

Casenote

Administering *Mayo* to Patents in Medicine and Biotechnology: Appropriate Dosage or Risk of Toxic Side Effects?

“That which distinguishes man from the brute is his power, in dealing with Nature, to milk her laws, and make them give forth their bounty.”¹

I. INTRODUCTION

In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,² the United States Supreme Court considered whether it would uphold patents on the “bounty” arising from laws of nature, specifically, diagnostic tests based on natural laws that determined the efficacy and toxicity of certain thiopurine drugs.³ In a unanimous ruling, the Court invalidated the patents, which were held by respondent Prometheus Laboratories, Inc. (Prometheus).⁴ The Court ultimately concluded that the processes for which Prometheus claimed patents did not add “significantly more” to the underlying laws of nature, and thus did not

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1. HENRY WARD BEECHER, PROVERBS FROM PLYMOUTH PULPIT 227 (1887).
 2. 132 S. Ct. 1289 (2012).
 3. *Id.* at 1296.
 4. *Id.* at 1295, 1305.

warrant patent protection.⁵ The *Mayo* decision is likely to have a strong impact on the future of patent protection in the fields of biotechnology and personalized medicine, particularly in the emerging area of patenting human genes.⁶

II. FACTUAL BACKGROUND

Prometheus was the licensee of two patents on diagnostic tests that it had designed. The tests measured the physiological effects of thiopurine drugs, which are used to treat various autoimmune diseases. When a patient ingests a medication containing thiopurine, the body metabolizes the drug and produces metabolites in the blood as a result. However, because different patients metabolize the drug differently, physicians have encountered difficulty in determining whether a given dose of a thiopurine compound is too high, risking adverse side effects, or too low, rendering the compound ineffective.⁷

Prometheus designed the diagnostic tests as an attempt to alleviate these uncertainties about thiopurine dosages. At the time the discoveries underlying the patents were made, scientists already knew that the levels of particular metabolites in a patient's bloodstream could signal whether a given dosage of a thiopurine compound would be either harmful or ineffective. However, they did not know exact correlations between metabolite levels and the predicted effects of thiopurine. Prometheus's patent claims emerged from its discovery that blood metabolite levels within specified ranges indicated the likelihood that the drug dosage was either too high or too low. The claims established processes for maximizing the efficacy of the drug. The method consisted of administering the drug to the patient, determining the level of metabolites produced in the patient's bloodstream, and increasing or decreasing the dosage if the metabolite levels fell outside the predetermined safe and effective range.⁸

The petitioners, Mayo Clinic Rochester and Mayo Collaborative Services (Mayo), bought and used the diagnostic tests which relied on the processes described in Prometheus's patents. However, in 2004, Mayo stated that it intended to market a somewhat different diagnostic test, which would use higher metabolite levels to determine toxicity. Prometheus sued Mayo, alleging that Mayo's test infringed on its

5. *Id.* at 1297.

6. See, e.g., Rochelle K. Seide & Salim Mamajiwalla, *Treating Prometheus: What Is the Prognosis for Process Claims?* BMA BIOTECH WATCH, Aug. 22, 2012, available at 2012 WL 3578295.

7. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294-95 (2012).

8. *Id.* at 1295.

patents. The United States District Court for the Southern District of California found that Mayo's proposed test did infringe on the patents, but nevertheless granted summary judgment to Mayo, with the rationale that the patents essentially claimed natural laws that were not patentable.⁹ The United States Court of Appeals for the Federal Circuit reversed the district court's decision, holding that the processes were eligible for patent protection under that circuit's "machine or transformation test" because the processes covered by the patents "involve[d] the transformation of the human body or of blood taken from the body."¹⁰ Mayo then filed a petition for certiorari with the Supreme Court.¹¹ The Supreme Court granted the petition, vacated the judgment, and remanded the case to the Federal Circuit in light of *Bilski v. Kappos*,¹² which clarified that the "machine or transformation test" was not an exclusive test for determining patent eligibility.¹³ After the Federal Circuit affirmed its prior decision, Mayo filed another petition for certiorari, which the Court granted.¹⁴ The Court held that the patents attempted to claim laws of nature, and thus invalidated Prometheus's patents.¹⁵

III. LEGAL BACKGROUND

Patentability is governed by section 101 of the Patent Act,¹⁶ which provides that "[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."¹⁷ The Patent Act further specifies that an invention must be "novel"¹⁸ and "non-obvious"¹⁹ to receive patent protection. The Court has interpreted various portions of this statute in a number of patent cases.

