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## Separating Preemption from the Subject Matter Analysis of 35 U.S.C. § 101

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## SEPARATING PREEMPTION FROM THE SUBJECT MATTER ANALYSIS OF 35 U.S.C. § 101

Rodney Swartz\*

*With what seems to be a fluke of history, the Supreme Court has developed a subject matter analysis framework embodied in 35 U.S.C. § 101 that relies on the preemption doctrine to justify invalidation. This Article establishes that preemption has a distinct objective that is more closely aligned with the written description framework of § 112 than with the subject matter eligibility framework of § 101. As a result of relying on preemption, the Court has created an arbitrary and difficult to apply test, resulting in a chasm between the United States Patent and Trademark Office (USPTO) and courts that is reminiscent of the difficulties in the patent system that lead up to the Patent Act of 1952.*

*In response, this Article proposes a new framework that separates the preemption analysis from the subject matter eligibility analysis. Under this new framework, subject matter eligibility would revert to its pre-Benson approach, where judicial exceptions only cover natural phenomena, natural laws, and abstract ideas but not their equivalents. Further, this new framework is based on an objective standard where a claim is determined to be overly broad if it covers more than what the inventor has established they invented or modifications that are obvious to a person having ordinary skill in the art. After developing the new framework, this Article applies the approach to Parker v. Flook, Diamond v. Diehr, and Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC. This analysis demonstrates the new framework, provides a reasonable explanation for why the field limitation in Flook is not sufficient for satisfying claim breadth, which was unclear in the Court's decision, and addresses the issues around the perceived per se law against medical devices.*

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## I. INTRODUCTION

Society benefits through the liberal reward of inventiveness<sup>1</sup> so long as the reward is for novel<sup>2</sup> and non-obvious<sup>3</sup> creations known to the inventor.<sup>4</sup> This statement reflects the idea that patents promote the progress of science by granting a time-limited exclusive right to the

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1. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 8 (1966).

2. 35 U.S.C. § 102 (2012).

3. 35 U.S.C. § 103 (2011).

4. *O'Reilly v. Morse*, 56 U.S. 62, 113 (1853) (“For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff’s specification. His invention may be less complicated—less liable to get out of order—less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.”).

invention,<sup>5</sup> but that progress may be stalled if patents are rewarded for known innovations, trivial improvements,<sup>6</sup> or are so broad as to cover future innovations.<sup>7</sup> While this statement may seem self-evident, it is not a reflection of where the patent system and its case law have been or where it currently stands.

For example, before the Patent Act of 1952 (“1952 Act”), the courts struggled to articulate a reasonable test for inventiveness (what is now known as non-obviousness), creating at times confusing and difficult to apply laws.<sup>8</sup> In probably the best-known case on the subject, *Cuno Engineering Corp. v. Automatic Devices Corp.*,<sup>9</sup> the Supreme Court articulated a test that required a “flash of creative genius” to satisfy inventiveness and, further, that the genius must be apparent from the invention.<sup>10</sup> This test was perceived by many to be confusing and difficult to apply, and it took an act of Congress in the 1952 Act before predictability was restored to the patent system.<sup>11</sup> In the 1952 Act, Congress replaced the subjective “flash of genius” test articulated by the Court with a more objective framework based on being “obvious . . . to a person having ordinary skill in the art,” which they embodied in 35 U.S.C. § 103.<sup>12</sup> This new framework proved very useful and set the stage for the Supreme Court in *Graham v. John Deere Co.*,<sup>13</sup> to develop the standards necessary to analyze cases against that framework, setting the modern obviousness test by which the courts and USPTO would judge patents. As a result of this effort, the doctrine of non-obviousness, and the doctrine of novelty have formed the cornerstone of modern patentability.

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5. See *Graham*, 383 U.S. at 8-9 (“[Jefferson] rejected a natural-rights theory in intellectual property rights and clearly recognized the social and economic rationale of the patent system. The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge.”).

6. See *id.* at 9 (“Only inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly. Jefferson did not believe in granting patents for small details, obvious improvements, or frivolous devices.”).

7. See *O’Reilly*, 56 U.S. at 113.

8. David K. Mroz & Umber Aggarwal, *Patent Law Could Use Another Judge Rich Right Now*, FINNEGAN (Nov./Dec. 2017), <https://www.finnegan.com/en/insights/articles/patent-law-could-use-another-judge-rich-right-now.html>.

9. *Cuno Eng’g Corp. v. Automatic Devices Corp.*, 314 U.S. 84 (1941).

10. *Id.* at 91 (“That is to say the new device, however useful it may be, must reveal the flash of creative genius not merely the skill of the calling. If it fails, it has not established its right to a private grant on the public domain”).

11. Mroz & Aggarwal, *supra* note 8.

12. Patent Act of 1952, Pub. L. No. 82-593, § 103, 66 Stat. 792, 798 (1952).

13. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1 (1966).

Courts find themselves struggling to formulate reasonable and predictable tests once again, but this time it is around subject matter eligibility. The Court has long recognized that implied in the subject matter eligibility framework of 35 U.S.C. §101 is the recognition that some subject matter—abstract ideas, natural phenomenon, and laws of nature—are so fundamental to science that patenting them would preempt the future progress of science.<sup>14</sup> However, courts have struggled to distinguish when a claim crosses the line from patent eligible subject matter to cover subject matter that should be deemed patent ineligible. Under the modern framework, the Supreme Court supplied a two-part test in *Alice Corp. v. CLS Bank* (“*Alice*”).<sup>15</sup> Under this test the court first considers whether the claim is “directed to” ineligible subject matter, and, if so, whether the claim recites an “inventive concept” that “transform[s] the nature of the claim” into patent-eligible subject matter.<sup>16</sup> However, since the *Alice* decision, the patent system has struggled to consistently and reliably apply this framework to determine when a patent is directed to patent eligible subject matter or not.<sup>17</sup> As Judge Plager of the Court of Appeals for the Federal Circuit said, “[t]here is little consensus among trial judges (or appellate judges for that matter) regarding whether a particular case will prove to have a patent with claims directed to an abstract idea, and if so, whether there is an ‘inventive concept’ in the patent to save it.”<sup>18</sup>

