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An Overview of Patentable Subject Matter and the Effect of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*

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— Comment —

AN OVERVIEW OF PATENTABLE
SUBJECT MATTER AND THE EFFECT OF
*MAYO COLLABORATIVE SERVICES V.
PROMETHEUS LABORATORIES, INC.*

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INTRODUCTION

This Comment provides a summary of the Supreme Court's most recent decision analyzing the bounds of patent eligibility: *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*¹ In this March 2012 decision, the Court significantly departed from the Federal Circuit's² prevalent use of the "machine-or-transformation test" for determining the limits of patentable subject matter.³ The Court unanimously reversed the Federal Circuit's decision in favor of

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1. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).
 2. The United States Court of Appeals for the Federal Circuit was established in 1982 and has nationwide jurisdiction over patent law appeals arising from any United States District Court. *Court Jurisdiction*, U.S. CT. APPEALS FOR FED. CIRCUIT, <http://www.cafc.uscourts.gov/the-court/court-jurisdiction.html> (last visited Oct. 27, 2012).
 3. *See Mayo*, 132 S. Ct. at 1303 (precluding the "machine-or-transformation" test from trumping the "law of nature" exclusion).

Prometheus and found that the correlation between thiopurine drug dosage and a patient's subsequent metabolic response amounted to an unpatentable law of nature.⁴

The synopsis herein is intended as a general overview of subject matter that is patentable under 35 U.S.C. § 101, as well as the impact of the *Mayo* decision on patent examination and patent eligibility.⁵ Thus, this Comment is predominantly intended for nonspecialists, as it does not scrutinize the scientific principles of Prometheus's patents or the decision's overall impact on the field of medical technology.⁶ Part I of this Comment provides a brief introduction to the statutory bounds of patentable subject matter under 35 U.S.C. § 101. Part II summarizes the patents at issue in *Mayo* and the complex history of Prometheus's dispute. That section goes on to clarify the meaning and impact of the Court's landmark interpretation regarding the patent eligibility of natural laws. Finally, Part III discusses the effect of the *Mayo* ruling on patent examination procedures at the United States Patent and Trademark Office and the holding's potential impact on pending Federal Circuit cases.

I. PATENT ELIGIBILITY: THE MERGER OF STATUTORY GUIDANCE UNDER 35 U.S.C. § 101 AND PATENT LAW PRECEDENT

Under 35 U.S.C. § 101, a patent is conferred upon “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,” subject to the additional requirements of the Patent Act.⁷ In a broad sense, § 101 acts as a threshold to patentability by distinguishing between the *discovery* of an existing principle versus the *creation* of an original invention. Of course, the subsequent questions of whether an

4. *Id.* at 1292, 1305.

5. Given the sweeping reform to United States patent law that will stem from the March 2013 implementation of the Leahy-Smith America Invents Act, it is important to note that the text of 35 U.S.C. § 101 will remain unchanged. The only mention of § 101 in Leahy-Smith notes that “[n]othing in this section shall be construed as amending or interpreting categories of patent-eligible subject matter set forth under section 101 of title 35, United States Code.” Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 18(e), 125 Stat. 284, 331 (2011).

6. Following oral arguments in the *Mayo* decision, SCOTUSblog reported that “[t]he Supreme Court finished an hour of oral argument . . . on a highly complex patent case, seemingly as deep in confusion at the end as at the beginning . . .” Lyle Denniston, *Argument Recap: For Want of a Good Hypothetical*, SCOTUSBLOG (Dec. 7, 2011, 4:43 PM), <http://www.scotusblog.com/2011/12/argument-recap-for-want-of-a-good-hypothetical>.

7. 35 U.S.C. § 101 (2006).

invention is novel,⁸ nonobvious,⁹ and adequately filed¹⁰ are critical inquiries that encompass the bulk of patent examination and litigation.¹¹ But in order to warrant further examination, an inventor must first overcome the subject matter eligibility threshold of § 101.¹²

The underlying premise of patent law is to incentivize progress and innovation by rewarding an inventor with the right to exclude others from capitalizing upon his advancements for a particular period of time.¹³ To grant an inventor a monopoly over a general scientific rule would directly counteract patent law's purpose of promoting innovation.¹⁴ Thus, even celebrated breakthroughs such as Newton's law of gravity and Einstein's revelation that $E=mc^2$ would not constitute patentable subject matter.¹⁵ Although such discoveries were previously unknown and groundbreaking scientific advancements, the concepts as a whole describe existing natural laws and do not satisfy the patentability requirements of § 101.¹⁶

Thus, the policy rationale behind subject matter inquiries—and patent law as a whole—is to balance an individual's right to capitalize upon his invention against the risk of hindering innovation by imposing an effective monopoly through patenting.¹⁷ The *Mayo* Court

8. 35 U.S.C. § 102.

