A CALL TO ACTION: FIXING THE JUDICIALLY-MURKIED WATERS OF 35 U.S.C. § 101

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INTRODUCTION

The Sequenom Center for Molecular Medicine, a wholly owned subsidiary of Sequenom, Inc., discovered a certain type of DNA present in pregnant women carrying babies with birth defects and patented a prenatal test[1] for those defects.[2] This diagnostic test was a "breakthrough" because it could determine the characteristics of a fetus *without having to take samples from either the fetus or the placenta*.[3]

A patent gives its holder the right to exclude others from making, using, or selling the patentee's invention.[4] The patent's claims, which are set off from the remainder of the document in a section that begins, "I" or "We Claim," define and limit that right to exclude. There are several statutory requirements that need to be fulfilled in order to obtain a patent.[5] These statutory requirements are codified at 35 U.S.C. §§ 101, 102, 103, and 112.[6]

For an invention to be patentable under 35 U.S.C. § 101, it must be new and useful, and it must fall into one of four broad categories.[7] These categories are: (1) process; (2) machine; (3) manufacture; and (4) composition of matter.[8] Processes are steps or acts that change the subject matter into something different.[9] A machine includes mechanical devices and other articles that have parts.[10] A manufacture is something "produced from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations."[11] A composition of matter is an article composed of two or more substances.[12] The language of § 101, on its face, renders this patent-eligibility statute a "coarse

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1. U.S. Patent No. 6,258,540 (issued July 10, 2001).

2. *The Science of Creating a Better Tomorrow*, SEQUENOM, https://www.sequenom.com/company#about-sequenom [https://perma.cc/KE2S-RHQY] (last visited Mar. 31, 2017).

3. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1381 (Fed. Cir. 2015), *reh'g en banc denied*, 809 F.3d 1282 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016).

4. 35 U.S.C. § 271 (2012).

5. *Id.* §§ 101-03, 112.

6. *Id.*

7. *Id.* § 101.

8. *Id.*

9. *Patent Subject Matter Eligibility*, USPTO, http://www.uspto.gov/web/offices/pac/mpep/s2106.html [https://perma.cc/XNN8-88H5] (last visited Apr. 1, 2017).

10. *Id.*

11. *Id.*

12. *Id.*

http://doi.org/10.18060/4806.1160

filter" and leaves the other patent statutes to act as a fine filter.[13]

However, the United States Supreme Court has created judicial exceptions that can operate to bar patenting an invention that meets the statutory requirements under § 101.[14] These exceptions relate to inventions that contain patent claims, which improperly encompass laws of nature, natural phenomena, and abstract ideas; all are not considered to be patent-eligible.[15] Commonly recited examples of such claims are those directed to newly discovered naturally occurring minerals, Einstein's mathematical equation "$E=mc^2$," and the law of gravity.[16]

An increased number of patents are being challenged and invalidated under 35 U.S.C. § 101.[17] For example, the United States Court of Appeals for the Federal Circuit (CAFC) recently held Sequenom's patent covering its diagnostic method to be patent-ineligible under § 101.[18] Many scholars and judges agree that Sequenom's claims likely were invalid under one of the other "finer" statutory filters such as § 112 instead of being unpatentable under § 101.[19] Nonetheless, the lower courts are bound by the Supreme Court's judicial exceptions and have no choice but to follow precedent.[20]

Sequenom is not alone; a similar scene is playing out in *Bristol-Myers Squibb v. Merck & Company, Inc*.[21] Bristol-Myers Squibb's (BMS) patent contains claims that cover methods of treating a cancer patient by administering antibodies against a particular endogenous protein.[22] In their motion to dismiss BMS' infringement claim, Merck asserted that BMS' patent claims cover ineligible subject matter.[23] Merck reasoned that the patent claims cover the result of natural phenomenon.[24] Specifically, Merck argued that BMS' treatment methods involve the body's natural reaction to the administered antibody.[25] In a promising development for BMS, the district denied Merck's motion to dismiss.[26] The court found the claims relate to natural phenomena, but the question of whether the

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13. Research Corp. Techs. v. Microsoft Corp., 627 F.3d 859, 869 (Fed. Cir. 2010).

14. Diamond v. Diehr, 450 U.S. 175, 185 (1981).

15. *Id.*

16. *Id.*

17. *See, e.g.*, Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1381 (Fed. Cir. 2015), *reh'g en banc denied*, 809 F.3d 1282 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016) (deciding a claim brought under § 101).

18. *Id.* at 1373.

19. *Sequenom*, 809 F.3d at 1286 (Lourie, J., concurring).

20. *Id.* at 1286-87.

21. No. 14-CV-00131, 2016 U.S. Dist. LEXIS 90532 (D. Del. July 13, 2016).

22. U.S. Patent No. 8,728,474 (issued May 20, 2014).

23. Defendants Reply Brief Supporting their Motion to Dismiss at 4, Bristol-Myers Squibb v. Merck, No. 15-560-GMS (D. Del. Oct. 14, 2015) (No. 1:15-cv-00560).

24. *Id.* at 1.

25. *Id*.

26. Bristol-Myers Squibb v. Merck, No. 15-560-GMS, 2016 WL 1072841, at *1 (D. Del. Mar. 17, 2016).

claims add "significantly more" to the natural phenomena should be determined after completion of fact and expert discovery.[27]

The end result of this battle will be interesting. As BMS argues, any medicinal treatment will involve the body's natural reaction to the antibody, and if a method of treatment is patent ineligible because it relies on the body's natural reaction to the drug, then "patent protection for medical treatments would be eviscerated."[28] As drafted, Sequenom's and BMS' claims likely would be unpatentable under one of the other patent statutes; however, those claims at least should pass the coarse filter of § 101.[29] *Sequenom* and *BMS* are just two recent examples of how the Supreme Court's § 101 holdings have created confusion and potentially devastating implications, most notably for the software, diagnostic, and pharmaceutical industries.[30]

The purpose of this Note is to address two recently proposed changes to the § 101 analysis. Part I of this Note broadly discusses the patent system and the statutory requirements for obtaining a patent, along with the problems associated with the Supreme Court's § 101 holdings. Part II provides an overview of cases brought under 35 U.S.C. § 101. Part III reviews two recent proposals on how to change the § 101 analysis and applies each proposal to *Sequenom*.

I. INTRODUCTION TO THE PATENT SYSTEM

Congress has been given authority from Article 1, Section 8 of the Constitution "[t]o 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."[31] Using this authority, Congress has created the patent system by establishing the United States Patent and Trademark Office (USPTO).[32]

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27. *Id.* at *1 n.1.

28. Plaintiff's Opposition to Defendants' Motion to Dismiss the Complaint for Failure to State a Claim at 9, Bristol-Myers Squibb v. Merck, No. 15-560-GMS (D. Del. Sept. 25, 2015) (1:15-cv-00560).

29. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1286 (Fed. Cir. 2015) (Lourie, J., concurring), *cert. denied*, 136 S. Ct. 2511 (2016).

30. *See, e.g.*, *Where Do We Stand One Year After Alice?*, LAW360 (June 17, 2015, 8:27 PM), http://www.law360.com/articles/668773/where-do-we-stand-one-year-after-alice [http://perma.cc/34NY-NDEU] (discussing the impact of *Alice Corp. v. CLS Bank* on industries such as the computer and biotechnology industries).

31. U.S. CONST. art. 1, § 8; *see, e.g.*, *General Information Concerning Patents*, USPTO (Oct. 2014), http://www.uspto.gov/patents-getting-started/general-information-concerning-patents [perma.cc/54LL-MNME] (providing background on the source of Congress' authority and how it has decided to exercise it).

32. *See, e.g.*, *General Information Concerning Patents*, USPTO (Oct. 2015), http://www.uspto.gov/patents-getting-started/general-information-concerning-patents [http://perma.cc/V3DS-YGNC] (discussing Congress' power to enact patent laws).

Patents are issued by the USPTO and grant a property right to the patentee.[33] This property right gives the patentee the right to exclude others from making, using, offering for sale, or selling the invention in the United States or importing the invention into the United States.[34]

The USPTO is the administrative agency that oversees the granting of patents and other patent-related matters.[35] The USPTO has substantively existed since 1802, and has been part of the Department of Commerce since 1905, where it remains today.[36] The USPTO employs patent examiners who review patent applications, communicate with applicants throughout patent prosecution, and issue valid patents.[37]

A. Statutory Requirements for Obtaining a Patent

To be valid and enforceable, a patent has to satisfy the statutory requirements set forth in 35 U.S.C. §§ 101, 102, 103, and 112.[38]

1. 35 U.S.C. § 101 (The Eligibility Requirement).—Section 101 is devoted to patent-eligible subject matter, and it provides: "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."[39]

Therefore, claims must cover a process, a machine, a manufacture, or a composition of matter, the subject matter must be new and useful, and someone must have invented or discovered the claimed subject matter.[40] One may think that meeting these criteria would satisfy all of the requirements of 35 U.S.C. § 101, as a facial reading of that statute suggests.[41] But the § 101 analysis is not so straightforward because the Supreme Court has created judicial exceptions to the parameters laid out in § 101.[42] According to Supreme Court precedent, laws of nature, natural phenomena, and abstract ideas are not patent-eligible.[43]

2. 35 U.S.C. § 102 (The Novelty Requirement).—Section 102 requires that

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33. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 730-31 (2002).

