

PEEKING THROUGH THE LOOKING GLASS: HOW ALICE HAS SHAPED PATENT ELIGIBILITY

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I. INTRODUCTION

The world of patents is an area of law distinct from all others, featuring the collision of laws, both scientific and judicial. Congress and the judiciary have combined to create a massive body of law to protect everything from life-saving drugs¹ to methods of exercising your cat.² The entire spectrum of patents from the substance to the form of patent applications has been heavily adjudicated and multiple acts have been passed by Congress to shape patent law. However, due to the very nature of the subject, innovation necessitates evolving law.

Few sections of the Patent Act of 1952 have survived unscathed long, however one such section is quite impactful. The beginning of all patent analysis, 35 U.S.C. § 101 states, “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, subject to the conditions and requirements of this title.”³ As this section is the threshold to patentability, what exactly qualifies as a process, machine, or composition of matter has often come into contention.

Over time, the Court found the categories of patentable subject matter lacking and therefore created their own exceptions. An unintended consequence was the warping of the question of subject matter eligibility beyond a threshold to patent eligibility to an examination of the entire patent through the narrow lens of patent eligible subject matter jurisprudence. This note discusses how the Supreme Court constructed the current test and the flaws that have arisen from it, through the lens of *Genetic Technologies Ltd. v. Merial L.L.C.*,⁴ which exemplifies the current shortcomings of the patent eligibility test created by the Court.

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1. U.S. Patent No. 8,870,827 B2 (filed Aug. 17, 2010) (better known as the EpiPen).

2. U.S. Patent No. 5,443,036 (filed Nov. 2, 1993) (quite simply a laser pointer, the results can be assumed).

3. 35 U.S.C. § 101 (2012).

4. *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016).

II. BACKGROUND

A. The Patent-Eligibility Trilogy

Patentable subject matter has been a highly contested area since the conception of patent law within the U.S., often stemming from the legislative history of the Patent Act of 1952 which stated that statutory subject matter includes “anything under the sun that is made by man.”⁵ However, Congress did not enact a law so broad, instead narrowing the field to processes, machines, compositions of matter, or any improvement thereof.⁶ The issue of this wide scope was brought to the forefront in the 1970s when the Supreme Court introduced the concept of judicial exceptions in a series of cases involving the patentability of abstract ideas.⁷ The first case, *Gottschalk v. Benson*,⁸ dealt with a patent claiming a method to convert numbers into the binary form used by digital computers without the need for human interaction or arithmetic (i.e., 2 is converted to 0010) and without a limitation to any particular technology or use.⁹ The Court conducted a thorough search of precedent in an attempt to draw the line between patent-eligible subject matter¹⁰ and an idea that is itself not patentable.¹¹ The Court came to the conclusion that while laws of nature, mental processes, and abstract concepts are not patentable, the creation of a novel or useful structure with the aid of these concepts is.¹² The numerical conversion process in question did not create a novel or useful structure according to the Court; in fact, the claim was so broad that the patent would only affect the algorithm itself.¹³

The next case of the trilogy, *Parker v. Flook*,¹⁴ dealt with a similar situation, though the application of the algorithm was much more limited.¹⁵ The patent applied an algorithm to constantly update alarm

5. S. REP. NO. 82-1979, at 6 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399.

6. 35 U.S.C. § 101 (Inventions Patentable).

7. See Gleb Epelbaum, *From Benson to Alice: Evolution of Patent Eligibility of Computer-Implemented Inventions Under 35 U.S.C. § 101*, 87 TEMP. L. REV. 15 (2015).

8. *Gottschalk v. Benson*, 409 U.S. 63 (1972).

9. *Id.* at 64. More specifically the patent claimed a method to program a computer to convert signals from decimal form into the binary form used by digital computers without the need for human interaction/arithmetic. *Id.* at 65.

10. Defined by 35 U.S.C. § 101 as a process, machine, manufacture, or composition of matter.

11. *Gottschalk*, 409 U.S. at 67 (citing *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. 498, 507 (1874)).

12. See *id.* (citing *Funk Bros. Seed Co. v. Kalo Co.*, 333 U.S. 127, 130 (1948); *Mackay Co. v. Radio Corp.*, 306 U.S. 86, 94 (1939)).

13. *Id.* at 71–72.

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

15. *Id.* at 585.

triggers, such as temperature, to warn of inefficiency or danger during an oil refinery process.¹⁶ Initially, *Flook* seemed to distinguish itself from *Benson* as the patent claim would not be infringed by mere solving of the algorithm; rather, it would only be infringed upon the application of that solution to alarm limits.¹⁷ Unfortunately for the inventor, the Court feared that any competent patent drafter would be able to transform ineligible subject matter into a patentable process by tacking on some post-solution activity.¹⁸ Doing little to clarify, the Court also stated that this does not preempt a process containing a law of nature or algorithm from being patented.¹⁹ Instead, the focus was placed on the novelty of the process as a whole rather than being satisfied by the novelty of only the algorithm, which by itself was not patentable.²⁰ Weary to expand patent rights beyond congressional intent, the Court again struck down the patent.²¹

The final case, *Diamond v. Diehr*, was a bit of a departure from the prior cases, granting a patent for a process of curing synthetic rubber with several steps employing a mathematical formula or algorithm.²² The Court seemed to disagree with the prior decisions, finding that the ineligibility of the algorithm in isolation is not a bar when the process incorporates it in an efficient solution.²³ The inventor was not seeking a patent on the otherwise well-known algorithm; he sought to prevent others from using his algorithm in conjunction with all other steps in the claimed process.²⁴ Curing synthetic rubber was not a new process and neither was the algorithm, however the two together created a new and efficient process and were therefore a patentable subject matter.²⁵ The Court also addressed the novelty requirement that seemed to spill over

16. *Id.* at 585–86. More specifically, the patent claimed a method of calculating alarm limits for process variables during a catalytic conversion process. Fixed limits allow for smooth operation normally; however, fluctuating conditions during start-ups require quick recalculation of the alarm limits.