9. 35 U.S.C. § 103.

10. 35 U.S.C. § 112.

11. Although § 101 contains the somewhat misleading “new and useful” language, the question of whether an invention satisfies the threshold of patentable subject matter discussed herein is wholly separate from the subsequent considerations of statutory novelty and nonobviousness. *See* *Diamond v. Diehr*, 450 U.S. 175, 190–91 (1981) (noting that an invention may fail either the nonobvious or novelty requirements but still satisfy the threshold requirement for patent protection under § 101).

12. *Id.*

13. *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980). Patent law in the United States originates from Congress's constitutional power to “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.” U.S. CONST. art. I, § 8, cl. 8.

14. *See Mayo Collaborative Servs. v. Prometheus Labs. Inc.*, 132 S. Ct. 1289, 1293 (2012) (“[M]onopolization of [scientific] tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.”).

15. *Id.*

16. *See Diehr*, 450 U.S. at 185 (“A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.” (quoting *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1853))).

17. *Mayo*, 132 S. Ct. at 1293.

described the balance between rewarding innovation and protecting the public domain:

Patent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements.¹⁸

Both courts and commentators frequently cite the notion that an inventor may patent “anything under the sun that is made by man.”¹⁹ In practice, though, such a broad statement is ambiguous and somewhat misleading. Defining the precise bounds of what constitutes a patentable “process, machine, manufacture, or composition of matter” under § 101 has been a source of considerable debate, given the vague language of the statute and the fast pace of scientific advancements. Although not explicit in the language of § 101, courts are bound by the fundamental precedent that “laws of nature, physical phenomena, and abstract ideas” are not patentable subject matter.²⁰ The purpose of these exceptions is to bar an inventor from monopolizing discoveries that are “manifestations of . . . nature, [that must remain] free to all men and reserved exclusively to none.”²¹

Although laws of nature, physical phenomena, and abstract ideas are never patentable, the boundaries that these exceptions encompass are frequently less straightforward than the aforementioned examples of attempting to patent gravity or the law of relativity. In *Diamond v. Diehr*, the Supreme Court noted that “a process is not unpatentable simply because it *contains* a law of nature or a mathematical algorithm,” because, in fact, “an *application* of a law of

18. *Id.* at 1305.

19. *See* *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (noting that the Committee Reports of the 1952 Patent Act provide the origin of the famous “anything under the sun” language); Helen M. Berman & Rochelle C. Dreyfuss, *Reflections on the Science and Law of Structural Biology, Genomics, and Drug Development*, 53 UCLA L. REV. 871, 873 (2006) (discussing the Supreme Court’s broad “anything under the sun” language and its implications for patent law).

20. *Chakrabarty*, 447 U.S. at 309, 315 (“Congress has performed its constitutional role in defining patentable subject matter in § 101; we perform ours in construing the language Congress has employed.”).

21. *Id.* at 309 (first alteration in original) (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

nature or mathematical formula to a known structure or process may well be deserving of patent protection.”²² In *Diehr*, the Court analyzed whether a mathematical formula, the Arrhenius equation, was a patentable matter within a process for curing synthetic rubber.²³ The Court held that although the “Arrhenius equation is not patentable in isolation,” the inventors merely incorporated the equation to calculate optimal cure time, and the patent as a whole provided an innovative, new approach to the entire precision molding process.²⁴ Thus, the Court held that the “process [was] at the very least not barred at the threshold by § 101.”²⁵

The boundary that separates prohibited recitations of natural laws from permissible applications of the same natural laws is unclear and thus a prime target for litigation. *Mayo* was the most recent effort by the Court to clarify where, precisely, this boundary exists.²⁶

II. OPPOSITE SIDES OF A BRIGHT-LINE RULE: THE CONFLICTING CONCLUSIONS OF THE FEDERAL CIRCUIT AND THE SUPREME COURT

Prometheus was the exclusive licensee of U.S. Patent No. 6,355,623²⁷ and U.S. Patent No. 6,680,302.²⁸ In essence, the process protected by the patents instructed medical personnel to first administer a thiopurine drug to a patient and thereafter to measure the metabolites in a sample of the patient’s blood.²⁹ The medical