34. 35 U.S.C. § 271 (2012).

35. *General Information Concerning Patents*, *supra* note 32.

36. *Id.*

37. Sue A. Purvis, *The Role of the Patent Examiner*, USPTO (Apr. 8, 2013), http://www.uspto.gov/sites/default/files/about/offices/ous/04082013_StonyBrookU.pdf [https://perma.cc/RV9P-WV4B].

38. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1303 (2012).

39. 35 U.S.C. § 101 (2012).

40. *Id.*

41. *Id.*

42. *See, e.g.*, Diamond v. Diehr, 450 U.S. 175, 185 (1981) (citing Parker v. Flook, 437 U.S. 584, 584 (1978); Gottschalk v. Benson, 409 U.S. 63, 63 (1972); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)).

43. *Id.*

claims cover novel subject matter over the prior art.[44] The term "prior art," for the purposes of § 102, generally constitutes publications that are available to the public.[45] Examples of prior art include patents, patent applications, and journal articles.[46] Additionally, if the subject matter is available to the public through public use or if it is for sale, it is considered to be prior art for the purposes of this section.[47] For a § 102 analysis, if each element of a claim is known in one piece of prior art, then the claim is not novel.[48] Even if one element of a claim is missing from the piece of prior art, the claim will not be rejected under § 102.[49]

There are exceptions to what would be considered prior art, though.[50] For example, a patent with a named inventor is not considered prior art against a patent application if: (a) the later-filed patent application names the same inventor as the earlier-filed patent application; and (b) the later-filed patent application is filed within one year of the earlier-filed application.[51]

3. 35 U.S.C. § 103 (The Non-Obviousness Requirement).—Section 103 was enacted by the 1952 Patent Act and requires the differences between the claimed subject matter and the prior art to not be "obvious."[52] The standard for evaluating whether differences are "obvious" is to look at the differences through the lens of a "person of ordinary skill in the art."[53]

In the 1966 case *Graham v. John Deere*, the Supreme Court laid out the test for determining if a claim is obvious under § 103.[54] To determine if a claim is "obvious," the patent examiner or judge should: (1) determine the scope and the content of the prior art; (2) determine the differences between the prior art and the claims at issue; (3) establish the level of a person of ordinary skill in the art; and (4) take into account secondary considerations of non-obviousness, such as commercial success, unmet medical needs, and prior failures of others.[55]

Another test that has been used to determine "obviousness" is the teaching, suggestion, or motivation test (referred to as the TSM test).[56] The TSM test determines if the person of ordinary skill would have been motivated to combine the teachings of the prior art or if there is some suggestion in the prior art to

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44. 35 U.S.C. § 102 (2012).

45. *Id.*

46. *Id.*

47. *Id.*

48. *See, e.g.*, Verdegaal Bros. v. Union Oil Co. of Cal., 814 F.2d 628, 631 (Fed. Cir. 1987) (stating "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference").

49. *Id.*

50. 35 U.S.C. § 102 (2012).

51. *Id.*

52. *Id.* § 103.

53. *Id.*

54. Graham v. John Deere Co., 383 U.S. 1, 17 (1966).

55. *Id.*

56. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 407 (2007).

combine such teachings.[57] The CAFC applied the TSM test to determine non-obviousness in *KSR International Co. v. Teleflex Inc*.[58] Teleflex, the assignee of a patent with claims covering a mechanism for combining an electronic sensor and an adjustable car pedal, brought an infringement suit against KSR.[59] KSR had also developed an adjustable car pedal system.[60] Contrary to the holding by the CAFC, the Supreme Court rejected the narrow and rigid use of the TSM test employed by the CAFC and implemented an "obvious to try" standard.[61]

If a combination is "obvious to try," then it could signal that the claim is obvious under § 103.[62] For instance, a claim may be "obvious to try" if there is commercial pressure to solve a problem and: (1) there is only a finite and limited number of solutions that already are identified in the prior art; (2) the solutions are predictable; and (3) a person of ordinary skill in the art would have anticipated success with the solutions.[63] Consequently, in *KSR*, the Court upheld the use of the *Graham* factors in deciding non-obviousness under § 103, wherein the second *Graham* factor encompassed an "obvious to try" test.[64]

4. 35 U.S.C. § 112 (The Written Description, Enablement, and Best Mode Requirements).—Section 112 contains the written description, enablement, and best mode requirements.[65] This section requires the specification in the application to contain such "full, clear, concise, and exact terms" as to enable a person of skill in the art to make and use the invention.[66] Further, it must contain a written description of the claimed invention and describe the best mode for practicing the invention.[67]

In *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, Ariad brought suit against Eli Lilly and Co. for infringement of its patent covering methods of inhibiting a protein that plays a role in the immune response.[68] The CAFC held 35 U.S.C. § 112 has separate requirements for enablement and for the written description.[69] Phrased differently, the specification should show to the public that the inventor actually invented the claimed subject matter.[70] Here, the court held the claims directed to all methods of inhibiting a particular protein were invalid for lack of

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57. *Id.* at 405.
58. *Id.* at 407.
59. *Id.* at 405.
60. *Id.* at 399.
61. *Id.* at 415.
62. *Id.* at 421.
63. *Id.*
64. *Id.* at 415; *see generally* Douglas L. Rogers, *Federal Circuit's Obviousness Test for New Pharmaceutical Compounds: Gobbledygook?*, 14 CHI.-KENT J. INTELL. PROP. 49 (2014).
65. 35 U.S.C. § 112 (2012).
66. *Id.*
67. *Id.*
68. 598 F.3d 1336, 1340 (Fed. Cir. 2010).
69. *Id.*
70. Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997).

written description.[71] The court reasoned that the specification only disclosed, at best, molecule structures.[72] In fact, the specification did not disclose different species that would support a claim for a genus of compounds.[73]

In *Regents of University of California v. Eli Lilly & Co.*, the University of California filed suit against Lilly for infringing its patent covering cDNA encoding *mammalian* insulin.[74] cDNA contains only the DNA exons, as opposed to DNA, which contains both exons and introns.[75] The CAFC stated that, for claims encompassing cDNA, the written description needs to have a "precise definition" and should include structure(s), formula(s), or other specific characteristics.[76] In *Lilly*, the court therefore held the University of California's claims, which covered cDNA encoding *mammalian* insulin, were invalid because the specification described only *rat* insulin cDNA.[77] A person of skill in the art could not recognize the members of the claimed genus (i.e., mammalian insulin).[78] To show the invention of a genus, one needs to do more than simply describe the boundaries of the genus.[79]

B. 35 U.S.C. § 101 as a "Coarse Filter"

The intent of Congress was that "statutory subject matter [is] to include anything under the sun that is made by man."[80] The 1952 Patent Act also added the words "or discovered" into the definition of "invention" in § 100(a) so that the distinction between "discovered" and "invented" was considered irrelevant.[81] The term "invention" in § 100(a) now "means invention or discovery."[82] The Senate Report on the 1952 Patent Act explains that 35 U.S.C. § 103, the obviousness requirement, has existed for over a century, but only because it was created by the courts.[83] The 1952 Act then implemented an "obviousness" test that is now found in § 103.[84]

However, the courts continue to blur the lines between the different patent statutes.[85] There are many reasons 35 U.S.C. § 101 should be kept as a coarse