17. *Id.* at 587; *see also In re Flook*, 559 F.2d 21 (1977) (the initial appeal from the PTO Board of Appeals' rejection of the claims, where the United States Court of Customs and Patent Appeals distinguished the claims from *Benson* and reversed the rejection).

18. *Parker v. Flook*, 437 U.S. at 590 (stating that the prior court's ruling would allow the Pythagorean Theorem to be patented if applied to improve existing survey techniques); *see also id.* (explaining that a post-solution activity is merely a change to the alarm limit after the formula is solved or more generally, a basic application of the result of an algorithm or abstract idea).

19. *Id.* (citing *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45, 43 (1923)).

20. *Id.* at 591–92 (stating that the algorithm or any underlying abstract idea must be viewed as prior art whether or not it was known at the time).

21. *Id.* at 596.

22. *See generally Diamond v. Diehr*, 450 U.S. 175 (1981).

23. *Id.* at 188.

24. *Id.* at 187.

25. *Id.*

from § 102²⁶ in the *Flook* opinion, and found that novelty is distinct from a question of subject matter and should not be considered.²⁷

This trilogy had a large impact on the patent subject matter eligibility, though the somewhat grey area left the lower courts attempting to the fill in the gaps. In an attempt to summarize, another court stated: “The goal is to answer the question ‘What did applicants invent?’ If the claimed invention is a mathematical algorithm, it is improper subject matter for patent protection, whereas if the claimed invention is an application of the algorithm, § 101 will not bar the grant of a patent.”²⁸ Hesitant to expand upon patent rights and impose limitations inconsistent with the text of the Patent Act, the categorical exceptions created by the Court remained laws of nature, mental processes, and abstract concepts.²⁹

B. The Construction of the Mayo/Alice Test

*Mayo Collaborative Services v. Prometheus Laboratories, Inc.*³⁰ involved a patent claim covering processes that assist doctors in determining the proper dosage of a certain medicine in autoimmune disease patients.³¹ The claims asserted the application of natural laws, which govern the interaction of the medicine and the cells within the patients’ bodies.³² The question presented by the Court was, “[D]o the patent claims add *enough* to their statements of the correlations to allow the process they describe to qualify as patent-eligible processes that *apply* natural laws?”³³ This was in an effort to prevent the patent from being merely a drafting effort designed to prevent others from utilizing the law of nature itself.³⁴ The Court found that this patent did just that; the claim was merely an attempt to form a monopoly by telling others to simply “apply the law [of nature].”³⁵

In order to come to this determination, the Court examined the

26. 35 U.S.C. § 102 (2012) (addressing the novelty requirement of patents).

27. See *Diamond*, 450 U.S. at 191 (stating that “it may later be determined that the respondents’ process is not deserving of patent protection because it fails to satisfy the statutory conditions of novelty under § 102 or nonobviousness under § 103. A rejection on either of these grounds does not affect the determination that respondents’ claims recited subject matter which was eligible for patent protection under § 101.”).

28. *In re Abele*, 684 F.2d 902, 907 (C.C.P.A. 1982).

29. See Joseph S. Classe, *Genes and the Supremes: Will the Supreme Court Uphold Patents for Isolated Gene Sequences?*, 45 TEX. TECH L. REV. 533, 539 (2013).

30. *Mayo Collaborative v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

31. *Id.* at 72.

32. *Id.*

33. *Id.* at 77 (emphasis in original).

34. *Id.*

35. *Id.*

claimed process in both individual steps and as a whole.³⁶ The process was broken down into three steps: (1) an “administering step,” where the drug was given to the patient; (2) a “determining step,” where the metabolite levels resulting from the drug were measured; and (3) a “wherein step,” where the measured results were compared to the relevant “natural law.”³⁷ First, the “administering step” was determined to be a reference to the relevant audience, a signal to doctors that had already been using the drug employed by the claimed process long before.³⁸ Finally, the “determining step” instructed doctors (in any way they wished) to test the patient and act according to the stated natural law.³⁹ Finally, the “wherein step” was clearly just a statement of the relevant natural law discovered, another patent ineligible concept.⁴⁰ The Court went on to state that even the process considered as a whole adds nothing to the law of nature; the patent is essentially an instruction to doctors to apply the new discovery to a routine process.⁴¹

The framework established by *Mayo* was clearly outlined and adopted by the Court in the recent decision of *Alice Corporation Pty. Ltd. v. CLS Bank International*.⁴² The patent at issue claimed a process to mitigate settlement risk in financial transactions by using a computer system as a third-party intermediary.⁴³ In order to determine if the process satisfied § 101, the Court employed a two-part test: determining (1) whether the claims were directed to a patent ineligible concept and (2) whether the claims contained an “inventive concept” sufficient to “transform” the claimed abstract idea into a patent eligible application.⁴⁴ The Court determined that the claim in question, a computer implemented scheme to mitigate settlement risk, was undeniably an abstract idea: intermediated settlement.⁴⁵ While the claim used a computer as the third-party, on its face, it was a fundamental economic practice in commerce to employ *some* third-party in said situations and therefore the claim was ultimately directed towards an abstract idea.⁴⁶ The Court then proceeded to step two in an effort to again determine whether the

36. *See Mayo*, 566 U.S. at 78–79.

37. *Id.* at 78.

38. *Id.*

39. *Id.* at 79.

40. *Id.* at 79.

41. *Id.*

42. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S.Ct. 2347, 2355 (2014).

43. *Id.* at 2351–52.