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22. *Diamond v. Diehr*, 450 U.S. 175, 187 (1981) (first emphasis added) (quoting *Parker v. Flook*, 437 U.S. 584, 590 (1978)). *Diehr* was decided in the year following *Chakrabarty*, and together the two cases redefined the methods of analyzing subject matter patentability. *See id.* at 181–82 (discussing the history of subject matter patentability and citing *Chakrabarty*).
 23. *Id.* at 177.
 24. *Id.* at 188.
 25. *Id.*
 26. *See Mayo Collaborative Servs. v. Prometheus Labs. Inc.*, 132 S. Ct. 1289, 1297 (2012) (“To put the matter more precisely, do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?”).
 27. *Method of Treating IBD/Crohn’s Disease & Related Conditions Wherein Drug Metabolite Levels in Host Blood Cells Determine Subsequent Dosage*, U.S. Patent No. 6,355,623 (filed Apr. 8, 1999).
 28. *Methods of Optimizing Drug Therapeutic Efficacy for Treatment of Immune-Mediated Gastrointestinal Disorders*, U.S. Patent No. 6,680,302 (filed Dec. 27, 2001).
 29. Adam Liptak, *Justices Back Mayo Clinic Argument on Patents*, N.Y. TIMES, Mar. 21, 2012, at B3.

researchers behind the invention calculated the optimal ratios of the drug dosage to the patient's blood sample in order to maximize the dosage's efficiency while minimizing the risk of overdose.³⁰ Thus, the final aspect of the patented process indicated that a doctor should adjust the amount of thiopurine subsequently administered to the patient based on these precise ratios.³¹

Thiopurine drugs are typically administered to treat gastrointestinal disorders such as ulcerative colitis and Crohn's disease.³² Prior to the patents' claimed discoveries, researchers in the field understood the general relationship between the dosage of thiopurine relative to the amount of metabolites in a patient's blood; however, medical researchers had not established any sort of precise test to evaluate the correlation or determine the likely effectiveness of the medicine.³³

Prometheus developed the patented research into tangible diagnostic tests for medicinal use.³⁴ As the exclusive licensee of the technology, Prometheus sold the diagnostic tests to Mayo Medical Laboratories and Mayo Collaborative Services.³⁵ In June 2004, Mayo announced the company's intention to begin marketing its own diagnostic test with similar—though not precisely the same—thiopurine dosage parameters, and thus Mayo effectively terminated its relationship with Prometheus.³⁶ Immediately following Mayo's announcement, Prometheus Laboratories sued for patent infringement on June 15, 2004.³⁷

A. *Mayo's Inescapable Ties to the
Parallel Bilski v. Kappos Proceedings*

Prometheus's lengthy, and ultimately unsuccessful, effort to uphold their patents' validity was riddled with unusual procedural twists. Initially, the United States District Court for the Southern

30. *Id.*

31. More precisely, the patents claimed the diagnostic correlation between the dosage of thiopurine and the concentration of 6-TG or 6-MMP metabolite in a patient's blood. *Mayo*, 132 S. Ct. at 1295.

32. *Id.* at 1294–95.

33. *Id.* at 1295.

34. *Id.* The Prometheus Laboratories website features various diagnostic tests sold by the company. *See Products and Services: Diagnostics*, PROMETHEUS, http://www.prometheuspatisents.com/Products_Diagnostics.asp (last visited Dec. 19, 2012).

35. *Mayo*, 132 S. Ct. at 1295.

36. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 04cv1200 JAH (RBB), 2008 WL 878910, at *1 (S.D. Cal. Mar. 28, 2008).

37. *Id.*

District of California found the Prometheus patents to be invalid and granted summary judgment in favor of Mayo.³⁸ The court concluded that the patents simply claimed correlations between thiopurine levels and the drug's therapeutic effects, and thus the patents were no more than a recitation of data-gathering steps for evaluating natural phenomena.³⁹

It is crucial to emphasize that the District Court's decision came in March 2008.⁴⁰ Given the infrequency of § 101 patent eligibility questions reaching the Supreme Court, it is important to note that the short time span of 2008 through 2012 included two important § 101 patent litigations running in parallel to one another.⁴¹ The first, *Mayo*, questioned the patentability of laws of nature; the second, *Bilski v. Kappos*, questioned the patentability of an abstract idea.⁴² At nearly the precise midpoint of the one year span between *Mayo*'s District Court decision and subsequent Federal Circuit appeal, the Federal Circuit in *Bilski* declared the so-called "machine-or-transformation test" as the definitive mechanism for determining a patent's § 101 eligibility.⁴³ The machine-or-transformation test is a test of whether an invention for a process or method "is (1) tied to a particular machine or apparatus, or (2) transforms a particular article to a different state or thing."⁴⁴

Thus, on the aforementioned appeal by Prometheus in September 2009, the Federal Circuit reversed the District Court's ruling based on their use of *Bilski*'s machine-or-transformation test as a bright-line rule.⁴⁵ The Federal Circuit held that the steps of administering a certain amount of the thiopurine drug in relationship to the patient's metabolite levels were "*transformative* methods of treatment, not

38. *Id.*

39. *Id.* at *6

40. *Id.* at *1.