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71. *Ariad Pharms.*, 598 F.3d at 1358.
72. *Id.*
73. *Id.* at 1350.
74. 119 F.3d 1559, 1563 (Fed. Cir. 1997).
75. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2109 (2013).
76. Eli *Lilly & Co.*, 119 F.3d at 1568.
77. *Id.* at 1567.
78. *Id.* at 1568-69.
79. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1340 (Fed. Cir. 2010).
80. Diamond v. Diehr, 450 U.S. 175, 185 (1981) (internal quotations omitted); CLS Bank Int'l v. Alice Corp. Pty., 717 F.3d 1269, 1295 (Fed. Cir. 2013).
81. *Alice*, 717 F.3d at 1295.
82. 35 U.S.C. § 100(a) (2012).
83. S. REP. NO. 82-1979, at 2397, 99 (1952).
84. *Alice*, 717 F.3d at 1296.
85. *See, e.g.*, Alan J. Heinrich & Christopher T. Abernethy, *The Myriad Reasons to Hit*

filter, particularly during litigation.[86] For instance, assessing the eligibility of the subject matter via § 101 at the beginning of litigation can reduce resources spent on claim construction.[87] Second, if the claim is found to be patent-ineligible under § 101, both parties will save time and money by not having to proceed through the litigation.[88] Using § 101 as a coarse filter is also beneficial during patent prosecution.[89] By efficiently eliminating patent claims through a 101 filter, there will be more resources for examiners in the United States Patent and Trademark Office.[90] The requirements under §§ 102, 103, and 112 should be kept separate from an analysis under § 101.[91]

C. United States Patent and Trademark Office's Attempts to Provide Meaningful Guidance

The USPTO occasionally publishes guidance materials to assist its employees in determining subject matter eligibility under § 101.[92] The first guidance was published in December of 2014.[93] In July of 2015, the USPTO issued an update to the 2014 guidance,[94] and in May of 2016, Deputy Commissioner Robert Bahr issued a memorandum to assist examiners in applying the 2014 guidelines.[95]

The USPTO guidance provides a flow chart with the steps an examiner should take when evaluating whether claims are eligible under § 101.[96] Step one is to determine if the claim falls into one of the four statutory categories of

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"Reset" on Patent-Eligibility Jurisprudence, 47 LOY. L.A. L. REV. 117, 209 (2013) (arguing the Supreme Court is reading a time element into 35 U.S.C. § 101 that is found in 35 U.S.C. § 103).

86. *See, e.g.*, Research Corp. Techs. v. Microsoft Corp., 627 F.3d 859, 869 (Fed. Cir. 2010).

87. *See, e.g.*, I/P Engine, Inc. v. AOL Inc., 576 Fed. App'x 982, 992 (Fed. Cir. 2014) (nonprecedential) (Mayer, J., concurring).

88. *Id.*

89. *Id.*

90. *Id.*

91. *See generally* Joshua A. Kresh, *Patent Eligibility After Mayo: How Did We Get Here and Where Do We Go?*, 22 FED. CIR. B.J. 521 (2012-2013).

92. *2014 Interim Guidance on Subject Matter Eligibility*, USPTO, http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0 [perma.cc/93K3-C6QX] (last visited Apr. 3, 2017).

93. *Id.*

94. *July 2015 Update: Subject Matter Eligibility*, USPTO, http://www.uspto.gov/sites/default/files/documents/ieg-july-2015-update.pdf [perma.cc/YE7E-ZVFF] (last visited Apr. 3, 2017).

95. Memorandum: Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant's Response to a Subject Matter Eligibility Rejection, USPTO (May 4, 2016), https://www.uspto.gov/sites/default/files/documents/ieg-may-2016-memo.pdf [https://perma.cc/64QE-JHQK].

96. *2014 Interim Eligibility Guidance Quick Reference Sheet*, USPTO, http://www.uspto.gov/patents/law/exam/2014_eligibility_qrs.pdf [perma.cc/EMT6-EWRG] (last visited Apr. 3, 2017).

process, machine, manufacture, or composition of matter, that are required for eligibility.[97] If the claims do not fall into one of these four categories, they are automatically deemed ineligible subject matter.[98] If they do fall into one of these categories, then the examiner must ask if the claims are directed to one of the judicial exceptions of either law of nature, natural phenomenon, or an abstract idea.[99] If the claims do not fall into one of these exceptions, then they are eligible under § 101.[100] If the claims fall within one of these exceptions, the examiner must ask if there are additional elements in the claim that make the claim "significantly more than the judicial exception."[101] These steps are derived from the two-part test that the Court set out in *Mayo*.[102]

D. A Call for Change

Although the USPTO tries to clarify its patent eligibility analysis for its examiners, its guidance does not lead to a complete understanding of the patent eligibility requirements for patent applicants.[103] In its most recent attempt, the USPTO posted an October 17, 2016 Federal Register Notice requesting the public's thoughts on specific parts of patent subject matter eligibility.[104] In response, organizations such as the American Bar Association (ABA) and the American Intellectual Property Law Association (AIPLA) voiced their concerns about the current state of § 101 jurisprudence.[105]

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97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.*

102. *Id.*

103. *See, e.g.*, *2014 Interim Guidance on Subject Matter Eligibility*, *supra* note 92.

104. *Notice of Roundtables and Request for Comments Related to Patent Subject Matter Eligibility*, FED. REG. (Oct. 17, 2016), https://www.federalregister.gov/documents/2016/10/17/2016-24888/notice-of-roundtables-and-request-for-comments-related-to-patent-subject-matter-eligibility [https://perma.cc/5WD7-VTX3].

105. Am. B. Ass'n, *Re: Request for Comments Related to Patent Subject Matter Eligibility*, USPTO (Jan. 18, 2017), https://www.uspto.gov/sites/default/files/documents/RT2%20Comments%20ABA-IPL.pdf [https://perma.cc/YC49-HRG7] ("[T]he current jurisprudence on patent eligibility under section 101 is confusing, creates uncertainty as to the availability and enforceability of patent assets, arguably risks the incentive to innovate provided by patents in technologies in which U.S. industry has historically led the world, and potentially places the U.S. in a less advantageous position on patent protection than our leading competitor nations."); Am. Intell. Prop. L. Ass'n, *Re: Comments of the AIPLA on Notice of Roundtables and Request for Comments Related to Patent Subject Matter Eligibility, 81 Fed. Reg. 71485, 10/17/2016*, USPTO (Jan. 18, 2017), https://www.uspto.gov/sites/default/files/documents/comments_aipla_jan182017.pdf [https://perma.cc/3W2E-RRRC] (answering question about "[w]hat particular inventions or specific types of technologies that should be patent eligible are not patent eligible, or are likely to be challenged as patent ineligible, under *Mayo/Myriad*," by responding: "Every invention relating to or involving the life

Numerous scholars have published on § 101.[106] The United States Supreme Court's judicially-created exceptions[107] to § 101, coupled with the conflation of § 101 with the other patent statutes,[108] have resulted in a disproportionate impact on certain fields, such as the computer software, diagnostic, pharmaceutical, and biotechnology industries.[109] In fact, what constitutes patent-eligible subject matter changes over time with Supreme Court holdings.[110] This has created some uncertainty in the patent system and has left the bounds of what is patent-eligible ambiguous.[111] The impact of these Supreme Court cases are leading to particular industries relying more and more on trade secret, instead of patent protection, to protect its intellectual property.[112] This defeats the purpose of the § 101 coarse filter in encouraging innovation and public disclosure.[113]

Moreover, scholars point out that many of the claims found ineligible under § 101 could have been found unpatentable under 35 U.S.C. §§ 102, 103, or 112.[114] For example, claims directed to combining different strains of bacteria should have been held unpatentable under § 103 rather than ineligible under § 101.[115] Other examples include claims held to be ineligible under § 101 that lacked enablement or written description and therefore should have been rejected under § 112, or claims that would have been rejected more appropriately under

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sciences is likely to be challenged and could be found ineligible under the overreaching and malleable *Mayo* test.").

106. *See, e.g.*, Heinrich & Abernethy, *supra* note 85, at 117; Joshua D. Sarnoff, *Patent-Eligible Inventions After Bilski: History and Theory*, 63 HASTINGS L.J. 53 (2011); Kresh, *supra* note 91, at 521; Bruce D. Sunstein, *How Prometheus Has Upended Patent Eligibility: An Anatomy of* Alice Corporation Proprietary Limited v. CLS Bank International, 49 NEW ENG. L. REV. 1 (2014) (discussing Supreme Court holdings on § 101).

107. Diamond v. Diehr, 450 U.S. 175, 185 (1981).

108. *See, e.g.*, Heinrich & Abernethy, *supra* note 85, at 157 (discussing the concern with conflating patent eligibility with novelty and obviousness in *Flook*).

109. *See, e.g.*, *Where Do We Stand One Year After* Alice*?*, *supra* note 30 (discussing the impact of *Alice Corp. v. CLS Bank* on industries such as the computer and biotechnology).

110. Brandon Smith, *The Patentability of Human Embryonic Stem Cells in Light of Myriad*, 96 J. PAT. & TRADEMARK OFF. SOC'Y 112, 113 (2014).

111. *See, e.g.*, Kresh, *supra* note 91, at 522.

