

Patent Owners versus the Supreme Court: Changing the Law Underlying Patent Eligible Subject Matter

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Patent eligible subject matter, as stated in 35 U.S.C. 101, includes “any new and useful process, machine, manufacture, or composition of matter.” Courts excepted laws of nature, natural phenomena, and abstract ideas from patent eligible subject matter, and recent Supreme court decisions have created uncertainty and controversy as to what is and should be eligible for patenting. This Note discusses proposals to clarify patent eligible subject matter through legislation by three intellectual property advocacy organizations, the Intellectual Property Owners Association (IPO), American Intellectual Property Law Association (AIPLA), and American Bar Association Section of Intellectual Property Law (ABA). This Note compares and contrasts two proposals to amend 35 U.S.C. Section 101, one a joint proposal from the IPO and AIPLA and the other from the ABA. The proposals are substantively similar but take different approaches. The IPO-AIPLA proposal replaces the above three judicial exceptions with two new but similar ones, while the ABA proposal retains the exceptions but restricts only patent claims that would preempt the use of an excepted type of subject matter. This Note recommends that patent owners, inventors, and other interested parties advocate for the ABA proposal because it more closely follows the Supreme Court’s stated concern of preemption of the patenting of laws of nature, natural phenomena, and abstract ideas.

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I. INTRODUCTION

Intellectual property protections, including patents, drive innovation in our society. Patents represent a bargain between inventors and the public—the inventor will teach his invention in exchange for a period of exclusivity to make and sell that invention. Certain limitations are placed on what inventions are deserving of the period of exclusivity. The placement of the line separating the deserving and undeserving is a matter of debate with great economic consequences.

In attempting to draw the line in a logical location, Congress laid out criteria for what constitutes a patentable invention in 35 U.S.C. Section 101 (Section 101), and the courts have limited the broad language of that section with three judicial exceptions to patent eligible subject matter:¹ laws of nature, physical phenomena, and abstract ideas.²

Case law, especially in the last seven years, has set some of the boundaries for those three judicial exceptions. Importantly, many methods of medical diagnosis fall within the exception of natural laws. This means that entities that discover a disease marker are not eligible for intellectual property protection, a determination with huge financial impacts. A similar result stems from the wide breadth of inventions considered to be physical phenomena or abstract ideas, especially impacting methods used by biotechnology and software companies.

This limitation on patent eligible subject matter has elicited several responses from interested parties. Notably, organizations dedicated to an efficient patent system (or rather, a system that favors inventors, in the eyes of critics) are pushing Congress to amend Section 101.

This Note argues that the American Bar Association’s (ABA) proposal to change Section 101 takes the most prudent approach to addressing patent eligible subject matter. This Note will first describe the evolution of patent eligible subject matter and the Supreme Court’s rationale underlying the judicial exceptions. It will then analyze and compare the proposals of three leading intellectual property organizations: the ABA Section of Intellectual Property, Intellectual Property Owners Association (IPO), and American Intellectual Property Law Association (AIPLA). Finally, this Note will argue why patent owners and applicants should support the ABA proposal.

1. *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (stating “[t]he relevant legislative history also supports a broad construction”).

2. *See Alice Corp. Pty. Ltd. v. CLS Bank Int’l.*, 134 S. Ct. 2347, 2354 (2014) (explaining the judicial exceptions).

II. BACKGROUND

A. The Foundations of Patent Eligible Subject Matter

The United States patent system owes its origins to power granted to Congress by the Constitution to establish the system in order to encourage technological innovation.³ The Patent and Copyright Clause of the Constitution declares this purpose: “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”⁴

Pursuant to its constitutional powers, Congress laid out the patent system in Title 35 of the United States Code. Patent eligible subject matter is addressed in Title 35, Section 101 of the United States Code: “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.”⁵ Judicial interpretation of Section 101 significantly impacts the patent system and those who rely upon it.⁶

The courts have added limitations to Section 101 regarding what constitutes patent eligible subject matter through a series of decisions. Section 101 allows patents for four categories of inventions: processes, machines, manufactures, and compositions of matter.⁷ However, the courts have added three judicial exceptions to what is patentable: natural phenomena, laws of nature, and abstract ideas.⁸ Four cases decided by the Supreme Court in the 20th century illustrate some of the bounds placed on patent eligible subject matter by the Court.⁹

B. The Supreme Court Builds its Framework for Patent Eligible Subject Matter

Although the doctrine of patent eligible subject matter originated long ago,¹⁰ its current shape began to take hold in the last 50 years.

The Court delivered its rationale of preventing preemption of the use of ideas when, in *Gottschalk v. Benson* in 1972, the Court held that a method to convert binary-coded-decimal (BCD) numerals to pure binary numerals was not patent eligible subject matter.¹¹ The Court reasoned, “[i]t is conceded that *one may not patent an idea*. But in practical

3. U.S. CONST. art. I, § 8, cl. 8.

4. *Id.*

5. 35 U.S.C. § 101 (2012).

6. See, e.g., Erika Check Hayden, *Biotech Reels Over Patent Ruling: Firms Fight for the Right to Patent Natural Products and Processes*, 511 NATURE 138 (2014), https://www.nature.com/polopoly_fs/1.15522!/menu/main/topColumns/topLeftColumn/pdf/511138a.pdf (discussing the effects of the judicial exceptions in United States Patent and Trademark Office rules and the biotechnology industry); Heidi Ledford, *Personalized Medicine Takes Hit*, 536 NATURE 382 (2016) https://www.nature.com/polopoly_fs/1.20436!/menu/main/topColumns/topLeftColumn/pdf/nature.2016.20436.pdf (discussing the effects of the judicial exceptions on medical diagnostic patents and the personalized medicine industry); Susan Decker, *When a Tech Patent is Neither*, BLOOMBERG BUSINESSWEEK (Aug. 17, 2016), <https://www.bloomberg.com/news/articles/2016-08-17/why-hundreds-of-software-patents-are-being-thrown-out> (discussing the effects of the judicial exceptions on the software industry).