41. There is the possibility of a third § 101 opinion reaching the Court in an upcoming term. For further discussion, see *infra* Part III.B.

42. See *In re Bilski*, 545 F.3d 943, 949 (Fed. Cir. 2008) (noting that the patent at issue covered a business method process for evaluating risk in price changes, which necessitated the subject matter analysis of abstract ideas), *aff'd sub nom.* *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

43. *Id.* at 956 (reaffirming in October 2008 "that the machine-or-transformation test properly applied, is the governing test for determining patent eligibility of a process under § 101.").

44. Memorandum from John J. Love, Deputy Comm'r for Patent Examination Policy, on Guidance for Examining Process Claims in view of *In re Bilski* (Jan. 7, 2009), available at http://www.uspto.gov/patents/resources/methods/bilski_guidance_memo.pdf.

45. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1349–50 (Fed. Cir. 2009).

correlations,” because “[t]he inventive nature of the claimed methods stems . . . from the application of a natural phenomenon in a series of *transformative* steps comprising particular methods of treatment.”⁴⁶

Bilski reached the Supreme Court first, and the Court reassessed the importance of the machine-or-transformation test, declaring that it was simply “a useful and important clue” in evaluating patent eligibility, rather than the bright-line definitive rule for subject matter patentability.⁴⁷ The next day, the Court granted certiorari in *Mayo* and summarily reversed and remanded in light of *Bilski*.⁴⁸

When *Mayo* subsequently reached the Federal Circuit for a second time in 2010, the case was closely watched for its potentially widespread impact on the “personalized medicine” field.⁴⁹ However, rather anticlimactically, the Federal Circuit once again relied on the machine-or-transformation test and reaffirmed its decision in favor of Prometheus.⁵⁰ The Federal Circuit elaborated upon the transformative aspect of the patented invention:

Determining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation. Some form of manipulation, such as the high pressure liquid chromatography method specified in several of the asserted dependent claims or some other modification of the substances to be measured, is necessary to extract the metabolites from a bodily sample and determine their concentration. As stated by Prometheus’s expert, “at the end of the process, the human blood sample is no longer human blood; human tissue is no longer human tissue.” That is clearly a transformation.⁵¹

The Federal Circuit’s opinion did take care to repeatedly refer to the machine-or-transformation test as a “useful clue” rather than a

46. *Id.* at 1349 (emphasis added).

47. *Bilski v. Kappos*, 130 S. Ct. 3218, 3227 (2010).

48. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 130 S. Ct. 3543 (2010) (mem.), *vacating and remanding* 581 F.3d 1336 (Fed. Cir. 2009). *Bilski* was decided on June 28 and certiorari was granted and the judgment vacated and remanded in *Mayo* on June 29.

49. Andrew Pollack, *Court Backs Patents for Diagnostic Tests*, N.Y. TIMES (Dec. 17, 2010, 5:12 PM), <http://prescriptions.blogs.nytimes.com/2010/12/17/court-backs-patents-for-diagnostic-tests>.

50. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1359 (Fed. Cir. 2010).

51. *Id.* at 1357 (citing Decl. of Dr. Yves Théorêt in Support of Prometheus Labs. Inc.’s Opposition to Defendants’ Motion for Summary Judgment of Patent Invalidity under 35 U.S.C. § 101 ¶ 6, *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 04-CV-1200 JAH (RBB) (S.D. Cal. Mar. 29, 2007) (No. 528-2)).

bright-line rule; however, the court's opinion seemed to indicate that the *Bilski* holding did little to change the Federal Circuit's prior ruling.⁵²

Following this second defeat in the Federal Circuit, Mayo once again filed a petition for certiorari, which was granted.⁵³ The final hurdle in the winding procedural road to the Supreme Court came just prior to oral arguments in December 2011, when Prometheus revealed to the Court that Nestle had purchased the company the prior July.⁵⁴ Though seemingly unrelated to the medical patents at issue, it emerged that Justice Breyer's wife owned stock in Nestle, which would have necessitated his recusal from the proceedings.⁵⁵ However, the Nestle stock was sold on the morning of December 7, which permitted Justice Breyer to be present that afternoon for oral arguments and to go on to write the Court's opinion.⁵⁶