This uncertainty has not gone unnoticed by litigators. There has been a ten-fold increase in the number of claims deemed ineligible under 35 U.S.C. § 101 (“§ 101”), and a nine-fold increase in the number of patents invalidated.<sup>19</sup> Many commenters, echoing concerns leading up to the 1952 Act, have argued the court has once again created a subjective, and at times arbitrary, test for measuring patentability.<sup>20</sup> As

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

15. *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208 (2014).

16. *Id.* at 217.

17. See generally *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333 (Fed. Cir. 2019) (en banc) (containing eight separate opinions disagreeing on the application of the U.S. Supreme Court’s Section 101 jurisprudence with four concurring with the en banc denial and another four dissenting from the decision); Daniel R. Cahoy, *Patently Uncertain*, 17 NW. J. TECH. & INTELL. PROP. 1, 2 (2019) (statement of Hon. Paul R. Michel (Ret.)) (“I spent twenty-two years on the Federal Circuit and nine years since dealing with patent cases, and I cannot predict in a given case whether eligibility will be found or not found.”).

18. Cahoy, *supra* note 17, at 38.

19. See Dani Kass, *Alice Axed Claims From Over 1,000 Patents In 5 Years: Study*, LAW360 (Sept. 3, 2019, 10:10 PM), <https://www.law360.com/articles/1194300/alice-axed-claims-from-over-1-000-patents-in-5-years-study>.

20. See generally INTELLECTUAL PROP. OWNERS ASS’N, PROPOSED AMENDMENTS TO PATENT ELIGIBLE SUBJECT MATTER UNDER 35 U.S.C. § 101 (2017) [hereinafter IPOA].

they point out, *Alice* has blurred the lines between subject matter analysis of § 101 and the non-obvious/novelty analysis of § 102 and § 103, and worse yet, imported an inventiveness standard reminiscent of the standard the 1952 Act sought to abolish.<sup>21</sup>

While these are valid concerns, the more fundamental issue, and the one this Article focuses on, is that the framework established in *Alice* relies on a fundamental assumption that the subject matter eligibility doctrine—a doctrine concerned with what subject matter should receive protection—can and should be used to address issues relating to preemption—a doctrine concerned with not patenting the future. This Article recognizes that the two doctrines have largely co-existed for over 200 years. However, this coexistence has been due to the courts *laissez faire* approach to subject matter eligibility.<sup>22</sup> But recent case law has brought new life to the subject matter eligibility analysis and has started to show the incompatibilities of the two doctrines.

Since *Alice*, there has been a considerable amount of scholarly work focusing on how the decision has blurred the lines between subject matter analysis and the non-obvious/novelty analysis.<sup>23</sup> However, there has been far less discussion exploring the mixing of preemption analysis with subject matter analysis. This Article is timely as the courts and Congress continue to struggle with the subject matter eligibility framework introduced by *Alice*.<sup>24</sup>

This Article contends that the fundamental issue of the modern subject matter analysis framework is that it mixes the subject matter eligibility analysis with the preemption analysis, and that the objectives of the two analysis are inherently incompatible. Part II of this Article reviews the history of patent invalidation, starting with the history that culminated in the 1952 Act. This period of time is instructive as many of the issues that existed at that time parallel the issues faced by the patent system now, and the objective framework introduced by the 1952

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21. *See id.* at 3.

22. KEVIN J. HICKEY, CONG. RESEARCH SERV., R45918, PATENT-ELIGIBLE SUBJECT MATTER REFORM IN THE 116TH CONGRESS 15 (2019) (“Development of the patent-eligible subject matter law was primarily left to the Federal Circuit, whose decisions generally expanded patentable-eligible subject matter, such that by the late 1990s Section 101 became perceived as ‘a dead letter.’”).

23. *See generally* IPOA, *supra* note 20.

24. *See, e.g.,* *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333 (Fed. Cir. 2019) (en banc) (providing a fractured opinion on the proper application of the Supreme Court’s Section 101 jurisprudence); *see also* Press Release, Thom Tillis U.S. Senator for N.C., Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Section 101 Patent Reform Framework (Apr. 17, 2019), <https://www.tillis.senate.gov/2019/4/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-section-101-patent-reform-framework>.

Act can likely serve as a starting point for developing a new framework for measuring preemption. The section then moves to the more recent challenges around subject matter eligibility, and the modern case law that has culminated in the *Alice/Mayo* framework for subject matter analysis. Finally, the section discusses some of the criticism of the framework and potential congressional reform proposed by Senators Tillis and Coons.

Part III of this Article looks at two doctrines that have formed the foundation of subject matter analysis: the judicial exceptions doctrine and the preemption doctrine. The section starts off with a discussion on the origins of each doctrine and shows that while the two have historically been intermixed, the objectives that each are intended to progress are quite different. Further, the section contends that because the preemption doctrine conditions patentability on only covering what is known, and not whether it is directed to a particular subject matter, it is wholly inappropriate to form part of the subject matter analysis framework. Building off that distinction, the section then tries to address the question of why the two doctrines became intermixed. Finally, the section concludes with highlighting the key issues that have resulted from intermixing the two doctrines paying particular attention to the court's use of concepts of novelty and non-obviousness as a proxy for addressing the objectives of the preemption doctrine.