44. *Id.* at 2355–57 (citing *Mayo Collaborative v. Prometheus Labs., Inc.* 566 U.S. 66, 72 (2012) (internal quotation marks omitted)).

45. *Id.* at 2356.

46. *Id.*; *see also Bilski v. Kappos*, 561 U.S. 593 (2010) (holding a patent describing a process to hedge risks a fundamental economic practice and therefore an abstract idea).

claim extended beyond a drafting effort intended to monopolize an abstract idea.⁴⁷ Applying the *Mayo* framework, the claim did nothing to transform the abstract idea into an application, only introducing a computer to the process.⁴⁸ Failing to include an adequate inventive concept to the abstract idea, the patent was ruled invalid.⁴⁹ Between the framework of *Mayo* and application by *Alice*, the Court outlined a definitive test for patent claims: determining (1) whether the claims are directed to a patent ineligible concept and (2) whether the claims contains an “inventive concept” sufficient to “transform” the claimed abstract idea into a patent eligible application.

C. Genetic Technologies Ltd. v. Merial L.L.C.⁵⁰

GeneType A.G. applied for a patent on September 23, 1992, which was granted on March 18, 1997 as U.S. Patent No. 5,612,179 (‘179).⁵¹ The invention claimed was a method for detection of an allele of a genetic locus to be used in direct determination of the haplotype.⁵² Put more simply, the process was able to determine coding regions in DNA that can be associated to particular traits or diseases in an individual.⁵³ In order to do this, a man-made “primer” attaches to the DNA and amplifies or replicates the section of interest to create a quantity sufficient to analyze.⁵⁴ What is unique about the ‘179 patent is the location these primers are attached. Prior to the patent, a majority of the scientific community was only interested in exons, or coding regions, the sections of DNA that actually produce physical manifestations within the human body.⁵⁵ However, Genetic Technologies Limited (GTG) determined a link between regions of the DNA that do nothing, called introns, and the same traits and diseases that are of interest.⁵⁶ Exploiting this link, GTG was able to establish a new and unique way to test individuals’ DNA for certain traits or predisposition to disease.⁵⁷

47. *Alice*, 134 S.Ct. at 2357 (citing *Mayo Collaborative v. Prometheus Labs., Inc.*, 566 U.S. 66, 77 (2012)).

48. *Id.*

49. *Id.* at 2360.

50. *Genetic Techs. Ltd. V. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016).

51. U.S. Patent No. 5,612,179 (filed Sep. 23, 1992).

52. *Id.* at [57].

53. See generally Montgomery Slatkin, *Linkage Disequilibrium — Understanding the Evolutionary Past and Mapping the Medical Future*, 9 NAT. REV. GENET. 477 (2008).

54. See generally *Polymerase Chain Reaction (PCR)*, NAT’L HUMAN GENOME RES. INST., <https://www.genome.gov/10000207/polymerase-chain-reaction-pcr-fact-sheet/> (last viewed June 16, 2015).

55. *Genetic Techs. Ltd. v. Agilent Techs., Inc.*, 24 F. Supp. 3d 922, 926 (N.D. Cal. 2014).

56. *Id.*

57. *Id.*

GTG brought multiple actions against competitors, alleging infringement of the '179 patent.⁵⁸ The court granted the defendants' motions to sever the claim and transferred the resulting cases to various venues around the country.⁵⁹ All defendants moved to dismiss the actions on assertion that the patent claim was directed to an ineligible subject matter.⁶⁰ The court in *Genetic Technologies Ltd. v. Agilent Technologies, Inc.* applied the *Mayo*⁶¹ framework in an attempt to determine if the '179 patent contained a sufficient "inventive concept" to transform the law of nature concerning the alleles to a patentable application.⁶² The Northern District of California interpreted the inventive requirement to concern proper limitations and whether or not the natural law is preempted.⁶³ The court stated four considerations given by the Federal Circuit for use when determining if a claim lacks proper limitation: (1) preemption of all practical applications of the natural law,⁶⁴ (2) insignificant pre-solution or post-solution activity,⁶⁵ (3) overgeneralized limitations,⁶⁶ and (4) a requirement for a particular machine or transformation of matter.⁶⁷

The court addressed the issue of preemption, stating that this application of the natural law requires a very specific method and that plaintiff's complaint itself state that there are numerous methods available to analyze the natural law without utilizing that specific method.⁶⁸ The court then contrasted the overgeneralized limitations presented in this case with that of *Mayo*.⁶⁹ The court compared *Mayo*, which only required the doctor to employ whatever technique they wish, with the '179 patent which requires and claims only one specific

58. *Id.* at 922; *see also* *Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521 (D. Del. 2014).

59. *Agilent*, 24 F.Supp.3d at 925.

60. *See id.* at 922; *Bristol-Meyers*, 72 F. Supp. 3d at 521–22.

61. *Alice* had not yet been decided by the Supreme Court.

62. *Agilent*, 24 F. Supp. 3d at 928 (internal quotation marks omitted).

63. *Id.* at 930.

64. *Id.* Stifling all innovation centered around a basic principle by effectively blocking its use. For example, patenting multiplication and claiming infringement on anyone who performs math.

65. *Id.* Attempting to circumvent the judicial exceptions through drafting. Continuing with the example above, it would be similar to attempting to patent multiplication simply by having a computer perform the math.

66. *Id.* (better known as the machine-or-transformation test, where a patent claim is sufficiently limited where "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing"; *see* *Bilski v. Kappos*, 561 U.S. 593 (2010) (giving an in-depth analysis of the machine-or-transformation test)).

67. *Agilent*, 24 F. Supp. 3d at 930 (citing *Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335, 1344–67 (Fed. Cir. 2013)).

68. *Id.* at 931.