*B. A Unanimous Decision: Analyzing Application
Rather than Transformation*

Though propelled by dual Federal Circuit victories, Prometheus was soundly defeated at the Supreme Court in a 9–0 decision on March 20, 2012.⁵⁷ In a broad sense, the Court agreed with the original ruling of the California District Court, holding that the Prometheus patents simply described the relationship between thiopurine dosage and patent side effects, which is a natural law and therefore unpatentable subject matter under 35 U.S.C. § 101.⁵⁸

Following the examples of each of the preceding courts, the Supreme Court relied on the following language from the '623 patent as the representative scope of the invention for analyzing patentability:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

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52. *See id.* at 1355 (“Thus, the Court did not disavow the machine-or-transformation test. And, as applied to the present claims, the ‘useful and important clue, an investigative tool,’ leads to a clear and compelling conclusion . . . that the present claims pass muster under § 101.”).
53. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 131 S. Ct. 3027 (2011) (granting certiorari).
54. Liptak, *supra* note 29, at B3.
55. *Id.*
56. *Id.*
57. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1292, 1305.
58. *Id.* at 1305.

- (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
- (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.⁵⁹

Justice Breyer emphasized that the patents simply stated “that *if* the levels of 6-TG in the blood (of a patient who has taken a dose of a thiopurine drug) exceed about 400 pmol per 8×10^8 red blood cells, *then* the administered dose is likely to produce toxic side effects.”⁶⁰ Thus, the patents merely contained a procedural recitation, instructing doctors to (1) measure the current level of the relevant metabolite through any available means, (2) use the laws of nature to calculate the patient’s toxicity limits, and (3) reconsider the thiopurine dosage in light of the natural law.⁶¹ In the above three succinct steps, Justice Breyer explained that the patents lacked the critical element of an *application* of a law of nature and instead amounted to no more than a recitation of natural laws.

The Court chided the Prometheus patents for encompassing “nothing significantly more than an instruction to doctors to apply the applicable laws [of nature] when treating their patients” and using only “what is [a] well-understood, routine, conventional activity, previously engaged in by those in the field.”⁶² The Court’s opinion gave credence to the “transformative” aspect of the machine-or-transformation test by noting that the central issue before the Court hinged on “whether the . . . processes have transformed . . . unpatentable natural laws into patent-eligible applications of those laws.”⁶³ But the Court did not accept the Federal Circuit’s reliance on the process steps of high-pressure liquid

59. *Id.* at 1295 (citing claim 1 of Method of Treating IBD/Crohn’s Disease & Related Conditions Wherein Drug Metabolite Levels in Host Blood Cells Determine Subsequent Dosage, U.S. Patent No. 6,355,623 col. 20 ll. 10–20 (filed Apr. 8, 1999)). The Court clarified that “[f]or present purposes we may assume that the other claims in the patents do not differ significantly from claim 1.” *Id.*

60. *Id.* at 1296–97.

61. *Id.* at 1299.

62. *Id.* at 1292, 1298.

63. *Id.* at 1294.

chromatography and other lab work that “transforms” the patient’s blood sample to a different “thing” in order to extract and measure metabolites.⁶⁴ The Court held that the actions of administering the thiopurine drug and subsequently measuring the metabolites obviously constituted necessary interventions; however, the invention as a whole simply encompassed a patient’s internal response to a dose of medicine, which occurs entirely independent of outside involvement.⁶⁵

III. THE IMPACT OF *MAYO* ON FUTURE PATENT EXAMINATION AND LITIGATION

The U.S. Patent and Trademark Office (USPTO) governs all aspects of applying for, examining, and obtaining a patent. The USPTO responded almost immediately to the *Mayo* holding and issued a short brief to update patent examiners on the changes to their § 101 analysis on March 21, 2012, one day after the Court’s decision in *Mayo*.⁶⁶ The USPTO then further updated the guidance measures in July with a lengthier Guidance Memo.⁶⁷ Thus, the USPTO has clearly taken proactive measures to ensure the widespread precedential impact of the *Mayo* holding on subject matter eligibility inquiries. There is, however, some uncertainty as to whether the Federal Circuit will be as willing to comply.

A. *New 35 U.S.C. § 101 Patent Examination Procedures in the Wake of the Mayo Ruling*

In general, patents are either granted or denied as a result of ongoing communications between an inventor and an examiner at the USPTO. Patent applications are reviewed by the examiner for compliance with the Patent Act, and the examiner is required to interpret the application in the broadest terms that would be reasonable to a person of ordinary skill in the art.⁶⁸ Thus, the process

64. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1355, 1357 (Fed. Cir. 2010).

65. *Mayo*, 132 S. Ct. at 1297.

66. Memorandum from Andrew H. Hirshfeld, Assoc. Comm’r for Patent Examination Policy, on the Supreme Court Decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (Mar. 21, 2012), available at http://www.uspto.gov/patents/law/exam/mayo_prelim_guidance.pdf.