7. 35 U.S.C. § 101 (2012).

8. See *infra* Part II.B.

9. *Id.*

10. *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852) (stating “a principle is not patentable”).

11. *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972).

effect that would be the result if the formula for converting BCD numerals to pure binary numerals were patented in this case.”¹² That reasoning hints at the three judicial exceptions to patent eligible subject matter: laws of nature, natural phenomena, and abstract ideas. The Court also gives a hint to one policy rationale behind those exceptions, “here the ‘process[]’ claim is so abstract and sweeping as to cover both known and unknown uses of the BCD to pure binary conversion.”¹³ That is, allowing patent-dependent exclusivity over the excepted matters would limit their use, and, thus, progress.¹⁴

The Court began to explain what would transform a non-patentable idea to a patentable process in 1978 with its decision in *Parker v. Flook*.¹⁵ The patent at issue dealt with a mathematical formula that could be used to adjust alarm limits during catalytic conversion.¹⁶ The only difference between the process at issue and the prior art was the mathematical formula.¹⁷ The Court determined that permitting the patent would be to permit a monopoly on the formula itself and ruled the formula to be non-patent eligible.¹⁸ However, it did foreshadow the idea of an inventive concept that would allow a patent claim to involve such a formula by saying, “[y]et it is equally clear that a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.”¹⁹

In 1981, in *Diamond v. Diehr*, the Court found such a process—one containing a law of nature—to be patent eligible subject matter.²⁰ The patent involved a method to cure rubber that used a mathematical formula to determine the timing of the curing process.²¹ The inventors claimed that “their contribution to the art [resides] in the process of constantly measuring the actual temperature inside the mold.”²² They explained that their process combined the mathematical formula with several novel steps, including “the continuous measuring of the temperature inside the mold cavity, the feeding of this information to a digital computer which constantly recalculates the cure time, and the signaling by the computer to open the press.”²³ The Court found that the process included a mathematical formula that was not by itself patent eligible subject matter, but that the patent covered the steps of using the formula rather than the formula itself.²⁴ The Court explained that when a patent claim involves a mathematical formula, the test is whether the claim seeks protection for the mathematical formula itself.²⁵ Bringing up a theme that would be revisited by future courts, the *Diehr* Court held that “insignificant post-solution

12. *Id.* at 71 (emphasis added).

13. *Id.* at 68.

14. Contradicting the purpose of the Patent and Copyright Clause.

15. *Parker v. Flook*, 437 U.S. 584, 588–89 (1978).

16. *Id.* at 585.

17. *Id.*

18. *Id.* at 590.

19. *Parker*, 437 U.S. at 590.

20. *Diamond v. Diehr*, 450 U.S. 175, 192–93 (1981).

21. *Id.* at 177.

22. *Id.* at 178.

23. *Id.* at 179.

24. *Id.* at 187. In contrast, the respondents here do not seek to patent a mathematical formula. Instead, they seek patent protection for a process of curing synthetic rubber. Their process admittedly employs a well-known mathematical equation, but they do not seek to pre-empt the use of that equation. Rather, they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process. *Diehr*, 450 U.S. at 187.

25. *Id.* at 191.

activity will not transform an unpatentable principle into a patentable process.”²⁶ The concept of what will transform a patent ineligible invention to a patent eligible one are thus mentioned by the *Diehr* Court, but what would constitute “insignificant post-solution activity” is still a matter of debate and uncertainty.²⁷

Finally, two of the most central concepts to the patent eligible subject matter question were laid out in *Diamond v. Chakrabarty* in 1980.²⁸ The Court stated that the range of patent eligible subject matter is broad, but supported judicial exceptions to patent eligible subject matter.²⁹ The Court first explored 35 U.S.C. Section 101, stating that “[i]n choosing such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.”³⁰ However, the Court then set forth the three currently recognized judicial exceptions to patent eligible subject matter: laws of nature, physical phenomena, and abstract ideas.³¹ The Court found that the engineered microorganism at issue was patent eligible subject matter because it had been engineered and was thus a new organism not produced by nature.³²

The view of patent eligible subject matter expressed in *Chakrabarty*, allowing patenting of a modified natural product—as opposed to a natural product—was favorable to patent seekers. All patents rely in part on at least one of the judicially excepted subject matters—all inventions build upon what was previously known and are ultimately based on natural phenomena, laws of nature, and abstract ideas. The Court’s view seemed to permit patenting as long as the excepted subject matter had been modified in some way. However, subsequent decisions would not embrace the previously wide scope of the doctrine.

C. The Supreme Court Creates a Test for Patent Eligible Subject Matter

A flurry of decisions limiting patent eligible subject matter began with *Bilski v. Kappos* in 2010, where the Court explained its concern with preemption.³³ The patent at issue covered a method to hedge risk during certain transactions in the energy market.³⁴ The Court compared the claimed method with those in the *Benson*, *Flook*, and *Diehr* cases and found the *Bilski* claims did not fulfill the criteria set forth in *Diehr*, and instead were similar to the situations in *Benson* and *Flook*.³⁵ The Court also provided an important policy rationale for the judicial exceptions to patent eligible subject matter, stating that granting an inventor exclusive rights to such a broad principle “would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.”³⁶ This rationale would underlie and justify many of the decisions that have since defined the

26. *Id.* at 191–92.

27. *Id.* at 191.

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

29. *Id.* at 313–15.

30. *Id.* at 308.

31. *Id.* at 309.

32. *Id.* at 310.

