

Akamai: A Cure for Medical Process Patent's Prometheus Ailment?

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I. Introduction

In its recent decision, *Mayo v. Prometheus*, the Supreme Court addressed the subject matter eligibility of process claims containing a law of nature as a limiting element.¹ The Court reiterated the long-standing rule that laws of nature are not patentable, but that applications of them may be patent-eligible.² After *Mayo*, the fate of medical process patents related to naturally occurring correlations seemed to be in jeopardy.³ The Court attempted to distinguish between unpatentable concepts and practical applications of those concepts, but left many in the biotech and medical industries wondering how to draft patent-eligible claims. Practitioners have been forced to rethink claiming strategies, and at best, this decision has made their task significantly more challenging and uncertain.⁴ Many law firms have provided guidance on how to approach drafting claims to prevent a subject matter eligibility rejection from the United States Patent and Trademark Office (“USPTO”),⁵ and the USPTO

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

2. *Id.* at 1293–94.

3. See Angela L. Morrison, *Mayo v. Prometheus: Patent Eligibility of Claims Covering Natural Laws*, 41 COLO. LAW. 77, 81 (2012).

4. Christopher Holman, *Preliminary Thoughts on the Implications of Prometheus v. Mayo for Biotechnology*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (Apr. 3, 2012), <http://www.genengnews.com/blog-biotech/preliminary-thoughts-on-the-implications-of-i-prometheus-i-i-v-mayo-i-for-biotechnology/679> (last visited Oct. 20, 2012).

5. See, e.g., Robert M. Shulman & David A. Kelly, Hunton & Williams LLP, Presentation, *Subject-Matter Eligibility in the Wake of Mayo v. Prometheus* (Apr. 20,

has provided examiners with its own detailed guidance on how to address these types of claims.⁶ At worst, this decision has depleted any remaining value from medical diagnostic patents because many patent-eligible claims post-*Mayo* would be difficult to infringe.⁷

This note will discuss the problem of subject matter eligibility for medical process patents post-*Mayo* as it relates to the likelihood of infringement of those patents. After the *Mayo* decision, practitioners are attempting to redraft claims to ensure they contain patent eligible subject matter, but in doing so, they may be drafting claims that are impossible to directly infringe. Put another way, in order to cure the subject matter eligibility deficiency of medical process patents, practitioners may be forced to add steps to method claims that require additional actors to complete. This means that no one actor would complete all of the steps of the method, and therefore, there would be no direct infringer. This note proposes that the Federal Circuit, in *Akamai Technologies, Inc. v. Limelight Networks, Inc.*,⁸ effectively provided a solution to this problem by readdressing the law of divided infringement in the inducement context. Despite all of the industry and academic focus on the *Mayo* decision,⁹ without *Akamai*,¹⁰ many medical process patents, while they may still exist, would be worthless.

This note will begin by providing context with a brief introduction to medical process patents and patent subject matter eligibility. To fully explain the implications of both the *Mayo* and *Akamai* decisions on medical process claims, this note will explore the prominent decisions leading up to both cases. Following the exploration of the *Mayo* line of cases, this note will discuss the application of the principles outlined in *Mayo* in cases decided after

2012), available at http://www.hunton.com/files/Uploads/Documents/Events/Prometheus_Presentation.pdf.

6. Memorandum of Andrew H. Hirshfeld, Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature (July 3, 2012) [hereinafter Hirshfeld Memorandum], http://www.uspto.gov/patents/law/exam/2012_interim_guidance.pdf (last accessed Oct. 20, 2012).

7. See Corrected Brief of Amicus Curiae, Myriad Genetics, Inc., in Support of Neither Party, *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301 (2012) (No. 2009-1372), at 17 (recognizing, before a final determination in *Mayo*—which made it more difficult to obtain medical process patents relating to laws of nature—that requiring an analysis step in diagnostic process patents leaves applicants to receive a worthless patent that can easily be infringed due to the Court’s joint infringement decisions).

8. 692 F.3d 1301, 1305 (2012).

9. 132 S.Ct. 1289 (2012).

10. See *infra* notes 7 and 8.

the landmark decision and the guidance provided by the USPTO. This will be followed by an analysis of an exemplary medical process claim containing a naturally occurring correlation, which highlights the practical difficulties created by *Mayo*. An explanation of possible deficiencies of the claim post-*Mayo* will be provided and possible remedies will be proposed. Finally, after a discussion of the *Akamai* line of cases and the decision itself, this note will demonstrate how *Akamai* potentially saves the exemplary claim from worthlessness and will discuss a potential problem that still remains.

II. Introduction to Medical Process Patents

Originally, medical processes were not considered patent-eligible subject matter.¹¹ Case law addressing medical process patent disputes dates back to the 19th century, when in *Morton v. New York Eye Infirmary* a patent owner sought to recover damages for infringement of a patent covering a procedure for administering ether to surgical patients as an anesthetic.¹² The court acknowledged the usefulness of the method but held that it was not patentable.¹³ Courts thereafter “interpreted this holding as prohibiting the patenting of any medical procedures.”¹⁴ In 1945, the Patent Office Board of Appeals explicitly held that “methods or modes of treatment of physicians of certain diseases are not patentable.”¹⁵ Several years later, in 1954, the Patent Office Board of Appeals overruled its prior decision and reestablished the patent eligibility of medical and surgical processes under 35 U.S.C. § 101.

Generally, medical and surgical procedures remain patent eligible subject matter.¹⁶ However, the scope of enforceability of medical process patents has been significantly limited through legislative means.¹⁷ Legislative action came in response to outrage

11. Scott D. Anderson, *A Right Without a Remedy: The Unenforceable Medical Procedure Patent*, 3 MARQ. INTELL. PROP. L. REV. 117, 122 (1999).

12. *Id.* (citing *Morton v. New York Eye Infirmary*, 17 F. Cas. 879, No. 9,865 (C.C.S.D.N.Y. 1862)).

13. *Morton*, 17 F. Cas. at 883.

14. Anderson, *supra* note 11, at 123.

15. *Ex parte Brinkerhoff*, 27 J. Pat. Off. Soc’y 797, 798 (1945) (reviewing 24 Comm’n Manuscript Decision 349 (Pat. Off. Bd. App. 1883) (Case No. 182)).

16. Anderson, *supra* note 11, at 130–131 (explaining the unenforceability of medical process patents against a medical practitioner’s performance of a medical activity under 35 U.S.C. §§ 271(a) or (b), 281, 283, 284 and 285).

17. *Id.*

over the 1995 case of *Pallin v. Singer*.¹⁸ There, Pallin, an ophthalmologist, sued for patent infringement when another ophthalmologist used his method of performing cataract surgery without stitches.¹⁹ After the American Medical Association (“AMA”) expressed concern that medical process patents could lead to inadvertent infringement by medical professionals, Congress amended the Patent Act to prevent enforcement of such patents against medical practitioners directly infringing, or induced infringing acts, if completed in the course of medical activity.²⁰ Despite this limitation on enforcement, many believe that without the security of the patent system, investment in the biotechnology industry would undoubtedly decrease.²¹ Therefore, medical process patents remain an important tool for many in the industry.

III. Introduction to Subject Matter Eligibility

Section 101 of the Patent Act defines patentable subject matter and states that “whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor.”²² The section 101 patent-eligibility inquiry is a threshold test.²³ Even if an invention potentially qualifies for a patent under this section, in order to receive the Patent Act’s protection, the claimed invention must also satisfy additional requirements included in the Act.²⁴ Similarly, section 101 is “a coarse eligibility filter,” not the final arbiter of patentability,²⁵ and it “does not permit a court to reject subject matter categorically because it finds that a claim is not worthy of patent.”²⁶

18. *Pallin v. Singer*, Civ. A. No. 2:93-CV-202, 1996 WL 274407 (D. Vt. Mar. 28, 1996).

19. See Margaret Kubick, *An Uncertain Future: The Impact of Medical Process and Diagnostic Method Patents on Healthcare in the United States*, 9 NW. J. TECH. & INTELL. PROP. 280, 285 (2010) (discussing *Pallin v. Singer*).

20. *Id.* at 21–22.

21. Julianne Befeler, *Seeking A Better Prescription for Physicians: Patent Eligibility for Diagnostic Methods in A Post-Bilski and Prometheus Era*, SEATON HALL LEGIS. J. 484, 508–09 (2011) (discussing the importance of patent protection for diagnostic method patents).

22. 35 U.S.C. § 101 (2006).

23. *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010).

24. *Id.*; see, e.g., 35 U.S.C. § 102 (novelty); 35 U.S.C. § 103 (obviousness).

25. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1066 (2011) (quoting *Research Corp. Techs. v. Microsoft Corp.*, 627 F.3d 859, 868 (Fed. Cir. 2010)).

26. *Research Corp. Techs.*, 627 F.3d at 869.

The Court has recognized three specific exceptions to section 101's patent eligibility criteria: "laws of nature, physical phenomena, and abstract ideas" are not patentable.²⁷ In drafting the 1952 Patent Act, Congress intended to provide a broad scope for patent eligibility in order to encourage ingenuity.²⁸ These exceptions are not statutorily required, but they have been recognized since the 19th century and they reflect the notion that a patentable process must be new and useful.²⁹ Additionally, these exceptions encompass the "basic tools of scientific and technological work, which are free to all men and reserved exclusively to none."³⁰

In *Mayo v. Prometheus*, the Court addressed how the natural law exception to subject matter eligibility applied to a medical process patent claiming a correlation between a certain metabolite level in a patient's blood and pharmaceutical effectiveness.³¹ Leading up to this decision, the Court heard a series of cases discussing the non-statutory exceptions to section 101. In 1948, in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, the Court reiterated the law of nature exception when it held unpatentable product claims reciting a combination of individually naturally occurring species of bacteria.³² Most of the cases following *Funk Brothers* but prior to *Mayo* involved software claims and the abstract idea exception. These cases provide additional direction on how to apply the subject matter eligibility exceptions and a more thorough discussion of the abstract idea exception.³³ While the decisions contain some inconsistencies, the *Mayo* decision concludes this line of discussion by combining four interrelated ideas seen throughout this jurisprudence: insignificant pre- or post-solution activity; the application of the law of nature or abstract idea; preemption; and how to address the claimed steps, individually or as a whole. Since these ideas can encompass each other and can easily be conflated, an appropriate section 101 analysis need not consider each individually, as long as the underlying rationale of each is addressed. The following section will track how

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

28. *Bilski*, 130 S. Ct. at 3225.