67. See *infra* Part III.A.

68. See Memorandum from Andrew H. Hirshfeld, Assoc. Comm’r for Patent Examination Policy, on the 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature 2 (July 3, 2012), available at http://www.uspto.gov/patents/law/exam/2012_interim_guidance.pdf [hereinafter 2012 Guidance Memo] (“Establish the

of patenting an invention is, in essence, a back-and-forth “conversation” between the applicant and examiner to accept, reject, amend, and clarify the description and wording of the invention in search of patentability. Any granted patents, including the two at issue in *Mayo*, have a presumption of validity since they were approved by a USPTO examiner.⁶⁹

On July 3, 2012, the USPTO issued a memorandum outlining the new analytic methods patent examiners should use in evaluating patentable subject matter in light of the Court’s holding in *Mayo*.⁷⁰ The new Guidance Memo sets forth revised procedures with the specific intention that if Prometheus’s patent applications were before an examiner today, they would not be approved as patentable subject matter.

The new USPTO criterion sets forth a three-prong inquiry that analyzes subject matter eligibility in a question and answer format:

- (1) Is the . . . invention directed to a process, defined as an act, or a series of acts or steps? . . .
- (2) Does the [invention] focus on use of a law of nature, a natural phenomenon, or naturally occurring relation or correlation (collectively referred to as a natural principle herein)? (Is the natural principle a limiting feature of the [invention]?) . . .
- (3) Does the [invention] include additional elements/steps or a combination of elements/steps that integrate the natural principle into the . . . invention such that the natural principle is practically applied, and [is] sufficient to ensure that the [invention] amounts to significantly more than the natural principle itself? (Is it more than a law of nature [plus] the general instruction to simply “apply it”?)⁷¹

Inquiry 1 simply serves as a threshold question regarding whether *Mayo* is applicable to the type of invention disclosed in the patent application. Inquiry 2 then describes the category of potentially

broadest reasonable interpretation of the claims when read in light of the specification and from the view of one of ordinary skill in the art.”).

69. See 35 U.S.C. § 282 (2006).

70. 2012 Guidance Memo, *supra* note 68. The 2012 Guidance Memo superseded the analytic methods from the previous March 21 memorandum discussed in the text accompanying note 66.

71. 2012 Guidance Memo, *supra* note 68, at 2. The memo indicates that the guidance therein is interim, while the USPTO awaits issuing comprehensive guidance after the Court’s reconsideration of the *Myriad* and *Ultramercial* cases discussed *infra* Part III.B. See *id.* at 1.

“dangerous” subject matter that could warrant further examination.⁷² The Guidance Memo clarifies inquiry 2 by defining a natural principle to be “the handiwork of nature [that] occurs without the hand of man.”⁷³ The USPTO gives the examples of the disinfecting property of sunlight or the correlation between blood glucose levels and diabetes as rather simplistic versions of natural principles.⁷⁴ As discussed previously, if the patent encompasses an abstract idea rather than a natural principle, then *Bilski* governs the analysis rather than *Mayo*.⁷⁵ An abstract idea under *Bilski* includes, for example, mental steps or plans for performing an action.⁷⁶

Inquiry 3 is the defining question at the heart of *Mayo*. If satisfied, the invention is eligible subject matter.⁷⁷ The Guidance Memo instructs that “[a] bare statement of a naturally occurring correlation, albeit a newly discovered natural correlation or very narrowly confined correlation, would fail [inquiry 3].”⁷⁸ The USPTO directly quotes the *Mayo* holding throughout the memo, noting that “[a]dding steps to a natural biological process that only recite well-understood, routine, conventional activity previously engaged in by researchers in the field would not be sufficient” to satisfy the subject matter requirements of § 101.⁷⁹

The Guidance Memo provides sample applications of the three-prong inquiry, most notably to the Prometheus patents themselves.⁸⁰ The Prometheus invention would pass inquiries 1 and 2, since as discussed in Part II.B, the correlation of thiopurine dosage to red blood cells comprised (1) a process and (2) the use of a law of

72. See 2012 Guidance Memo, *supra* note 68 (noting that the memo is applicable in examining all patents that include “process claims in which a law of nature, a natural phenomenon, or [a] naturally occurring relation or correlation . . . is a limiting element or step”).

73. *Id.* at 3.

74. *Id.*

75. 2012 Guidance Memo, *supra* note 68 (stating that “[p]rocess claims that do not include a law of nature, a natural phenomenon, or [a] naturally occurring relation or correlation as a claim limitation” should continue to be examined in light of their subject matter eligibility under *Bilski v. Kappos*).