33. *See Bilski v. Kappos*, 561 U.S. 593, 611–12 (2010) (denying eligibility because of pre-emption concerns).

34. *Id.* at 599.

35. *Id.* at 611.

36. *Id.* at 612.

limits of patent eligible subject matter.

In 2012, the Court laid the groundwork for a two-part test to determine patent eligibility in *Mayo v. Prometheus*.³⁷ The dispute centered around a patent covering a method for adjusting medication dosage based on the patient's levels of the drug's metabolite in the patient's blood.³⁸ Essentially, it was a claim to a method to diagnose patients as metabolizing the drug quickly, slowly, or normally, and then adjusting the patient's dosage based on that diagnosis. The Court found this to be a claim on a law of nature, the law of nature being the relationship of the amount of drug given to a patient, the amount of metabolite in the patient's blood, and the efficacy and safety of the drug dosage for the patient.³⁹

An analysis of the Court's reasoning in *Mayo* informs of the current state of the judicial exceptions to patent eligible subject matter. The Court stated the claims at issue centered on the law of nature itself rather than a method of applying it in an inventive manner. The Court reasoned:

The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws? We believe that the answer to this question is no.⁴⁰

This meant that inventors must add an "inventive concept" that transforms the claim from one covering the natural law to one covering patent eligible subject matter.⁴¹ The transformation must be substantive and not just based on the "draftsman's art."⁴² Further, the Court stated that the transformation must be above and beyond "well-understood, routine, conventional activity previously engaged in by researchers in the field."⁴³ Finally, the Court refined its policy rationale, "upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries."⁴⁴

The Court subsequently applied its patent eligibility test to the field of natural products. Another case, *Ass'n for Molecular Pathology v. Myriad Genetics*, was before the Supreme Court at the same time as *Mayo*. *Myriad* involved claims to diagnostic methods similar to *Mayo* along with claims to isolated DNA sequences.⁴⁵ The diagnostic claims were found to not cover patent eligible subject matter after remand to the Federal Circuit Court of Appeals.⁴⁶ The claims to isolated DNA sequences were found by the Court of

37. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72 (2012).

38. *Id.*

39. *Id.* at 78–79.

40. *Id.* at 77.

41. *Id.* at 72.

42. *Mayo*, 566 U.S. at 72. (explaining "to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'").

43. *Id.* at 73.

44. *Id.* at 85 (citing an example of preemption).

45. *See generally* *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

46. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1346–47 (Fed. Cir. 2012).

Appeals to be patent eligible.⁴⁷ However, that finding was overturned by the Supreme Court, which held that DNA sequences are products of nature and, thus, not patent eligible.⁴⁸ The decision was the Court's first application of its test to natural products.

Finally, the Court applied its test to abstract ideas. The last major Supreme Court decision related to patent eligible subject matter, *Alice Corp. v. CLS Bank International*, clarified the “*Mayo* framework.”⁴⁹ The Court stated the two-part test originally formulated in *Mayo*: “first, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, “[w]hat else is there in the claims before us?””⁵⁰ The second question related to whether there was an “inventive concept” that transforms the patent ineligible subject matter in the claim into a claim that, read as a whole, is patent eligible subject matter.⁵¹ The Court applied the test to the claim at issue covering a method of using a computer to implement a way of managing financial risk called an intermediated settlement.⁵² The Court found the intermediated settlement to be an abstract idea and the computer to not be sufficient to make the claims directed to something other than that abstract idea.⁵³ The Court decided the second part of the test by comparing the claims at issue with those from *Mayo*, *Benson*, *Flook*, and *Diehr*.⁵⁴ This method of answering the second part of the *Mayo* test—by comparing the claims to claims in previous cases—has led to uncertainty about the line determining transformation of a claim from inside the judicial exceptions to patent eligible subject matter.

D. The Mayo Framework Application in the Lower Courts

The most significant case related to patent eligible subject matter since *Alice* tested the boundaries between patent ineligible to patent eligible subject matter. In *Ariosa v. Sequenom*, the Federal Circuit Court of Appeals analyzed the patent eligibility of a medical diagnostic test.⁵⁵ The test involved identifying cell-free fetal DNA in the blood of a pregnant woman and analyzing it for chromosomal abnormalities.⁵⁶ The court found the claims to be directed to a natural phenomenon, namely the DNA.⁵⁷ The “inventive concept,” or transformative step, was of great interest to onlookers. Before the method at issue, the very existence of cell-free fetal DNA was unknown.⁵⁸ Furthermore, the process for preparing the cell-free fetal DNA for analysis was unknown. The patent owners sought to be rewarded for their discoveries and contributions to fetal testing.⁵⁹ Unfortunately for

47. *Id.* at 1326.

48. *Myriad Genetics*, 569 U.S. at 579 (2013). The Court's citation to Chakrabarty summarizes the reasoning underlying its decision, “Products of nature are not created, and manifestations . . . of nature [are] free to all men and reserved exclusively to none.” (internal quotation marks omitted). *Id.* at 589 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)).

49. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014).

50. *Id.* at 2355 (internal citation omitted) (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 78 (2012)).

51. *Id.*

52. *Id.* at 2357.

53. *Id.*

54. *Alice*, 134 S. Ct. at 2357–58.

55. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (Fed. Cir. 2015).

56. *Id.*

57. *Id.* at 1376.

58. *Id.*

59. *Id.* at 1379.

the patent owners, the individual steps in the DNA preparation process were known, even though the combination of steps was not. The court strictly applied the *Mayo* test in deciding there was no “inventive concept that transforms” the claimed invention into patent eligible subject matter.⁶⁰

Since the *Ariosa* decision, courts have taken a hard line by denying the patent eligibility of many diagnostic methods. The Federal Circuit Court of Appeals has upheld dismissals of several infringement claims for failure to state a claim.⁶¹ The determination of whether a claim is patent eligible subject matter is one of law. Judges analyze the eligibility of the infringement accuser’s patent claims, find them to be patent ineligible subject matter covered by one or more of the judicial exceptions—meaning the claim is invalid—and dismiss the infringement case because the suit is not based on a valid patent claim.