9. *Id.* at 1295-96.

10. *Id.* at 1296.

11. *Id.*

12. 130 S. Ct. 3218 (2010).

13. *Mayo*, 132 S. Ct. at 1296.

14. *Id.*

15. *Id.* at 1305.

16. 35 U.S.C. § 101 (2006).

17. *Id.*

18. 35 U.S.C. § 102 (2006 & Supp. 2012).

19. 35 U.S.C. § 103 (2006 & Supp. 2012).

A. *Gottschalk v. Benson: Overly Broad and Abstract Claims May Preempt Natural Laws*

In 1972, the Supreme Court in *Gottschalk v. Benson*²⁰ considered patent claims proposed by respondents, who sought to obtain patents for a process of converting binary-coded decimal (BCD) numbers into pure binary numerals.²¹ The patents were to cover any use of this method in any general-purpose digital computer. The question before the Court was whether this method was a "process" within the meaning of the Patent Act.²² The Court held that the process being claimed for a patent was "abstract and sweeping," with an almost unlimited number of applications.²³ According to the Court, to hold the patents valid would be equated with patenting an abstract idea, which is not permissible under the Patent Act.²⁴ Moreover, the mathematical formula involved in the patent claims lacked any "substantial practical application except in connection with a digital computer."²⁵ Thus, any patent issued would preempt the use of the mathematical formula, and essentially be a patent on the formula itself.²⁶ Therefore, the Court overturned the respondent's patents.²⁷

B. *Parker v. Flook: Patent Claims Must Be Valid in Substance, Not Only in Form*

Several years later, the Supreme Court in the 1978 case of *Parker v. Flook*²⁸ invalidated patent claims for "alarm limits" used in the catalytic chemical conversion of hydrocarbons.²⁹ When variables in the chemical conversion process, such as temperature or pressure, exceed a predetermined limit, an alarm can then signal an abnormal or dangerous condition. The respondent's patent claim employed an algorithm to calculate one such alarm limit value.³⁰

The respondent argued that the existence of "post-solution activity"—adjusting alarm limits to match the number computed by the

20. 409 U.S. 63 (1972).

21. *Id.* at 64.

22. *Id.* at 64, 67-68; *see also* 35 U.S.C. § 101.

23. *Benson*, 409 U.S. at 68.

24. *Id.* at 71; *see also* 35 U.S.C. § 101.

25. *Benson*, 409 U.S. at 71.

26. *Id.* at 72.

27. *Id.* at 73.

28. 437 U.S. 584 (1978).

29. *Id.* at 585-86.

30. *Id.*

formula—should make the process patentable, but the Court disagreed.³¹ The Court indicated that almost anyone could draft around the patent requirements in this way, which would allow patentable subject matter to rely heavily on “the draftsman’s art.”³² The Court also held that there was no “inventive concept” in the respondent’s process, and that the only added idea was the use of the algorithm.³³ In fact, the only difference between the respondent’s way of determining alarm limits and conventional methods was the use of the formula.³⁴ The Court concluded with a word of warning: “[W]e must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress.”³⁵

C. Diamond v. Chakrabarty: Asserting the Court’s Right to Interpret the Patent Statutes

In 1980, the Court in *Diamond v. Chakrabarty*³⁶ considered a microbiologist’s patent claims related to a genetically engineered bacterium.³⁷ The bacterium, unlike any naturally-occurring bacteria, had the capability of breaking down crude oil, and thus could be useful for managing oil spills. The respondent’s claims were for the bacterium itself, as well as the process of creating it.³⁸ The question before the Court was whether Chakrabarty’s bacterium comprised a “manufacture” or “composition of matter” as described in the Patent Act.³⁹

The Court ruled that the respondent’s man-made bacterium was clearly patent-eligible, as it had characteristics which were quite different from those found in naturally-occurring bacteria.⁴⁰ It also addressed, but ultimately rejected, some of the petitioner’s arguments against patent eligibility of the claims.⁴¹ The petitioner argued that microorganisms could not be patented until Congress explicitly allowed for such patent protection, and that Congress could not have predicted the genetic technology at issue in this case when it enacted the original Patent Act.⁴² However, the Court asserted its right to interpret the

31. *Id.* at 590.

32. *Id.* at 593.

33. *Id.* at 594-95.

34. *Id.*

35. *Id.* at 596.

36. 447 U.S. 303 (1980).

37. *Id.* at 305.