76. *Id.* at 3.

77. It is crucial to note the difference between “eligible subject matter” under § 101 and the novelty, nonobviousness, and substantive filing requirements that govern an inventor’s ability to actually be granted a patent. See *supra* text accompanying notes 7–12.

78. 2012 Guidance Memo, *supra* note 68, at 3.

79. *Id.* at 4.

80. *Id.* at 8.

nature.⁸¹ However, if the Prometheus patent applications were considered by an examiner today, under the new guidance rules, the inventor would be barred from patenting under inquiry 3.⁸² This is because, as noted by the Court, the Prometheus patents essentially present a law of nature with the general instructions “to apply the laws in question.”⁸³ Patentable subject matter requires additional steps so that the invention amounts to substantially more than a recitation of a natural principle.⁸⁴

B. Will the Federal Circuit Acquiesce to the Mayo Holding?

Following the *Mayo* decision, the Supreme Court vacated and remanded two cases to the Federal Circuit for reconsideration of their subject matter patentability in light of the Court’s holding. The first case, *WildTangent, Inc. v. Ultramercial, LLC*,⁸⁵ has not yet been reheard by the Federal Circuit. The § 101 inquiry at issue in *Ultramercial* is the eligibility of a patent covering a method of distributing copyrighted material, such as songs or movies, over the Internet in exchange for a consumer viewing an advertisement.⁸⁶ The technology relates to the widely-debated issue of patenting software, which at first impression seems far removed from the medical field and the realm of natural laws. But the now-vacated *Ultramercial* Federal Circuit opinion seemed to tie the principles of *Bilski* to those of *Mayo* in noting that “[a]lthough abstract principles are not eligible for patent protection, an *application* of an abstract idea may well be deserving of patent protection.”⁸⁷ Thus, the Supreme Court’s decision to vacate and remand *Ultramercial* may indicate an intention to extend *Mayo*’s strict-eligibility requirements for a patent to

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81. See *id.* (defining the relevant analysis for patentability).
82. See *id.* (rejecting the example claim “because [it] is directed to non-statutory subject matter because it is not a patent-eligible practical application of a law of nature”).
83. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1299 (2012).
84. It is important to note that an initial rejection from an examiner does not foreclose future patentability. Thus, the Guidance Memo notes potential arguments an applicant may present following an initial rejection under the *Prometheus* three-pronged inquiry. See 2012 Guidance Memo, *supra* note 68, at 9 (“It would . . . be proper for the applicant to present persuasive arguments that the additional steps add something significantly more to the claim than merely describing the natural principle. A showing that the steps are not routine, well-known or conventional could be persuasive.”).
85. *WildTangent, Inc. v. Ultramercial, LLC*, 132 S. Ct. 2431 (2012) (mem.), *vacating and remanding* 657 F.3d 1323 (Fed. Cir. 2011).
86. *Ultramercial, LLC v. Hulu, LLC*, 657 F.3d 1323, 1324 (Fed. Cir. 2011).
87. *Id.* at 1327 (emphasis added).

incorporate an application that is significantly more than reciting a law of nature, or, in this case, an abstract idea.

The second case remanded, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, was reheard by the Federal Circuit on August 16, 2012, and has far more obvious ties to the *Mayo* decision.⁸⁸ In essence, the dispute questions three aspects surrounding Myriad's patents over the human genes associated with a person's predisposition to suffer ovarian or breast cancers: Can Myriad patent (1) the isolation of the genes, (2) the methods "for comparing DNA sequences," or (3) the process of screening the genes to evaluate cancer risk?⁸⁹ The *Myriad* case has been closely followed not necessarily for the intricacies of its § 101 arguments, but predominantly because of the moral and political debates surrounding the concept of patenting human genes.⁹⁰

The New York Times noted that Myriad's stock dropped immediately following the *Mayo* decision, based on investors' fears that the company's gene patents would be reconsidered as laws of nature and thus invalid.⁹¹ But in spite of the Supreme Court's holding in *Mayo*, the Federal Circuit in *Myriad* held that "*Mayo* does not control the question of patent-eligibility" of the Myriad patents, because the "isolated DNA molecules before us are not found in nature . . . [t]hey are obtained in the laboratory and are man-made, the product of human ingenuity."⁹² The court held that the patents consisted of compositions of matter, which in general are a "thing" rather than a *Mayo*-type law of nature or a *Bilski*-type abstract idea. Therefore, the Federal Circuit upheld the validity of Myriad's gene

88. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012) (mem.), *vacating and remanding* 653 F.3d 1329 (Fed. Cir. 2011).

89. *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office (Myriad)*, 689 F.3d 1303, 1324 (Fed. Cir. 2012).