The development and application of the *Mayo* framework has prompted calls for change from organizations such as AIPLA, the IPO, and the ABA Section of Intellectual Property Law. Those responses, including their similarities and differences, will be the topic of the next Part of this Note.

III. ANALYSIS

This Part will interpret, analyze, and compare the proposals of the IPO, AIPLA, and ABA. There is little commentary on their recent proposals as they were all released only in the last several months. This Note seeks to evaluate the proposals by elucidating their differences, and by applying the proposals to past cases to illustrate how they might affect the patent system. It is important to understand exactly what the proposed language changes are and how they affect the statute. This Part will then discuss how the proposed statutes, if they were in place at the time, might have affected certain recent cases.

The recent patent eligible subject matter decisions, in particular the *Mayo* test articulated in *Alice*, have generated considerable controversy in the past few years,⁶² as many critics believe they have shifted and blurred the line between what is and is not patent eligible subject matter.⁶³ One response encompasses proposed changes to Section 101 from

60. *Ariosa*, 788 F.3d at 1376.

61. FED. R. CIV. P. 12(b)(6); *see, e.g.*, *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1376–77 (Fed. Cir. 2016) (invalidating claims directed to a law of nature and lacking an inventive concept); *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 715–17 (Fed. Cir. 2014) (invalidating claims directed to abstract ideas and lacking an inventive concept).

62. USPTO, PATENT ELIGIBLE SUBJECT MATTER: REPORT ON VIEWS AND RECOMMENDATIONS FROM THE PUBLIC (July 2017), https://cdn.patentlyo.com/media/2017/07/101-Report_FINAL1.pdf (discussing the “considerable discussion” caused by recent decisions).

63. *See id.* at 1; Letter from Donna P. Suchy, Section Chair, Section of Intellectual Property Law, Am. Bar Ass’n., to Michelle K. Lee, Under Sec’y of Commerce for Intellectual Prop. and Dir. of the USPTO (Jan. 18, 2017),

https://www.americanbar.org/content/dam/aba/administrative/intellectual_property_law/advocacy/advocacy-20170117-comments.authcheckdam.pdf (stating “the Supreme Court has injected ambiguity into the subject-matter eligibility determination”); Letter from Mark L. Whitaker, President, Am. Intellectual Prop. Law Ass’n., to Michelle K. Lee, Under Sec’y of Commerce for Intellectual Prop. and Dir. of the USPTO (Jan. 18, 2017), https://www.uspto.gov/sites/default/files/documents/comments_aipla_jan182017.pdf (discussing “uncertainty and inefficiency for patent applicants and litigants” caused by recent decisions); INTELLECTUAL PROP. OWNERS ASS’N., PROPOSED AMENDMENTS TO PATENT ELIGIBLE SUBJECT MATTER UNDER 35 U.S.C. SECTION 101 (Feb. 7, 2017), http://www.ipo.org/wp-content/uploads/2017/02/20170207_IPO-101-TF-Proposed-Amendments-and-

three leading intellectual property advocacy organizations: the ABA, IPO, and AIPLA.⁶⁴ As discussed below, two different strategies have been adopted by the three organizations.

A. Proposals from the IPO and AIPLA

The proposals from the IPO and AIPLA, along with their joint proposal, use a similar strategy by proposing to clarify and limit (or eliminate) current judicial exceptions of laws of nature, natural phenomena, and abstract ideas. The organizations seek to expand patent eligible subject matter under section 101 and rely on other criteria, specifically under sections 102, 103, and 112 that require novelty, non-obviousness, and an enabling written description, respectively, to screen out non-patentable inventions.⁶⁵ This Note will focus on the proposed changes to Section 101 in the joint proposal.⁶⁶

Eligible Subject Matter

a) Whoever invents or discovers, and claims as an invention, any useful process, machine, manufacture, composition of matter, or any useful improvement thereof, shall be entitled to a patent therefor, subject only to the conditions and requirements set forth in this title.

Sole Exception to Subject Matter Eligibility

b) A claimed invention is ineligible under subsection (a) if and only if the claimed invention as a whole (i) exists in nature independently of and prior to any human activity or (ii) is performed solely in the human mind.

Sole Eligibility Standard

c) The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard to: (i) the requirements or conditions of sections 102, 103, and 112 of this title; (ii) the manner in which the claimed invention was made or discovered; or (iii) whether the claimed invention includes an inventive concept.

1. The Joint Proposal's Proposed Changes to Section 101, in the Form of a New Section 101(a)

The joint proposal's changes to the current textual body of Section 101(a) take

Report.pdf (stating recent decisions “have dramatically narrowed the scope of patent protection for life sciences and software technology by significantly expanding the judicially-created exceptions to patent-eligible subject matter”) [hereinafter IPO].

64. IPO, *supra* note 63; AIPLA, AIPLA LEGISLATIVE PROPOSAL AND REPORT ON PATENT ELIGIBLE SUBJECT MATTER (May 12, 2017), <http://admin.aipla.org/resources2/reports/2017AIPLADirect/Documents/AIPLA%20Report%20on%20101%20Reform-5-19-17-Errata.pdf> [hereinafter AIPLA]; Letter from Donna P. Suchy, Section Chair, Section of Intellectual Prop. Law, Am. Bar Ass'n., to Michelle K. Lee, Under Sec. of Commerce for Intellectual Prop. and Dir. of the USPTO (March 28, 2017) (on file with the American Bar Association), <http://patentdocs.typepad.com/files/letter-5.pdf> [hereinafter ABA Letter]; IPO & AIPLA, JOINT IPO-AIPLA PROPOSAL CONCERNING LEGISLATIVE AMENDMENT OF 35 U.S.C. § 101, https://www.aipla.org/docs/default-source/uploadedfiles/documents/advocacy/congress/documents/aipla-ipo-joint-proposal.pdf?sfvrsn=a4067549_0 (last visited October 2, 2018) [hereinafter Joint Proposal].