29. *Id.*; see *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852).

30. *OIP Techs., Inc., v. Amazon.com, Inc.*, No. C-12-1233 EMC, 2012 WL 3985118, at *4 (N.D. Cal. Sept. 11, 2012) (citing *Mayo*, 132 S. Ct. at 1293).

31. 132 S. Ct. at 1295.

32. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948).

33. See *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Parker v. Flook*, 437 U.S. 584 (1978); *Diamond v. Diehr*, 450 U.S. 175 (1982).

the Court has developed and applied these ideas, concluding with its most recent pronouncement in *Mayo*.

IV. Noteworthy Supreme Court Cases on the Road to *Mayo*

Funk Brothers v. Kalo Inoculant

In *Funk Brothers*, the Court laid the foundation for its later discussion of the application of a law of nature to new and useful ends.³⁴ The Court clearly reaffirmed its decision in *Le Roy v. Tatham*³⁵ that the discovery of a law of nature is not patent-eligible.³⁶ The Court explained that laws of nature are free to everyone, so an invention must come from the inventive application of the law of nature.³⁷ The concept that an inventive application of a law of nature is patent-eligible is continually referenced in the cases leading up to *Mayo*, and in *Mayo* itself.

Gottschalk v. Benson

In *Gottschalk v. Benson*,³⁸ the Court discussed both if and how an abstract idea can be applied to a new end, and the intertwined idea of preemption.³⁹ In this case the Court considered whether the claimed method of programming a general-purpose computer was indeed a patent-eligible discovery, or merely a mathematical formula without any practical application.⁴⁰ Following on ideas expressed in *Funk Brothers*, the Court explained that phenomena of nature (even if just discovered), mental processes, and abstract ideas are not patentable because they are the basic tools of science and technology.⁴¹ If laws of nature, mental processes, or abstract ideas themselves were patentable, without any meaningful application, the protection a patent affords would prevent others from building on foundational scientific knowledge. The Court noted that “a novel and useful structure created with the aid of knowledge of scientific truth” might be patentable,⁴² but explained that allowing a patent on the claimed

34. See *Funk Brothers*, 333 U.S. at 130.

35. *Le Roy v. Tatham*, 55 U.S. 156 (1852).

36. *Funk Brothers*, 333 U.S. at 130.

37. *Id.*

38. *Gottschalk v. Benson* at 409 U.S. 63.

39. *Id.* at 71–72.

40. *Id.* at 71.

41. *Id.* at 67.

42. *Id.*

method, without application except in relation to a general purpose computer, would “wholly pre-empt the mathematical formula and in practical effect would be [allowing] a patent on the algorithm itself.”⁴³ So, in light of its discussion regarding the lack of application of the abstract idea and the current claims’ ability to preempt future innovation, the Court held the process patent-ineligible.

Parker v. Flook

In *Parker v. Flook*, the Court presented a method of analyzing a claimed process that includes a law of nature, abstract idea or mental process, the idea of a claim containing an “inventive concept,” and the concept of “conventional post-solution activity.”⁴⁴ The patent at issue in this case was directed toward a method of updating alarm limits during the catalytic chemical conversion of hydrocarbons.⁴⁵ The Court noted that the mathematical algorithm in the process was the only distinguishing element between conventional methods and the claimed method.⁴⁶ With this backdrop, the Court analyzed the claim assuming the algorithm was within the prior art.⁴⁷ The Court disclaimed the relevance of the novelty of the mathematical algorithm and explained that once it was assumed to be part of the prior art, the application contained no patentable invention.⁴⁸ The Court considered the claims as a whole only in relation to its method of analysis: Assume the law of nature or abstract idea is part of the prior art, then determine if the remaining application of the law of nature or abstract idea is inventive.⁴⁹ Flook argued that the addition of post-solution activity distinguished his method from that in *Benson*, and therefore made his process patentable.⁵⁰ The Court vehemently disagreed, explaining that allowing post-solution activity to remedy the patent ineligibility of a law of nature or an abstract idea “exalt[ed] form over substance.”⁵¹ The Court held Flook’s method recited an unpatentable abstract idea, and the addition of conventional post-

43. *Id.* at 71–72.

44. *Parker v. Flook*, 437 U.S. 590, 590–94 (1978).

45. *Id.* at 585–86.

46. *Id.*

47. *Id.* at 591–94.

48. *Id.* at 594.

49. *Id.* (stating “once that algorithm is assumed to be within the prior art, the application, *considered as a whole*, contains no patentable invention”) (emphasis added).

50. *Parker v. Flook*, 437 U.S. at 590.

51. *Id.*

solution activity failed to convert it into an inventive application of that idea.⁵²

Diamond v. Diehr

In *Diamond v. Diehr*, the Court continued to rely on the interrelated ideas of preemption, post-solution activity and how the natural law is applied in analyzing subject matter eligibility, but it rejected the method of claim analysis presented in *Flook*.⁵³ In *Diehr*, the claimed invention was a “process for molding raw, uncured synthetic rubber into cured precision products,” by constantly measuring the actual temperature inside a mold shaping the material and using this data, in combination with a programmed computer, to repeatedly recalculate the cure time.⁵⁴ The Court acknowledged that several steps of the claimed method relied on a mathematical equation and a digital computer, but explained that their inclusion in the method did not prevent it from being patentable.⁵⁵ The Court concluded that the claims at issue applied a mathematical formula in a process that was performing a function that patent law was designed to protect—an industrial process for molding synthetic rubber—and was therefore patent eligible.⁵⁶

In reaching this result, the Court emphasized that to determine subject matter eligibility under section 101, the claims must be examined as a whole.⁵⁷ Repudiating its decision in *Flook*,⁵⁸ the Court explained that it is inappropriate to analyze the elements of a process claim individually.⁵⁹ Separating a claim into new elements and old elements, then ignoring the old elements is improper because a new combination of steps in a process may be patentable despite all of the steps being previously well known or in common use before the combination.⁶⁰ The Court clarified that the “novelty of any element or step in a process, or even of the process itself, is of no relevance in

52. See *Parker v. Flook*, 437 U.S. 590, 590–94 (1978).

53. See *Diehr*, 450 U.S. at 185.

54. *Id.* at 177–79.

55. *Id.* at 185.

56. *Id.* at 192–93.

57. *Id.* at 188.

58. See *Parker v. Flook*, 437 U.S. 584 (1978).

59. *Diehr*, 450 U.S. at 188.

60. *Id.*

determining whether the subject matter of a claim falls within the section 101 categories of possibly patentable subject matter.”⁶¹

The Court also continued to consider whether the proposed claims attempted to preempt future innovation, and whether they actually applied the mathematical formula or merely recited it with appended insignificant post-solution activity.⁶² The Court explained that while the claimed process employed a well-known mathematical equation, it did not seek to preempt the use of the equation.⁶³ Rather, it only prevented others from using the equation in conjunction with the remaining steps of the method, which does not present a bar to patent-eligibility.⁶⁴ In distinguishing *Flook*, the Court explained that here the invention is not a mathematical formula, but an application of that formula to a process for curing synthetic rubber.⁶⁵ The claimed application of the equation does not wholly preempt it from further general use.⁶⁶ In contrast, in *Flook*, the patent claimed a formula for computing an alarm limit with no additional meaningful disclosure, which amounted to claiming the formula itself.⁶⁷ Additionally, the Court reiterated that the addition of “insignificant post-solution activity will not convert an unpatentable principle into a patentable process.”⁶⁸ Analyzing all of the elements of the proposed claim together, the Court found that the proposed method did not preempt further use of the mathematical equation. Thus, the method was not merely the equation with the addition of a conventional post-solution activity, but was an application of the formula to an industrial process that was patent-eligible.⁶⁹

V. *Mayo v. Prometheus*

In *Mayo*, the Court again confronted whether a claimed process constituted patent-eligible subject matter or an unpatentable

61. *Id.* at 188–89 (The Court recognized that the injection of the novelty analysis into subject matter eligibility may be the result of the “new and useful” language in section 101, but failed to acknowledge its conflation of these concepts in its previous cases, for example, in *Parker v. Flook*.).

62. *Id.* at 188, 192.

63. *Id.* at 187.

64. *Id.*

65. *Diehr*, 450 U.S. at 187.

66. *Id.*

67. *Id.* at 186–87.

68. *Id.* at 188, 191–92 (citing *Parker v. Flook*, 437 U.S. 584 (1978)).

69. *See id.* at 191–92.

exception to section 101. While the decision does not clearly explain how to address subject-eligibility concerns going forward, it does build on the foundation the Court laid in its prior precedent. The decision compiles the intertwined ideas regarding subject matter eligibility expressed in the cases leading up to this decision: preemption, application, pre- or post-solution activity, and the method of claim analysis.

The claims at issue cover a medical process that informs a doctor using thiopurine drugs to treat patients with autoimmune diseases about the efficacy of a given dosage of the drug.⁷⁰ In response to ingesting a thiopurine drug, the human body will metabolize the drug and form metabolites,⁷¹ specifically 6-thioguanine (6-TG) and 6-methyl-mercaptopurine (6-MMP), in the blood.⁷² Each person, however, metabolizes thiopurine drugs differently.⁷³ Therefore, although it was known in the field that 6-TG and 6-MMP were associated with the effectiveness of a particular dosage of a thiopurine drug, the precise correlations between these metabolite levels and efficacy or harm were unknown.⁷⁴ Prometheus's claims cover a method embodying the discovery that blood concentration levels of 6-TG or 6-MMP beyond a certain amount indicates an over-dose of the thiopurine drug, while concentration levels of the metabolites below a certain amount indicates an under-dose of the thiopurine drug.⁷⁵ Prometheus sells diagnostic tests that embody the claimed process, and for a time, sold these tests to Mayo Clinic Rochester and Mayo

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

71. Metabolites are a substance essential to the metabolism of a particular organism or to a particular metabolic process. They are usually small molecules and have various functions, for example, fuel or signaling. *Metabolite*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/metabolite> (last visited Feb. 22, 2013).

