for determining patent eligible subject matter. In doing so, the Court set forth a detailed roadmap for lower courts to follow in analyzing the specific facts of cases but

112. SmartGene, Inc. v. Advanced Biological Labs, No. 08-00642, 2012 U.S. Dist. LEXIS 44138 (D.D.C. 2012).

113. *Id*. at *24–40.

114. *Id*. at *40–58.

115. MPEP § 2106.01 (8th ed. Rev. 9, Aug. 2012).

116. *Id*.

117. *Id*.

118. *Id*.

119. *Id*.

120. *Id*.

accomplished little to clarify the boundaries of patent eligible subject matter for methods involving laws of nature. The discussion focuses first on the Court's failure to add any substantial clarification to the law concerning patent eligibility of methods involving laws of nature. Then, the discussion argues that evaluating the scope of the claims is superior to consideration of inventive concept and, finally, proposes legislative action to clarify the exception to patentable subject matter for laws of nature, abstract ideas, and mathematical formulas.

A. Interpreting Mayo

The Court's opinion in *Mayo* assembled much of the Court's prior precedent with respect to patent eligible subject matter for use of natural laws into a three-approach method, effectively rearranging its toolbox without adding any new tools. The first approach relied on inventive concept, which first appeared with respect to subject matter eligibility of laws of nature in the *Morse* case and further developed in *Flook* and *Bilski II*.[121] In the second approach, the Court compared the facts of *Mayo* against the facts of two guidepost cases, *Flook* and *Diehr*. Courts have used this method since the founding of our legal system. As part of its analysis in *Morse*, the Court compared the facts before it to the facts of a case from the English Court of Exchequer.[122] In the third approach, the Court looked at the language of the patent claims and determined that the language was general enough to encompass all future processes making use of the correlation and, therefore, would negatively impact future research.[123] To make that determination, the Court compared the facts before it against prior cases, namely *Morse* and *Gottschalk*.[124] Each of the three approaches involved fact-intensive inquiries based on prior precedents and comparison to prior cases. Because of the Court's reliance on precedent in its analysis, the Court added very little to the substantive applicability of the judicial exception for laws of nature.

In fact, the Court may have actually taken a tool out of the toolbox, thereby perhaps reducing available precedent rather than creating precedent. In addressing the Federal Circuit's use of the machine or transformation Test, the Court stated that it had not "implied that the test trumps the 'law of nature' exclusion."[125] Although the Court indicated

121. *See supra* notes 33–36, 63–72.

122. *See supra* note 28.

123. *See supra* notes 89–90.

124. *See supra* notes 86–88.

125. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1303 (2012).

that the test may be a clue to patentability,[126] it was careful not to incorporate any part of or reference to the test in its three approach method. This exclusion of the machine or transformation test indicated disapproval of this method of determining the patent eligibility of uses of natural laws.

In addition to the nature of the Court's analysis, its own admissions testified to the lack of substantive change made to the law. At the end of the opinion, the Court stated, "[the Court] must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another."[127] Declining to make any new legal rules, the Court confined its opinion to the task of organizing and repackaging its prior precedents into a more usable method for making the patent eligible subject matter decision.

Although the Court may have established a clear roadmap for undertaking the patent eligible subject matter analysis, the opinion does not add clarity to the boundary of subject matter eligibility for laws of nature. Inventors and practitioners are still not able to distinguish between what is and is not permissible incorporation of a law of nature. The Court reiterated that some other inventive concept is necessary to make the use of a natural law patentable and emphasized that conventional pre- and post-solution activity does not make use of a natural law patentable.[128] However, the Court did not provide any guidance on the nature of added method steps that would satisfy the inventive concept requirement. The inventive concept standard continues to be a very malleable standard.

The guidepost approach also added little clarity to defining the boundary of patentable subject matter. In summarizing its guidepost discussion, the Court stated that the *Mayo* claims were "weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook*."[129] Presumably the opportunity for clarification exists between the two guideposts, since one was patent eligible and the other was not. Yet because the Court said that the *Mayo* claims were "no stronger than" *Flook*, the case did not exist in the space between *Diehr* and *Flook*, and therefore did nothing to further clarify the boundary between patentable and not-patentable. All *Mayo* provided was another set of facts to be an additional guidepost, but the location of that guidepost is almost indistinguishable from the *Flook* guidepost, which does nothing at all to resolve the boundary.

The *Mayo* opinion will likely not have a major impact on the

126. *Id*.

127. *Id*. at 1305.

128. *See supra* notes 35–36.

129. *Mayo*, 132 S. Ct. at 1299.

patenting of medical methods. Apart from the process set forth for examining the question of patent eligible subject matter, the opinion focused on the specific facts of *Mayo*. Because of the fact intensive nature of the inquiry, the finding of invalidity was confined to the specific case before the court, and any precedential treatment should be limited to the process of analysis and *Mayo's* position as a potential guidepost for future litigation.