112. *Id.* (describing that many industries are turning to trade secret to protect their intellectual property).

113. *See, e.g.*, Courtenay C. Brinckerhoff, *Judge Rader Explains 35 USC 101 in* Ultramercial v Hulu, PHARMAPATENTS (June 24, 2013), https://www.pharmapatentsblog.com/2013/06/24/judge-rader-explains-35-usc-101-in-ultramercial-v-hulu/ [https://perma.cc/F6NU-BDZP] ("[T]he purpose of the Patent Act is to encourage innovation, and the use of broadly inclusive categories of statutory subject matter ensures that ingenuity . . . receive[s] a liberal encouragement.") (internal quotation marks omitted) (quoting Ultramercial, Inc. v Hulu, LLC, 722 F.3d 1335, 1341 (Fed. Cir. 2013), *vacated sub nom.* WildTangent, Inc. v. Ultramercial, LLC, 134 S. Ct. 2870 (2014)).

114. Kresh, *supra* note 91, at 544-45.

115. *Id.* at 545 (referring to Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948)).

§ 102.[116] In fact, one study found that ninety-four percent of claims questioned at the Board of Patent Appeals and Interferences on § 101 grounds also were rejected under §§ 102, 103, or 112.[117] It can also be argued that all patents rely on laws of nature and that the Supreme Court's decision in *Mayo* (discussed below) could conceivably lead to more patents being challenged under § 101.[118]

In denying rehearing en banc in *Sequenom*,[119] Judges Lourie and Dyk concurred,[120] and Judge Newman dissented.[121] Judges Lourie and Dyk concurred, at least in part, because they were bound by the broad language in the Supreme Court's opinion in *Mayo*.[122] This view is consistent with Judge Linn's concurrence in the panel's opinion.[123] Judge Lourie gave weight to arguments that the panel's decision in *Sequenom* could put the diagnostics industry at great risk.[124] In her dissent, Judge Newman argued that Sequenom's "breakthrough" discovery is not patent-ineligible, but warrants an analysis under the other patentability requirements.[125] The concurring opinions and dissent in the denial of a rehearing en banc add fuel to the fire to the suggestion that the lower courts were seeking guidance.[126]

II. REVISITING HISTORY: UNITED STATES SUPREME COURT DECISIONS BASED ON 35 U.S.C. § 101

A. The Early Cases

1. Funk Bros. Seed Co. v. Kalo Inoculant Co.—In the 1948 case *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, the Supreme Court held the discovery of phenomena of nature is not patent-eligible subject matter.[127] Kalo had granted patent claims for a mixed culture of root-nodule bacteria.[128] This combination of naturally occurring bacteria did not mutually inhibit one another and could be used as an inoculant in order to increase the efficiency of nitrogen-fixing of

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116. *Id.*

117. *Id.* at 543.

118. *Id.* at 539-40.

119. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1284 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016).

120. *Id.* at 1284 (Lourie, J., concurring); *id.* at 1287 (Dyk, J., concurring).

121. *Id.* at 1293 (Newman, J., dissenting).

122. *Id.* at 1284 (Lourie, J., concurring); *id.* at 1287 (Dyk, J., concurring).

123. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1381 (Fed. Cir. 2015) (Linn, J., concurring), *reh'g en banc denied*, 809 F.3d 1282 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016).

124. *Sequenom*, 809 F.3d at 1285 (Lourie, J., concurring).

125. *Id.* at 1294 (Newman, J., dissenting).

126. *See generally id.*

127. 333 U.S. 127, 132 (1948).

128. *Id.* at 130.

certain plants.[129] Kalo brought suit against Funk Bros. for infringement, and Funk Bros. filed a counterclaim for a declaratory judgment that the claims were invalid.[130]

In holding the claims were not patent-eligible, the Court found the discovery of non-mutual inhibition is the discovery of a product of nature and therefore is not patentable.[131] Each species of bacteria was the same as what was found in nature, and the bacteria acted like they normally did in nature.[132] The bacteria did not have any new properties outside of those that were naturally occurring.[133]

The Court reasoned that the bacteria were essentially laws of nature and that these laws of nature should be made available to everyone.[134] If such a discovery were to be an invention, there would have to be a new and useful application of the discovery.[135] Interestingly, even though the Court recognized that the bacteria were mixed together and served some new advantageous purpose for the farmer, the Court still found that there was no change or improvement in the way that the bacteria function in nature.[136] The majority ultimately held the claims were not patent-eligible because the mixture of naturally-occurring strains of bacteria was not a "discovery" or "invention" as those terms are used in the statute.[137]

In his concurring opinion, Justice Frankfurter cautioned about using the terms "laws of nature" and "work of nature."[138] He argued that every patentable material has "the laws of nature" in its properties.[139] For example, compounds and materials such as multi-purpose tools and vitamin complex composites have new properties as a result of a combination of known properties.[140] Therefore, to use the terms "the work of nature" and the "laws of nature" is risky because it could lead to practically every patent being challenged for being ineligible.[141] Justice Frankfurter cautioned about creating criteria that would lead to harmful implications for the patentability of future inventions.[142]

2. Diamond v. Chakrabarty.—In contrast to *Funk Bros*., the Supreme Court held in *Diamond v. Chakrabarty* that genetically-modified (man-made) organisms qualified as patentable subject matter.[143] Chakrabarty filed suit against Diamond for infringement of its claims directed to a genetically engineered bacteria that

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129. *Id.*
130. *Id.* at 128.
131. *Id.* at 131.
132. *Id.*
133. *Id*.
134. *Id.* at 130.
135. *Id.*
136. *Id.* at 131.
137. *Id.* at 132.
138. *Id.* at 134-35 (Frankfurter, J., concurring).
139. *Id.* at 135.
140. *Id.*
141. *Id.* at 136.
142. *Id.* at 135.
143. 447 U.S. 303, 305 (1980).

could break down crude oil.[144] The Court stated that a man-made organism is a "manufacture" or "composition of matter"; therefore, the genetically engineered bacteria fell into one of the categories required for patent eligibility under § 101.[145]

The Court reasoned that "manufacture" and "composition of matter" should be defined broadly,[146] and by choosing these terms, Congress intended that patent laws be interpreted broadly.[147] The Patent Act of 1793 defined eligible subject matter such that it reflected Thomas Jefferson's belief that people should be encouraged to invent.[148] When the patent laws were recodified in 1952, "art" was replaced with "process," but everything else remained the same as it was in the Patent Act of 1793.[149] This provided rational insight into Congress's desire to keep Thomas Jefferson's interest in subject matter eligibility alive.[150] The Court stated that Congress intended for eligible subject matter to include anything that is man-made.[151]

The Court further asserted that § 101 was written to be interpreted broadly; and therefore, should be interpreted by courts according to the statutory purpose of promoting inventions, as is afforded by the Constitution itself.[152] The Court also cautioned that courts should not add limitations into patent laws that Congress has not conveyed.[153] The Court reasoned that *Chakrabarty* differed from *Funk Bros.* in that *Chakrabarty* involved a new bacterium that was different from any naturally occurring bacterium, and it had potential for significant use in the crude oil industry.[154]

B. The Patent-Eligibility Trilogy[155]

Three hallmark Supreme Court cases dealt with the use of the machine-or-transformation test when determining patent eligibility.[156] These three cases,

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144. *Id.*

145. *Id.*

146. *Id.* at 308.

147. *Id.*

148. *Id.*

149. *See, e.g.*, *id.* at 308-09 (stating the definition of eligible subject matter prior to the 1952 Patent Act was "any new and useful *art*, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]") (emphasis added) (internal quotation marks omitted) (quoting Patent Act of 1793, ch. 11, 1 Stat. 319 (1793)).

150. *Id.*

151. *Id.* at 309.

152. *Id.* at 315.

153. *Id.* at 308.

154. *Id.* at 310.

155. Tup Ingram, Association for Molecular Pathology v. Myriad Genetics, Inc.*: The Product of Nature Doctrine Revisited*, 29 BERKELEY TECH. L.J. 385, 387 (2014).