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

73. *Id.*

74. *Id.*

75. *Id.* Prometheus' claim 1: "A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising: (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." U.S. Patent No. 6,355,623 col. 20, ll. 10–20 (filed Apr. 8, 1999).

Collaborative Services (“*Mayo*”).⁷⁶ However, in 2004, Mayo announced it would begin using and selling its own test with a slight variation and Prometheus commenced an action for patent infringement.⁷⁷

The Court found that Prometheus’s claims were directed to patent-ineligible subject matter because they claimed a relationship between a specific metabolite and the likelihood that a specific dosage of a thiopurine drug was ineffective or harmful, which is a law of nature.⁷⁸ In coming to its decision, the Court discussed the main ideas of subject matter eligibility seen in the cases leading up to *Mayo*. First, the Court emphasized that a process reciting a law of nature, without additional features that prevent monopolization of the law itself, is not patentable.⁷⁹ Allowing Prometheus’ claims to stand would “risk disproportionately tying up the use of the underlying natural laws,” thus inappropriately preempting further innovation.⁸⁰ Second, the Court reiterated that a process that focuses on the use of a law of nature must contain other elements, or a combination of elements, that amount to an “inventive concept” or an inventive application of the law.⁸¹ An inventor must do more than state a law of nature and add the words “apply it.”⁸² Prometheus’s claims instructed doctors to gather data and draw inferences in light of a naturally occurring correlation, which the Court held is not inventive.⁸³ And, third, the Court again explained that “the prohibition against patenting a [natural law] cannot be circumvented by adding insignificant post-solution activity.”⁸⁴ Prometheus’s claims informed a relevant audience about a specific natural law with additional well-understood, conventional activity that amounted to no more than insignificant pre-solution activity.⁸⁵ This was not enough to convert the unpatentable law of nature into a patentable application

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

77. *Id.* at 1296.

78. *Id.*

79. *Id.* at 1297.

80. *Id.* at 1294.

81. *Id.*

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

83. *Id.* at 1298.

84. *Id.*

85. *Id.*

of that law.⁸⁶ The Court found Prometheus's claims undeserving of a patent because they effectively claimed the underlying law of nature.⁸⁷

The Court did not provide direct instruction on which model of claim analysis is appropriate (the model presented in *Flook* or in *Diehr*) and instead used both of the two previously presented techniques. In analyzing Prometheus's claims, the Court broke the claims into three basic steps: an administering-the-drug step, a determining-the-level-of-metabolite step, and a wherein step which informs the doctor of a need to increase or decrease the amount of drug.⁸⁸ The Court then engaged in an analysis of each step individually, similar to method used in *Flook*.⁸⁹ However, after considering and dismissing each of the three steps, the Court addressed the steps as an ordered combination, citing *Diehr*.⁹⁰ While most of the opinion consists of analysis of each of the claimed steps individually, the Court repeatedly refers to viewing those steps as a whole.⁹¹ Additionally, the Court did not explicitly state that the law of nature should be assumed to be part of the prior art.⁹² The Court's analysis arguably contained both methodologies or a combination of the two, and did not explicitly promote or reject one over the other. It is unclear if the Court intended to revert back to the *Flook* method of claim analysis by engaging in mostly that type of discussion. However, without a clear directive, the *Diehr* methodology appears to still be good law.

The *Mayo* court does explicitly discuss both *Diehr* and *Flook*, and finds the claims at issue present a weaker case for patentability than the patent-eligible claims in *Diehr* and a case no stronger than the patent-ineligible claims in *Flook*.⁹³ The Court distinguished *Diehr* by focusing on the fact that the *Diehr* court never suggested that the steps of the claimed method, or at least the combination of steps, were obvious or conventional.⁹⁴ Therefore, the additional steps

86. *Id.*

87. *Id.* at 1305.

88. *Mayo*, 132 S. Ct. at 1297–98.

89. *Id.* at 1297.

90. *See id.*

91. *See id.* at 1297–99.

92. *See id.* at 1289.

93. *Id.* at 1299.

94. The *Diehr* Court did not engage in an “obviousness” or “novelty” analysis because it rejected the relevance of such considerations in subject matter eligibility. *See Diehr*, 450 U.S. at 191.

transformed the process into an inventive application without preempting further use of the equation.⁹⁵ *Flook*, the Court explained, did no more than provide an unpatentable formula and add well-known steps such that the claims involved no inventive concept at all.⁹⁶ Since the claims at issue in *Mayo* consisted of a law of nature and “well-understood, routine, conventional activity, previously engaged in by those in the field,” and since applying the law of nature necessitated taking the steps in order, the Court found the claims closer to those in *Flook* than those in *Diehr*.⁹⁷ The Court also distinguished the claimed process in *Neilson v. Harford* by explaining that the process included, beyond the law of nature, “several unconventional steps . . . that confined the claims to a particular, useful application of the principle.”⁹⁸

While the Court did not provide any specific guidance as to how to remedy the patent-ineligibility of process claims relating to a law of nature, it seemed to suggest two specific instances in which it would uphold similar claims. The Court declined to decide whether the claim at issue in *Mayo* would be patent eligible if the included steps were less conventional, highlighting only that the included steps added nothing of significance.⁹⁹ But, in contrast to the steps at issue, the Court suggested that a patent on a new drug, or a new way of using an existing drug, would remain patentable because its reach would be confined to a particular application of the laws of nature it is built upon.¹⁰⁰

VI. Application of *Mayo* to Recent Cases and the USPTO's Guidance

Now the question becomes how to determine what is patent eligible subject matter in a post-*Mayo* world. Since the Federal Circuit's decision in *Myriad* did not provide much guidance on how to

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

96. *Id.*

97. *Id.* at 1299–1300.

98. *Neilson v. Harford*, Web. Pat. Cases 295, 371 (1841), is an English case in which a patent applicant asserted a claim covering a method for improved application of air to produce heat using a blowing apparatus. The court found the process explained how the law of nature—that hot air promotes ignition—could be implemented in an inventive way. See *Mayo*, 132 S. Ct. at 1300.

99. *Mayo*, 132 S. Ct. at 1302.

100. *Id.*

approach process claims with a law of nature as a limiting element,¹⁰¹ an examination of the PTO's and district courts' interpretations of *Mayo* may be helpful. Post-*Mayo* decisions and the Patent Office's interim guidance on the case have both continued discussion of the role of preemption and how natural law is to be applied, as well as the relative insignificance of post-solution activity. While the PTO's guidance does not explicitly address the status of the *Diehr* and *Flook* methods of analysis after *Mayo*, it explains that a claim should be evaluated by considering the additional steps beyond the natural law and a combination of all of the steps.¹⁰² Thus, the USPTO's guidance implies both inquires remain relevant.¹⁰³ Generally, to increase patent-eligibility post-*Mayo*, the steps of a claim, either alone or in combination, must recite an application of a law of nature that is specific enough not to preempt all future uses of the natural law and that does not merely contain the natural law and conventional pre- or post-solution activity. Additionally, as seen in *Classen*, the addition of a treatment step may transform a natural law into a practical application of the law and therefore may increase the likelihood of patent eligibility.

A. Post-*Mayo* Cases

The district court cases relating to subject matter eligibility decided since *Mayo* prove to be instructive. This section summarizes the Court's subject matter eligibility jurisprudence relating to methods incorporating laws of nature as it stands after the *Mayo* decision and discusses the decision's application to recently filed cases.

In one recent district court decision, after reviewing a large portion of section 101 jurisprudence, the court summarized instructive principles for analyzing subject-matter eligibility of method claims incorporating a law of nature post-*Mayo*.¹⁰⁴ The court reiterated that "a patent may not simply restate laws of nature . . . or apply them in some rudimentary fashion; instead, the invention must

101. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1334 (Fed. Cir. 2011), *cert. granted, vacated sub nom. Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012), *vacated, appeal reinstated*, 467 F. App'x 890 (Fed. Cir. 2012).

102. *See* Hirshfeld Memorandum, *supra* note 6.

103. *Id.*

104. *OIP Techs., Inc., v. Amazon.com, Inc.*, No. C-12-1233 EMC, 2012 WL 3985118, at *12 (N.D. Cal. Sept. 11, 2012).

add some ‘innovative concept’ to ‘transform the process into an inventive application of the . . . law of nature.’¹⁰⁵ This principle requires inventive application of the law of nature and adding insignificant or conventional steps is not enough. Additionally, the court discussed the role of preemption in determining patentability of a process.¹⁰⁶ The court explained that when determining if a patent preempts a field of use, the inquiry is “whether ‘upholding the patents would risk disproportionately tying up the underlying . . . natural laws, inhibiting their use in making further discoveries.’”¹⁰⁷ The court failed to address the appropriate methodology for analyzing a process claim, possibly because the *Mayo* decision left this unclear.

In *Classen v. Biogen*, the District Court of Maryland confronted these issues in the context of medical process patents on reconsideration of its order denying a motion to dismiss Classen’s claims for unpatentability.¹⁰⁸ The patents at issue recited methods for choosing an immunization schedule for infants to minimize the likelihood of developing immune-related disorders or infectious diseases.¹⁰⁹ They contain three basic steps: an identifying step, which selects two groups (one immunized by one schedule, the second immunized by a second schedule); a comparing step, which compares the effectiveness of the two immunization schedules to identify which is the higher or lower risk schedule; and an immunizing step, which immunizes according to the identified lower-risk schedule.¹¹⁰ The Court determined that despite the possibility that Classen’s patents may recite a law of nature with the instruction “apply it,” a process clearly held patent-ineligible in *Mayo*, the reasoning used to

105. *Id.* at 12 (quoting *Mayo*, 132 S. Ct. at 1292).

106. *Id.* at 12 (citing *Mayo*, 132 S. Ct. at 1294).

107. *Id.*

108. *Classen Immunotherapies, Inc. v. Biogen IDEC*, CIV. WDQ-04-2607, 2012 WL 3264941, at *2 (D. Md. Aug. 9, 2012). The procedural history of this case is slightly more complex and deserves explanation. On August 31, 2011, the Federal Circuit held that two of the patents at issue in this case contained patent-eligible subject matter. *See id.* On February 3, 2012, Classen filed an amended complaint at the district court alleging infringement of those two patents, and an additional patent not considered by the Federal Circuit. On May 30, 2012, the district court dismissed the complaint for failure to state a claim and concluded that additional briefing in light of *Mayo* was not needed, but provided Classen the opportunity to file a third amended complaint. GlaxoSmithKline (GSK), the named defendant along with Biogen IDEC, asked for reconsideration in light of the *Mayo* decision. After additional complaints and briefs were filed, the Court granted reconsideration.