B. Consideration of the Scope of Claims is the Only Appropriate Method for Evaluation the Natural Law Exception to Patentability

Of the three approaches that the Court set forth in *Mayo*, the scope of claims method is the only appropriate method for assessing the judicial exception to patent eligible subject matter for natural laws. First, the step-by-step inventive concept method is not an appropriate method. The Court's step-by-step analysis focused on identifying an inventive concept above and beyond the mere statement of the drug dosage correlation itself. In doing so, the Court reiterated its prior holding that something more than well-known, routine, and conventional steps is required to show that the claims represent a practical application of the law of nature and not an attempt to patent the law of nature itself.[130] Some commentators have supported expansion of this inventive concept approach to patent eligible subject matter,[131] but their support is misplaced.

Analyzing the claims in search of an inventive concept beyond the statement of the law of nature is not the appropriate inquiry to determine whether an invention is patent eligible subject matter under § 101. First, incorporating inventive concept into the subject matter eligibility determination is redundant when combined with the other requirements for patentability under 35 U.S.C. §§ 102 and 103, the novelty and non-obviousness requirements.[132] The non-obviousness requirement in 35 U.S.C. § 103 is itself the codification of a long-held judicial patentability exception based upon inventive concept.[133] If the question

130. *See supra* notes 35–36.

131. Bernard Chao, *Moderating Mayo*, 107 NW. U. L. REV. 423 (2012) (advocating for strengthening the point of novelty (inventive concept) aspect of the *Mayo* decision).

132. 35 U.S.C. §§ 102, 103 (2006).

133. JANET M. MUELLER, PATENT LAW 191–95 (Aspen Publishing, 3d ed., 2009) (The idea of "inventive concept" existed in the United States from the time of the first enactment of the patent law in 1790. The idea that some "inventive concept" was necessary to the question of patentability was a judicial exception to the existing requirements of novelty and utility that existed before1952. In 1952, Congress codified this judicial exception into the obviousness requirement set forth in 35 U.S.C. § 103(a)); Graham v. John Deere, Co., 383 U.S. 1, 9 (1966) (quoting Thomas Jefferson in letter to Isaac McPherson (Aug. 1813)) (Thomas Jefferson found "difficulty in 'drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not'").

of inventive concept is established up front in the patent eligible subject matter determination, then the patent system would have little reason for the non-obviousness requirement. In responding to the government's amicus brief in *Mayo*, the Court stated that § 102 and § 103 inquiries may overlap at times with the patentable subject matter inquiry, but that § 102 and § 103 inquiries should not be used to make the patentable subject matter determination. By introducing and advocating the use of "inventive concept," the Court appeared to be doing just that—making obviousness, or inventive concept, the key to a subject matter determination by requiring that any steps added to a natural law represents a further non-obvious inventive step.

Second, the inventive concept approach does not fulfill the law of nature exception's purpose, which is to promote progress by preventing a patentee from monopolizing a law of nature and foreclosing the use of that law of nature for future scientific research or innovation.[134] The approach asks if another inventive concept exists in the claims, but does not consider whether the scope of the claims forecloses the use of the law of nature in future development. Therefore, the presence of an additional inventive concept might make a method or invention patent eligible subject matter under the standard, but the scope of the claims may also leave no non-infringing use of the law of nature. In cases like *Diehr*, the inventive concept approach appears to work, because the Arrhenius equation is very broad in scope with nearly unlimited applicability, and patenting the use of the equation to calculate the residence time for a rubber injection molding process only carves out an insignificant sliver of the full scope of application of the natural law. For laws of nature that have a very small scope, such as the correlation between blood concentrations of metabolites and drug effectiveness, any incorporation into an invention forecloses a huge chunk of the potential future uses of the law of nature. In this second example, use of the inventive concept approach would fail to preserve the use of the natural law for future innovation.

Third, requiring an additional inventive concept is strikingly similar to narrowing the use of the law of nature to a specific field of endeavor, which the Court has held is not sufficient to make a law of nature patent eligible subject matter.[135] Finally, the inventive concept approach does not provide a clear, unambiguous standard for the lower courts to apply. "Inventive concept" itself is an ambiguous term susceptible to various interpretations of just how much inventive concept is necessary to make the claims patent eligible subject matter. The *Bilski II* Court held that

134. *See supra* notes 29–31.

135. *See supra* note 36.

well-known, routine, and conventional steps are insufficient to provide the necessary inventive concept.[136] The other data point is *Diehr*, which involved a detailed rubber molding process, of which the law of nature was only a small part.[137] The space in between is subject to near infinite interpretation.