156. *Id.*

which are known as the patent-eligibility trilogy, are *Gottschalk v. Benson*,[157] *Parker v. Flook*,[158] and *Diamond v. Diehr*.[159] These cases formed the rule that a claim contains patent-eligible subject matter if the process is carried out by a conventional machine by non-conventional means, or if the process transforms an article from one state to another.[160]

1. Gottschalk v. Benson.—In 1972, the Court in *Benson* held claims covering a method for converting binary-coded decimal numbers into binary numbers were invalid under § 101.[161] The Court reasoned that the claims covered an idea, and if the claims were not held invalid, they would wholly preempt the mathematical algorithm.[162] The method described in the claims at issue was so broad and abstract that it would cover even unknown uses of the conversion method.[163] The claims were abstract ideas.[164] The method was not a "process" within the meaning of the Patent Act.[165] The Court further stated that transforming an article into something different is key to the patentability of a process claim that lacks a specific machine.[166] If no particular machine is included in a process claim, the claim is likely of eligible subject matter if the article is transformed to a different state or thing.[167]

2. Parker v. Flook.—In 1978, the Court in *Flook* analyzed the patentability of claims covering a method of updating alarm limits.[168] The method included the use of a computer algorithm step that differed from what already was known in the art.[169] The Court held the claims were not patentable subject matter because the application provided only a new method for calculating alarm limit values.[170] The Court reasoned that even if natural phenomena are well-known in the art, natural phenomena still might be patent-eligible if there is an "inventive application."[171] However, post-solution activity that is conventional or obvious cannot by itself transform patent-ineligible subject matter into eligible subject matter.[172] The Court stated that a court must determine if the claims contain

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157. 409 U.S. 63 (1972).

158. 437 U.S. 584 (1978).

159. 450 U.S. 175 (1981).

160. Lawrence Ashery, *Death of the Software Patent? It Doesn't Have to Be*, LEGAL INTELLIGENCER (May 7, 2014), http://ratnerprestia.com/blog/?p=2251 [http://perma.cc/V6KA-VT2T].

161. 409 U.S. at 71.

162. *Id.* at 72.

163. *Id.* at 68.

164. *Id.*

165. *Id.* at 64.

166. *Id.* at 70.

167. *Id.* at 70.

168. 437 U.S. 584, 584 (1978).

169. *Id.*

170. *Id.* at 594-95.

171. *Id.* at 594.

172. *Id.* at 590.

patent-eligible subject matter prior to determining if the discovery is new or obvious.[173] However, Justice Stewart, in his dissent, cautioned that this decision expanded § 101 to include the criteria of novelty and inventiveness.[174]

3. Diamond v. Diehr.—Finally, in 1981, the Court held in *Diamond* that claims covering a process for curing rubber with a process that uses a computer algorithm were eligible subject matter.[175] The Court reasoned that these claims involved the transformation of rubber and that these types of processes traditionally have been eligible.[176] As the Court pointed out, just because there is a mathematical equation and a digital computer involved in the process, it does not mean that the claim contains ineligible subject matter.[177] The Court emphasized that claims must be considered as a whole and that one cannot divide claims into old and new parts.[178] Even if all parts of a process are known, it is necessarily ineligible subject matter.[179] Similar to Justice Stewart's dissent in *Flook*, the Court in *Diamond* stated that novelty should not be considered under § 101.[180] The Court in *Diamond* reasoned that the claims may be found to be unpatentable in the future under §§ 102 or 103, but this is independent of the § 101 analysis.[181]

Under the Supreme Court's § 101 holdings, claims that include laws of nature, natural phenomena, and abstract ideas are patent-ineligible.[182] Laws of nature are free for all to use.[183] Examples are new minerals, new plants, $E=mc^2$, and the law of gravity.[184] The Court in *Diamond* reiterated that Congress intended for statutory subject matter to include anything made by man.[185]

C. The Later Cases

1. Bilski v. Kappos.—In 2010, the Court in *Bilski v. Kappos* signaled a change from the patent-eligibility trilogy.[186] In *Bilski*, the claims at issue covered a procedure that helped customers protect themselves against price fluctuations, and they included instructions on how to reduce risk, along with a mathematical

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173. *Id.* at 593.

174. *Id.* at 600 (Stewart, J., dissenting).

175. Diamond v. Diehr, 450 U.S. 175, 177 (1981).

176. *Id.* at 184.

177. *Id.* at 187.

178. *Id.* at 180-81, 188.

179. *Id.* at 188.

180. *Id.* at 191.

181. *Id.*

182. *See, e.g.*, *id.* at 185 (citing Parker v. Flook, 437 U.S. 584, 584 (1978); Gottschalk v. Benson, 409 U.S. 63, 67 (1972); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)).

183. *Id.* (citing Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

184. *Id.*

185. *Id.* at 182 (internal quotation marks omitted).

186. 561 U.S. 593 (2010).

formula.[187] The CAFC held the machine-or-transformation test was the only test that should be used to determine if a process contains eligible subject matter.[188] However, the Supreme Court rejected the machine-or-transformation test as the sole test.[189] The Court held these claims to be ineligible subject matter because they contained abstract ideas.[190] The Court reasoned that new technologies in today's era might require different tests than the machine-or-transformation test.[191] Specifically, the Court stated that the machine-or-transformation test may have made sense for processes in the Industrial Age, but did not necessarily make sense for processes in the modern Information Age.[192] The Court added that the machine-or-transformation test still could be used as a useful clue, although it should not be used as the sole test.[193] The Court then reiterated that § 101 is "only a threshold test," and the claimed invention must also pass the requirements found in 35 U.S.C. §§ 102, 103, and 112.[194]

2. Mayo Collaborative Services v. Prometheus Laboratories, Inc.—Prometheus was the sole exclusive licensee for two patents that had process claims for treating patients having an autoimmune disease. The claims comprised an "administering" step, a "wherein" step, and "determining" step.[195] The "administering" step refers to the doctors.[196] The "wherein" step tells the doctor to take the "relevant natural laws" into account when treating a patient, and the "determining" step tells the doctor to measure the level of the metabolites in the blood through no specified means.[197]

Mayo filed an infringement action, and following remand in light of *Bilski*, the CAFC held the claims were patent-eligible because the claims were not claims of laws of nature nor did the claims preempt natural law.[198] However, in a 2012 unanimous decision, the Supreme Court held Prometheus' claimed process of treating patients having an autoimmune disease with thiopurine drugs was not patent-eligible.[199] The Court stated that a process that focuses on natural phenomena must contain an "inventive concept," such as other elements.[200] Since the claimed processes at issue in this case were routine and conventional, there

187. *Id.* at 599.

188. *Id.* at 598.

189. *Id.* at 605-06.

190. *Id.* at 612.

191. *Id.* at 606.

192. *Id.* at 605.

193. *Id.* at 603.

194. *Id.* at 602.

195. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1295 (2012) (citing U.S. Patent No. 6,355,623 (filed Apr. 8, 1999)).

196. *Id.* at 1291.

197. *Id.* at 1297-98.

198. *Id.* at 1296.

199. *Id.* at 1291.

200. *Id.* at 1294.

was no "inventive concept."[201]

Taken as a whole, the steps did no more than each step individually added together. Therefore, the steps did not transform the natural phenomena into patent-eligible claims.[202] The Court was concerned that the claims would restrict the doctor's treatment decision and inhibit the development of better treatment options.[203] The resulting *Mayo* two-step test is as follows: determine (1) if the invention covers a patent-ineligible idea; and (2) whether the elements of the claim transform the claim into patent-eligible subject matter.[204]

3. Ass'n for Molecular Pathology v. Myriad Genetics, Inc.—In 2013, the Court in *Myriad* held claims covering DNA are not patent-eligible, but claims covering cDNA are patent-eligible.[205] The claims at issue covered isolated DNA and complementary DNA (cDNA), and the CAFC was split on the issue of whether isolating DNA is an inventive act. [206] Judge Lourie found the DNA claims were patent-eligible because isolated DNA is chemically different from natural DNA.[207] Specifically, the BRCA1 and BRCA2 DNA are natural phenomena, but once the DNA is isolated by a human, it is no longer the same DNA that is found in nature.[208] Myriad's discovery was determining the location and sequence of the BRCA1 and BRCA2 genes, and the Court held simply removing the gene from its surrounding material was not inventive.[209]

4. Alice Corp. v. CLS Bank International.—In 2014, after a divided CAFC opinion, the Supreme Court in *Alice* held claims covering a computerized method for reducing settlement risk were not patent-eligible because the claims were an abstract idea.[210] The dissent, in a divided en banc CAFC, argued that the claims were patent-eligible because a requirement of something more than novelty is only found in 35 U.S.C. § 103.[211] The Supreme Court, however, explained that if the claims are directed to natural phenomena or abstract ideas, then a court should ask if there is anything else in the claim.[212] This search for an inventive concept includes considering the elements of the claim individually and as a combination to see if there is an element that transforms the natural phenomena into something that is patent-eligible.[213] Comparing *Alice* to *Mayo*, *Flook*, and

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201. *Id.*

202. *Id.* at 1298.

203. *Id.* at 1302.

204. Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2353 (2014).

205. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2111 (2013).

206. *Id.* at 2113-14.

207. *Id.* at 2114-15.