69. *Id.* at 932.

technique.⁷⁰ The '179 patent also satisfied the machine-or-transformation⁷¹ test as the primers used in the process are man-made and qualify as machines.⁷² Satisfied, the court dismissed Agilent's claim that the patent failed to meet § 101 requirement for subject matter.⁷³

However, the *Bristol-Myers* court declined to follow the *Agilent* court's lead.⁷⁴ The court applied the *Mayo* framework to the case as well, finding that the application of the law to primer replication, a widely practiced art, did little to separate the underlying law of nature from the application.⁷⁵ Consequently, the "amplifying" step of the claim was insufficient to meaningfully limit the claims.⁷⁶ The court went on to compare the use of primers in the claim to the "wherein" step of the claim at issue in *Mayo*, characterizing it as a mere restatement of the natural law.⁷⁷ Consequently, the claims of the '179 patent were ruled invalid and the infringer's motion to dismiss was granted.⁷⁸ GTG moved to appeal and the case, *Genetic Technologies Ltd. v. Merial L.L.C.*, was brought before a three-judge panel of the Federal Circuit comprised of Judges Taranto, Dyk, and Chief Judge Prost.⁷⁹

On appeal, the Federal Circuit again applied the *Mayo* framework, though it also relied on the definitive test articulated by the *Alice* court.⁸⁰ The court found the first step to be clearly satisfied.⁸¹ Much like *Mayo*, the claim in *Merial* centered on the analysis of a biological sample.⁸² While GTG argued that this particular discovery did not qualify due to the diversity and difference in every human,⁸³ the court found that all variations were still entirely a consequence of naturally occurring phenomena.⁸⁴

Moving to the second step, the court rejected all arguments that the additional elements of the claim provided an inventive concept

70. *Id.*

71. *Id.* at 928.

72. *Id.*

73. *Agilent*, 24 F. Supp. 3d at 933.

74. *Genetic Techs. Ltd. V. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 533 (D. Del. 2014).

75. *Id.*

76. *Id.* at 534.

77. *Id.* (internal quotation marks omitted).

78. *Id.* at 539.

79. *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016).

80. *Id.* at 1374.

81. *See id.* (finding that the concept centered around a naturally occurring relationship within the body as disequilibrium linkage will occur regardless of any outside input and was therefore a law of nature).

82. *Id.* at 1375.

83. *Bristol-Myers*, 72 F. Supp. 3d at 530.

84. *Merial*, 818 F.3d at 1377.

necessary to render the claim patent eligible.⁸⁵ The court found the “amplification” step and the “analyzing” step to be well known routines and thus, these steps failed to separate the application from the law of nature.⁸⁶ During the patent prosecution process, GTG was forced to argue that the amplification technique was widely known and employed at the time of filing in order to satisfy the enablement requirement.⁸⁷ Similarly, GTG conceded that the amplifying techniques described in the patent were admittedly known at the time.⁸⁸ Almost every step of the claimed process was drawn parallel to *Mayo* and thus the court failed to see any reason to uphold the patent as valid.⁸⁹ After this decision, the Supreme Court denied GTG’s petition for a writ of certiorari.⁹⁰

III. DISCUSSION

The threshold of eligible subject matter was always intended to be a coarse filter, the further requirements of novelty, nonobviousness, and specification were seen as adequate tools for the USPTO to reject inventions which fell outside the scope of patent protection. However, years of judicial activism have narrowed the filter, creating a hurdle that impedes progress rather than protects it. First, the *Alice* test must be examined as a whole; there is little merit in examining the application of a broken test in an attempt to discuss a solution. This is done step by step as well as examining the evidentiary and burden shifting problems that have arisen. Once the shortcomings of the *Alice* test are realized, then it can be viewed through the lens that is *Merial*. Finally, the consequences of this test and the Supreme Court’s denial of certiorari moving forward will be discussed.

A. Laws of Nature: Scientific vs. Legal Approach

While judges and law students alike enjoy a simple and effective test to apply to future cases, the *Alice* test does little to clarify the actual distinction between patent eligible subject matter and abstract ideas. The first step of the *Alice* test calls for the court to “determine whether the claims at issue are directed to a patent-ineligible concept.”⁹¹

85. *Id.*

86. *Id.*

87. *Id.*; see also 35 U.S.C. § 112 (2012) (requiring a patent application to “enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same”).

88. *Id.*

89. See generally *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016).

90. *Genetic Techs. Ltd. v. Merial L.L.C.*, 137 S. Ct. 242 (2016).

91. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355 (2014).

However, determining whether or not a patent claim is drawn to a law of nature, natural phenomena, or abstract idea is difficult when even the Court admits that at some level all inventions rest upon these concepts.⁹² The Court offers little help in this regard, often declining to paint the boundaries of abstract ideas, instead simply agreeing that the patent claims rest upon ineligible subject matters.⁹³

Discovering a law of nature is a coveted achievement. Articulating a new law of nature is almost sure to place you with other scientific greats such as Einstein or Newton, however not every scientific discovery can be so highly regarded. While there are a variety of theories on what constitutes a law of nature, there are eight general criteria that must be fulfilled. The first criterion, universality, requires a statement to be true under any and all conditions.⁹⁴ Next, the necessity criterion requires that a statement *must* be true and not just true by definition (for example “all humans are mammals” is only true because we created the definition ourselves). This criterion distinguishes laws of nature from universal truths.⁹⁵ The explanation criterion requires the statement to explain all instances of the phenomena of interest.⁹⁶ The next two criteria, prediction and inference, require the statement make predictions of future instances and inferences to further facts which can be confirmed.⁹⁷ Sixth, counterfactuals, requires the statement to be true in hypothetical situations where everything is the same except for the specific facts that the law generalizes.⁹⁸ The objectivity criterion requires the statement to not depend on any human knowledge, belief, interest, need, or other subjective or pragmatic consideration. Lastly, the law must be scientific; the relevant scientific community must recognize the evidence and explanation and consider the statement a law of nature.⁹⁹

Yet the majority of decisions that have shaped subject matter jurisprudence have discussed little, if any, of the above criteria, or utilized any kind of scientific reasoning to justify claiming a law of nature. The court in *Mayo* begins its analysis by simply stating that the

92. *Mayo Collaborative v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012).