109. *Id.* at *1.

110. *See* U.S. Patent No. 6,638,739 col. 52 ll. 21–57 (filed Apr. 18, 2002).

invalidate such claims in *Mayo* did not apply to Classen's claims.¹¹¹ First, similar to the argument made in *Diehr*, and recognized in *Mayo*, the District Court found the record insufficient to enable it to conclude that the claims involved "well-understood, routine [or] conventional activity."¹¹² Additionally, and arguably more importantly for future applications of *Mayo*, the Court relied on the presence of a mandatory application step (the immunization step) in addition to the data-gathering step, which was absent from the claims in *Mayo*.¹¹³ The Court relied on the prior Federal Circuit's opinion¹¹⁴ in dismissing Classen's contention that the prohibition on transforming patent ineligible laws of nature into patentable subject matter by adding insignificant post-solution activity was newly created in *Mayo*.¹¹⁵ Thus, the Court suggested, in agreement with the Federal Circuit,¹¹⁶ that the process recited in the claims at issue was more than a law of nature with added post-solution activity, it was a specific application, and therefore patent eligible.¹¹⁷

B. USPTO Guidance

In response to the *Mayo* decision, the USPTO issued a memorandum providing examiners guidance for analyzing the subject matter eligibility of process claims involving laws of nature as a limiting element or step.¹¹⁸ While the instructions in this document do not carry the same weight as judicial decisions, they delineate how examiners should issue rejections to pending applications. If a practitioner's goal is to avoid a section 101 rejection in the first place, these guidelines may prove useful.¹¹⁹ If nothing else, they provide a floor on which a practitioner can build his claim, as the Patent Office

111. *Classen*, 2012 WL 3264941, at *4.

112. Specifically because this issue was being addressed on a motion to dismiss for failure to state a claim. *Id.*

113. *Id.* at 5.

114. See *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1067 (2011) (relying on *Bilski* and *Diehr*).

115. *Classen*, 2012 WL 3264941, at *5.

116. *Classen*, 659 F.3d at 1068 (after reciting the rule regarding the insignificance of adding post-solution activity, explaining that the additional step of immunization moves the claims from an abstract scientific principle to a specific application).

117. *Classen*, 2012 WL 3264941, at *5.

118. Hirshfeld Memorandum, *supra* note 6.

119. Note that the goal is not to get invalid claims issued in light of *Mayo*. The point is that the USPTO's guidance may provide useful information to practitioners interpreting *Mayo*, and this author believes it is worth considering.

is the gatekeeper of the patent system and issuance must occur before a suit for infringement or invalidity.

The USPTO memorandum summarized the issue presented when examining claims of this type as “whether the claim includes additional elements/steps or a combination of elements/steps that integrate the natural principle into the claimed invention such that [it] is practically applied, and are sufficient to ensure that the claim amounts to significantly more than the natural principle itself.”¹²⁰ While this inquiry does not especially illuminate the status of the law post-*Mayo*, the memorandum goes on to provide a solid framework for examiners when issuing rejections.¹²¹ Practitioners can therefore use this framework to aid in avoiding such rejections. The analysis of a proposed process claim containing a law of nature as an element consists of a three-step inquiry.¹²² First, not surprisingly, it must be established that the claimed invention is directed to a process.¹²³ A process is defined as an act, or a series of acts.¹²⁴ If the claim is not directed toward a process, then *Mayo* does not apply.¹²⁵ Second, it must be determined that the “claim focus[es] on [the] use of a law of nature, a natural phenomenon or [a] naturally occurring relation or correlation (collectively referred to as a natural principle”¹²⁶ Once these threshold inquiries are answered affirmatively, the actual analysis begins. Third, the examiner, and therefore the practitioner, must decide if the claim integrates the natural principle into the invention such that it is an application of the law of nature, claims more than the natural principle itself, and is more than a recited law of nature with instructions to apply it.¹²⁷ If this inquiry can be answered affirmatively, the claims cover patent-eligible subject matter and can then be analyzed under the remaining statutory requirements.¹²⁸

While at first glance this three-inquiry process does not appear to provide much instruction at all, on closer inspection the

120. Hirshfeld Memorandum, *supra* note 6, at 1.

121. *Id.*

122. *Id.* at 2.

123. *Id.*

124. *Id.*

125. *Id.*

126. Hirshfeld Memorandum, *supra* note 6, at 2.

127. *Id.*

128. *Id.* For information on other statutory requirements for the issuance of a patent see, *e.g.*, 35 U.S.C. § 102 and 35 U.S.C. § 103.

memorandum provides useful clarification as to how to apply the second and third inquiries, as well as valuable examples of how to apply the inquiry process. The memorandum clarifies the definition of a natural principle as the handiwork of nature without the hand of man and provides an example relevant to the analysis of medical process and diagnostic patents: “a correlation that occurs naturally when a man-made product, such as a drug, interacts with a naturally occurring substance, such as blood.”¹²⁹ With regard to the third inquiry, the memorandum clarifies that it is not necessary for every claimed element to integrate the natural principle, as long as it is applied in some practical manner that does not amount to post-solution activity.¹³⁰ The memorandum provides an example of such post-solution activity: In a claim with steps correlating the presence of specific bacterium in blood to a bacterial infection, the step of recording the diagnosis on a chart is insufficient to integrate the correlation into the invention.¹³¹ Additionally, it provides examples of claims the PTO would consider patent eligible: claiming a natural correlation in combination with a novel drug, or a new use of an existing drug.¹³² These claims pass the three-inquiry test because they amount to significantly more than claiming the natural correlation, and although the examples suggest novelty or non-obviousness is required, the memorandum expressly denies this.¹³³ The memorandum concludes with a list of nine factors to consider when answering the third inquiry and a step-by-step application of the three-inquiry method to sample claims, including the claims in *Mayo*.¹³⁴

VII. Proposed Sample Claim

A sample claim analysis may help demonstrate the profound effect of *Mayo* on medical process patents and the importance of *Akamai* in salvaging them. Consider the following sample claim 1:

129. Hirshfeld Memorandum, *supra* note 6, at 3.

130. *Id.*

131. *Id.*

132. *Id.*

133. *Id.* at 4 (“A claim that recites a novel drug or a new use of an existing drug, in combination with a natural principle, would be sufficiently specific to be eligible because the claim would amount to significantly more than the natural principle itself. However, a claim does not have to be novel or non-obvious to qualify as a subject matter eligible claim.”).

134. *Id.* at 4–12.

A method for assessing the effectiveness of a treatment for sleep apnea, wherein said method comprises:

*determining whether or not the level of expression of a nucleic acid in a mammal being treated for sleep apnea changes during sleep, wherein a change in said level during sleep indicates that said treatment is ineffective.*¹³⁵

VIII. Implications of *Mayo* on Sample Claim and Proposed Remedies

Proceeding through the three-inquiry analysis, the threshold inquiries are easily satisfied. First, sample claim 1 clearly recites a process because it is a method with concrete steps. Second, the claim focuses on a naturally occurring relation, specifically, the relationship between a nucleic acid in a mammal and the occurrence of sleep apnea. The third inquiry is also easily addressed. This claim does not contain any application steps at all and amounts to the natural principle itself, the correlation between a nucleic acid and sleep apnea.¹³⁶ Since a law of nature is not patentable without more, neither is a process reciting the law of nature.¹³⁷ This claim, if patent eligible, would monopolize the correlation between the nucleic acid and sleep apnea, precisely the result the *Mayo* Court was trying to avoid.

Additionally, this claim is similar to, but even weaker than, the patent-ineligible claim in *Mayo*. This claim, like the claim in *Mayo*, contains a “determining step.” This step tells the scientist to determine if there is a change in a patient’s nucleic acid expression during sleep through whatever process she wishes and informs the scientist of the natural law.¹³⁸ The Court found the “administering step” in *Mayo* merely narrowed the audience of the claim, which did not cure its ineligibility.¹³⁹ This claim does not include an administering step and fails to narrow its scope in any way. For many

135. This claim was filed as claim 10 in U.S. Patent Appl. No. 12/680,073 (filed Sept. 8, 2010). The claim is likely indefinite under 35 U.S.C. § 112, however, in the application in which it was filed a dependent claim following this claim specifies which nucleic acids are covered by the claims.

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

137. *Id.* at 1297.

138. See *id.*

139. *Id.*

reasons, this claim, as it stands, fails to be patent-eligible after *Mayo*.¹⁴⁰

In order to make this claim patent-eligible, additional steps must be added to integrate the natural principle into the claimed invention and practically apply it in a way that amounts to more than the natural principle itself.¹⁴¹ The additional steps, either alone or in combination with the existing steps, must prevent the claims from preempting all future use of the correlation, apply the natural principle in an inventive way, and must do more than add insignificant post-solution activity.¹⁴² A possible variation could be sample claim 2:

A method for assessing the effectiveness of a treatment for sleep apnea, wherein said method comprises: administering treatment X for sleep apnea to a mammal before sleep; determining whether or not the level of expression of a nucleic acid in a mammal being treated for sleep apnea changes during sleep, wherein a change in said level during sleep indicates that treatment X is ineffective; and modifying treatment X based on the level change identified.

This claim is stronger than sample claim 1 and the claim found ineligible in *Mayo*. Depending on what treatment X is, this claim may have a high likelihood of being patent eligible. As with sample claim 1, this claim is clearly directed toward a process and focuses on the same natural correlation—the relationship between a nucleic acid and sleep apnea. The question of patent eligibility again hinges on the third-inquiry identified in the USPTO’s guidance: if the additional steps, here the administering and modifying treatment steps, individually or in combination, integrate the law of nature such that it is practically applied and limited in scope (i.e., not preemptive).¹⁴³ It seems quite clear that the administering step, alone, or in combination with the determining and wherein steps, is insufficient to transform the claim. If the only addition to the claim is the

140. Although this specific claim was not elected for continued prosecution in response to a restriction requirement, similar claims in this application did indeed receive a section 101 rejection from the examiner. See Office Action, Sept. 11, 2012, <http://portal.uspto.gov/external/portal/pair> (select “Application Number”; search “12/680,073”; follow “Image File Wrapper” hyperlink; follow “Non-Final Rejection” hyperlink).