Building on the premise that the preemption doctrine and subject matter eligibility have two distinct objectives, Part IV focuses on creating a framework that can adequately address the objectives of both doctrines. This section first contends that because subject matter eligibility is concerned with distinguishing applications from principles and the preemption doctrine is concerned with not protecting the unknown, the two doctrines are inherently incompatible, and should not form the same analysis. The section then moves on to establish a new framework to analyze claims by. The framework moves the preemption analysis to after the initial § 101 threshold test and introduces an objective standard to measure claims by. Finally, the section concludes with several examples illustrating how the framework would work in practice.

## II. BACKGROUND

The challenges facing the U.S. patent system are nothing new. The Court's focus on invalidating patents often tracks with public sentiment towards the patent system. Whether this is the court recognizing a flaw in the patent system, or simply the court reflecting the mood of society is beyond the scope of this Article. But what is clear is that while the

Court's increased attention on the patent system can be challenging at first, such pushes have helped the patent system to progress from being a convoluted and muddled body of law, reminiscent of its English origins,<sup>25</sup> to a body of law that is predictable and efficiently progresses science.

#### *A. The Inventiveness Issue*

The depression of the 1890s would cast an unfavorable light on the patent system. The monopolistic practices of big companies had resulted in the dire economic crisis that the United States was facing and patents were perceived as promoting that system.<sup>26</sup> Many people strongly opposed the patent system, and courts reflected that sentiment through frequent invalidation of patents.<sup>27</sup> Congress's response at that time was to target the monopolistic practices of the big companies through the enactment of the Sherman Antitrust Act, leaving the patent system largely unaffected.<sup>28</sup>

However, following the Great Depression, the Court would once again set its sights on the patent system. During this period, the courts routinely invalidated patents relying on a concept of inventiveness that was not only subjective, but at times arbitrary.<sup>29</sup> Eventually, the Court settled on an "inventive genius" test.<sup>30</sup> The test proved hard to manage in practice and created an "ever-widening gulf" between the Patent Office and the courts.<sup>31</sup> The disparity between patents the USPTO deemed valid and patents the Court deemed invalid came to a head in the famous case of *Cuno Engineering Corp. v. Automatic Devices Corp.*, where Justice Douglas declared that a patent "however useful it may be, must reveal the flash of creative genius, not merely the skill of the calling."<sup>32</sup> This statement ignited a vigorous debate in the patent community with Justice Jackson famously commenting "that the only

25. H. Jared Doster, *The English Origins of the Judicial Exceptions to 35 U.S.C. § 101*, A.B.A. (Mar./Apr. 2019), [https://www.americanbar.org/groups/intellectual\\_property\\_law/publications/landslide/2018-19/march-april/english-origins-judicial-exceptions-35-usc-section-101/](https://www.americanbar.org/groups/intellectual_property_law/publications/landslide/2018-19/march-april/english-origins-judicial-exceptions-35-usc-section-101/).

26. See *A brief history of the patent law of the United States*, LADAS & PARRY (May 7, 2014), <https://ladas.com/a-brief-history-of-the-patent-law-of-the-united-states-2/>.

27. *Id.*; see also Christopher Beauchamp, *The First Patent Litigation Explosion*, 125 YALE L. J. 848 (2016), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2699964](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2699964).

28. See *A brief history of the patent law of the United States*, *supra* note 26.

29. See IPOA, *supra* note 20, at 3; see also Stefan A. Riesenfeld, *The New United States Patent Act in the Light of Comparative Law I*, 102 U. PA. L. REV. 291, 307-08 (1954).

30. *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 148 n.1, 154 (1950).

31. Riesenfeld, *supra* note 29, at 308.

32. *Id.* at 307; *Cuno Eng'g Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 91 (1941).

patent that is valid is one which this Court has not been able to get its hands on.”<sup>33</sup>

In response, Congress enacted the Patent Act of 1952 to realign the Patent Office and the courts. The 1952 Act formalized the concept of inventiveness, providing an objective framework for its measurement.<sup>34</sup> While at first it was unclear whether the 1952 Act would have the stabilizing effect that Congress intended,<sup>35</sup> the Supreme Court in *Graham v. John Deere Co. of Kansas City* laid those concerns to rest.<sup>36</sup> In its decision, the Court set the stage for our modern understanding of non-obviousness which has become the cornerstone of patent eligibility.<sup>37</sup> In its decision, the Court first recognized that 35 U.S.C. § 103 codified one hundred years of judicial precedent on determining inventiveness and made it an express condition on patentability.<sup>38</sup> Second, the Court recognized that the statute abolished the controversial “flash of creative genius” test.<sup>39</sup>

While, the 1952 Act did not address all questions of patentability, in particular those around what it means to be obvious,<sup>40</sup> the Court believed those difficulties were comparable to ones “encountered daily by the courts in such frames of reference as negligence and scienter, and [would] be amenable to a case-by-case development.”<sup>41</sup> In its decision, the Court foresaw a “uniformity and definiteness which Congress called for in the 1952 Act” so long as the courts strictly adhered to the requirements set forth in *Graham*.<sup>42</sup> A vision that would turn out to be true.

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33. Riesenfeld, *supra* note 29, at 308.

34. *Id.* at 308-09 (“Section 103 fixes an objective standard of invention by specifying on the one hand that ‘a patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains,’ and by declaring on the other hand that ‘patentability shall not be negated by the manner in which the invention was made.’ In addition, the new act elevates the presumption of validity to the dignity of a statutory mandate.”).

35. *Id.* at 309 (“Whether these provisions will have the desired ‘stabilizing effect’ remains to be seen . . . Perhaps the most that can be said is that Congress has ‘expressed a mood.’”).

36. *See* *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 12-13 (1966).

37. *See id.* at 13-14.

38. *Id.* at 14.

39. *Id.* at 15.