65. IPO, *supra* note 63, at 27; AIPLA, *supra* note 64, at 2; Joint Proposal, *supra* note 64.

66. Joint Proposal, *supra* note 64.

predominantly two forms: removing the concept of newness and limiting the reach of judicial exceptions. The latter includes new exceptions and the interpretations of exceptions by the United States Patent and Trademark Office (USPTO) and the courts.

The first proposed change is to remove “new” from Section 101 and replace it with “and claims as an invention,” which has two effects. First, the removal of “new,” places the patentability requirement of novelty solely with within Section 102.⁶⁷ This would eliminate any confusion as to legislative intent around the question of whether “new” in the current Section 101 establishes a separate requirement from the novelty inquiry of Section 102. Second, the use of “claims as an invention” rather than “new” places the focus onto the applicant’s claim of an invention, essentially letting the applicant get through the gate of patent eligible subject matter by initially placing the inquiry of whether the applicant has a new invention upon the subjective view of the applicant themselves.

Second, the joint proposal seeks to limit the effects of judicial exceptions by clarifying that an applicant is in fact “entitled” to a patent if all of the statutory provisions are met.⁶⁸ The joint proposal replaces “may obtain” with “shall be entitled to,” seemingly in order to require the USPTO to grant a patent whenever all of the statutory requirements are met.⁶⁹ Although the joint proposal does not state it, this seems to be establishing congressional intent to prevent the addition of further judicial exceptions,⁷⁰ which are themselves limited later in the proposed statute. Secondary to indirectly limiting further judicial exceptions, the entitlement provision would prevent the USPTO from making expansive interpretations of any of the exceptions to patent eligible subject matter proposed in the statute.

The joint proposal then seeks to directly limit any further judicial exceptions. It adds the word “only” to Section 101(a) to give the reading, “subject only to the conditions and requirements set forth in this title.”⁷¹ This is a clear attempt to halt the expanding influence of the courts on the criteria for patent eligible subject matter and prevent any future judicial exceptions.⁷² The addition of “only” would also check any expansion of the interpretations of the exceptions to patent eligible subject matter provided later in the proposed statute.

2. A New Section 101(b) Sole Exceptions to Subject Matter Eligibility

The IPO-AIPLA joint proposal’s sole exceptions restructure the current judicial exceptions into a more favorable regime for patent applicants and owners. It proposes three significant clarifications and changes to the judicial exceptions doctrine.

The most significant change is to replace the current judicial exceptions with exceptions that could be more easily circumvented, benefiting patent seekers and holders. The proposal narrows the current three judicial exceptions of laws of nature, natural phenomena, and abstract ideas into what seems to be, in fact, two exceptions: a combination of laws of nature and natural phenomena and a reworking of abstract ideas. The two new exceptions would apply to an invention that “exists in nature independently

67. 35 U.S.C. § 102 (2012) (requiring novelty as determined by no availability to the public as certain forms of prior art).

68. Joint Proposal, *supra* note 64.

69. See IPO, *supra* note 63, at 28.

70. See, e.g., AIPLA, *supra* note 64, at 12 (explaining the AIPLA’s effort to make Congressional intent clear).

71. Joint Proposal, *supra* note 64.

72. See IPO, *supra* note 63, at 29.

of and prior to any human activity” or “is performed solely in the human mind.”⁷³

These changes allow one to add features to a claim to a law of nature, natural phenomenon, or abstract idea to bring the claim outside of the exception. For example, a previously excepted DNA molecule isolated from a human⁷⁴ would be chemically distinct from what exists in nature, and thus eligible, because of chemical changes introduced to the molecule during the DNA isolation process.⁷⁵ An abstract idea like a mathematical formula could be eligible if it was used to implement a process, such as using a mathematical formula to adjust alarm limits during catalytic conversion.⁷⁶ The Court might view the easy workarounds of the new exceptions to patent eligible subject matter as allowing claims broad enough to preempt all or most uses of the exception.⁷⁷ These changes to the exceptions to patent eligible subject matter would have substantial impacts on the biotechnology, medical diagnostic, and software industries.

Another significant change proposed by the IPO and AIPLA is to explicitly state that the appropriate inquiry is whether “the claimed invention as a whole” falls within the proposed statutory exceptions.⁷⁸ The Court in *Diehr* set the standard for the inquiry as analysis of the claim as a whole.⁷⁹ However, the Court in *Alice* modified that to allow analysis of the elements of a claim as an ordered combination.⁸⁰ This would minimize the tendency of courts to fail to consider whether the claim as a whole contains an “inventive concept,”⁸¹ which might be more difficult to find when looking at one claim element at a time. The change in analysis would eliminate a frequent cause of patent application rejection.⁸²

3. The Proposed New Section 101(c) Sole Eligibility Standard

The final subsection the IPO and AIPLA propose is basically a codification of some of the concepts underlying their suggested changes. It explicitly separates any analysis under Section 101 from those of Section 102, 103, and 112.⁸³ It then eliminates the search for an “inventive concept,”⁸⁴ apparently to prevent it from entering the previously explained proposed statutory exceptions.

73. Joint Proposal, *supra* note 64.

74. See *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2115 (2013).

75. *Id.* (citing “the chemical changes that result from the isolation of a particular section of DNA”).