93. *Alice*, 134 S. Ct. at 2356; *see also* *Bilski v. Kappos*, 561 U.S. 593, 609 (2010) (refusing to adopt categorical rules, the Court simply states that the claims are not patentable due to an attempt to patent an abstract idea).

94. Robert R. Sachs, *Bad Science Makes Bad Patent Law—No Science Makes It Worse (Part I)*, BILSKI BLOG (Sept. 13, 2016), <http://www.bilskiblog.com/blog/myriad/>.

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.*

99. *Id.*

claimed relationship is a law of nature.¹⁰⁰ The sparse reasoning provided stated that since it is an entirely natural process, existing apart from any human action, then it must qualify as a law of nature.¹⁰¹ The Court's narrow focus on the objectivity criteria of natural law and blindness to all other elements is not a rare occurrence either.¹⁰² The *GTG* court's entire analysis relies upon similarities to *Mayo* and it is not the only example of courts' arbitrary declaration of laws of nature.¹⁰³

This failure to adopt any kind of clear direction with little analysis has created another "I know it when I see it" situation famously adopted by Justice Stewart when dealing with obscenity.¹⁰⁴ This is perfectly illustrated by a district judge in a case decided shortly after the *Alice* test was established.¹⁰⁵ Judge Wu admitted that the test was essentially a one-part test which follows a subjective finding of a patent ineligible concept.¹⁰⁶ He explained that *Alice*, the case meant to guide the lower courts, actually lacks any reasoning of its own and instead only relies back to previous cases.¹⁰⁷ This has left the lower courts scrambling to determine when the "two-part" test is satisfied.¹⁰⁸ This lack of direction has resulted in a uniform wave of lower court decisions invalidating patents as directed to an abstract idea.¹⁰⁹ The entire purpose of the test is to determine if a patent claim falls within the judicial exceptions, yet the step of the analysis dedicated to the matter falls incredibly short.

B. Patent Eligible or Patentability Analysis?

In the second, and much more substantive, step of the *Alice* test the Court examines "the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed

100. *Mayo Collaborative v. Prometheus Labs., Inc.*, 566 U.S. 66, 77 (2012).

101. *Id.*

102. *See, e.g., Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1375 (Fed. Cir. 2016) ("While it takes a human action . . . to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action." (citing *Mayo*, 566 U.S. at 77)).

103. *See id.*; *see also* Sachs, *supra* note 94 (listing cases where courts of all levels have deemed biological generalizations as laws of nature).

104. *Jacobellis v. Ohio*, 378 U.S. 184, 197 (1964) (the classic obscenity case decided by the Supreme Court).

105. *Eclipse IP LLC v. McKinley Equip. Corp.*, No. SACV 14-154-GW, 2014 WL 4407592, at *3 (C.D. Cal. Sept. 4, 2014).

106. *Id.*

107. *Id.*

108. *Id.* at *4.

109. Eric Guttag, *The Broken Patent-Eligibility Test of Alice and Mayo: Why We Urgently Need to Return to Principles of Diehr and Chakrabarty**, IPWATCHDOG (Sept. 25, 2014), <http://www.ipwatchdog.com/2014/09/25/broken-patent-eligibility-test-of-alice-and-mayo/id=51370/>

abstract idea into a patent-eligible application.”¹¹⁰ While the structure and analysis behind this step is fairly sound on its own, it is simply misplaced. The Court completely departed from the area of patent eligible subject matter and enters into the area of patentability, novelty, and obviousness.¹¹¹ The analysis behind the second step in *Mayo* relies on the fact that the drug used in the claim was preexisting and required doctors to engage in “well-understood” and “conventional activity.”¹¹² Similarly, the Court in *Alice* parroted their reasoning in *Mayo* while failing to find the required inventive concept.¹¹³ The Court undertakes an almost identical analysis when determining if a patent is novel and obvious.¹¹⁴ During a novelty analysis, the USPTO or court will examine prior art to determine whether or not the invention or process has been made or done before. Should they find the same invention, the patent lacks novelty. If the patent is even only slightly different than the prior art there is no question of novelty, but the patent may have been obvious. Should a person of reasonable skill in the art, who is assumed to have access to all relevant prior art, deem the invention to be obvious then a patent will not be granted. This is exactly what the court is doing when it discusses whether the claim was a process done for many years in the field, or whether it is a *simple* command to apply the discovery to an old process.

This is in stark contrast to the long-standing rule that the threshold question of patent eligibility is separate from and unaffected by conditions for patentability set forth by 35 U.S.C. §§ 102 (novelty) and 103 (obviousness).¹¹⁵ Compounding the issue, the Court declines to perform patentability analysis, but narrows the scope to the “better established inquiry” of patent eligible subject matter under § 101.¹¹⁶ This abandons a long and well-developed jurisprudence for patentability in order to comply with poor reasoning in a narrow decision,¹¹⁷ as well as precedent that state § 101 is a coarse eligibility filter and threshold that allows patentability requirements to eliminate those that survive erroneously.¹¹⁸ This muddled analysis has created confusion in place of

110. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2357 (2014).

111. Gutttag, *supra* note 109.

112. *Mayo Collaborative v. Prometheus Labs., Inc.*, 566 U.S. 66, 89 (2012).

113. *Alice*, 134 S.Ct. at 2357–58.