38. *Id.*

39. *Id.* at 307; *see also* 35 U.S.C. § 101.

40. *Diamond*, 447 U.S. at 309-10.

41. *Id.* at 310-17.

42. *Id.* at 311-12.

laws that Congress had enacted, and indicated that the statute at issue was not ambiguous.⁴³ The majority entirely rejected the essence of the petitioner's argument, which was that "unanticipated inventions are without [patent] protection."⁴⁴ The Court held that it would construe the language of the statute as it was unambiguously expressed, unless Congress acted to limit patentability in the areas at issue.⁴⁵

D. Diamond v. Diehr: Adding Steps to a Natural Law Can Result in Patentability

In *Diamond v. Diehr*,⁴⁶ the Court again considered the question of whether a structure or process that relied heavily on a mathematical formula warranted patent protection.⁴⁷ The Court held that such a formula cannot itself be patented; however, when a patent claim containing a formula applies to a process which serves an overall function the patent laws are designed to protect, then the claim can be patented.⁴⁸

In this case, the respondents filed a patent application for a process of turning uncured synthetic rubber into cured rubber products. They used a mathematical equation to determine the precise length of time that the rubber would need to cure inside a mold and the exact temperature needed inside the molding press.⁴⁹ The Court upheld the patents on the process, emphasizing the need to view the process as a whole.⁵⁰ It explained that a law of nature, including a mathematical formula, could not be patented; however, the respondents simply used that formula as one of several steps in a process for curing synthetic rubber, constituting an overall process which was patentable.⁵¹ The Court emphasized that although the respondents used a mathematical equation in their process, they were not trying to preempt its use.⁵² Instead, they only attempted to preclude others from using that equation with the other components of their multi-step process.⁵³ Although the "equation [wa]s not patentable in isolation," the Court upheld the patent because it concluded that the respondents were not trying to patent the

43. *Id.* at 315.

44. *Id.* at 315-16.

45. *Id.* at 318.

46. 450 U.S. 175 (1981).

47. *Id.* at 177.

48. *Id.* at 188-89.

49. *Id.* at 177-78.

50. *Id.* at 188-89.

51. *Id.* at 191-93.

52. *Id.* at 187.

53. *Id.*

equation, but rather a process for curing rubber that implemented that equation in combination with other steps.⁵⁴

E. Bilski v. Kappos: The “Machine-or-Transformation Test” Is Not Exclusive

The 2010 case of *Bilski v. Kappos*⁵⁵ presented the Supreme Court with the question of the patentability of an invention that described how buyers and sellers in the energy market could protect, or hedge, against the risk of price changes.⁵⁶ When the United States Court of Appeals for the Federal Circuit heard the case, it relied on the “machine-or-transformation test” in its analysis.⁵⁷ According to this test, “an invention is a ‘process’ only if: ‘(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.’”⁵⁸ The Supreme Court, however, held that this was too limited a definition of the word “process.”⁵⁹ Instead, the Court held that the so-called “machine-or-transformation test” is not the exclusive test, but rather an important clue to determining whether an invention is a “process” within the statutory meaning of the Patent Act.⁶⁰ In this case, the Court held that the concept of hedging against the risk of price changes was well-known and fundamental, and thus the concept itself could not be patented.⁶¹ If the Court were to allow the petitioners to patent price hedging, they would claim a “monopoly over an abstract idea.”⁶² Thus, the Court focused not only on the proper interpretation of the patent statute, but also on the policy rationale behind its refusal to uphold the patents. The Court’s concern with preventing monopolies on abstract concepts vigorously reemerged in the *Mayo*⁶³ decision.

IV. COURT’S RATIONALE

In *Mayo*,⁶⁴ the Court considered the validity of patent claims based on a biological process for determining the effectiveness of certain thiopurine drugs.⁶⁵ It extended its prior precedents that prohibited patents on

54. *Id.* at 188, 192-93.

55. 130 S. Ct. 3218 (2010).

56. *Id.* at 3223-24.

57. *Id.* at 3225-26.

58. *Id.* at 3225 (quoting *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008)).

59. *Id.* at 3226.

60. *Id.*; see also 35 U.S.C. §§ 100(b), 101.

61. *Bilski*, 130 S. Ct. at 3231.

62. *Id.*

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

64. *Id.* at 1294.