Moving on to the Court's second approach, the guidepost analysis is insufficient to address patent eligible subject matter at this time. The guidepost approach compared the facts of the case to data points generated from prior litigation. This method can be effective if the guideposts clearly define the boundary between allowed and disallowed conduct, but in the case of the judicial exception to patent eligible subject matter, the space between any two guideposts is too large to provide notice of the uses of a natural law that are patentable. In *Mayo*, the guideposts consisted of *Flook* and *Diehr*, which were too far apart to give any greater insight into the boundary between patentable and unpatentable. Like the inventive concept approach, the guidepost approach also does not directly assess the preclusive effect of the claims and, therefore, does not address the underlying purpose of the judicial exception.

The most appropriate approach to decide the patent eligibility of practical uses of natural laws is to analyze the scope of the patent claims at issue and determine whether the claims substantially foreclose the use of the law of nature in other applications. The Court in *Gottschalk* stated that natural laws are the building blocks of scientific research,[138] and the *Mayo* Court suggested that patent protection of these laws of nature may actually impede innovation.[139] Bearing in mind this initial purpose of the judicial exception, the proper standard for evaluating the patent eligible subject matter requirement should focus on the scope of the claims and the preclusive effect of that scope. Any other inquiry would fail to satisfy the underlying purpose of the exception.

Like inventive concept, claim scope analysis also introduces ambiguity into the question of patent eligible subject matter for uses of laws of nature, but unlike inventive concept, which attempts to impose a clear rule based on the text of the claims, claim scope analysis is necessarily a case-by-case balancing of interests. The key element of claim scope analysis is interpreting the scope of the claims, and lower courts should have sufficient experience in construing claims, because of the courts' duty to decide issues of claim construction in patent

136. *Bilski II*, 130 S. Ct. 3218, 3230 (2010).

137. Diamond v. Diehr, 450 U.S. 175, 177–84 (1981).

138. Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

139. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012).

infringement cases.[140] Courts can add objectivity and definiteness to the claim scope analysis by developing key factors such as the narrowness of the natural law, the existence and scope of non-infringing applications of the natural law, and the intent of the infringing party.[141] The Court is well-accustomed to performing such multi-factor balancing inquiries in the patent law field,[142] which makes a scope of claims analysis easier to implement in the lower courts compared to inventive concept. The Court might also ease the difficulty of claim scope analysis by shifting the burden to the patentee, upon a sufficient showing of ineligible subject matter by the defendant, to demonstrate substantial non-infringing uses of the natural law.

Because a scope of claims analysis promotes the underlying purpose of the judicial exception for natural laws and the lower courts are accustomed to performing multi-factor balancing approaches in patent law, a scope of claims analysis is the most appropriate approach to deciding the question of patent eligible subject matter for inventions incorporating a law of nature.

C. Patent Eligibility for Natural Laws is Ripe for Legislative Action

Evaluating the scope of patent claims and determining whether or not the claims foreclose the use of a natural law in further innovation is often a judgment call that could have broad implications outside of the subject matter at issue. One important consideration is whether or not allowing such claims would have an effect on the pace of innovation in the field of endeavor and how significant that effect would be. This leads to public policy questions on the importance of research and development activities in several areas, such as computer science, genetics, and medical methods.

Although the Court is often called upon to make such policy judgments, Congress is better suited to consider such public policy issues. First, members of Congress are elected by popular vote and, therefore, are accountable to their constituents and political supporters, and because of this accountability, members of Congress are more in tune with the needs and desires of the public and better suited to

140. *See* Markman v. Westview Instruments, 517 U.S. 370, 384–91 (1996).

141. In *Mayo*, the circumstances and facts giving rise to the case might suggest that Mayo intended to get around the patent rather than attempting to improve upon the correlation.

142. *See* Graham v. John Deere, 383 U.S. 1, 17–18 (1966) (setting forth four factors for determining nonobvious under 35 USC § 103); *see also In re* Klopfenstein, 380 F.3d 1345, 1350–51 (Fed. Cir. 2004) (establishing factors for determining whether a prior art reference is publicly accessible); *see also, e.g.*, City of Elizabeth v. American Nicholson Pavement Co., 97 U.S. 126 (1878) (listing factors for determining if a public use qualifies for the experimental use exception to the 102(b) loss of patent right). Federal courts have used multi-factor analysis for a very long time.

addressing questions of public policy. In contrast, federal judges are appointed for life, which means they are not reliant on a constituency for re-election and not accountable to the public beyond a sense of duty. Beyond being accountable to the public, Congress has more resources with which to determine and evaluate public policy. Congress possesses the exclusive power of appropriation, which is necessary to commission extensive investigation into public policy matters, and employs an extensive political process to expose potential legislative solutions to public comment and criticism. Also, the process of legislation itself exposes a proposed solution to scrutiny and debate from various interests and public policies. The Court, on the other hand, is limited to information contained in the record of the case and submitted by the parties and amici. Though the justices may debate amongst themselves in chambers, this is a far cry from the public debate on the floor of the House of Representatives. The Court in *Mayo* even recognized the role that Congress has in clarifying the law.[143]