76. See *Parker v. Flook*, 437 U.S. 584, 588 (1978) (holding the mathematical formula was not patent eligible).

77. This concern of preemption is the primary motivation to the ABA’s proposal to limit the current judicial exceptions.

78. *Supra* Part III.A (showing the proposed language of Section 101(a)).

79. See *Diamond v. Diehr*, 450 U.S. 175, 191 (1981) (explaining “when a claim . . . which, when considered as a whole, is performing a function which the patent laws were designed to protect . . . , then the claim satisfies the requirements of Section 101”).

80. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l.*, 134 S. Ct. 2347, 2355 (2014) (explaining “we consider the elements of each claim both individually and ‘as an ordered combination’”).

81. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72 (2012).

82. IPO, *supra* note 63, at 31.

83. *Id.* at 1.

84. See *Mayo*, 566 U.S. at 72–73 (requiring an inventive concept); IPO, *supra* note 63, at 1.

B. Proposal from the ABA

The ABA Section of Intellectual Property Law focuses on assuaging the Court's concern about the preemption of the uses of laws of nature, natural phenomena, and abstract ideas. It has similarities to the IPO-AIPLA joint proposal, particularly in establishing a modified version of the current Section 101 as a new Section 101(a).⁸⁵ However, the ABA proposes a Section 101(b) with the sole exception to patent eligible subject matter being a patent that would preempt the previously established judicial exceptions. It reads:

Section 101. Conditions for patentability: eligible subject matter.

(a) Eligible Subject Matter. - Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, shall be entitled to obtain a patent on such invention or discovery, absent a finding that one or more conditions or requirements under this title have not been met.

(b) Exception.- A claim for a useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may be denied eligibility under this section 101 on the ground that the scope of the exclusive rights under such a claim would preempt the use by others of all practical applications of a law of nature, natural phenomenon, or abstract idea. Patent eligibility under this section shall not be negated when a practical application of a law of nature, natural phenomenon, or abstract idea is the subject matter of the claims upon consideration of those claims as a whole, whereby each and every limitation of the claims shall be fully considered and none ignored. Eligibility under this section 101 shall not be negated based on considerations of patentability as defined in Sections 102, 103 and 112, including whether the claims in whole or in part define an inventive concept.⁸⁶

1. ABA's Proposed Changes to Section 101, in the Form of a New Section 101(a)

The ABA's proposed Section 101(a) has similar wording to the IPO-AIPLA joint proposal—and is functionally nearly identical. They both eliminate “new,” though the ABA does not replace it with the concept of a claimed invention.⁸⁷ They both also include the concept of entitlement to a patent.⁸⁸ Finally, the ABA replaces the last clause of Section 101 with “absent a finding that one or more conditions or requirements under this title have not been met.”⁸⁹ The ABA has not explained the reasoning behind its proposed changes or their expected outcomes, but it seems reasonable to assume they parallel those of the IPO and AIPLA.

2. A New Section 101(b) Exception—the ABA's Solution

The ABA takes an approach that leaves in place the categories of judicial exceptions

85. ABA Letter, *supra* note 64; *supra* Part III.A.

86. ABA Letter, *supra* note 64.

87. *Id.*

88. *Id.*

89. *Id.*

but limits their implementation to instances where the claim would widely preempt the use of a law of nature, natural phenomenon, or abstract idea. This is a more targeted approach than that of the IPO and AIPLA, one which the ABA presumably intends to go to the heart of the Court's concern and justification for the three judicial exceptions.⁹⁰

The ABA proposes limiting the judicial exceptions to those currently in place and limiting their application to situations in which "such a claim would preempt the use by others of all practical applications of a law of nature, natural phenomenon, or abstract idea."⁹¹ Rather than redefining the Court's exceptions (as the IPO and AIPLA propose), the ABA embraces two of the Court's concepts: the exceptions themselves and the justification behind them. It makes clear that preemption would be barred, but that the "practical application of a law of nature, natural phenomenon or abstract idea" would still be patent eligible subject matter.⁹² This is not inconsistent with what the Court has said in its opinions.

The next aspects of the ABA's proposed Section 101(b) looks to strengthen the focus of eligibility in the entire claim. It requires "consideration of [the] claims as a whole, whereby each and every limitation of the claims shall be fully considered and none ignored."⁹³ This functionally parallels the IPO-AIPLA position and likely has the same reasoning behind it.

Finally, as with the IPO and AIPLA, the ABA supports separation of the patent eligible subject matter analysis from the other patentability analyses and elimination of the idea of an "inventive concept": "Eligibility under this Section 101 shall not be negated based on considerations of patentability as defined in Sections 102, 103 and 112, including whether the claims in whole or in part define an inventive concept."⁹⁴

C. How the Mayo, Myriad, and Alice Decisions Would Have Been Affected

The claims at issue in the *Mayo*, *Myriad*, and *Alice* cases would be analyzed differently under the ABA and IPO-AIPLA proposals. Both would allow the claim at issue in *Mayo*, but only the IPO-AIPLA joint proposal would allow the claims in *Myriad* and *Alice*.

The claim at issue in *Mayo* involved a natural law being used in a test for drug metabolite levels that would then be used to adjust drug dosage up or down depending on the metabolite levels in the patient's blood.⁹⁵ Under the IPO-AIPLA joint proposal's Section 101(b), the test would not fall within the sole exception to patent eligible subject matter because it does not "exist[] in nature independently of and prior to any human activity or . . . is performed solely in the human mind."⁹⁶ The claim would be permissible under the ABA Section 101(b) because it would not "preempt the use by others of . . . [the]

90. *Id. see* *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014) (stating "the concern that drives this exclusionary principle as one of pre-emption"); *see also* *Gottschalk v. Benson*, 409 U.S. 63, 72 (1972) (stating "the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself").