65. *Id.*

laws of nature into the realm of clinical care and medical diagnoses, ultimately concluding that Prometheus's processes did not add enough to the underlying laws of nature to be patent-eligible.⁶⁶ Justice Breyer delivered the opinion for a unanimous Court.⁶⁷

First, Justice Breyer defined "patentable subject matter" under § 101 of the Patent Act, but explained that there was a significant implied exception to what was deemed patentable under the Act.⁶⁸ Quoting *Diamond v. Diehr*, he explained, "[L]aws of nature, natural phenomena, and abstract ideas' are not patentable."⁶⁹ Breyer reasoned that granting patents for natural processes and products could hinder, rather than promote, innovation.⁷⁰ Yet he acknowledged that if this "exclusionary principle" were applied too broadly, it could sound the death knell for patent law as it presently exists because all inventions in some fashion are based upon "laws of nature, natural phenomena, or abstract ideas."⁷¹ He thus recognized that certain applications of natural laws could be patented.⁷²

Breyer examined the Court's precedent in *Parker v. Flook*,⁷³ which had warned against basing patent eligibility on the semantics of the claim, rather than on the core principles behind the refusal to grant patents for natural laws.⁷⁴ In order for the process at issue to be patented, it would need to add elements to the natural law to ensure that the patent made a substantial addition to the law of nature.⁷⁵ The key issue before the Court was whether the patent claims "d[id] significantly more than simply describe" the natural processes.⁷⁶

The Court held that Prometheus's patent claims did not meet the requirement of adding sufficiently to the law of nature being used.⁷⁷ It emphasized that the claimed processes did not differ from conventional activity already in use.⁷⁸ The Court also noted the public policy concern that sustaining Prometheus's patents could potentially

66. *Id.* at 1305.

67. *Id.* at 1292.

68. *Id.* at 1293; *see also* 35 U.S.C. § 101.

69. *Mayo*, 132 S. Ct. at 1293 (alteration in original) (quoting *Diamond v. Diehr*, 447 U.S. 175, 185 (1981)).

70. *Id.*

71. *Id.*

72. *Id.*

73. 437 U.S. 584 (1978).

74. *Mayo*, 132 S. Ct. at 1294.

75. *Id.* at 1297.

76. *Id.*

77. *Id.* at 1294.

78. *Id.*

monopolize the use of the natural laws at issue, preventing them from being used effectively for future discoveries.⁷⁹ Here, the Court held that “the steps in the claimed processes . . . involve well-understood, routine, conventional activity previously engaged in by researchers in the field.”⁸⁰

Next, the Court engaged in a detailed analysis of the claims at issue to further explain why the claims were ineligible for patent protection.⁸¹ The majority indicated that the initial step of giving the drugs to the patients—the “administering” step—referred merely to the physicians who used thiopurine drugs to treat patients, a treatment process used long before Prometheus asserted its patent claims.⁸² The second step in the process, which stated that the physician needed to determine resulting metabolite levels, simply informed doctors about the relevant laws, implying that they should consider them for patient treatment.⁸³ The final step in the patent claims indicated that the doctor should measure the level of metabolites in the blood.⁸⁴ However, the Court indicated that the measurement of blood metabolites resulting from thiopurine compounds was a well-established procedure in the field.⁸⁵ After considering the steps individually, Justice Breyer concluded that combining the three steps added nothing significant to the laws of nature not already present when the steps were viewed as separate components.⁸⁶

The Court also considered prior precedent in arriving at its decision.⁸⁷ First, Justice Breyer assessed whether Prometheus’s patents more closely aligned with those embodied in *Diehr*⁸⁸ or with those in *Flook*, cases in which the Court reached different conclusions.⁸⁹ Discussing *Diehr* and its use of a mathematical equation for the curing of synthetic rubber, Justice Breyer emphasized that the Court deemed the process eligible for patent protection because “the additional steps of the process integrated the equation into the process as a whole.”⁹⁰ On the other hand, analyzing *Flook* and its process for calculating alarm

79. *Id.*

80. *Id.*

81. *Id.* at 1297-98.

82. *Id.* at 1297.

83. *Id.*

84. *Id.*

85. *Id.* at 1297-98.

86. *Id.* at 1298.

87. *Id.*

88. 450 U.S. 175 (1981).

89. *Mayo*, 132 S. Ct. at 1298.