90. *See, e.g.*, Brief of *Amici Curiae* Rosetta Genomics, Ltd. et al. in Support of Defendants-Appellants, Supporting Reversal at 2, *Myriad*, 689 F.3d 1303, 1324 (Fed. Cir. 2012) (No. 2010-1406), 2010 WL 4853324 at *2 ("This case has generated significant public comment regarding so called 'gene patents.' The ACLU and Plaintiffs-Appellees have welcomed, and in fact encouraged, the public attention and resulting controversy."); Daniel Fisher, *D.C. Court Upholds Myriad Breast-Cancer Patents, Snubbing Supreme Court*, FORBES (Aug. 16, 2012, 2:23 PM), <http://www.forbes.com/sites/danielfisher/2012/08/16/d-c-court-upholds-myriad-breast-cancer-patents-snubbing-supreme-court> ("Human DNA is a natural entity . . . [i]t does not belong to any one company." (quoting American Civil Liberties Union staff attorney Chris Hansen)).

91. Liptak, *supra* note 29, at B3. The Federal Circuit had earlier upheld two patents held by Myriad Genetics claiming the process of analyzing extracted DNA for the genes BRCA1 and BRCA2, in which mutations indicate a risk of developing breast or ovarian cancers. *Id.*

92. *Myriad*, 689 F.3d at 1325.

patents without a truly comprehensive consideration of *Mayo*'s precedent.⁹³

Thus, the Federal Circuit in essence has defined human DNA to be outside the realm of natural laws.⁹⁴ But Judge Moore's concurring opinion raised a question: "Does the isolation process change the DNA from an unpatentable manifestation of nature into a patentable composition of matter?" Judge Moore went on to suggest that the task of addressing such complicated scientific principles is better left to Congress than the Court.⁹⁵ The Federal Circuit judges did not reach a collective opinion in *Myriad*, and the holding has been noted as a veritable "snub" to the Supreme Court's *Mayo* decision.⁹⁶ But just as the Prometheus patents were twice upheld by the Federal Circuit before being defeated in the Supreme Court, commentators predict that the *Myriad* case may reach the Court in an upcoming term, perhaps with a very different outcome.⁹⁷

CONCLUSION

The *Mayo* dispute was unquestionably controversial and garnered several amicus curiae briefs on each side.⁹⁸ The Court noted that medical experts strongly opposed patentability because of the ever-present concern of undue monopolization and the risk of "disproportionately tying up the use of . . . underlying natural laws," which would inhibit medical researchers from making further discoveries.⁹⁹

93. *Id.*

94. *See id.* at 1331 ("The remand of this case for reconsideration in light of *Mayo* might suggest . . . that the composition claims are mere reflections of a law of nature. Respectfully, they are not . . . [t]hey are the products of man, albeit following, as all materials do, laws of nature.").

95. *Id.* at 1340, 1345 (Moore, J., concurring).

96. Fisher, *supra* note 90.

97. *See id.* ("There's still a great deal of uncertainty because the Supreme Court has not had the final word on this issue." (quoting Antoinette Konski, an intellectual property attorney at Foley and Lardner in Palo Alto, California)); Jonathan Stempel, *Myriad Wins Gene Patent Ruling from US Appeals Court*, REUTERS (Aug. 16, 2012), <http://www.reuters.com/article/2012/08/16/us-myriad-patent-idUSBRE87F12K20120816> ("Although the decision will probably be appealed to the U.S. Supreme Court . . . today . . . the decision is 'a win.'" (quoting biotech patent attorney Tim Worrall of Dorsey and Whitney)).

98. The Court cited the following organizations by name: the American Medical Association, the American College of Medical Genetics, the American Hospital Association, the American Society of Human Genetics, the Association of American Medical Colleges, and the Association for Molecular Pathology. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1304–05 (2012).

99. *Id.* at 1294.

While most patent applications present a tangible invention or “thing” and easily traverse the § 101 threshold, recent advancements in the biological and computer sciences have necessitated a thorough reexamination of our ability to patent “anything under the sun that is made by man.”¹⁰⁰ The Supreme Court’s years of silence on subject matter eligibility prior to *Bilski* and *Mayo* resulted in glaring inconsistencies among patent examiners, district courts, and the Federal Circuit, which have weakened the integrity of the statutory language. But now the Supreme Court and the USPTO have begun to take proactive measures to redefine the outer boundaries of patent-eligible subject matter. Perhaps *Ultramercial*, along with a potential future appeal in *Myriad*, will resolve the remaining inconsistent approaches to applying § 101 doctrine.

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100. See *supra* text accompanying note 19.

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