40. *Id.* at 18.

41. *Id.*

42. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 18 (1966).

### B. The Subject Matter Issue

By the 1990s, the United States saw an explosion in the number of patents granted that mirrored the explosion in technology.<sup>43</sup> However, the economic woes following the bursting of the dot-com bubble, and subsequent emergence of entities whose sole purpose was asserting patents obtained from these defunct companies at fire sale prices would once again sour public sentiment towards the patent system.<sup>44</sup> Many argued that the patent system was replete with examples of overly broad claims that resulted from the liberal grant of patents during the explosion in the 1990s.<sup>45</sup> In response, the Court, relying on earlier case law, began a campaign to invalidate these broad patents by focusing on subject matter eligibility.<sup>46</sup> The rationale being that an overly broad claim directed to ineligible subject matter is a patent on the ineligible subject matter itself.

#### 1. Initial Subject Matter Analysis

The first Supreme Court case to take on the issue in this period was *Bilski v. Kappos*.<sup>47</sup> The claim in *Bilski* was directed to a method for hedging against price-fluctuations in the energy and commodity markets.<sup>48</sup> While the Court recognized that “[h]edging is a fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class,”<sup>49</sup> which would have likely served as a valid ground for invalidation under novelty, it did not consider whether the patent was invalid on novelty or non-obviousness grounds. Rather, because § 101 patent-eligibility inquiry is a threshold test, the Court only needed to consider the other requirements of patentability only if §101 was satisfied.<sup>50</sup> Relying on earlier precedent, the Court determined the concept of hedging was “an unpatentable abstract idea,” as the claims were so broad that they would preempt use of the abstract idea in all fields and would in effect grant a monopoly on the idea itself.<sup>51</sup>

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43. PETER MENELL ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE: 2018: PERSPECTIVES, TRADE SECRETS, PATENTS 282 (2018).

44. *Id.*

45. See Beauchamp, *supra* note 27, at 850.

46. See Erin E. Block & Eric Chadwick, *Subject Matter Eligibility post Alice: A Boon Or A Bane For Tech Companies?*, HENNEPIN COUNTY BAR ASS'N, <https://www.mnbar.org/hennepin-county-bar-association/resources/hennepin-lawyer/articles/2020/02/04/subject-matter-eligibility-post-alice-a-boon-or-a-bane-for-tech-companies>.

47. *Bilski v. Kappos*, 561 U.S. 593 (2010).

48. *Id.* at 599.

49. *Id.* at 611.

50. *Id.* at 602.

51. *Id.* at 611-12.

The Supreme Court was not alone and Congress also responded to concerns about overly broad patents by introducing the biggest reforms to patent law since the Patent Act of 1952 with the America Invents Act (AIA).<sup>52</sup> Congress's approach was to improve the efficiency of invalidating patents by creating a new administrative law body, the Patent Trial and Appeal Board (PTAB), with the purpose to decide issues of patentability, and add more trial like administrative procedures, including post-grant review (PGR), and *inter partes* review (IPR).<sup>53</sup> However, while the AIA may have created a more efficient process for invalidation,<sup>54</sup> it did not substantively change or clarify the law around what constitutes a valid patent.<sup>55</sup> This would be left to the courts.

## 2. Modern Alice/Mayo Framework

Following the AIA, the Supreme Court heard *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (“*Mayo*”).<sup>56</sup> The Court's rationale in *Mayo* is of particular interest as it served as the basis for the Court's decision in *Alice* and would form the foundation of what became the *Alice/Mayo* test for subject matter eligibility.<sup>57</sup> The claim in *Mayo* was directed to a method for optimizing dosage of thiopurine drugs for treating autoimmune diseases by administering the drug, measuring a metabolite, and adjusting the dosage based on that measurement.<sup>58</sup>

Writing for a unanimous Court, Justice Bryer held that the invention was directed to patent ineligible subject matter—a law of nature.<sup>59</sup> The Court reiterated earlier warnings that overly broad patents risk preempting future development and “that a process that focuses upon the use of a natural law [must] also contain other elements or a combination of elements, sometimes referred to as an ‘inventive concept,’ sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.”<sup>60</sup> To reach

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52. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

53. *See id.* §§ 6-7.

54. U.S. PATENT & TRADEMARK OFFICE, COMMERCE, RULES OF PRACTICE FOR TRIALS BEFORE THE PATENT TRIAL AND APPEAL BOARD AND JUDICIAL REVIEW OF PATENT TRIAL AND APPEAL BOARD DECISIONS 2 (2012), [https://www.uspto.gov/sites/default/files/aia\\_implementation/general\\_trial\\_rules.pdf](https://www.uspto.gov/sites/default/files/aia_implementation/general_trial_rules.pdf) (“The purpose of the AIA . . . is to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs”).

55. One notable exception is the AIA changing the U.S. patent system from a first-to-invent to a first-to-file system. *See* Leahy-Smith America Invents Act § 3.

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

57. *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208 (2014); *see* HICKEY, *supra* note 22, at 16.

58. *Mayo Collaborative Services*, 566 U.S. at 72.