141. See Hirshfeld Memorandum, *supra* note 6, at 3.

142. See *Mayo*, 132 S.Ct. at 1290.

143. See Hirshfeld Memorandum, *supra* note 6, at 3.

administering step, the claim becomes a mirror of the claim determined patent ineligible in *Mayo* and it would likely be patent ineligible for the same reasons.

However, the addition of the modifying treatment step, a step missing in *Mayo*, may be enough to transform the claim. First, it can be argued that the modification of the treatment based on the information determined in the second step of the claim is not insignificant, post-solution activity. The *Mayo* Court interpreted the claims as merely telling doctors to gather data from which they may draw an inference.¹⁴⁴ There, the administering step added nothing to patent-eligibility because it was a conventional activity already known in the community.¹⁴⁵ However, sample claim 2, when analyzed as a whole, arguably integrates the law of nature into the process by taking a meaningful step, modifying treatment X, which would be impossible to perform without the data derived from the natural law. Therefore, sample claim 2 applies the law of nature. Like the claims in *Classen*,¹⁴⁶ the modification step in combination with the information gathered in the determining step may not constitute insignificant post-solution activity and may transform the claim from one reciting an abstract law of natural to one specifically applying the law.¹⁴⁷ The interim guidance from the USPTO further supports the notion that the modification step in sample claim 2 is more than trivial post-solution activity, as it clearly limits the use of the law of nature to more than recording a diagnosis on a chart.¹⁴⁸

Second, a good argument can be made that sample claim 2 does not disproportionately tie up the natural correlation claimed, and therefore should be patent eligible.¹⁴⁹ Sample claim 2 does not inhibit others from using the natural correlation between the nucleic acid and sleep apnea to make future discoveries because the claim scope is limited to the correlation's relation to treatment X. Additionally, adding the modifying treatment step to sample claim 2 prevents the claim from eliminating a doctor's ability to determine proper

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

145. *Id.*

146. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011). This case was decided prior to *Mayo*, but relied on the same cases as the Supreme Court.

147. *Cf. id.* at 1067–68 (explaining the immunization requirement in accordance with a lower-risk schedule moved the claims “from abstract scientific principle to specific application”).

148. See Hirshfeld Memorandum, *supra* note 6.

149. See *Mayo*, 132 S.Ct. at 1294.

treatment based on the natural correlation cited because the claim scope is limited only to the correlation's use with treatment X.¹⁵⁰ Therefore, sample claim 2 does not cover all processes that use the correlation between the nucleic acid and sleep apnea. It does not generally limit a doctor's subsequent treatment decisions or anyone's future discoveries. As in *Diehr*, the claimed method does not preempt the use of the natural correlation, but only forecloses its use in conjunction with the remaining limitations of the claim, specifically, use with treatment X.¹⁵¹

Nevertheless, sample claim 2 is still susceptible to scrutiny for the reason that "the line between a patentable 'process' and an unpatentable 'principle' is not always clear."¹⁵² First, it could easily be argued that the additional steps, specifically, the modifying step, is too general to make this claim patent-eligible.¹⁵³ To rectify this, and increase the chances of patent-eligibility, additional information about the specific steps of treatment X could be added. For example, adding detailed information about treatment with a Continuous Positive Airway Pressure ("CPAP")¹⁵⁴ machine including, specific pressure levels, durations, humidity levels, etc. and how they should be modified, may help.¹⁵⁵

Second, the claim may not be patent-eligible if the modifying step is interpreted to be well-understood, routine, or conventional activity.¹⁵⁶ Continuing with the CPAP example provided above, since CPAP is a known method of treatment for sleep apnea, the Court may interpret the modifying step as conventional post-solution activity that does not transform an unpatentable law of nature into a patent-eligible application of the law.¹⁵⁷ But, the Court stated in *Mayo* that a claim should be analyzed for subject matter eligibility as

150. *See id.* at 1302 (noting that in telling a treating doctor to measure metabolite levels and consider the results, the claims tie up subsequent treatment decisions regardless of if those decisions change from inferences drawn using the correlation).

151. *See Diamond v. Diehr*, 450 U.S. 187 (1982).

152. *Parker v. Flook*, 437 U.S. 584, 589 (1978).

153. *See Mayo*, 132 S.Ct. at 1294.

154. Continuous positive airway pressure is a type of ventilation therapy often prescribed for those suffering from sleep apnea. *See Sleep Apnea*, MAYO CLINIC (July 24, 2012), <http://www.mayoclinic.com/health/sleep-apnea/DS00148/DSECTION=treatments-and-drugs>.

155. Angela L. Morrison, *supra* note 3 at 83.

156. *See Mayo*, 132 S. Ct. at 1298.

157. *See id.*

a whole.¹⁵⁸ So, the novelty of CPAP as a treatment alone should have no bearing on the analysis. Instead, the analysis should focus on the combination of the CPAP treatment with the information gathered from the nucleic acid-sleep apnea correlation. When the focus is shifted to the combination of the treatment step with the correlation, the claimed method no longer seems conventional.

However, it should be recognized that there is still a tension between the methods of analysis the Court applied in *Flook* and *Diehr*. In *Flook*, the Court held that the process was not patent-eligible because once the algorithm was assumed to be part of the prior art, the application contained no patentable invention.¹⁵⁹ If that same approach is applied here, sample claim 2 may be in trouble. Therefore, the more novelty included in the claimed method, the more likely the claim will be patent-eligible.¹⁶⁰ For example, including the following limitation in sample claim 2 would likely make it patent eligible: “wherein the step of determining whether or not the level of expression of a nucleic acid in a mammal being treated for sleep apnea changes during sleep includes performing assay 1 and then performing assay 2,” where the two assays are not conventionally used together.¹⁶¹ Furthermore, a novel method of treatment, like a new drug or a new use for an existing drug,¹⁶² may increase the claim’s patent-eligibility.

Sample claim 2 can be modified to address at least some of the arguments against patent eligibility. The level of specificity of treatment X contained within the claim can be increased. Additionally, a limitation can be added to specify how the determining step is completed. After these changes, modified sample claim 2 reads:

Administering CPAP treatment comprising two three hour intervals of at least 6 cm H2O to a mammal before sleep for sleep apnea, determining whether the level of expression of a nucleic acid in a mammal being treated for sleep apnea increases, wherein an increase of at least .2% in nucleic acid level during sleep indicates that CPAP is

158. *See id.* at 1297.

159. *Id.*

160. *See Morrison, supra* note 3, at 82–83.

161. *Id.*

162. *See Mayo*, 132 S.Ct. at 1302 (suggesting that method claims covering a new drug or a new way of using an existing drug remain patent eligible). *But see Morrison, supra* note 3, at 81.

ineffective, and wherein determining whether the level of expression of a nucleic acid in a mammal being treated for sleep apnea increases during sleep comprises performing assay 1 and then performing assay 2, and modifying CPAP treatment administered to a mammal being treated for sleep apnea who exhibits an increase of at least .2% in nucleic acid level, the modified CPAP treatment comprising three 2.5 hour intervals of at least 10 cm H2O.

IX. The Intersection of *Mayo* and *Akamai*

Sample claim 2, in its original and modified forms, more likely contains patent eligible subject matter post-*Mayo* after the addition of a treatment step relating to the naturally occurring correlation. However, it now also presents a problem of divided infringement. The combination of steps included in sample claim 2, especially in its modified form, requires at least 2 actors to complete them all. For example, referring to modified sample claim 2, a person who administers CPAP treatment will complete the first and third steps and a scientist will perform the second step. It is very unlikely that the scientist will also be administering the CPAP treatment. The claim requires at least both a CPAP treatment actor and a scientist to complete all of the steps of the claimed method, and therefore the claim poses a divided infringement problem.

While the Court's decision in *Mayo* highlights one difficulty practitioners face when drafting medical process patents, an examination of the law of divided infringement highlights another: drafting infringeable claims. The remainder of this note is dedicated to the discussion of the problem of divided infringement for medical process patents post-*Mayo*. This section will begin with an introduction to patent infringement focusing on induced infringement. The note will then explore the law of divided infringement leading up to, and including the *Akamai* and *McKesson* decision, and how the recent decision may effectively provide a solution to the divided infringement problem medical process patents face after *Mayo*. The note will conclude with a final analysis of the proposed sample claim incorporating both the *Mayo* and *Akamai* decisions.

X. Introduction to the Law of Patent Infringement

Patent infringement has generally been divided into two categories, direct infringement and indirect infringement. Direct infringement of a method claim requires a party perform each and

every step of a claimed method.¹⁶³ For a party to be liable for direct infringement of a patent under 35 U.S.C. § 271(a),¹⁶⁴ that party must commit all of the acts necessary to infringe the patent, either personally or vicariously.¹⁶⁵ Indirect infringement of a method claim occurs when a party participates in or encourages infringement, but does not directly infringe the patent.¹⁶⁶ Since the 1952 Patent Act there have been two types of statutorily defined indirect infringement: inducement and contributory infringement.¹⁶⁷ Inducement refers to the active and knowing aiding and abetting of another's direct infringement.¹⁶⁸ Under 35 U.S.C. § 271(b), "whoever actively induces infringement of a patent shall be liable as an infringer."¹⁶⁹ Contributory infringement occurs when a party offers to sell within the United States, or imports into the United States, a component especially adapted for an infringing use.¹⁷⁰ The goal of indirect infringement is to provide a patent owner a remedy in situations in which the direct infringer is either not truly responsible for the infringement, or when it is impractical to sue.¹⁷¹

Induced infringement is both narrower and broader than direct infringement.¹⁷² First, unlike direct infringement, which is a strict liability offense, induced infringement requires that the accused infringer know that the induced acts constitute patent infringement¹⁷³ and have the specific intent to encourage another's infringement.¹⁷⁴ Second, induced infringement only creates liability if the inducement

163. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007), *overruled by Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1306 (2012).