114. *See* 35 U.S.C. §§ 102–103 (2012) (outlining the novelty and obviousness requirements respectively); *see also generally* *Graham v. John Deere Co.*, 383 U.S. 1 (1966) (the classic Supreme Court case of obviousness in the modern era).

115. Teige P. Sheehan, *Mayo v. Prometheus: The Overlap Between Patent Eligibility and Patentability*, 21 NYSBA BRIGHT IDEAS 3, 4 (2012).

116. *Id.* (citing *Mayo*, 566 U.S. at 91).

117. *Id.* (discussing the general belief of practitioners on patentability jurisprudence).

118. *Id.* at 5.

clarity, directing district courts to create a poorly adjudicated body of case law under applications of the *Alice* test.¹¹⁹ This merging of patent eligible subject matter and patentability also seems to sweep the rules of prior art under the rug. The Patent Act and surrounding jurisprudence have created extensive rules for what can be considered by the USPTO and the court during novelty and obviousness analysis. A court is allowed to ignore this huge body of law conveniently, due to questions of subject matter being decided on motions to dismiss. Instead, the courts often look back at the field arbitrarily, not concerned with the time or evidentiary standard that is applicable.

C. Other Failures of the Alice Test

The *Alice* test also succeeded in changing, or at least confusing, the legal standard surrounding patent litigation. Due to the language of the Patent Act, a patent is presumed valid unless the challenger presents clear and convincing evidence to the contrary.¹²⁰ This places the burden of proof upon the challenger for the entirety of the claim. However, step two of the *Alice* test seems to shift this burden to the patent owner, requiring them to show the inventive step that transforms the abstract idea to patentable subject matter.¹²¹ Even if the Court did not intend this burden shift, the fact that the decision is a matter of law means that the clear and convincing evidentiary standard cannot apply.¹²² This effectively lowers the standard for the challenger and raises the bar for many patent owners.

While the Court claimed to build upon the past cases of *Flook* and *Diehr*, it seems to leave behind crucial analysis with every step taken.¹²³ While the two cases came to opposite conclusions, they both placed great weight on the patent eligibility as a whole rather than examining the abstract idea or post-solution activity in a vacuum.¹²⁴ However,

119. Kelly Mackin, *Federal Circuit Guidance Is Needed Because District Courts Are Misapplying Alice*, IPWATCHDOG (Apr. 7, 2016), <https://www.google.com/search?client=safari&rls=en&q=federal+circuit+guidance+is+needed+because+district+courts+are+misapplying+alice&ie=UTF-8&oe=UTF-8>.

120. 35 U.S.C. § 102 (2012) (“A person shall be entitled to a patent unless . . .”).

121. Dennis Crouch, *Affinity II: Who Has the Burden for Alice Step II?*, PATENTLY-O (Sept. 26, 2016), <https://patentlyo.com/patent/2016/09/affinity-burden-alice.html>.

122. *See id.*

123. *See generally* Mayo Collaborative v. Prometheus Labs., Inc., 566 U.S. 66 (2012); *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347 (2014) (both citing and relying on the past decisions to build the jurisprudence).

124. *See* Parker v. Flook, 437 U.S. 584, 591–92 (1978) (stating that the novelty of the abstract idea is not a determining factor at all, but the application of the idea to a new and useful end); *see also* Diamond v. Diehr, 450 U.S. 175, 188 (1981) (stating it is inappropriate to dissect the old and new

both *Mayo* and *Alice* offered extensive analysis to each element of the claim in question alone while offering little to the patent as a whole.¹²⁵ This departure from examination of a claim as a whole creates a dangerous pitfall that has been soundly addressed in another section of the Patent Act, obviousness.¹²⁶ Viewing elements of a claim in a vacuum during an obviousness analysis does little to contribute to outcome, as every element alone may be obvious, but when combined, creates a novel invention that has never been thought of. Therefore, completely isolating a claim that is directed to an abstract idea does little when every other step of the claimed process is an application of said abstract idea.

D. Misapplication of the Mayo/Alice Test

While it can be argued that, due to the shortcomings of the *Alice* test, the court should not have applied it in *Merical*, even more troubling is the misapplication of the test. The application of the test should have ended with step one: disequilibrium linkage is not a law of nature. The “law of nature” on which the claim rests lacked every necessary hallmark: reproducibility, predictability, and most importantly the empirical process necessary to determine if a scientific principle was indeed a law of nature.¹²⁷ Years of necessary experimentation can be thrown out the window by the court with no scientific evidence at all due to patent eligibility being a question of law.¹²⁸ Therefore, a panel of three to nine judges can declare a patent claim a law of nature with no expert testimony, no scientific findings, and no experimentation of any kind. Forget the costly experimentation, if a researcher wants their discovery declared a law of nature, he or she should simply apply for a patent.

Even with a rigorous review, the scientific community itself is unsure whether biological laws of nature exist.¹²⁹ This can be attributed to a lack of evidence as well as their very nature; biological systems are constantly changing and evolving.¹³⁰ One of the Court’s favorite

elements during patent eligibility analysis).

125. See generally *Mayo*, 566 U.S. 66; see also *Alice*, 134 S. Ct. 2347 (both analyzing the individual elements of the claim for patent eligible subject matter).

126. 35 U.S.C. § 103 (2012); see also *Graham v. John Deere Co.*, 383 U.S. 1 (1966) (the classic case on nonobviousness is the modern era).

127. Robert R. Sachs, *Bad Science Makes Bad Patent Law—No Science Makes It Worse (Part II)*, BILSKI BLOG (Sept. 19, 2016), <http://www.bilskiblog.com/blog/2016/09/bad-science-makes-bad-patent-law-no-science-makes-it-worse-part-ii.html>.