59. *Id.*

60. *Id.* at 72-73.

its conclusion, the Court first noted the claims “set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm,”<sup>61</sup> and that the question was whether the patent claims “add enough” to the natural law for the process to qualify as patentable subject matter.<sup>62</sup> In addressing this question, the Court reviewed the claim on an element by element basis finding that each element was “well-understood, routine, conventional activity already engaged in by the scientific community” and “when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.”<sup>63</sup> By its analysis, what the Court had done, was to set a rule that if a claim recites a law of nature, it is presumptively invalid, and the claim must recite something novel for it to be classified as patent eligible subject matter. A formulation that continues to be criticized.<sup>64</sup>

In *Alice Corp. v. CLS Bank*, the Court would solidify the *Mayo* decision as a two-part test and extend it to abstract ideas. The Court considered whether a patent directed to system for mitigating “settlement risk” was an abstract idea.<sup>65</sup> Largely relying on *Bilski*, the Court first held that the patent was directed to an abstract idea.<sup>66</sup> It noted that similar to risk hedging in *Bilski*, “the concept of intermediated settlement is ‘a fundamental economic practice long prevalent in our system of commerce.’”<sup>67</sup> Similar to *Bilski*, the Court did not consider whether the patent should have been invalidated on novelty or non-obviousness grounds. In addition, the Court took the position that a longstanding fundamental practice is an abstract idea.<sup>68</sup>

The Court, echoing *Mayo*, noted that the second step of the analysis is the search for an “inventive concept” that is “sufficient to ‘transform’ the claimed abstract idea into a patent-eligible application.”<sup>69</sup> However, instead of relying on the well settled law of non-obviousness in § 103 to determine the inventive concept, the Court proceeded through a more comparative analysis by measuring the claim in question against other §

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61. *Id.* at 77.

62. *Id.*

63. *Id.* at 79-80.

64. See generally *Diamond v. Diehr*, 450 U.S. 175 (1981); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333 (Fed. Cir. 2019) (en banc); IPOA, *supra* note 20.

65. *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 213 (2014).

66. *Id.* at 218-20.

67. *Id.* at 219.

68. *Id.* at 220 (“[A]ll of the claims at issue [in *Bilski*] were abstract ideas in the understanding that risk hedging was a ‘fundamental economic practice.’”).

69. *Id.* at 221.

101 decisions.<sup>70</sup> Relying on those decisions, the Court ultimately found that the implementation of a generic computer did not transform the ineligible abstract idea into a patent-eligible invention.<sup>71</sup>

While the *Mayo* decision would have a substantial impact on the examination of medical diagnostic applications,<sup>72</sup> the *Alice* decision had far broader implications. Not only did applicants see a sharp increase in §101 rejections at the USPTO, particularly in the computer science fields,<sup>73</sup> but the number of issued patents deemed invalid increased ten-fold.<sup>74</sup> Not surprisingly, litigators have tried to use the increase in invalidation to their advantage, and have stepped up their §101 attacks in the courts.<sup>75</sup> In response to the challenges applicants faced at the USPTO, Director Andrei Iancu has issued a number of guidelines to assist both applicants and examiners.<sup>76</sup> Whether or not these guidelines have helped still remains to be seen; however, it is clear that their reach in alleviating the issues faced by patent holders in the courts is limited, or worse yet, counter-productive.<sup>77</sup>

### 3. Criticism of *Alice/Mayo* Framework

The *Alice/Mayo* framework has been praised for reducing the number of overly broad patents.<sup>78</sup> However, it has also received a substantial amount of criticism.<sup>79</sup> One criticism is targeted particularly at *Mayo* for having a detrimental impact on innovation.<sup>80</sup> Many have

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70. See IPOA, *supra* note 20, at 16 (“But [the Court] did not simply import the longstanding obviousness standard under § 103 into the § 101 analysis. Rather, the ‘inventive concept’ analysis appears to be a far more arbitrary exercise, dependent on comparisons of the claims at issue to claims in other § 101 opinions.”).

71. *Alice Corp. Pty.*, 573 U.S. at 226-27.

72. See Colleen Chien, *The Impact of 101 on Patent Prosecution*, PATENTLY-O (Oct. 21, 2018), <https://patentlyo.com/patent/2018/10/impact-patent-prosecution.html> (“[Among medical diagnostic applications] the 101 rejection rate grew from 7% to 32% in the month after the *Mayo* decision and continued to climb to a high of 64%”).

73. *Id.*

74. IPOA, *supra* note 20, at 22 (noting that patent invalidations increased from an average of one to five per quarter prior to the *Alice* decision to almost fifty patents per quarter following *Alice*).

75. See Kass, *supra* note 19.

76. See *e.g.*, Notice, 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019).

77. See *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 Fed. Appx. 1013, 1020 (Fed. Cir. 2019) (“While we greatly respect the PTO’s expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance.”).

78. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1337 (Fed. Cir. 2019) (Dyk, J., concurring).

79. See HICKEY, *supra* note 22, at 20-23.

80. See IPOA, *supra* note 20, at 2; HICKEY, *supra* note 22, at 22.

argued *Mayo* has created a per se rule against diagnostic devices,<sup>81</sup> as they are directed at a law of nature—the detection of the law of nature—and use “data gathering steps or devices that can be said to be basic, conventional, or obvious.”<sup>82</sup> But, as Justice Chen noted, these devices “intuitively seem to be the kind of subject matter the patent system is designed for.”<sup>83</sup> That is, “to encourage the risky, expensive, unpredictable technical research and development that people would not otherwise pursue in the hope that *if* they discover something of great medical value, then they will be protected and rewarded for that successful effort with a patent.”<sup>84</sup>

Critics have also argued that the uncertainty caused by the *Alice/Mayo* framework has put the United States at a disadvantage to its competitors.<sup>85</sup> One rationale is that the current state of patentability in the U.S. after *Alice* has created what one commenter has dubbed “investment-killing” uncertainty.<sup>86</sup> Only after sinking considerable costs into the development of an invention along with the costs of prosecution and maintenance, has the investor found that, not only are they unable to protect their investment against infringers, but their invention has been contributed to the public as a result of the required disclosure.<sup>87</sup> Given that there is little consensus among the judges (trial or appellate) about whether a given claim is subject matter eligible, there is little an investor can do to minimize the risk caused by this uncertainty.<sup>88</sup> At best, the patent system becomes a pure gamble for the inventor.