164. 35 U.S.C. § 271(a) (2010) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.").

165. *Akamai*, 692 F.3d at 1305.

166. *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1272 (Fed. Cir. 2004).

167. See Mark A. Lemley, *Inducing Patent Infringement*, 39 U.C. DAVIS L. REV. 225, 227 (2005).

168. *Water Techs. Corp. v. Calco, Ltd.* 850 F.2d 660, 668 (Fed. Cir. 1988).

169. 35 U.S.C. § 271(b).

170. 35 U.S.C. § 271(c).

171. Lemley, *supra* note 167, at 228.

172. *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1308 (2012).

173. *Global-Tech Appl., Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2068 (2011).

174. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc).

produces actual infringement.¹⁷⁵ Actual infringement is required to establish liability for inducement because attempted patent infringement does not exist;¹⁷⁶ so if there is no infringement, there cannot be indirect infringement.¹⁷⁷ Finally, to be liable for direct infringement of a method claim, a party must either perform all the steps of the claimed method directly, or be in an agency-type relationship with the actors performing the steps.¹⁷⁸ In contrast, inducement does not require any special relationship between the parties beyond the performance of the acts of inducement themselves.¹⁷⁹

Divided infringement occurs when a patent may only be infringed by combining the conduct of multiple actors.¹⁸⁰ The problem of divided infringement in inducement cases generally occurs when the claims at issue are process claims.¹⁸¹ For example, divided infringement may occur when it is impossible for one actor to complete all the steps of a claimed method.¹⁸² As explained above, “when one person does not perform each and every step of the claimed process, no person directly infringes the claim.”¹⁸³ However, liability for inducement requires a finding of direct infringement.¹⁸⁴ Therefore, prior to the Federal Circuit’s decision in *Akamai*, there was a gaping hole in the statutory infringement scheme for patents containing divided claims.¹⁸⁵

175. *Akamai*, 692 F.3d at 1308.

176. This is because patent infringement is a strict liability offense. See *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007) (en banc).

177. *Akamai*, 692 F.3d at 1308.

178. See *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1311 (Fed. Cir. 2005).

179. See *Akamai*, 692 F.3d at 1308 (“[I]nducement does not require that the induced party be an agent of the inducer or be acting under the inducer’s direction or control It is enough that the inducer ‘cause[s], urge[s], encourage[s], or aid[s]’ the infringing conduct and that the induced conduct is carried out.”).

180. See Mark A. Lemley et al., *Divided Infringement Claims*, 6 SEDONA CONF. J. 117 (2005). Divided infringement may also occur when some of the steps of the method are completed outside of this country. See *id.* This scenario is outside the scope of this note.

181. *Akamai*, 692 F.3d at 1307.

182. See Lemley et al., *supra* note 180 at 58.

183. *Id.*

184. *Akamai*, 692 F.3d at 1308.

185. See Lemley et al., *supra* note 180, at 118.

XI. Cases Leading up to *Akamai* and *McKesson*

Prior to the Federal Circuit's decision in *BMC v. Paymentech*¹⁸⁶ there were two standards for finding joint infringement.¹⁸⁷ The first theory required an agency relationship between the jointly infringing parties and the second required only "some connection" or cooperation.¹⁸⁸ Leading up to *BMC* the Federal Circuit issued opinions using both rationales.¹⁸⁹ In *Cross Medical Products v. Medtronic*, the Court endorsed the agency standard for joint infringement when analyzing infringement of an apparatus claim for a bone anchor, determining that despite the presence of Medtronic representatives in the operating room, the surgeons making the apparatus were not agents of Medtronic.¹⁹⁰ The following year, the Federal Circuit appeared to support the "some connection" standard when it found proper a jury instruction explaining, "where infringement is the result of the participation and combined actions of one or more persons . . . they are jointly liable for the infringement."¹⁹¹ The following line of cases continued to narrow the requirement for joint infringement and set the stage for the Federal Circuit's most recent pronouncement in *Akamai*.

A. *BMC v. Paymentech*: Direction or Control Standard

In *BMC Resources v. Paymentech*, BMC asserted two patents covering PIN-less debit bill payment ("PDBP") methods against Paymentech and claimed both direct infringement and inducement.¹⁹² The patents at issue claim a method¹⁹³ for processing debit

186. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007).

187. Reza Dokhanchy, *Cooperative Infringement: I Get by (Infringement Laws) with a Little Help from My Friends*, 26 BERKELEY TECH. L.J. 135, 145 (2011).

188. *Id.*

189. *Id.* at 146–47.

190. *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1311 (Fed. Cir. 2005).

191. *On Demand Mach. Corp. v. Ingram Indus.*, 442 F.3d 1331, 1345 (Fed. Cir. 2006). *see* Dokhanchy, *supra* note 187.

192. *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1376 (2007).

193. BMC representative claim (claim 6): A method of paying bills using a telecommunications network line connectable to at least one remote payment card network via a payee's agent's system wherein a caller begins session using a telecommunications network line to initiate a spontaneous payment transaction to payee, the method comprising the steps of: prompting the caller to enter a payment number from one or more choices of credit or debit forms of payment; prompting the caller to enter a payment amount for the payment transaction; accessing a remote payment network associated with the entered payment number, the accessed remote payment network

transactions.¹⁹⁴ The method requires combined action by several participants, “including the payee’s agent (for example BMC), a remote payment network (for example, an ATM network), and the card-issuing financial institution.”¹⁹⁵ Paymentech began marketing a PIN-less debit bill payment service.¹⁹⁶ After a customer calls a merchant to pay a bill, the merchant collects the information and sends it to Paymentech.¹⁹⁷ Paymentech sends this information to a debit network, which forwards it to an affiliated financial institution.¹⁹⁸ The financial institution either authorizes or declines the payment, and if authorized, charges the customer based on the merchant provided information.¹⁹⁹ Finally, the flow of information reverses, and the status of the payment is sent from the financial institution to the debit network, which sends it to Paymentech, which sends it back to the merchant who informs the customer.²⁰⁰ Since both BMC and Paymentech agreed that the latter did not perform every step of BMC’s claimed method, the issue was if Paymentech was liable for direct infringement despite the fact that other parties performed some of the steps of the patented method.²⁰¹

The *BMC* Court held that when the steps of the claimed method are completed by multiple parties, the direct infringer must exert direction or control over all of the steps, including those completed by other parties.²⁰² It also reaffirmed the long-standing principle that “inducement requires a predicate finding of direct infringement.”²⁰³

determining, during the session, whether sufficient available credit or funds exist in an account associated with the payment number to complete the payment transaction, and upon a determination that sufficient available credit or funds exist in the associated account, charging the entered payment amount against the account with the entered payment number, adding the entered payment amount to an account associated with the entered account number, and storing the account number, payment number and payment amount in a transaction file of the system. *Id.*

194. *Id.*

195. *Id.* at 1375.

196. *Id.*

197. *Id.*

198. *See BMC Resources, Inc.*, 498 F.3d at 1376.

199. *Id.*

200. *Id.*

201. *Id.* at 1378.

202. *Id.* at 1380–81.

203. *See BMC Resources, Inc.*, 498 F.3d at 1380 (citing *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F. 3d 1263, 1272 (Fed. Cir. 2004)).

The Court recognized that the “direction or control” standard²⁰⁴ for joint infringement may provide a loop-hole to a finding of liability when parties enter into “arms-length” agreements, but decided that it did not warrant the expansion of the law of direct infringement.²⁰⁵ The Court was hesitant to expand the law of direct infringement because doing so would “subvert the statutory scheme for indirect infringement,” and the concern over arms-length agreements could be “offset by proper claim drafting.”²⁰⁶

Thus, the only issue remaining was if Paymentech exerted control over, or gave direction to, the debit networks and financial institutions whose actions were necessary, in conjunction with Paymentech’s to complete all of the steps of the claimed method.²⁰⁷ The Court failed to find evidence of Paymentech’s direction or control over either the debit networks, or the financial institutions, and therefore concluded that Paymentech was not liable for infringement.²⁰⁸

B. *Muniauction, Inc. v. Thomson Corp.*

In *Muniauction v. Thomson*, the Court addressed joint infringement in the context of internet auctioning.²⁰⁹ The asserted claims²¹⁰ cover electronic methods for conducting municipal bond

204. The Court noted that contracting steps of a claimed method to another party constitutes control, and therefore the contracting party may still be liable for direct infringement. *Id.* at 1381.

205. *Id.*

206. *Id.*

207. *Id.*

208. *Id.*

209. *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1321–22 (Fed. Cir. 2008). The *Muniauction* decision disposes of many of the asserted claims on the issue of obviousness but reaches a discussion of divided infringement with respect to the surviving dependent claims. *Id.* at 1328.

210. This is actually claim 1, which was found to be obvious, but is nonetheless representative of the claims at issue: “In an electronic auction system including an issuer’s computer having a display and at least one bidder’s computer having an input device and a display, said bidder’s computer being located remotely from said issuer’s computer, said computers being coupled to at least one electronic network for communicating data messages between said computers, an electronic auctioning process for auctioning fixed income financial instruments comprising: inputting data associated with at least one bid for at least one fixed income financial instrument into said bidder’s computer via said input device; automatically computing at least one interest cost value based at least in part on said inputted data, said automatically computed interest cost value specifying a rate representing borrowing cost associated with said at least one fixed income financial instrument; submitting said bid by transmitting at least some of said inputted data from

auctions where a municipality offers its bonds to underwriters using a web browser, the underwriters bid for and purchase the bonds, and then resell them to the public.²¹¹ The claimed invention provides an integrated system for the auctions without the use of additional specialized software and provides all parties to the auction the ability to monitor its status.²¹² The parties agreed that no single party performs every step of the claimed method because at least the step of inputting a bid is completed by the bidder and the majority of the remaining steps are completed by the auctioneer's system.²¹³

The Court reaffirmed, and then elevated, its holding in *BMC Resources*. The Court reiterated that *BMC Resources* presented the proper standard for determining when a method claim is directly infringed by the actions of multiple parties; if one party exerts direction or control over the entire process.²¹⁴ However, the Court then found that despite Thomson's control over access to its system and its instructions to bidders on its use, it was not liable for direct infringement.²¹⁵ It expressly disavowed the district court's reading of *On Demand Mach. Corp.*²¹⁶ as requiring a "connection less than 'direct control,'" and raised the standard for joint infringement to those situations in which the accused direct infringer is vicariously liable for the acts performed by another.²¹⁷

C. *Golden Hour Data Sys., Inc. v. emsCharts, Inc.*

In *Golden Hour Data Systems v. emsCharts, Inc.*²¹⁸ the Court further narrowed the "control or direction" standard for joint

said bidder's computer over said at least one electronic network; and communicating at least one message associated with said submitted bid to said issuer's computer over said at least one electronic network and displaying, on said issuer's computer display, information associated with said bid including said computed interest cost value, wherein at least one of the inputting step, the automatically computing step, the submitting step, the communicating step and the displaying step is performed using a web browser." *Id.* at 1322–23.