91. ABA Letter, *supra* note 64.

92. *Id.*, at 3.

93. *Id.*, at 3–4.

94. *Id.* at 4.

95. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 66–67 (2012).

96. Joint Proposal, *supra* note 64, at 1.

law of nature.”⁹⁷ It would not preempt the use by all others because the correlation between blood metabolite levels and drug dosage—the law of nature—would only be off limits to others with respect to that particular application.

The claim in *Myriad* to an isolated DNA sequence would be analyzed differently by the two Section 101 proposals. The IPO-AIPLA joint proposal would permit the claim because the isolation of DNA “creates new molecules with unique chemical compositions.”⁹⁸ Thus, the isolated DNA molecule did not exist in “nature independently of . . . any human activity.”⁹⁹ However, the ABA Section 101 would not permit the claim because a patent on the isolated DNA sequence would preempt all other uses of that DNA sequence.¹⁰⁰ Any purpose of using a human DNA sequence involves the necessary step of creating an isolated copy of the DNA sequence, and a patent on the isolated DNA sequence would thus prevent all others from using it for any purpose. Further, many laboratory techniques involve randomly copying DNA sequences, meaning that those techniques would cause researchers to accidentally infringe the patent, preempting even the use of those techniques. A similar situation arises with abstract ideas.

The claim in *Alice* involves a common situation—implementing an abstract idea through a computer—that would be analyzed differently under the Section 101 proposals.¹⁰¹ The joint proposal’s Section 101 would permit the claim because the use of a computer means the abstract idea is not “performed solely in the human mind.”¹⁰² However, the ABA Section 101 would prohibit the claim because the implementation of an abstract idea through a computer would have the effect of preempting “the use by all others of all practical applications of a[n] . . . abstract idea.”¹⁰³ Because any practical use of the abstract idea at issue—a business method—would involve its implementation by computer, no others would be permitted to use the idea.

Those hypothetical outcomes of the *Mayo*, *Myriad*, and *Alice* illustrate the consistency of the ABA proposal with the Supreme Court’s ultimate rationale for the judicial exceptions to patent eligible subject matter—to promote progress in the sciences. The ABA proposal allows applications of the judicial exceptions while still prohibiting the preemption of the use of laws of nature, physical phenomena, and abstract ideas—which would presumably hinder progress.

D. Summary and Brief Comparison of Proposals

The IPO, AIPLA, and ABA Section of Intellectual Property Law each released proposed reworkings of 35 U.S.C. in the first half of 2017, and then the IPO and AIPLA released a joint proposal in May 2018. The proposals are in response to considerable controversy and uncertainty caused by changing the landscape of what is and what is not patent eligible subject matter. The three proposals share certain features but take different approaches to limit the effects of the three judicially imposed exceptions to patent eligible subject matter.

97. ABA Letter, *supra* note 64, at 3.

98. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 587 (2013).

99. Joint Proposal, *supra* note 64, at 1.

100. ABA Letter, *supra* note 64, at 3.

101. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2352 (2014).

102. Joint Proposal, *supra* note 64.

103. ABA Letter, *supra* note 64.

All four proposals modify Section 101 into a new Section 101(a), with the modifications serving three main functions. First, they remove the concept of newness from Section 101 and leave it to the novelty test under Section 102. Second, they introduce an entitlement to a patent if the new Section 101 conditions are met, but still subject to the other patentability statutes,¹⁰⁴ in order to reduce flexibility to interpret and add judicial exceptions by the courts and USPTO. Third, they add language to prevent the addition of new judicial exceptions.

The proposals diverge when dealing with the current three categories of judicial exceptions to patent eligible subject matter. The IPO and AIPLA, both separately and in their later joint proposal, remove the three judicially introduced categories and replace them with two legislatively introduced categories: essentially what already exists in nature absent any modifications by human activity and what exists or can exist solely in the human mind. The ABA takes a more restrained approach by retaining the judicially introduced categories but limiting them based on the Court's expressed concern of preemption. The Recommendation section will explain why the proposal of the ABA is more attractive to more interested parties and should be pursued by patent applicants and owner.

IV. RECOMMENDATION

As previously discussed, uncertainty surrounds the issue of patent eligible subject matter, and the proposal to clarify that uncertainty by the ABA takes the most effective approach. Thus, this Note recommends that patent owners support—through advocating for legislative changes to Section 101—the ideas in that proposal over the approach taken by the IPO and AIPLA. The ABA approach effectively clarifies the role of Section 101, addresses judicial concerns over the constitutional role of the patent system, and fares at least as well as the other two proposals legislatively and with the public.

A. Restoring the Role of Section 101

The criteria defining what is and is not patent eligible subject matter under Section 101 has changed over the last several decades. As P.J. Federico¹⁰⁵ famously said in 1951, “Now, under [S]ection 101 a person may have invented a machine or a manufacture, which may include anything under the sun that is made by man, but it may not necessarily be patentable unless the conditions [of patentability] are fulfilled.”¹⁰⁶ The view at that time was that Section 101 was a gateway to allow any patentable invention¹⁰⁷ to undergo the further scrutiny of the rest of the patentability statutes.¹⁰⁸ However, while acknowledging that congressional intent, the Court in *Chakrabarty* maintained the removal of three categories of subject matter, effectively making Section 101 another condition on patentability.¹⁰⁹ The ABA proposal restores the gating role of Section 101, by removing

104. See 35 U.S.C. §§ 102, 103, 112 (2012).

105. The former Examiner-in-Chief of the USPTO and a drafter of the 1952 Patent Act.

106. *Patent Law Codification and Revision: Hearing on H.R. 3760 before Subcomm. No. 3 of the H. Comm. On the Judiciary*, 82d Cong., 37 (1951).

107. 35 U.S.C. § 101 (1952) (“[A]ny new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”).