Critics have also pointed out that not only does the framework hinder innovation, it is also legally flawed.<sup>89</sup> The congressional intent of 35 U.S.C. § 101 reflects Jefferson’s belief that innovation should be liberally rewarded.<sup>90</sup> The *Alice/Mayo* framework, in contrast, introduces “extra-statutory” requirements that significantly limit what is classified as patentable subject matter which some argue is “contrary to congressional intent or the constitutional purpose of patent law.”<sup>91</sup> In

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81. See *Athena Diagnostics, Inc.*, 927 F.3d at 1350 (“[T]he Supreme Court has made clear that detecting a law of nature (without more than conventional steps for accessing the law of nature) does not qualify as a patent-eligible application of a law of nature.”).

82. *Id.*

83. *Id.* at 1352.

84. *Id.*

85. HICKEY, *supra* note 22, at 22-23.

86. Cahoy, *supra* note 17, at 6.

87. See *id.* at 14-17.

88. See *id.*

89. HICKEY, *supra* note 22, at 21-22.

90. *Id.* at 1.

91. HICKEY, *supra* note 22, at 21.

addition, the *Alice/Mayo* framework undermines the intent of the 1952 Act by intermixing elements of novelty and non-obviousness with the subject matter analysis.<sup>92</sup>

While the *Alice/Mayo* framework may be helpful in invalidating patents that are particularly low quality,<sup>93</sup> it has come at the expense of also invalidating countless other patents.<sup>94</sup> The issues facing the *Alice/Mayo* framework raises serious questions about whether it will be part of subject matter eligibility analysis of the future, or whether it will face the same fate as the “flash of creative genius” test articulated in *Cuno*.<sup>95</sup> Many agreed that *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC* (“*Athena*”),<sup>96</sup> was the opportunity for the Supreme Court to salvage the *Alice/Mayo* framework and add much needed clarity to the subject matter analysis.<sup>97</sup> However, the Court refused to hear the case, and it seems to have left it to Congress to bring much needed changes to the 35 U.S.C. § 101.<sup>98</sup>

#### 4. Potential Congressional Reform

In an attempt to reform § 101, Senators Thom Tillis and Chris Coons revived the Senate Judiciary Subcommittee on Intellectual Property.<sup>99</sup> On April 17, 2019, they “released a bipartisan, bicameral framework on Section 101 patent reform” which was later revised on May 22, 2019 after receiving feedback.<sup>100</sup> But while the Tillis-Coons framework is a recognition that § 101 needs reform, it may be years before it will have any effect, if ever. After a considerable amount of effort, no draft bill is in sight, and while the bill is not dead per se, it is

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92. See generally IPOA, *supra* note 20.

93. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1337 (Fed. Cir. 2019) (Dyk, J., concurring).

94. IPOA, *supra* note 20, at 26 (“Using section 101 to invalidate poor quality patents is like using a sledgehammer to crack walnuts: it’s hard to stop the damage at just the shell. What distinguishes a good quality patent from a bad one is unrelated to the requirements of eligibility”).

95. See *id.* at 5.

96. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333 (Fed. Cir. 2019) (en banc).

97. See Ryan Davis, *Fed. Circ. Pleads For Patent Eligibility Clarity: What Now?*, LAW360 (July 10, 2019, 9:13 PM), <https://www.law360.com/articles/1176454>.

98. Eileen McDermott, *It’s Official: SCOTUS Will Not Unravel Section 101 Web*, IPWATCHDOG (Jan. 13, 2020), <https://www.ipwatchdog.com/2020/01/13/scotus-will-not-unravel-section-101-web/id=117800/>.

99. Press Release, Patent Reform Framework, *supra* note 24.

100. *Id.*; Press Release, Thom Tillis U.S. Senator for N.C., Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act (May 22, 2019), <https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act>.

“on life support.”<sup>101</sup> The main obstacle holding up the bill is reaching a consensus on the statutory language.<sup>102</sup>

However, a more fundamental issue with the Tillis-Coons bill, and the majority of discussions around § 101 reform, is the inability to reconcile two competing objectives that currently exist in subject matter analysis. The first objective embodied in the original Congressional intent of § 101 is to promote the progress of science through the liberal reward of inventiveness. The second objective embodied in the preemption doctrine is to prevent hindering the progress of science by granting a reward that is too broad. Historically, both objectives have been reflected in the subject matter analysis of 35 U.S.C. § 101. However, except in the most extreme cases, the courts have struggled to adequately satisfy both objectives in a single test. The remainder of this Article focuses on identifying the root cause of the issues and proposing a framework that would progress both objectives.

### III. PREEMPTION ANALYSIS IS DISTINCT FROM SUBJECT MATTER ELIGIBILITY

The judicial exceptions have been part of the U.S. patent system since the mid-nineteenth century and trace their origins to the English courts where they were imported into U.S. law by the Court in *Le Roy v. Tatham*.<sup>103</sup> From the outset, the court recognized that while abstract principles, and natural laws are not patentable, the applications may be.<sup>104</sup> For 120 years, subject matter eligibility was a relative low bar to overcome, and “merely required that the patentee ‘carry the principle into effect, however simple and self-evident such means may be.’”<sup>105</sup> While principles that underlie preemption would occasionally be used to justify classifying a claim as a judicial exception, they generally were not used to distinguish a principle from its application.<sup>106</sup>

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101. Richard Lloyd, *Even if you forget about 101 reform, don't forget about DC*, IAM (Dec. 14, 2019), <https://www.iam-media.com/frandseps/even-if-you-forget-about-101-reform-dont-forget-about-dc>.

102. *Id.*

103. Doster, *supra* note 25; HICKEY, *supra* note 22, at 12-13 (“*Le Roy* relied on influential English patent cases to set forth a basic distinction between abstract ‘principles’ and natural laws (which may not be patented) and *practical applications* of those principles (which may be patented.)”); *Le Roy v. Tatham*, 55 U.S. 156 (1852).