128. *Id.*

129. See *id.*; see also Pawan K. Dhar & Alessandro Giuliani, *Laws of Biology: Why So Few?*, 4 SYS. SYNTHETIC BIOLOGY, 7 (2010) (discussing the reasoning behind the lack of biological laws being due to the lack of evidence).

130. *Id.*

examples of a law of nature is Einstein's theory of relativity, $E=mc^2$.¹³¹ However, much like Newton's laws of motion, this is based entirely on physical law, and no matter what evolutionary changes occur within humanity, the law will remain. In contrast, the patent claim examined by the *Merial* court relied on a relationship found in human genetics; a relationship that could disappear within a few generations.¹³²

The patent claim in *Merial* falls decidedly short of the criteria discussed above. The first factor alone is almost impossible to claim, as to prove universality the claim must be tested under every possible condition. Even a person found without the genetic relationship can cast doubt upon the claim. Furthermore, the claim makes no explanation of the association between the DNA regions, nor can it predict the associations that will occur or be found in the future. Without further evidence, the *Merial* claim is merely an accidental generalization, a statement that happens to be true for a large amount of observations.¹³³

Oddly enough, a supposed law of nature is subject to more scrutiny in a tort case. In order to prevail in a toxic tort case, the scientific evidence presented by the plaintiff must be generally accepted, empirically validated, and peer reviewed.¹³⁴ Meanwhile, a patent case that revolves entirely around the science presented can be decided on a baseless assertion.¹³⁵ This lack of scientific scrutiny caused the *Merial* court to error in declaring disequilibrium linkage a law of nature. However, the blame cannot be placed entirely on them as the direction supplied by the Supreme Court did little to guide them to making an informed decision.¹³⁶ The Federal Circuit was forced to invoke their inner Justice Stewart, however obscenity is arguably easier to identify with a simple look than a law of nature.

Unfortunately, the Court concluded that the claim was directed to ineligible subject matter and therefore moved to step two of the test,¹³⁷ again misapplying it. As discussed above, the amplification technique that GTG utilized was a widely known technique and since the "new" portion introduced was a "law of nature" it must also be treated as prior

131. *Mayo Collaborative v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012).

132. *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1371–72 (Fed. Cir. 2016).

133. *Sachs*, *supra* note 94.

134. *Id.* For all factors considered when evaluating scientific evidence, see *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

135. See Allison Orr Larsen, *The Trouble with Amicus Facts*, 100 VA. L. REV. 1757, 1789 (2014) (stating that "[m]ore often than not a Justice citing an amicus brief to support a factual claim relies on only the amicus brief as authority without accompanying evidence").

136. See Gutttag, *supra* note 109 (likening the *Alice* test to Justice Stewart's famous phrase of "I know it when I see it").

137. *Merial*, 818 F.3d at 1376.

art.¹³⁸ This statement itself was misplaced as prior art and the body of jurisprudence accompanying it have only ever been applied to the novelty and obviousness statutes of the Patent Act. While the appeal only dealt with the issue of patent eligible subject matter, the discussion of the court seemed to be centered on whether or not the claimed process was new.

Finding that the combination of an old process and a law of nature removed any patent eligible subject matter, the court seemed to conveniently look away from major precedent such as *Diehr* which states, “This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.”¹³⁹ The courts analysis sounded very similar to that undertaken when a patent’s novelty or nonobviousness is challenged. While the amplification technique was emerging and arguably widely known, the disequilibrium linkage theory had never been employed to detect an allele through a non-coding DNA region.¹⁴⁰

Contrasted with *Mayo*, where the claims merely instructed doctors to compare usual results with the claimed relationship without changing the process, the ‘179 patent applies a known technique to a previously ignored area of DNA to create an entirely new process. While the Federal Circuit was quick to point out that the ‘179 patent does not invent a new way to analyze genetic loci,¹⁴¹ it entirely ignores the fact that the process as a whole is an improvement from the prior practice, an entire eligible subject matter for patents.¹⁴² So while the court has taken upon itself to declare laws of nature, it has also oversimplified the applications of these laws to the point that substantial changes and improvements are seen as simply “more informative.”¹⁴³

138. *Id.* at 1377.

139. *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

140. *See generally* Petition for Writ of Certiorari, *Genetic Techs. Ltd. v. Merial L.L.C.*, 137 S. Ct. 242 (2016) (No. 16-188).

141. *Merial*, 818 F.3d at 1378. This point by the court seems fairly weak, as the physical process of amplifying the genetic loci remains the same, the overall process is vastly different. The two methods target entirely different portions of DNA.

142. *See* Gene Quinn, *More Software Patent Eligible, Federal Circuit Says Lip Synchronization Not Abstract*, IPWATCHDOG (Sept. 14, 2016), <http://www.ipwatchdog.com/2016/09/14/software-patent-eligible-federal-circuit-lip-synchronization/id=72832/> (pointing to the emphasis the Federal Circuit placed on innovation and improvement of an existing technique in *McRo, Inc. v. Bandai Namco Games America*, 837 F.3d 1299 (Fed. Cir. 2016)). *See also* 35 U.S.C. § 101 (2012), which states that patents may also be obtained on any new and useful *improvement* of a process, machine, manufacture, or composition of matter (emphasis added).

143. *Merial*, 818 F.3d at 1378.

E. Consequences of the Alice Test

The source of all patent law, Article I, Section 8, Clause 8 of the United States Constitution,¹⁴⁴ sets forth the basis for all acts of Congress to be the promotion the progress of science and useful arts. One of the main arguments employed by the courts is that patents issued on these broad laws of nature will preempt all innovation or progress in entire fields of science.¹⁴⁵ However much like *Mayo*, the *Merial* court lacked any reasoning as to how the '179 patent preempts disequilibrium linkage from being used. While the amplification technique is widely used, it is not the only technique that can be utilized to analyze DNA.¹⁴⁶ The '179 patent only prevents the “law of nature” from being used in the very limited context of one amplification technique, a limitation clearly recognized by the Court in *Flook* but left to the wayside in modern days.¹⁴⁷

Rather than promote progress, the denial of such a wide array of patents inhibits it. Since *Alice* the invalidation of patents due to ineligible subject matter has soared above eighty percent.¹⁴⁸ This denial of protection to a public, or non-rivalrous, good creates a market failure scenario. A lack of ability to profit from intellectual property combined with the ability to obtain others' freely means there is no incentive to create.