90. *Id.*

limits for the catalytic conversion of hydrocarbons, Breyer indicated that the steps in the process were well-known and were not limited to a particular application.⁹¹ Moreover, the steps did not add any "inventive concept" to the mathematical application they claimed to apply and thus were not patentable.⁹² The Court concluded that Prometheus's claims "present[ed] a case for patentability that is weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook*."⁹³

Breyer strongly implied that Prometheus's diagnostic tests should not be deemed patentable because they accomplished nothing new or significant.⁹⁴ The claims "simply" told physicians to measure the patient's levels of the relevant metabolite, to use unpatentable laws of nature to determine toxicity and inefficacy limits, and to reconsider the dosage of the thiopurine drug in light of the law of nature.⁹⁵ The Court emphasized that all of these steps are routine, well-known, and regularly used in the field.⁹⁶

Justice Breyer also discussed the case from a public policy standpoint, indicating that the Court had previously focused on the concern that patent law should not hinder potential discovery by monopolizing the future use of natural laws.⁹⁷ He acknowledged competing concerns associated with patent protection—patents can serve both as a reward that can encourage discovery and also as an overly broad protection to natural laws that can "foreclose[] more future invention than the underlying discovery could reasonably justify."⁹⁸ The Court explained that Prometheus's patent claims told physicians to consider patient's metabolite levels in light of the range they described, thus impacting the doctor's treatment decision.⁹⁹ These patent claims could threaten future development of other treatment recommendations that would combine the correlations described by Prometheus with newly-discovered features of metabolite levels and individual patient traits.¹⁰⁰ Thus, the language of the patent claims was too general, threatening to foreclose

91. *Id.* at 1299.

92. *Id.* (quoting *Parker v. Flook*, 437 U.S. 584, 594 (1978)).

93. *Id.*

94. *Id.* at 1299-1300.

95. *Id.* at 1299.

96. *Id.*

97. *Id.* at 1301.

98. *Id.*

99. *Id.* at 1302.

100. *Id.*

future developments in the area even if they purported to measure metabolite levels in different ways.¹⁰¹

Finally, the Court considered several arguments that Prometheus and the lower courts made in favor of patent protection, but rejected each one.¹⁰² First, the Federal Circuit had explained that the processes were eligible for patent protection because, under *Benson's* "machine-or-transformation test," they involved a transformation of the human body by the administering of a drug and the transformation of the blood through an analysis to determine the levels of resulting metabolites.¹⁰³ However, the Supreme Court indicated that the process could be completed without transformation if science would develop a new method for measuring metabolite levels.¹⁰⁴ Moreover, according to the Court, the "machine-or-transformation test" could not overcome the exclusionary principle for patents on laws of nature.¹⁰⁵

The Court also considered Prometheus's argument that its claims embodied narrow and specific laws of nature, and that its patents should be validated on that basis.¹⁰⁶ However, Justice Breyer countered this argument with the assertion that even a patent on a narrow law of nature could hamper future research.¹⁰⁷ Prometheus also argued that any addition to a statement of a law of nature should transform it into a patent-worthy application of that law.¹⁰⁸ Yet Justice Breyer indicated that this could make the prohibition on patenting natural laws a "dead letter."¹⁰⁹ Prometheus also wielded a public policy argument, claiming that a lack of patent coverage would inhibit medical research, especially in the area of diagnostic tests.¹¹⁰ However, the Court claimed that policy considerations could just as easily suggest a contrary response.¹¹¹ It left the question open as to whether discoveries of

101. *Id.* at 1303.

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.*

106. *Id.*

107. *Id.* Furthermore, Justice Breyer noted that earlier cases did not differentiate among varying laws of nature on the basis of their narrowness, but instead recognized a "bright-line prohibition" against patents on natural laws. *Id.*

108. *Id.*

109. *Id.*

110. *Id.* at 1304.

111. *Id.* For example, Justice Breyer cited assertions offered by a number of medical authorities that claimed that issuing patents for the body's own responses to illness and medication could impede physicians' ability to provide quality medical care. He concluded that patent protection must always balance competing concerns of rewarding innovation with monetary incentives while not promoting so much exclusivity as to impede the use

natural laws related to medical diagnoses deserved increased patent protection for policy reasons.¹¹²

V. IMPLICATIONS

The *Mayo* opinion¹¹³ immediately impacted subsequent patent cases before the Court. Although in several cases it led to the Court's rejection of particular patents, skillful drafting strategies may help patent claims survive and thrive even after *Mayo*.¹¹⁴ The decision is likely to curtail patent protection most notably in the field of personalized medicine, which focuses on patients' individual medical needs and proposes treatment regimens accordingly.¹¹⁵ Although the development of personalized medicine could foreseeably be hindered, the decision may also be instrumental in reining in rising healthcare costs by expanding availability of treatment options.¹¹⁶