208. *Id.* at 2118.

209. *Id.* at 2116-17.

210. Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2351-52 (2014).

211. CLS Bank Int'l v. Alice Corp., 717 F.3d 1269, 1292, 1294 (Fed. Cir. 2013) (Rader, C.J., dissenting), *aff'd*, 134 S. Ct. 2347 (2014).

212. *Alice*, 134 S. Ct. at 2355.

213. *Id.* (internal quotations omitted).

Diehr, the Court in *Alice* dissected the claim into each element and concluded each element was routine and conventional.[214]

5. Ariosa Diagnostics, Inc. v. Sequenom, Inc.—In its 2015 *Sequenom* decision, a panel on the CAFC held claims covering methods of using cell-free fetal DNA found in maternal plasma and serum were not patent-eligible.[215] The claims at issue included making a prenatal diagnosis based on detected DNA inherited from the biological father.[216] The court performed the test found under *Mayo* and determined the claims were directed to patent-ineligible material because the method began and ended with natural phenomena, and the elements of the claim did not transform the natural phenomena into a claim that was patent-eligible.[217] In his concurring opinion, Judge Linn voiced his concern with the holding because it rested on the broad language the Supreme Court used in *Mayo*, making the claims ineligible. [218] Otherwise, Judge Linn saw nothing in policy or in statute indicating why the "breakthrough invention" should be ineligible.[219] Rehearing en banc subsequently was denied.[220] As a further blow to Sequenom and the proponents of a judicially-created change in the § 101 analysis, the Supreme Court denied certiorari in June 2016.[221]

III. ANALYSIS OF PROPOSED CHANGES OF A 35 U.S.C. § 101 ANALYSIS

The Supreme Court has dug itself into a hole with its judicially-created exceptions to § 101[222] so much so that some commentators have even proposed completely eliminating the statutory categories in § 101.[223] Although this suggestion may be going a little too far,[224] two examples of other proposed changes to the 35 U.S.C. § 101 analysis include codifying the exceptions[225] and eliminating the exceptions through a new two-step framework.[226]

A. Codifying the Judicial Exceptions

One proposed change to 35 U.S.C. § 101 relates to the statute's application

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214. *Id.* at 2357-59.

215. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1376-77 (Fed. Cir. 2015), *reh'g en banc denied*, 809 F.3d 1282 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016).

216. *Id.* at 1373.

217. *Id.* at 1375-76.

218. *Id.* at 1380 (Linn, J., concurring).

219. *Id.* at 1381.

220. *Sequenom*, 809 F.3d at 1284.

221. *Sequenom*, 136 S. Ct. 2511.

222. Diamond v. Diehr, 450 U.S. 175, 185 (1981).

223. Aaron J. Zakem, *Rethinking Patentable Subject Matter: Are Statutory Categories Useful?*, 30 CARDOZO L. REV. 2983, 3012 (2009).

224. *See, e.g.*, Kresh, *supra* note 91, at 545 (explaining there are things such as books that should not be patent-eligible because they are better protected under copyright laws).

225. Smith, *supra* note 110, at 114.

226. Heinrich & Abernethy, *supra* note 85, at 224.

to the patentability of embryonic stem cells in light of *Myriad*.[227] In a recent 2014 article, associate Brandon Smith reasons that, post-*Myriad*, it is unlikely that claims covering purified embryonic stem cells would be patent-eligible because they simply are purified from their natural environment.[228] Smith addresses the uncertainty regarding just how far the Court might extend its holding in *Myriad*, [229] such as whether purified embryonic stem cells are eligible subject matter after *Myriad*.[230]

Regardless of whether or how far the Court extends its holding in *Myriad* to embryonic stem cells, uncertainty in the patent field does not promote innovation.[231] For example, assuming that the *Myriad* decision extends to embryonic stem cells and purified embryonic stem cells are found to be patent-ineligible,[232] Smith reasons that it is plausible scientists might modify the stem cells in such a way that they would then become patent-eligible.[233] In other words, scientists may incorporate an inventive step to overcome a rejection under § 101.[234] However, researchers likely would be less interested in these stem cells because of their unnatural characteristics.[235] The uncertainty regarding how far the *Myriad* holding might extend could dampen life-altering innovation in the medical field, raising the need for more clarity regarding the judicially-created exceptions to § 101.[236]

Smith proposes changes to both 35 U.S.C. §§ 101 and 100.[237] Specifically, Smith proposes to codify the judicially-created exceptions under a proposed new § 101(b), titled "Exceptions," which would read, "Products of nature, natural laws, and abstract ideas shall not be patentable subject matter unless modified by an inventive step."[238] The current § 101 then would be § 101(a).[239] Smith argues that leaving the current language in § 101, which would be called 101(a), is ideal because it would not upset precedent.[240]

However, Smith's proposed § 101(b) admittedly will still lead to confusion over what is an "inventive step."[241] To clarify the meaning of "inventive step," Smith's proposed new § 100(k) would provide a definition of "inventive step" and read as follows: "An inventive step is (1) a step that is not conventional,

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227. Smith, *supra* note 110, at 114.
228. *Id.* at 133.
229. *Id.* at 134.
230. *Id.* at 114.
231. *Id.* at 134.
232. *Id.* at 133.
233. *Id.*
234. *Id.*
235. *Id.*
236. *Id.* at 134.
237. *Id.* at 136.
238. *Id.* (internal quotations omitted).
239. *Id.*
240. *Id.*
241. *Id.*

routine, or well understood in the art and (2)(a) that is part of the claimed invention or (b) that causes the claimed invention to have markedly different characteristics from a product of nature, natural law, or abstract idea."[242]

Smith states that new § 101(b) is somewhat similar to an inquiry under § 103.[243] However, new § 101(b) would differ from § 103 in that under § 101(b), the courts would have to determine if the inventive step is conventional in the art and not obvious in light of the prior art.[244] Under this new framework, drafters may be more likely to claim the characteristics that result from the inventive step, especially if the method of purification of the product (e.g., embryonic stem cells) is routine and conventional.[245] If a drafter were to claim the characteristics resulting from an inventive step, it is likely that a routine purification step would not render a claim patent-ineligible.[246]

The above-outlined proposed statutory change is similar to what the European Patent Office (EPO) tried to do for their patent eligibility requirements.[247] In 2007, the EPO specifically excluded a list of subject matter categories, including "scientific theories and mathematical methods, aesthetic creations, rules and methods for performing mental acts, for playing games or for doing business, programs for computers, and presentations of information."[248]

The exclusion of specific subject matter buckets by the EPO seemingly has created more confusion than resolution.[249] This is due, in part, to the EPO stating that these categories are exceptions because they are not "technical."[250] The search for a concrete definition and meaning of the word "technical" has led to confusion, so much so that recent cases have held incorporating a physical apparatus into the claim will render it patent-eligible.[251] Recently, the EPO has been reverting back to using patent eligibility like a coarse filter and leaving the other patent statutes, especially novelty and inventive step,[252] to weed out invalid patents.[253]

In light of the confusion that both the United States and European courts have created with poorly-defined statutory exceptions to patent eligibility, perhaps the proposed 35 U.S.C. § 100(k), as outlined above,[254] could prove meaningful.

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242. *Id.* (internal quotations omitted).

243. *Id.*

244. *Id.* at 136-37.

245. *Id.* at 137-38.

246. *Id.*

247. Dan L. Burk, *The Curious Incident of the Supreme Court in Myriad Genetics*, 90 NOTRE DAME L. REV. 505, 525-26 (2014).

248. *Id.* at 526.

249. *Id.*

250. *Id.*

251. *Id.*

252. Inventive step in Europe is similar to the obviousness analysis in the United States. *Id.* at 526.

253. *Id.*

254. Smith, *supra* note 110, at 136.

However, the courts have not provided consistent and workable definitions of "laws of nature," "natural phenomenon," and "abstract ideas," leaving courts leeway to determine if an invention falls into one of these three categories.[255] Furthermore, even though § 100(k) defines "inventive step,"[256] there will continue to be confusion as to what constitutes an invention in one of the categories of judicial exceptions. Consequently, the proposed addition of an "inventive step" requirement itself could be troublesome.