108. See, e.g., 35 U.S.C. §§ 102, 103, 112 (1952) (discussing the requirements of novelty, nonobviousness, and a written description); S. REP. NO. 82-1979, at 2399 (1952).

109. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (“This is not to suggest that § 101 has no limits or

the word “new,” as do the proposals by the IPO and AIPLA.

B. The Reasoning of the Supreme Court

When planning a course of action to improve Section 101, it is necessary to consider the Court’s reasoning behind the judicial exceptions, and the ABA better addresses judicial concerns. The Court in *Graham v. Deere* explained

[I]t must be remembered that the federal patent power stems from a specific constitutional provision which authorizes the Congress “To promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their Discoveries” Art. I, Section 8, cl. 8. The clause is both a grant of power and a limitation . . . The Congress in the exercise of that power may not overreach the restraints imposed by the stated constitutional purpose.¹¹⁰

While the context of that quotation is a case involving nonobviousness, the Court’s constitutional reasoning applies to the entire patent system. The Court has interpreted the Constitution to best promote progress by excepting patents on laws of nature, natural phenomena, and abstract ideas.

The Court created the three exceptions as limitations on patent eligible subject matter to prevent hindrance of scientific progress. They expressed their concern as one of “pre-emption” of all uses of the excepted matter—allowing patents on excepted matter would prevent the matter’s use by all others.¹¹¹ The *Alice* Court explained that “the pre-emption concern . . . undergirds our Section 101 jurisprudence.”¹¹² The ABA’s proposal directly addresses that concern.

The approach of the ABA proposal is preferable judicially, because it is more consistent with the Court’s reasoning for the judicial exceptions than that of the IPO-AIPLA joint proposal. The ABA proposal addresses the Court’s main concern, pre-emption, while leaving the judicial exceptions it has imposed otherwise intact. The IPO and AIPLA, on the other hand, take a cut-and-replace approach by statutorily removing all current and future exceptions, and replacing them with two narrower exceptions—entirely natural products and ideas that reside in the mind. Addressing the Court’s concerns, rather than circumventing them, seems to be a strategy that is more likely to survive judicial review.

C. Resistance from Congress and the Public

Certain impediments to legislation incentivize getting it right the first time. The three proposals will face two other interrelated hurdles—reaction by the public and legislative gridlock—with no proposal having a clear advantage over the others. Patent owners prefer a system permitting patenting of as many of their inventions as possible, or at least reasonable. However, the public, freedom-of-information advocates,¹¹³ and other

that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable.”)

110. *Graham v. John Deere Co.*, 383 U.S. 1, 5–6 (1966).

111. *Gottschalk v. Benson*, 409 U.S. 63, 72 (1972) (“[T]he patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.”).

112. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2358 (2014).

113. *Patents*, ELEC. FRONTIER FOUND., <https://www EFF.org/issues/patents> (last visited Aug. 27, 2018).

opponents¹¹⁴ express concern about the extent of patent eligible subject matter. A frequent criticism is that patents prevent non-owners from using inventions that should be freely available. The ABA proposal keeps the judicial exceptions intact, but it permits excepted material to be patented narrowly. This could still be viewed as allowing a patent on, for example, a law of nature. The IPO and AIPLA proposals each provide two narrow exceptions. One would expect the public to be skeptical of permitting patents on abstract ideas with the only condition being that the invention is not “performed solely in the mind.”¹¹⁵ Basically, each proposal faces scrutiny from the public. That scrutiny is a hurdle to overcome before reaching the larger problem—legislative gridlock. In today’s political environment, any legislative proposal faces dim prospects, even with strong backing by supporters inside and outside of Congress. This means there is likely only one shot at reforming the doctrine of patent eligible subject matter, so it is important to find a proposal that would most likely survive judicial review, as the ABA proposal does.

D. Patent Owners Should Support the ABA Proposal

Patent owners, small and large, should advocate for adoption of the ABA approach because it is palatable, both judicially and legislatively. This Note has explained the judicial concerns with potential changes to Section 101 and why the ABA approach is preferable. Legislative concerns also occur before the ultimate judicial determination of whether any implemented changes will stand.

The conundrum faced by inventors and patent owners is the strength of intellectual property rights balanced by the likelihood of successful passage and survival of judicial review of any legislation. On balance, the proposals face the same or similar hurdles to passage by Congress. However, the ABA proposal may have much better potential at the Supreme Court because it better takes into account the Court’s expressed concerns.

The proposals to change Section 101 support the needs of individuals, non-profits, and corporations that own patents. They each face significant hurdles at the legislative and judicial review stages. They are not set in stone, and new ideas can be incorporated. However, as it stands now, the ABA proposal faces better prospects for adoption and survival, while still strongly supporting the needs of patent owners. Thus, this Note suggests support for the ABA proposal and the ideas therein.

V. CONCLUSION

The IPO, AIPLA, and ABA have formulated and proposed changes to 35 U.S.C. Section 101 with the purpose of limiting judicial exceptions to patent eligible subject matter. The Supreme Court explains its reasoning for the exceptions as a concern regarding the preemption by others of all uses of laws of nature, natural phenomena, and abstract ideas. The ABA proposal best limits the exceptions in a manner that is likely most acceptable to the Court by addressing its concern for preemption. Patent owners and applicants should thus support passage of legislation similar to the ABA proposal.

114. Josh Landau, *AIPLA Signs on to IPO’s Misguided Proposal on § 101*, PATENT PROGRESS (May 17, 2017), <https://www.patentprogress.org/2017/05/17/aip-la-signs-ipos-misguided-proposal/>.

115. IPO, *supra* note 63, at 1; AIPLA, *supra* note 64, at 4; Joint Proposal, *supra* note 64; ABA Letter, *supra* note 64.