A. *Subsequent Interpretation of Mayo and Impact on Later Patent Decisions*

A mere six days after the Court decided *Mayo*, it remanded a case that concerned gene patents to the Court of Appeals for the Federal Circuit for further consideration in light of the *Mayo* opinion.¹¹⁷ In the case, below named *Association for Molecular Pathology v. U.S. Patent & Trademark Office*,¹¹⁸ the Federal Circuit declared isolated DNA sequences that helped predict an individual's predisposition to developing certain breast and ovarian cancers to be patent-eligible, over the plaintiff's § 101 challenge.¹¹⁹ Mutations in the sequences, known as the BRCA genes, have been known to substantially increase a woman's lifetime risk of developing these cancers.¹²⁰ Diagnostic tests used to determine whether a woman carries one of the gene mutations are

and flow of information. *Id.* at 1304-05.

112. *Id.* at 1305.

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

114. *See, e.g.*, Seide & Mamajiwalla, *supra* note 6.

115. *Id.*

116. *See* Anne Paxton, *By Zeus! Prometheus Ruling Checks Patents*, COLLEGE OF AMERICAN PATHOLOGISTS (June 2012), <http://www.cap.org> (follow "Reference Resources and Publications" hyperlink; then click "CAP Today" hyperlink; then click "2012 Articles" hyperlink and locate June 2012 articles).

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

118. 653 F.3d 1329 (2011).

119. *Id.* at 1334; *see also* 35 U.S.C. § 101.

120. *Ass'n for Molecular Pathology*, 653 F.3d at 1339.

important because they can help her evaluate her risks and options, including the potential need for preventive surgery.¹²¹

On remand, the Federal Circuit held that the isolated DNA sequences were man-made and the products of human ingenuity—thus, it held that *Mayo's* “law of nature” exception to patent eligibility did not apply.¹²² Nevertheless, the case will likely be reheard by the Federal Circuit en banc or by the Supreme Court, indicating that the decision is still heavily disputed.¹²³

Furthermore, *Mayo* has since been interpreted as holding that patentability based on subject matter is the threshold test for determining patent validity under § 101 of the Patent Act.¹²⁴ In one case, patents for systems governing the choice of therapeutic treatment regimens for certain diseases were overturned under this precedent—the systems were considered patent-ineligible subject matter under the court’s interpretation of *Mayo* as creating a threshold test.¹²⁵ However, not all related methods have been deemed unpatentable under this precedent. For instance, in another case, claims on particular methods for selecting infant immunization schedules passed the threshold test under *Mayo*.¹²⁶ The decision is also expected to impact other forms of patent protection outside the medical realm, including software patents, making it incumbent on attorneys who specialize in

121. *Id.*

122. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1331 (Fed. Cir. 2012).

123. See Dennis Crouch, *Gene Patent Debate Continues: Federal Circuit Finds Isolated Human Genes Patentable*, PATENTLY-O BLOG (Aug. 16, 2012), <http://www.patentlyo.com/patent/2012/08/gene-patent-debate-continues-federal-circuit-finds-isolated-human-genes-patentable.html>. See also Andrew Bowman, *Genes 101: Are Human Genes Patentable Subject Matter?*, 18 RICH. J.L. & TECH. 15 (Summer 2012) (suggesting that *Mayo* and other cases indicate that isolated human genes are not eligible for patent protection); Michael Samardzija & Karthika Perumal, *On Remand, Federal Circuit Spreads Mayo on Myriad*, 28 No. 9 WESTLAW J. PHARM. 13 (Oct. 15, 2012) (discussing the remanded decision and the varieties of patent claims that are more likely to withstand challenge after *Mayo* and *Myriad*).

124. *SmartGene, Inc. v. Advanced Biological Labs., SA*, 852 F. Supp. 2d 42, 51-52 (D.D.C. 2012); see also 35 U.S.C. § 101.

125. *SmartGene, Inc.*, 852 F. Supp. 2d at 51-52; see also Nathan A. Reed, *A New Metric to Determine Patent Eligible Subject Matter for Medical Methods*, 16 MICH. ST. U. J. MED. & L. 321 (Winter 2012) (indicating ways to approach the subject-matter eligibility question for biotechnology claims arising post-*Mayo*).