104. Doster, *supra* note 25; HICKEY, *supra* note 22, at 11-12.

105. MENELL ET AL., *supra* note 43, at 277.

106. See, e.g., *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948) (“Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition.”); *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939) (“[The Court assume[d], without deciding the point, that [the] advance was [an] invention even though it was achieved by the logical application of a known scientific law to a familiar type

However, the Court would change this long-standing position in its first case to consider subject matter eligibility following the 1952 Act. In *Gottschalk v. Benson*,<sup>107</sup> the Court declared that the claim was ineligible because it was “so abstract and sweeping as to cover both known and unknown uses of the [principle]” and that if the patent were to be upheld, it “would wholly pre-empt the [principle] and in practical effect would be a patent on the [principle] itself.”<sup>108</sup> The analysis in *Benson* has complicated patent law as it is not clear at what point claim breadth crosses the line from covering a principle to covering its application. Recent cases such as *Alice* and *Mayo* have tried to address this question, but they have come up short. This section contends that the Court’s failure is a direct result of trying to apply principles of preemption and claim breadth to address issues of subject matter eligibility.

#### *A. Subject Matter Eligibility—Judicial Exceptions*

The principles of subject matter eligibility are embodied in § 101 and reflect the idea that inventiveness should be liberally rewarded.<sup>109</sup> However, the court has long recognized that implicit in § 101 is the principle that some subject matter is so fundamental to science that society never benefits if it is excluded.<sup>110</sup> The foundation of the judicial

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of antenna.”); *Am. Fruit Growers v. Brogdex Co.*, 283 U.S. 1, 11 (1931) (“Addition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property.”); *Dolbear v. Am. Bell Tel. Co.*, 126 U.S. 1, 534 (1888) (“In the present case the claim is not for the use of a current of electricity in its natural state as it comes from the battery, but for putting a continuous current, in a closed circuit, into a certain specified condition, suited to the transmission of vocal and other sounds, and using it in that condition for that purpose.”); *Tilghman v. Proctor*, 102 U.S. 707, 726-7 (1880) (clarifying that the claim in question in *O’Reily v. Morse* was invalidated because “[i]t was not a claim of any particular machinery, nor a claim of any particular process for utilizing the [natural phenomenon]; but a claim of the [natural phenomenon] itself”); *Corning v. Burden*, 56 U.S. 252, 263 (1853) (“‘A mere principle . . . is an abstract discovery; but a principle, so far embodied and connected with corporeal substances as to be in a condition to act and produce effects in any art, trade, mystery, or manual occupation, becomes the practical manner of doing a practical thing. It is no longer a principle, but a process.’”); *O’Reilly v. Morse*, 56 U.S. 62, 120 (1853) (“That is to say—[*Morse*] claims a patent, for an effect produced by the use of electro-magnetism distinct from the process or machinery necessary to produce it.”).

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

108. *Id.* at 68-72.

109. *Bilski v. Kappos*, 561 U.S. 593, 601 (2010) (“In choosing such expansive terms . . . modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope. Congress took this permissive approach to patent eligibility to ensure that ‘ingenuity should receive a liberal encouragement.’”).

110. *See, e.g., Neilson v. Harford* (1841) 151 Eng. Rep. 1266, 1270 (noting that inventors have “no right to take out [a] patent for a general notion or principle”); *Le Roy v. Tatham*, 55

exceptions is that “[t]he concepts covered by these exceptions are ‘part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none,’”<sup>111</sup> and any invention must come from its application.<sup>112</sup>

For example, in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*,<sup>113</sup> the Court considered whether a patent directed to selecting strains of bacteria for “leguminous plants” such that they did not inhibit each other was patent eligible.<sup>114</sup> At the outset of its opinion, the Court noted that the inventor did not modify the bacteria in any way to generate the inhibition, rather the inhibition was a product of nature.<sup>115</sup> The Court continued, that the products of nature such as “the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.”<sup>116</sup> As a result, the Court held that the claim was patent ineligible as the combination “produces no new bacteria [and] no change in the six species of bacteria,” and the discovery was only for “some of the handiwork of nature and hence is not patentable.”<sup>117</sup>

Thirty-two years later, the Supreme Court would decide the companion case, *Diamond v. Chakrabarty*.<sup>118</sup> In *Chakrabarty* the Court considered whether a “human-made, genetically engineered bacterium capable of breaking down crude oil” was patentable subject matter.<sup>119</sup> Echoing *Funk Bros.*, the Court noted that “a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter” as “[s]uch discoveries are ‘manifestations of . . . nature, free to all men and reserved exclusively to none.’”<sup>120</sup> However, unlike *Funk Bros.*, the claim in question was not to an “unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a

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U.S. 156, 175 (1852) (“A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right”).

111. *Bilski*, 561 U.S. at 602.

112. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

113. *Funk Bros. Seed Co.*, 333 U.S. 127.

114. *Id.* at 128 n.1 (“The product claims in suit are 1, 3, 4, 5, 6, 7, 8, 13, and 14. Claim 4 is illustrative of the invention which is challenged. It reads as follows: ‘An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus *Rhizobium*, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific.’”)

115. *Id.* at 130.

116. *Id.*

117. HICKEY, *supra* note 22, at 14; *Funk Bros. Seed Co.*, 333 U.S. at 130-32.

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

119. *Id.* at 303.