Europe has an inventive step requirement for patentability that is found in the 1932 Patents and Designs Act.[257] Despite several differences between the European inventive step requirement and the United States' obviousness requirement, the two are very similar.[258]

However, introducing an inventive step requirement into § 101 could lead to confusion if "inventive step" were to be analyzed like it is in Europe (i.e., similar to obviousness). Many scholars, and even Justices, have already mused that the Supreme Court has intertwined the requirements of the other patent statutes with the requirements of § 101.[259] The Court in *Diamond v. Diehr* cautioned that novelty should not be considered § 101 and claims may be found to be unpatentable in the future under §§ 102 or 103 independent of the § 101 analysis.[260] Interjecting an inventive step requirement into § 101, as Smith proposes, certainly could exacerbate these concerns. The U.S. patent system, though, has distinct and separate statutes, and each statute serves its own particular purpose. As the Court in *Alice* reiterated, the 1952 Patent Act put the requirement of "inventiveness" in 35 U.S.C. § 103, and this is where it should remain. [261]

If the proposed statutory fix were to be applied to *Sequenom*, the claims likely would still be invalid under § 101. Claim 1 of Sequenom's patent is:

> A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence

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255. Heinrich & Abernethy, *supra* note 85, at 210.

256. Smith, *supra* note 110, at 136.

257. *The European Patent Convention: Article 56*, EUR. PAT. OFF., http://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar56.html [https://perma.cc/L72U-C22G] (last visited Apr. 3, 2017) (highlighting the fact that scholars in England, who had knowledge of the developing non-obviousness requirement in the United States, brought the concept of non-obviousness to the European patent system).

258. STANDING COMM. ON THE LAW OF PATENTS, WORLD INTELLECTUAL PROP. ORG., STUDY ON INVENTIVE STEP 2-4 (July 6, 2015), http://www.wipo.int/edocs/mdocs/scp/en/scp_22/scp_22_3.pdf [perma.cc/WR2V-5LRF].

259. *See, e.g.*, Heinrich & Abernethy, *supra* note 85, at 157 (discussing the concern with conflating patent eligibility with novelty and obviousness in *Flook*).

260. 450 U.S. 175, 191 (1981).

261. CLS Bank Int'l v. Alice Corp., 717 F.3d 1269, 1296 (Fed. Cir. 2013).

of a paternally inherited nucleic acid of fetal origin in the sample.[262]

Under Smith's proposed §§ 101(b) and 100(k)[263] and the language of the opinion in *Sequenom*,[264] the nucleic acid of fetal origin is a product of nature and Sequenom's claims do not provide an inventive step. The court held the method steps in the claims were "routine" and "conventional."[265] Because the first part of Smith's § 100(k) is not satisfied in *Sequenom*, the analysis under § 101 comes to an end, and Sequenom is out of luck. Not because the claims were obviousness or there was a lack of written description, but because the claims covered ineligible subject matter. Even though this was the first time that researchers had measured and used this particular nucleic acid in maternal plasma or serum,[266] and the claimed invention provided the first non-invasive prenatal diagnostic test for diseases such as Down syndrome,[267] the claims would be unpatentable subject matter based on an obviousness-type eligibility analysis. This reading of an obviousness requirement into a § 101 analysis is inconsistent with the rationale for the creation of § 103 in the 1952 Patent Act.[268]

2. Eliminating the Judicially-Created Exceptions.—The opposite of incorporating the judicial exceptions into the statute is a proposal to eliminate the exception expressly and completely.[269] This can be done through a legislative change[270] or by a new framework for the analysis.[271]

Litigators Alan J. Heinrich and Christopher T. Abernethy argue that the *Myriad* Court deviated from the *Mayo* Court because the *Myriad* Court did not insert an inventive concept requirement into its § 101 analysis.[272] Rather, the Court only looked at whether the claims were covering something that was naturally occurring.[273] DNA (e.g., located in a cell) is naturally occurring and hence is per se ineligible, whereas cDNA is not naturally occurring and is patent-

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262. U.S. Patent No. 6,258,540 (issued July 10, 2001), https://www.google.com/patents/US6258540 [https://perma.cc/X7BT-CLEJ].

263. Smith, *supra* note 110, at 136.

264. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1375-78 (Fed. Cir. 2015), *reh'g en banc denied*, 809 F.3d 1282 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016).

265. *Id.* at 1377-78.

266. *Id.* at 1373.

267. *Id.* at 1381 (Linn, J., concurring).

268. CLS Bank Int'l v. Alice Corp., 717 F.3d 1269, 1296 (Fed. Cir. 2013).

269. Heinrich & Abernethy, *supra* note 85, at 224.

270. *See, e.g.*, Sunstein, *supra* note 106, at 37 (proposing a revised § 101 that reads "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to unless the conditions and requirements of this title have not been satisfied").

271. *See, e.g.*, Heinrich & Abernethy, *supra* note 85, at 224 (proposing a new framework for analysis under § 101).

272. *Id.* at 119.

273. *Id.* at 176.

eligible.[274]

Heinrich and Abernethy reason that the judicially-created exceptions have no basis in the statute or policy behind the 1952 Patent Act and that the Supreme Court is only relying on stare decisis in upholding the judicially-created exceptions.[275] They argue there is weak rationale to uphold these exceptions.[276] Furthermore, Heinrich and Abernethy correctly identify that the inventive concept test is not practical because the Court has yet to identify concretely how a law of nature, a natural phenomenon, or an abstract idea is defined.[277] Instead of relying on Congress, "the Court should clean up its own mess."[278] However, in light of the Supreme Court's recent denial of certiorari in *Sequenom*, the Court is not apparently ready to reconsider its own precedent.[279]

Heinrich and Abernethy further argue that the Court erroneously has left out a "discovery" from being patent-eligible and that a discovery should be patent-eligible as long as it is "new."[280] They posit that the word "new" was added to the Patent Act of 1793 because Congress intended for patent-eligible subject matter to be new to the world, regardless of whether it was known or used prior to its discovery.[281] They further clarify that an invention is new to the world if it does not exist in nature without human intervention.[282] The proposed framework is therefore: "(1) Does the claim, considered as a whole, literally recite a 'process, machine, manufacture, or composition of matter?' (2) If so, is the claimed process, machine, manufacture, or composition of matter one that is 'new' to the world?"[283] If the answer to both questions is "yes," it should be patent-eligible.[284] Heinrich and Abernethy conclude this framework is therefore consistent with the Court's holding in *Myriad*.[285]

Let us look at the patent claims at issue in *BMS v. Merck*.[286] Under Heinrich and Abernethy's proposed framework, these claims likely would be found to be patent-eligible. Claim 1 at issue in *BMS* reads: "A method for treatment of a tumor in a patient, comprising administering to the patient a pharmaceutically effective amount of an anti-PD-1 monoclonal antibody."[287] This claim is similar to one of the hypotheticals given by Heinrich and Abernethy in that both are

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274. *Id.*

275. *Id.* at 192-93.

276. *Id.*

277. *Id.* at 209-10.

278. *Id.* at 194.

279. Gene Quinn, *Supreme Court Denies Cert. in* Sequenom v. Ariosa Diagnostics, IPWATCHDOG (June 27, 2016), http://www.ipwatchdog.com/2016/06/27/70409/id=70409/.

280. Heinrich & Abernethy, *supra* note 85, at 222-23.

281. *Id.* at 127.

282. *Id.* at 226-27.

283. *Id.* at 224 (quoting 35 U.S.C. § 101 (2012)).

284. *Id.* at 224-29.

285. *Id.* at 232.

286. *See supra* text accompanying notes 21-27.

287. U.S. Patent No. 8,728,474 (issued May 20, 2014).

method claims for treating a disease.[288] Heinrich and Abernethy's hypothetical recites a method claim for curing cancer, wherein the hypothetical method comprises steps of dissolving lunar dust, injecting a cancer patient with the lunar dust solution, and curing the patient's cancer.[289]

Similar to Heinrich and Abernethy's conclusion for their hypothetical, the claims in *BMS* likely would satisfy the first part of the proposed framework because the claim as a whole falls into one of the categories of eligible subject matter.[290] Additionally, just as there is nothing to indicate that the method of curing cancer by injecting lunar dust occurs in nature, the method of treating a patient's tumor by administering an anti-PD-1 monoclonal antibody does not occur in nature because it requires human intervention for the administration.[291] Therefore, the claims in *BMS* would be patent-eligible under their framework.

An argument also exists for the eligibility of the *Sequenom* claims. Although Heinrich and Abernethy state that a naturally occurring process does not become "new" because it is carried out in a petri dish,[292] they conclude that a hypothetical claim for a "method of harvesting Eden tree sap" recites a process and is new to the world because the process does not occur in nature without human intervention.[293] When looking at the claims in *Sequenom* as a whole, detecting paternal cell-free DNA in maternal blood does not occur in nature without human intervention.[294] Therefore, the claims do recite patent-eligible subject matter under Heinrich and Abernethy's framework.