126. *Classen Immunotherapies, Inc. v. Biogen IDEC*, Civ. No. WDQ-04-2607, 2012 WL 3264941, at *1, *5 (D. Md. Aug. 9, 2012).

any area of intellectual property to be aware of its possible consequences for their practices.¹²⁷

It is not yet fully clear which claims will pass muster under *Mayo*—in fact, for many, the decision “raises more questions than it answers.”¹²⁸ Perhaps the most troubling part of the opinion was Justice Breyer’s insistence that patent-eligible claims must add significantly more to natural laws and possess “enough” originality; yet the decision never indicated precisely what “enough” means.¹²⁹ Moreover, *Mayo* could allow defendants accused of patent infringement to raise “patentable subject matter” defenses not previously contemplated before the decision.¹³⁰

B. The “Draftsman’s Art”: Drafting Strategies for Patent Counsel in the Wake of Mayo

Attorneys who encounter patent claims in the course of their practice should understand the impact that *Mayo* is likely to have on drafting claims.¹³¹ Counsel should produce claims with “varying levels of detail” to increase the chances that at least some of the claims will survive any patent eligibility challenges or litigation that may ensue.¹³² This process should be used until the Court’s precedents set more defined parameters for establishing patents on methods or processes, like Prometheus’s method claims.¹³³ Moreover, this strategy should be a familiar one, as it reflects “the current practice of including claims of varying scope to enhance the prospect of ensnaring infringers yet overcoming novelty or obviousness challenges.”¹³⁴ Nevertheless, patent counsel should be wary of drafting claims that are so broad as to monopolize laws of nature; instead, the application of the natural laws

127. See, e.g., *OIP Techs., Inc. v. Amazon.com, Inc.*, No. C-12-1233 EMC, 2012 WL 3985118, at *1, *20 (N.D. Cal. Sept. 11, 2012) (holding that plaintiff’s invention for facilitating “e-commerce price selection and optimization” was patent-ineligible because it represented an abstract idea); see also Michael J. Malecek & Kenneth M. Maikish, *The Prometheus Effect on Software Patents*, 24 No. 6 INTELL. PROP. & TECH. L.J. 3, 5 (June 2012) (indicating that software patent claims broken down into their constituent elements may be more vulnerable to challenge under 35 U.S.C. § 101 after *Mayo*, because they often contain “mental step[s]” and claim methods for performing different steps on a computer).

128. Bernard Chao, *Moderating Mayo*, 107 NW. U. L. REV. COLLOQUY 82, 82 (2012).

129. *Id.*

130. *Id.* at 90-91.

131. See Lynn C. Tyler & Peter Zura, *IP Litigation: A Quarterly Update*, 9 NANOTECHNOLOGY L. & BUS. 45, 46-47 (Spring-Summer 2012).

132. *Id.* at 46.

133. *Id.*

134. *Id.*

must be clear and limited.¹³⁵ If the claimed application of a particular law or abstract idea is especially broad, it could be worthwhile to pursue multiple patents for multiple applications of the law.¹³⁶

Another strategy would be to incorporate the underlying law of nature into the patent claim without stating it explicitly in a “wherein” clause, as *Prometheus* did.¹³⁷ Additionally, the inclusion of any novel and non-obvious elements in the process claim, whether these include drug dosage forms, routes of administration, or reagents, may amount to an “inventive concept” as required by *Mayo*.¹³⁸ A disclosure of any and all predicted uses of the natural law—for example, if multiple diseases could be treated based on the mechanisms of a drug within the body—should also be included in the patent claim.¹³⁹ Counsel may consider keeping at least one patent application pending for as long as possible in order to adapt new claims as needed.¹⁴⁰

Moreover, challenges to current or pending patents can be expected under the exacting *Mayo* standard.¹⁴¹ Businesses and research organizations whose patents could be affected are advised to consult with attorneys to prevent the value of their present assets from being compromised.¹⁴² These companies should also be aware of various claim drafting strategies to use in any pending patent applications.¹⁴³

135. *Id.* at 46-47.

136. *Id.* at 47.

137. Seide & Mamajiwalla, *supra* note 6.

138. *Id.* Seide and Mamajiwalla elaborate on how the novelty requirement will affect patent claims:

Claims to such methods now must include novel dosing regimens, novel and unobvious reagents, or combinations of reagents that otherwise would not be obvious to use in combination. If possible, patentees should consider incorporating into the claim novel devices for administration of the drug or even novel and unobvious routes of administration or dosage forms, which may lead to an unexpected increase in bioavailability at a lower dose and hence reduce adverse events.