Not only does the incentive to innovate slip away, the ability to even try does as well. Increasingly, scientific instruments have become more specialized and sophisticated and the price of running laboratories has skyrocketed.¹⁴⁹ How can this price be justified? Most costs are recouped when a patent is assigned or licensed to a third party that will monetize the invention. Without the protection of a patent, few inventors are likely to recover costs. Why assume the burden of research when it can be merely copied by another? This is precisely the problem occurring as fifty or more cancer treatment applications have been completely abandoned.¹⁵⁰ Further confusing the issue is the fact

144. U.S. CONST., art. I, § 8, cl. 8.

145. Sheehan, *supra* note 115, at 5.

146. See generally Fakruddin et al., *Nucleic Acid Amplification: Alternative Methods of Polymerase Chain Reaction*, 5 J. PHARMACY & BIOALLIED SCI. 245 (2013).

147. *Parker v. Flook*, 437 U.S. 584, 587 (1978).

148. Mackin, *supra* note 119.

149. Keith Veronese, *Here's What It Actually Costs to Run a University Science Lab*, GIZMODO (Aug. 10, 2011), <http://io9.gizmodo.com/5827381/heres-what-it-actually-costs-to-run-a-university-science-lab>.

150. Gene Quinn, *USPTO Handling of Patent Eligibility Sparks Substantive Discussion at PPAC Meeting*, IPWATCHDOG (Aug. 24, 2016), <http://www.ipwatchdog.com/2016/08/24/uspto-patent-eligibility-ppac-meeting/id=72298/>; see also Robert R. Sachs, *Will the USPTO's "Patents 4 Patients" Program Even Make it Off the "Cancer Moonshot" Launch Pad?*, BILSKI BLOG (June 30, 2016),

that these potential cancer treatments are funded by federal programs, which are designed to give patent protection as an incentive to spur lifesaving research.¹⁵¹ This shows the schism between the Court and the USPTO and what it deems to be patent eligible, the “guidance” being poor enough to drive the USPTO to turn to public input after the recent judicial decisions have created uncertainty in the patent system.¹⁵²

The quid pro quo of the U.S. patent system has always been to grant *limited* exclusive rights to inventors in exchange for their innovation and knowledge.¹⁵³ The Court seems to express concern over the blocking of entire fields to further research; however, that is precisely what the system is intended to do—grant a monopoly over the patent invention. The unnecessary narrowing of the field of patents only hinders scientific progress, one of the major concerns the Court has expressed when dealing with patent eligible subject matter.

IV. CONCLUSION

It is certainly not the first time, but in an attempt of clarity, the Supreme Court has instead muddled the waters even further. While it created a “test,” it offered little to no guidance on how to apply steps. Instead, it has created a free-for-all among the district courts as they boil the *Alice* test into a “I know it when I see it” subjective test.

The initial step of the *Alice* test has accidentally created an entirely new authority in the field of science. Giving one judge the ability to declare a law of nature, as a matter of law, is a huge misstep and somewhat of a mockery of the scientific community who takes years to discover and test “laws of nature.” This is especially true in *Merical* that was centered on the uncertain and ever-changing field of human biology and genetics. Even though the second step of *Alice* at least presents some analysis, it too is entirely misplaced. While the courts may attempt to push all they can under the subject matter umbrella, they have made a jumbled mess between patent eligibility and patentability.

This will not be a simple remedy; it will require clarification of not only the test, but the process of review. However, the solution does not seem to be near. Not only has the Supreme Court denied writ of certiorari to *Merical*, they have denied all pending subject matter cases

<http://www.bilskiblog.com/blog/2016/06/will-the-usptos-patents-4-patients-program-even-make-it-off-the-launching-pad-1.html> [hereinafter “*Patents 4 Patients*”] (listing the abandoned applications as well as the other countries where a patent was granted).

151. See “*Patents 4 Patients*,” *supra* note 150.

152. Dennis Crouch, *USPTO Seeks Further Public Input on Patent Subject Matter Eligibility*, PATENTLYO (Oct. 14, 2016), <https://patentlyo.com/patent/2016/10/further-subject-eligibility.html>.

153. Sheehan, *supra* note 115, at 5.

for the foreseeable future.¹⁵⁴ While I do not doubt the wisdom of these individuals, even those with extensive training and experience in the specific field can struggle with the science presented.¹⁵⁵ The Supreme Court needs to begin taking a more scientific approach to not only subject matter determination, but patent issues as a whole. The courts must embrace their shortcomings and construct a more thorough jurisprudence. An expanded process is necessary; leaving complex issues to be decided on a motion to dismiss gives too much power to one judge. This power is not necessarily a legal, but a scientific, power—the ability to make broad and sweeping determinations about new and uncharted territory.

Patents offer the unique melding of science and law, the joining of brilliant minds from both fields. However, recent decisions have strained this relationship, creating roadblocks rather than avenues for innovation. A return to protection rather than hindrance is critical, sooner rather than later.

154. Dennis Crouch, *Not Eligible: Supreme Court Denies All Pending Subject Matter Eligibility Petitions*, PATENTLYO (Oct. 3, 2016), <https://patentlyo.com/patent/2016/10/eligible-eligibility-petitions.html>.

155. The claimed invention is an “innovation” for a reason.