211. *Id.* at 1321–22.

212. *Id.* at 1322.

213. *Id.* at 1328–29.

214. *Id.* at 1329.

215. *See Muniauction, Inc.*, 532 F.3d at 1329.

216. *On Demand Mach. Corp. v. Ingrave Indus.*, 442 F.3d 1331 (Fed. Cir. 2006).

217. *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d at 1329.

218. *Golden Hour Data Systems v. emsCharts, Inc.*, 614 F.3d 1367 (Fed. Cir. 2010).

infringement by finding that a “strategic partnership” between allegedly joint infringers was not enough to establish liability.²¹⁹

The asserted patent covered an integrated system for dispatching medical services and collecting and managing patient clinical and billing data.²²⁰ The accused infringers, emsCharts and Softtech, produce medical charting and flight dispatch software respectively.²²¹ The two companies “enabled their two programs to work together and collaborated to sell the two programs as a unit.”²²² The Court repeated the control or direction standard and summarily affirmed the district court’s grant of JMOL, agreeing that there was insufficient evidence of joint infringement.²²³

D. Akamai and McKesson

In *Akamai v. Limelight* and *McKesson v. Epic Systems* (combined on appeal), the Court addressed joint infringement specifically in the context of induced patent infringement.²²⁴ While many believed the Court would address the continued use of the single-entity rule, the requirement that a single party perform all of the steps of a claimed method to be liable for direct infringement, the Court declined to do so.²²⁵ Instead, the decision focused on whether an actor may be held liable for induced infringement if she has partially performed the method herself and induced another to commit the remaining steps or has simply induced other actors to collectively perform the steps without a single direct infringer.²²⁶ The Court expressly overruled its previous decision in *BMC Resources* and held that for a party to be found liable for inducement all the steps of the claimed method must be performed, but every step does not have to be performed by a single entity.²²⁷ The Court argued that this was not a significant departure from joint infringement jurisprudence and rested its holding on statutory construction,

219. *Id.* at 1371, 1381–82.

220. *Id.* at 1369.

221. *Id.* at 1371.

222. *Id.*

223. *Id.* at 1380–81.

224. *Akamai Tech., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012).

225. *Id.* at 1306.

226. *Id.*

227. *Id.*

analogous liability in other areas of the law, precedent, and sound policy.²²⁸

Facts

The patents at issue in *Akamai* recite methods for delivery of web content by placing some of a provider's content on servers and modifying the provider's website to instruct users to retrieve the content from the server.²²⁹ Akamai alleged Limelight Networks, Inc. was liable for both direct and induced infringement through the maintenance of a network of servers that allow delivery of web content placed on its servers.²³⁰ Limelight instructs its users on how to modify their websites to access the server based information, but does not modify the sites directly.²³¹

McKesson filed a complaint against Epic Systems Corp. alleging induced infringement of a patent covering a method of electronic communication between a healthcare provider and their patient.²³² Epic Systems licenses its "MyChart" software to healthcare organizations, which permits them to communicate electronically with patients.²³³ Epic does not complete any of the steps of the patented method, and instead, those steps are completed by the patients who initiate the communications and the healthcare providers who perform the remaining steps.²³⁴

Statutory Construction

The Court asserts that a statutory analysis of section 271(b)²³⁵ of the Patent Act supports its proposition that "requiring proof that there *has been* direct infringement as a predicate for induced infringement is not the same as requiring proof that a single party would be liable as a direct infringer."²³⁶ In comparing the language of section 271(b)²³⁷ with section 271(a),²³⁸ the statute covering direct

228. *Id.*

229. *Id.*

230. *See Akamai Tech., Inc.*, 692 F.3d at 1306.

231. *Id.*

232. *Id.*

233. *Id.*

234. *Id.*

235. *Id.*

236. *See Akamai Tech., Inc.*, 692 F.3d at 1308–09 (emphasis in original).

237. 35 U.S.C. § 271(b) (2010).

238. *Id.*

infringement, it becomes apparent that section 271(b) is structured differently.²³⁹ Section 271(a) states that one who performs any of the specified acts (for example, making, using, selling . . . a patented invention) infringes the patent.²⁴⁰ But, section 271(b) states that one who induces infringement will be liable as an infringer.²⁴¹ The Court asserts that nothing in the text of section 271(b) limits “infringement” to acts by a single actor.²⁴² Instead, the Court suggests that “infringement” refers to the acts required to infringe the patent.²⁴³ In responding to the dissent’s argument that the Court’s approach defines direct infringement differently with respect to sections 271(a) and 271(b), the Court explains that section 271(b) can be interpreted as describing another type infringing conduct, i.e., inducement, and nothing in the text of either subsection suggests that inducement must fit into an act that would expose a person to liability under 271(a).²⁴⁴ Additionally, the Court relied on the legislative history of 1952 Patent Act to lend support for its statutory analysis.²⁴⁵

Comparison to Criminal and Tort Law

The Court recognized that holding an inducing party liable for an innocent party’s underlying acts is not a concept unique to patent law. The Federal Criminal Code section²⁴⁶ for aiding and abetting a crime against the United States is structured similarly to section 271 and has been interpreted to permit conviction of the inducer despite the acquittal of the principal.²⁴⁷ Tort law treats liability for inducing innocent actors similarly.²⁴⁸ The Court places great weight on the parallels between tort law and patent law because the doctrine of

239. *Akamai*, 692 F.3d at 1309.

240. 35 U.S.C. § 271(a).

241. *Id.* § 271(b).

242. *Akamai*, 692 F.3d at 1309.

243. *Id.*

244. *Id.* at 1313 (supporting this contention by comparing alternate parts of the Patent Act, for example, sections 271(e)(2) and 271(f)).

245. *See id.* at 1309–10 (referencing the intended broad scope of the inducement provision and testimony given by Giles Rich during hearings on the legislation that indirect infringement provisions were intended to apply to cases of divided infringement).

246. 18 U.S.C. § 2(a)–(b) (2012).

247. *Akamai*, 692 F.3d at 1311 (citing *Standefer v. United States*, 447 U.S. 10, 19 (1980)).

248. *Id.* at 1311–12.

indirect infringement, which was codified in section 271(b) in the 1952 Patent Act, was based on the principles of joint tortfeasance.²⁴⁹

Precedent

The Court explained that the misstep in its prior decisions occurred when the rule explained in *Dynacore*, that inducement liability requires an underlying act of infringement, was extended²⁵⁰ to require that a single-entity commit the entire act of infringement.²⁵¹ The extension of the law of inducement to include the single-entity rule was not supported by the *Dynacore* decision that set out the original proposition.²⁵² Nor is it supported by the Supreme Court's decision in *Aro Mfg. Co., v. Convertible Top Replacement Co.*²⁵³ In *Aro*, the Court found no contributory infringement not because the infringement required multiple actors, but because the acts completed²⁵⁴ were considered "repairs," not "reconstruction," and therefore were not infringement at all.²⁵⁵ Without an underlying act of infringement, the Court held there could not be contributory infringement.²⁵⁶ Additionally, the Court noted that the *Aro* decision involved infringement of product claims, which rarely, and did not in this case, implicate the divided infringement question it was addressing in *Akamai*.²⁵⁷

Furthermore, the Court explained its prior use of the words "some party" to describe the party accused of direct infringement in an induced infringement context was merely a recitation of the principle that a direct infringement is a prerequisite for induced infringement.²⁵⁸ The Court traced this proposition back to the *Aro* decision.²⁵⁹ Since the *Aro* decision did not hold that a single direct infringer is required, the use of "some party" was not an indication

249. *Id.* at 1312–13.

250. *BMC Resources Inc., v. Paymentech, L.P.*, 498 F.3d 1373, 1380 (Fed. Cir. 2007).

251. *Akamai*, 692 F.3d at 1315.

252. *Id.*

253. *Id.*

254. The *Aro* case involved a product claim. As the *Akamai* Court explained, "The party that adds the final element to the combination 'makes' the infringing product and thus is liable for direct infringement even if others make portions." *Id.*

255. *Aro Mfg. Co., v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961); *Akamai*, 692 F.3d at 1315–16.

256. *Akamai*, 692 F.3d at 1315–16.

257. *Id.* at 1305, 1316.

258. *Id.* at 1316.

259. *Id.*

that a single entity must commit all the steps of the direct infringement.²⁶⁰ The Federal Circuit explained that its cases, as well as those predating *Aro*,²⁶¹ had never held otherwise.²⁶² As a result of its precedential analysis, the Court found that *BMC*, and the cases following it, changed the law with respect to induced infringement of method claims.²⁶³

Sound Policy and Congressional Intent

The Court also found that requiring a single entity commit the underlying acts of direct infringement in order to create liability for inducement served no “sound policy based purpose” as it “invites evasion of the principles of patent infringement.”²⁶⁴ There is no reason to hold a party that induces multiple parties to collectively commit an act of direct infringement differently from one who induces a single party to.²⁶⁵ In either case, the impact on the patent holder is the same.²⁶⁶ It would be even more nonsensical to immunize from liability for indirect infringement an inducer who completes some of the steps of the claimed method himself, but induces another party to finish the job.²⁶⁷ A party who engages in acts of underlying infringement may be considered more culpable than one who does not perform any of the acts at all, and as long as the underlying act is completed, the harm to the patentee is identical.²⁶⁸ The Court concluded that Congress did not intend section 271(b) to be interpreted to permit parties to skirt liability without any “countervailing [societal] benefits.”²⁶⁹

260. *Id.*

261. *See id.* at 1317–18 (explaining that prior decisions in *Solva Waterproof Glue Co. v. Perkins Glue Co.*, 251 F. 64 (7th Cir. 1918), *Peerless Equipment Co. v. W.H. Miner, Inc.*, 93 F.2d 98 (7th Cir. 1937), and *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565 (Fed. Cir. 1983) support the contention that a single-party direct infringer is not required to create liability for inducement).