Heinrich and Abernethy admit that under their proposed framework, creative claim drafting could lead to method claims for otherwise patent-ineligible compositions of matter being found patent-eligible.[295] In their tree sap hypothetical, they conclude that, although a claim to the tree sap itself would be patent-ineligible because such tree sap was assumed to not be new to the world, a process of harvesting the tree sap would be patent-eligible because this process itself is new to the world.[296] Likewise, even though claims covering paternal cell-free DNA would be ineligible because this DNA is not new to the world, the method claims in *Sequenom* for detecting this DNA would be patent-eligible

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288. Heinrich & Abernethy, *supra* note 85, at 220.

289. *Id.*

290. *Id.* at 233.

291. *Id.*

292. *Id.* at 235.

293. *Id.*

294. *See* Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1376-78 (Fed. Cir. 2015), *reh'g en banc denied*, 809 F.3d 1282 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016).

295. Heinrich & Abernethy, *supra* note 85, at 235. The concept of the "draftsman's art" was also described in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* 132 S. Ct. 1289, 1294 (2012) (stating that the Court's precedent cases "warn us against interpreting patent statutes in ways that make patent eligibility 'depend simply on the draftsman's art' without reference to the 'principles underlying the prohibition against patents for [natural laws].'" (quoting Parker v. Flook, 98 S. Ct. 2522, 2527 (1978))).

296. Heinrich & Abernethy, *supra* note 85, at 235.

under this framework.[297]

Heinrich and Abernethy propose an interesting cure for this gap in their framework. Rejecting the "inventive concept" test, Heinrich and Abernethy come up with a solution that would invalidate the tree sap method claim under a § 103 analysis.[298] Their new rule is: "Pursuant to § 101, any 'process, machine, manufacture, or composition of matter' that is not 'new' to the world is 'prior art' for the purposes of a § 103 obviousness analysis."[299]

Under Heinrich and Abernethy's proposed rule, nature itself essentially can be used as prior art under a § 103 analysis.[300] Therefore, if something exists in nature, a person of skill in the art is *presumed* to have knowledge of it and its location, even if the person does not *actually* have this knowledge.[301] Therefore, Eden tree sap, which exists in nature without human intervention, would be considered prior art for a § 103 analysis.[302] It, therefore, would have been "obvious" to a person of skill in the art to use a routine method to harvest tree sap.[303] The claims would be patent-eligible under § 101 but would be invalid under § 103.[304] This new rule supports the role of § 101 as a coarse filter.[305]

Another hypothetical that Heinrich and Abernethy propose is very similar to the claims in *Sequenom*.[306] A claimed "method of detecting fetal DNA in maternal blood" would pass the § 101 test but would be found to be invalid under § 103.[307] Heinrich and Abernethy argue this is because fetal DNA exists in nature, is not new to the world, and is therefore prior art.[308] Using fetal DNA as prior art, the question is whether a person of ordinary skill in the art would find it obvious to use routine tests to detect the fetal DNA in blood.[309] Because, under the proposed rule, one of skill in the art is presumed to have knowledge of fetal DNA in maternal blood,[310] it is more likely that the claims in *Sequenom* would be invalid under § 103, even though no one knew cell-free DNA existed in maternal serum

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297. *See id.* at 235-37.

298. *Id.* at 237-43.

299. *Id.* at 240 (quoting 35 U.S.C. §§ 101, 103 (2012)).

300. *Id.* at 241. Also, note that what exists in the world that is not previously known is already available under the inherency doctrine as prior art under 35 U.S.C.§ 102. *Requirements of Rejection Based on Inherency; Burden of Proof*, MANUAL OF PATENT EXAMINING PROCEDURE CHAPTER 2100, USPTO (July, 2015), https://www.uspto.gov/web/offices/pac/mpep/s2112.html [https://perma.cc/X3DU-2NVY].

301. Heinrich & Abernethy, *supra* note 85, at 241.

302. *Id.* at 243.

303. *Id.*

304. *Id.*

305. *Id.* at 225.

306. *Id.* at 244.

307. *Id.*

308. *Id.*

309. *Id.*

310. *Id.*

or plasma.[311]

However, the proposed prior art rule might not be necessary. For example, § 112 could be used to invalidate similar types of claims. In fact, in his concurring opinion in the denial to hear *Sequenom en banc*, Judge Lourie stated that the claims should be evaluated under § 112.[312] He emphasized the claims may be too broad because they do not specify how to perform any of the claimed functions.[313] Likewise, Judge Dyk reasoned that the claims were overbroad and that breadth should be the key.[314] Judge Dyk's proposed framework relied on the patentee actually reducing to practice the claimed invention to ensure the claims are not preemptive.[315] Judge Dyk would limit the claims to those narrow claims that the patentee has actually developed and reduced to practice.[316] This is consistent with the written description and enablement requirements found in § 112.[317]

CONCLUSION

Sequenom[318] and *BMS*[319] are perfect examples of the bumpy road ahead for pharmaceutical and diagnostic inventors in obtaining patent protection for their discoveries.

To provide more clarity and certainty in what is patent-eligible subject matter, Smith proposed that Congress codify the judicial exceptions.[320] This would entail introducing an "inventive step" requirement into a new § 101(b) and a definition of "inventive step" in a new § 100(k).[321] This proposal is fairly in line with the Supreme Court's holdings but does not provide the necessary clarity on how to keep an obviousness-type analysis out of the patent-eligibility analysis.[322]

Heinrich and Abernethy proposed to eliminate the judicial exceptions through

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311. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1376-78 (Fed. Cir. 2015), *reh'g en banc denied*, 809 F.3d 1282 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016).

312. *Sequenom*, 809 F.3d at 1286 (Lourie, J., concurring).

313. *Id.*

314. *Id.* at 1291, 1293 (Dyk, J., concurring).

315. *Id.* at 1291; *see also* Jackie Hutter, *A Definite and Permanent Idea? Invention in the Pharmaceutical and Chemical Sciences and the Determination of Conception in Patent Law*, 28 J. MARSHALL L. REV. 687, 696 (1995) (explaining actual reduction to practice "occurs when the inventor tests the idea and shows that it works for its intended purpose").

316. *Sequenom*, 809 F.3d at 1291.

317. *Id.* at 1292 n.5.

318. Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1376-78 (Fed. Cir. 2015), *reh'g en banc denied*, 809 F.3d 1282 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016).

319. Bristol-Myers Squibb v. Merck & Co., Inc., No. 14-CV-00131, 2016 U.S. Dist. LEXIS 90532 (D. Del. July 13, 2016).

320. Smith, *supra* note 110, at 136.

321. *Id.*

322. *See, e.g.*, CLS Bank Int'l v. Alice Corp., 717 F.3d 1269, 1296 (Fed. Cir. 2013) (stating the 1952 Patent Act put the requirement of "inventiveness" in 35 U.S.C. § 103).

a two-step framework for the courts to implement.[323] This framework appears reasonable and workable; however, the proposed new prior art rule is unwarranted. Even without allowing for naturally-occurring compositions of matter, for example, to be used as prior art, many claims of the sort at issue would be found invalid under another patent statute, such as § 112.[324]

The Supreme Court's denial of certiorari in *Sequenom* is likely a signal that the Court will not change its eligibility analysis anytime soon.[325] Perhaps the only hope for a change in the near future is in the hands of Congress.[326] Fortunately, there has been a surge in efforts within the patent community to try to reach a consensus regarding § 101 and ultimately to convince Congress to take action to amend § 101.[327] Time will tell if Congress will listen.

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323. Heinrich & Abernethy, *supra* note 85, at 224.

324. Kresh, *supra* note 91, at 544-45.

325. Quinn, *supra* note 279.

326. *Id.*

327. *See e.g.*, Robert A. Armitage, Comment Letter on Patent Subject Matter Eligibility: Roundtable 2, https://www.uspto.gov/sites/default/files/documents/Armitage%20Response%20to%20USPTO%20Federal%20Register%20Notice%20on%20Patent%20Eligibility%20%20%20.pdf [https://perma.cc/488H-MYHX] (last visited Apr. 3, 2017) (discussing the considerations for a legislative amendment, and proposing an amended § 101 that eliminates the judicially-created exceptions to patent subject matter eligibility, including the *Mayo* two-part test, and instead incorporates "explicit subject matter limitations on patent eligibility"); David O. Taylor, Assoc. Professor of Law, SMU Dedman Sch. of Law, Comment Letter on Patent Subject Matter Eligibility: Roundtable 2 (Jan. 18, 2017), https://www.uspto.gov/sites/default/files/documents/RT2%20Comments%20David%20Taylor.pdf [https://perma.cc/A74B-UB4G] (proposing two legislative approaches including "eliminating the judicial exceptions to eligibility" and "codifying a standard to govern eligibility that includes appropriate objective limitations").