Id. The authors also include possible redrafted versions of all of *Prometheus*'s method claims. *Id.*

139. *Id.*

140. *Id.*

141. See, e.g., Mandy Wilson Decker, *U.S. Supreme Court Decision Gives Rise to New Challenges for Patent Protection in the Field of Personalized Medicine and Beyond*, STITES & HARBISON, PLLC NEWS & EVENTS (Mar. 21, 2012), <http://www.stites.com/news/657/u-s-supreme-court-decision-gives-rise-to-new-challenges-for-patent-protection-in-the-field-of-personalized-medicine-and-beyond>.

142. *Id.*

143. *Id.*

C. *Effects on Personalized Medicine and Healthcare Costs*

“Personalized medicine promises to be one of the most important human developments since the tragic Greek figure Prometheus brought fire to humanity.”¹⁴⁴ Personalized medicine, also called individualized medicine, is an emerging field which focuses on individual metabolic and physiological differences among patients in determining treatment regimens.¹⁴⁵ It depends on genotyping and other methods to determine which patients may benefit most from a particular treatment option for a particular disease.¹⁴⁶ Such individualized treatment is likely to improve treatment efficacy while decreasing healthcare costs.¹⁴⁷

Personalized medicine has grown exponentially in the last decade; the market for this emergent field in the United States alone was estimated at \$225 billion in 2009 and is expected to expand further in the next several years.¹⁴⁸ Thus, the financial stakes cannot be ignored, especially if the potential decrease in healthcare costs is also considered.¹⁴⁹ However, this field relies heavily on the development of diagnostic tests like those of Prometheus, and the *Mayo* precedent is likely to overturn some of the patents on these tests.¹⁵⁰ In fact, when interpreted broadly, “the correlation between a particular genotype and which medical regimen is likely to be efficacious for a particular patient can be construed to be a law of nature, and the diagnostic test would merely instruct the practitioner to apply that law in any given case.”¹⁵¹ If diagnostic methods are unlikely to receive patent protection, it may become difficult to fund this emergent, yet unquestionably important, field.¹⁵²

However, although personalized medicine is expected to reduce healthcare costs, patent protection itself can increase them.¹⁵³ For

144. Wayne Keown, *How Prometheus Pecks the Liver out of Personalized Medicine*, FURMAN, GREGORY, & DEPTULA BLOG (Mar. 23, 2012), <http://www.fgd-law.com/940/>.

145. *Id.*

146. *Id.*

147. *Id.*

148. Seide & Mamajiwalla, *supra* note 6.

149. *Id.*

150. Keown, *supra* note 143.

151. *Id.*

152. *Id.* See also Denise DeFranco, *Mayo: A Force to Be Reckoned With*, 4 No. 6 LANDSLIDE 24 (July/Aug. 2012). DeFranco notes a possible internal inconsistency in the *Mayo* rationale as it relates to discoveries in personalized medicine: “Taken to its extreme, the court’s decision suggests that if you discover that a drug treats a disease you can get a patent on that discovery, but if you discover the precise dosage amounts that treat the disease you may not get a patent on that discovery.” *Id.* at 27.

153. Paxton, *supra* note 115.

example, if a laboratory, via a patent, owns the exclusive rights to administer a certain test, patients are forced to obtain the tests at that laboratory's prices and are precluded from obtaining a second opinion.¹⁵⁴ Thus, the cost of lab testing could rise substantially if patent protection became excessive.¹⁵⁵ Moreover, if a particular test has a sole provider, there is no peer review process and patients have no option to receive the test from another facility if desired, which could reduce the quality of care.¹⁵⁶

VI. CONCLUSION

One of the Court's main concerns in *Mayo* was preventing a monopoly on the laws of nature which would both hinder the flow of information and unnecessarily increase expense,¹⁵⁷ and the *Mayo* precedent is likely to prevent this undesirable result. Patients are likely to have greater access to more and cheaper diagnostic and treatment options and will be able to "shop around" for the type of care that best meets both their health needs and budgets to a greater extent. In turn, this could prove particularly beneficial for those who still lack adequate health insurance. With appropriate claim drafting strategies, some of the decision's threat to patent protection, especially in personalized medicine and biotechnology, may be curtailed. Nevertheless, only time will tell whether *Mayo* will significantly hinder research efforts by sharply reducing patent protection—which could be a toxic side effect indeed.

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154. *Id.*

155. *Id.*

156. *Id.*

157. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. at 1289, 1304-05 (2012).