262. *Akamai*, 692 F.3d at 1316.

263. *Id.* at 1318.

264. *Id.* at 1317–18.

265. *Id.* at 1309.

266. *Id.*

267. *Id.*

268. *Akamai*, 692 F.3d at 1309.

269. *Id.* at 1318.

XII. Implications of *Akamai* and *McKesson* on Sample Claim

In order to adequately explain the implications of *Akamai* in the context of medical process patents, let us reexamine the sample claims previously presented. Sample claim 1, an exemplary claim that may have been patent-eligible prior to *Mayo*, recites:

A method for assessing the effectiveness of a treatment for sleep apnea, wherein said method comprises:

determining whether or not the level of expression of a nucleic acid in a mammal being treated for sleep apnea changes during sleep, wherein a change in said level during sleep indicates that said treatment is ineffective.

This claim does not present the divided infringement problem addressed in *Akamai* because it can clearly be infringed by the acts of a single party. The claim only recites one step that requires affirmative action, the determining step. It is possible for this step to be completed by a single party; for example a scientist performing two tests in a lab and comparing the results.²⁷⁰ Therefore, before *Mayo*, if this claim met the other requirements of the Patent Act and issued, it could be enforced against the lab employing the scientist performing the test or any party inducing the lab to do so.

In contrast, let us reexamine the original sample claim 2:²⁷¹

A method for assessing the effectiveness of a treatment for sleep apnea, wherein said method comprises: administering treatment X for sleep apnea to a mammal before sleep, determining whether or not the level of expression of a nucleic acid in a mammal being treated for sleep apnea changes during sleep, wherein a change in said level during sleep indicates that treatment X is ineffective, and modifying treatment X based on the level change identified.

270. In *Myriad's* amicus curiae brief, it is suggested that the wherein step is generally completed by a different party than the determining step. This argument may have been made because the Supreme Court had not yet decided the *Mayo* case at the time the brief was written, and *Myriad* may have been hedging its bets. Either way, the *Mayo* decision has significantly increased the likelihood additional steps that must be completed by other actors are required. See Corrected Brief of Amicus Curiae, *Myriad Genetics, Inc.*, in Support of Neither Party at 14, *Akamai Tech., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012).

271. Original sample claim 2 is used to simplify the example, however, modified sample claim 2 also presents a divided infringement problem. See *supra* Intersection of *Mayo* and *Akamai*, section IX.

This claim is more likely patentable post-*Mayo*,²⁷² but poses a divided infringement problem. This claim is nearly impossible to infringe by a single entity and the steps can easily be divided between parties who are not in an agency relationship. For example, the administering and modifying steps would likely be performed by a doctor, while the determining step, as explained above, would likely be completed by a scientist in a lab.²⁷³ Thus, a common scenario would include a diagnostic testing laboratory marketing the sleep apnea test to a physician, who would administer the initial treatment and then send the samples to the lab. The lab would then determine the results and provide guidance to the doctor, who would then modify treatment X.²⁷⁴ Additionally, it is rare for the lab and the treating doctor to be an agency relationship.²⁷⁵ And, even if the two would generally be in this type of relationship, it is easy for savvy parties to avoid.²⁷⁶ This means that prior to the *Akamai* decision, this claim was unenforceable. Neither the doctor nor the lab can be classified as a direct infringer²⁷⁷ because neither of them completes all the steps of the claimed method, and they are in the type of relationship that would categorize them as a single entity. No party can be held liable for indirect infringement because there is no act of underlying infringement. Now, however, post-*Akamai*, the patent holder of sample claim 2 would have redress. While it is clear that neither party could be held liable as a direct infringer, it would be possible to hold the diagnostic testing laboratory, or any other party for that matter, liable for inducement (as long as the other elements for inducement were satisfied).²⁷⁸ For at least inducement liability, it no longer matters which party completed which step of the claimed

272. See *supra* Implications of Mayo on Sample Claim and Proposed Remedies section VIII; *Classen Immunotherapies, Inc. v. Biogen IDEC*, No. WDQ-04-2607, 2012 WL 3264941, at *5 (D. Md. Aug. 9, 2012) (noting the inclusion of the mandatory application step missing from the claims in *Mayo*, which is included here).

273. See Corrected Brief of Amicus Curiae, *Myriad Genetics, Inc., in Support of Neither Party at 14, Akamai Tech., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012).

274. *Id.*

275. *Id.*

276. *Id.*

277. *Akamai* does not change the law of direct infringement and therefore neither party would be liable for direct infringement post *Akamai* either.

278. For example, the knowledge requirement. See *supra* Introduction to the Law of Patent Infringement.

method or what their relationship to each other is. So, as long as all the steps of a claimed method are completed, *Akamai* ensures that an inducer can be held liable. Therefore, while *Mayo* likely requires the actions of additional actors be included in medical process patent claims to ensure patent-eligibility, *Akamai* allows those patents to be enforced, at least in the inducement context.

While *Akamai* provides a solution for patents holders confronting a divided infringement problem, the additional requirements for inducement liability, specifically the intent requirement, may pose an additional barricade to enforcement. Inducement requires not only an act of direct infringement, but also that the alleged inducer possessed affirmative intent to cause the direct infringement.²⁷⁹ Therefore, for an alleged infringer to be held liable for inducement of a process patent, the patent holder must prove: the alleged infringer knew of the patent, that he knowingly induced the completion of all of the steps of the claimed method, and that he possessed a specific intent to encourage the completion of all of the steps of the claimed method.²⁸⁰ The intent requirement is concerning here because an alleged inducer may not possess the required intent for the completion of the treatment step. Unfortunately, the intent requirement for inducement and the subject matter eligibility requirements described in *Mayo* place many applying for medical process patents in a precarious position. The more specific the limitations in the claim, the more likely the claim will overcome the walls erected by *Mayo*. But, the more specific the limitations of the claim, the more difficult it will be to prove the intent prong of inducement if the claims require divided infringement.

A comparison of sample claim 2 in its original and modified forms may help explain the problem of proving intent for inducement of some medical process claims. The following analysis assumes the diagnostic test provider is the alleged inducer. In original sample claim 2, intent could likely be proven for the administering step because the test provider must intend for the doctor to administer treatment X in order to provide a proper sample for the diagnostic test. The test provider would likely complete the determining step itself with the provided sample. The issue in this claim is really in proving intent for the final step, modifying the treatment. If the step remains fairly general, it is easier to prove that the test provider

279. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006).

280. *See Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1328 (Fed. Cir. 2009).

intended for the doctor to make a change in his practice based on the results provided. Why would the doctor send the sample for testing if he hadn't been told what to do with the results? Put another way, how would the lab market the test if it did not explain how its results could be used to treat patients?

However, considering modified sample claim 2, the more specific the administering and treatment steps become, the more difficult it will be to prove the test provider possessed intent for all of the limitations in the claims. For example, modified sample claim 2 contains detailed information about how to administer CPAP treatment and exactly how the treatment should be modified after the lab provides test results. Since the alleged inducer must possess an affirmative intent to cause the direct infringement, he must intent for the doctor to complete the treatment step with every claimed limitation, no matter how specific. It would be significantly harder to prove that the test provider possessed specific intent for the doctor to modify the treatment in such a particular manner.

This concern may be overcome if the same entity provides the diagnostic services and the method of treatment. For example, referring back to sample claim 2, if the test provider also provides CPAP devices, it is more likely that the patent holder would be able to prove the test provider intended the doctor to modify treatment in the way specified in modified claim 2. While this seems slightly improbable with the method of treatment specified in the sample claims here, if the method of treatment includes the use of a pharmaceutical drug the arrangement becomes more realistic.²⁸¹ Since the FDA is encouraging the use of companion diagnostics²⁸² when applying for approval of therapeutic products, more companies have an incentive to provide both a diagnostic test and a method of treatment.²⁸³ So, if the method of treatment includes the use of a pharmaceutical drug, the likelihood of a patent holder being able to

281. See Andrew Pollack, *A Push to Tie New Drugs to Testing*, N.Y. TIMES (Dec. 26, 2011), <http://www.nytimes.com/2011/12/27/health/pressure-to-link-drugs-and-companion-diagnostics.html>.

282. The FDA defines a companion diagnostic as a test used to assist doctors to determine whether a patient with a particular disease or condition should receive a particular therapeutic product. See *Draft Guidance for Industry and Food and Drug Administration in Vitro Companion Diagnostic Devices*, FOOD AND DRUG ADMIN (July 14, 2011), available at www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm262292.htm#ft1 (last visited Nov. 20, 2012).

283. See Pollack, *supra* note 281.

prove inducement by such a company may be greater.²⁸⁴ Additionally, if the FDA's encouragement of companion diagnostics is extended to approval for medical devices then the problem of proving intent may become less severe.

XIII. Conclusion

Many believe that the patent system has provided the protection necessary to make leaps forward in many technological industries, but especially in those, like medical diagnostics, involving significant risk and substantial investment.²⁸⁵ *Akamai* serves to protect those investments by safeguarding the value of many patents containing claims that can only be jointly infringed. *Akamai* is especially important for those in medical diagnostics since *Mayo* increased the likelihood that medical process claims will pose a divided infringement problem. While the *Akamai* decision is more limited than many had hoped and does not abolish all obstacles to enforcement, medical process patents, and those on diagnostic methods in particular, live to be valued another day.

284. Note that if the method of treatment is a new drug, or a new use of an existing drug, *Mayo* may not pose a bar to patentability. In that case, the new drug would be patent eligible subject matter. There may still be a problem of divided infringement. While one entity may provide the diagnostic results and access to the treatment, another party (i.e. a medical professional) would still need to interface with the patient.

285. See Corrected Brief of Amicus Curiae, Myriad Genetics, Inc., in Support of Neither Party at 1, *Akamai Tech., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012).