Congress also has experience in making changes to the patent system to codify judicial exceptions or adapt to changing public policies. Congress adopted the judicial exception to patentability for inventions lacking inventive concept by enacting the non-obvious standard in 35 U.S.C. § 103 and implemented separate patent regimes for plant patents and design patents in response to changing public policies. Congress has proven quite capable at addressing these changes in public policy by enacting appropriate legislation. With the importance of health care innovation to the nation's economy and the potential impact upon the patent system, the time has come for Congress to take a closer look at this issue.

Concerning patent eligibility for laws of nature, Congress should start with a study addressing the potential impact on innovation. Only with concrete data can our lawmakers make sound public policy decisions. Otherwise, Congress would be doing exactly what the Court is doing—theorizing on potential arguments for and against patentability without any real information on the actual effects on research and development. Although comparative data may not be readily obtainable for the impact of the judicial exception on the rate of innovation in the medical method field, Congress's other actions to implement specific programs for plant and design patents may offer some insight. In addition, Congress should look to the impact of the 1952 codification of the non-obviousness requirement had on innovation. Last, Congress can look at the impact of some recent judicial decisions in the patent field, for instance the *KSR* decision, which broadened the reach of the obviousness requirement,

143. *See supra* note 99.

making it more difficult to obtain a patent.[144] Examining patent submissions and research and development expenditures following each of these events may be a starting point to find out the actual impact of changes to the patent law.

Should a study find a substantial impact on the rate of innovation, Congress should avoid making a far-reaching and unpredictable change to the law by confining regulation to the field of medical methods, specifically. Each field of endeavor poses unique challenges and, therefore, may not be adequately addressed by the same legislative actions. For instance, the software and computer fields present patent eligible subject matter issues, but also involve a rate of innovation far faster than the rate of innovation of medical methods. The nature of innovation is also vastly different based on the modular method of programming generally accepted by the software development industry. The *Mayo* Court expressed concern that a sweeping change in one area could have unforeseen consequences in other fields.[145] Because of this, Congress may find prudence in addressing each field independently.

As part of any regulatory system, Congress should begin by clearly defining terms, such as "law of nature," "abstract idea," and "mathematical algorithm." Second, Congress should enact legislation that requires an application step for medical method claims making use of a natural law or correlation. This would provide the USPTO with some basis to differentiate between patents that attempt to preclude the use of a natural law and those that do not. A goal of any regulatory patent system should be to promote the strength of the patents issued by the government.

Third, Congress should address the preemptive scope of patent claims that involve natural laws by making claims foreclosing the use of natural laws unenforceable against future uses of the nature law in research and development or innovation activities. Such a rule would allow patents involving natural laws to issue without overly intensive scrutiny, provided they first had an application step. Because every invention must rely on some manifestation of a law of nature, patent claims may be difficult to draft without referencing or describing a natural law on which the claim is based. Since preemptive scope is the foundation upon which the judicial exception was built, it makes sense to include this requirement in a regulatory scheme to codify the exception. The result would be to confine the infringement question to the differences between the patent and the infringing use with respect to the steps beyond description of the natural law. The effect would be to carve out

144. KSR Int'l Co. v. Teleflex, Inc., 127 S. Ct. 1727 (2007).

145. *See supra* note 98.

the natural law and compare what is left with the conventional tools of novelty and obviousness under § 102 and § 103. This approach would prevent preemption of the natural law for future innovation, and at the same time, discourage potential infringers from attempting to circumvent a patent by making a trivial change to the method, like Mayo Collaborative Services did by merely changing the toxicity limit.

VI. CONCLUSION

The medical methods industry waited, hopefully, for the opinion in *Mayo* to clarify the scope of patent eligible subject matter for medical methods based on natural laws. Sadly, the Court merely reorganized its toolbox of prior precedent into an elaborate and fact intensive process for evaluating the patent eligible subject matter requirement for uses of natural laws, but did little to actually clarify the boundary between what is patentable and what is unpatentable. The decision will likely have little effect on the future interpretation of the judicial exception for natural laws.

Because of the important public policy issues that arise with the patentability of natural laws, Congress is better suited to the task of clarifying the law with respect to the use of natural laws in patent claims. Although complete abrogation of any doubt over the boundaries of patentability is an impossible task, Congress, with a few small changes to the existing patent law system, can make a great improvement in the predictability of the patent law with respect to the use of natural laws. After all, this is really what we all want: a standard to help us decide what discoveries we can and cannot protect.