120. *Id.* at 309.

distinctive name, character [and] use.’”<sup>121</sup> As a result, the Court held that the claim did not cover a judicial exception as the bacteria was human-made and possessed “markedly different characteristics from any [bacteria] found in nature.”<sup>122</sup>

*Funk Bros.* and *Chakrabarty* represent the underlying principles of the judicial exceptions which is that some subject matter is so fundamental that it would be inappropriate to limit societies access to it. These are the “building blocks” of science, contained in the “storehouse of knowledge,” that should be “free to all men and reserved exclusively to none.”<sup>123</sup>

### B. Preemption

In contrast to the judicial exceptions, the fundamental premise behind preemption is that an inventor should only be rewarded for what they create and not for what is unknown.<sup>124</sup> The rationale being that granting such a right would prevent future improvements on the technology, limiting the progress of science.<sup>125</sup> In one of the earliest and most influential cases on the subject, Chief Justice Taney stated in *O’Reilly v. Morse*,<sup>126</sup> a case concerning Samuel Morse’s invention of the telegraph:

For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff’s specification. His invention may be less complicated—less liable to get out of order—less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.<sup>127</sup>

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121. *Id.* at 309-10.

122. *Id.* at 310.

123. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1366 (Fed. Cir. 2018); *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 208-09 (2014).

124. *See Gottschalk v. Benson*, 409 U.S. 63, 68 (1972) (“Here the ‘process’ claim is so abstract and sweeping as to cover both known and unknown uses of the BCD to pure binary conversion. The end use may (1) vary from the operation of a train to verification of drivers’ licenses to researching the law books for precedents and (2) be performed through any existing machinery or future-devised machinery or without any apparatus.”).

125. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012) (“[B]asic tools of scientific and technological work’ . . . might tend to impede innovation more than it would tend to promote it.”).

126. *O’Reilly v. Morse*, 56 U.S. 62 (1853).

127. *Id.* at 113.

More recently, the Supreme Court has echoed these same principles in *Gottschalk v. Benson*, which considered a “method for converting binary-coded decimal numerals into pure binary numerals” for use with general purpose computers.<sup>128</sup> The Court found the claim drafted in such broad terms as to cover both “known and unknown uses” with such uses “vary[ing] from the operation of a train to verification of drivers’ licenses to researching the law books for precedents” or “be performed through any existing machinery or future-devised machinery or without any apparatus.”<sup>129</sup>

What the case law has shown is that preemption analysis, at its core, is a question of claim scope. Is the claim narrow enough to cover only what is known to the inventor or is it so broad as to preempt future development by covering both the known and unknown applications? This objective is far more aligned with the written description requirement of 35 U.S.C. § 112(a) than it is the subject matter eligibility of § 101.<sup>130</sup> Despite this, courts have routinely mixed preemption analysis with subject matter analysis.<sup>131</sup> The literature is not clear why the courts have taken this approach. It may be partly historical, as preemption has been used since *O’Reilly v. Morse* to justify the judicial exceptions.<sup>132</sup> It may also be one of utility, as preemption has had success in distinguishing principles from applications in extreme cases.<sup>133</sup> However, whatever the reason, the objectives of the two doctrines are quite distinct, and as recent case law suggests, incompatible.

### *C. Genesis of Intermixing Preemption and Subject Matter Eligibility*

While *Morse* and *Benson* are helpful to understand the role preemption plays in patent analysis, the difficulty with these cases, and most cases relying on a theory of preemption, is that the preemption analysis is often intertwined with, and difficult to separate from, the

128. *Gottschalk*, 409 U.S. at 64.

129. *Id.* at 68.

130. *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1373 (Fed. Cir. 2017) (“Section 112 states that ‘[t]he specification shall contain a written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same . . . .’ This requirement ensures ‘that the inventor actually invented the invention claimed.’”); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (“The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not”).

131. *See, e.g., Benson*, 409 U.S. at 63; *Parker v. Flook*, 437 U.S. 584 (1978); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 66 (2012); *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014).

132. *See generally O’Reilly v. Morse*, 56 U.S. 62 (1853).

133. *See generally Benson*, 409 U.S. at 63.

subject matter analysis. For example, in *Benson*, the Court initially relied on a preemption style analysis of the claim, noting the claim covered both “known and unknown uses.”<sup>134</sup> However, it built off of that analysis to review the claim from a subject matter perspective, concluding the claim “would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.”<sup>135</sup>

There is a distinction in how early case law, and more modern cases have used preemption in their subject matter analysis. Generally, earlier cases considered the preemption doctrine to be a justification for classifying a claim as a principle instead of an application in extreme cases.<sup>136</sup> These cases tend to have more to do with the fact that the claims are for natural processes, but with some manifestations of a physical form that make it more difficult to simply classify it as such. Later cases on the subject have taken a step further from simply using preemption to justify a classification and incorporated the objectives of the preemption doctrine into its subject matter eligibility analysis.<sup>137</sup> While earlier case law has shown that combining preemption analysis with subject matter eligibility can work in the most extreme cases, as evidenced by the 120 years of case precedents,<sup>138</sup> extending that approach to analyze cases that deviate from these extremes has caused considerable issues in the more modern context.

### *I. Origins of Issue*

The court has long recognized that inventions should be rewarded not for the discovery of a natural principle, but its application.<sup>139</sup> In one of the cases that was instrumental in shaping patent eligibility doctrine in the U.S., the English Court of the Exchequer considered whether a patent for the improvement in the application of air in a bellows driven furnace was for the *discovery* that applying hot air to a furnace improved efficiency—which is a principle—or for the *mode* of applying the hot air—its application.<sup>140</sup> The court ultimately concluded that, while the patent was broad, it was directed to the “mode of applying [the principle]

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134. *Id.* at 68.

135. *Id.* at 72.

136. *Id.* at 71-72 (“The mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is affirmed, the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.”).

137. *See, e.g.*, *Parker v. Flook*, 437 U.S. 584 (1978).

138. If you exclude *Flook* and *Benson*, the case precedents are far longer.

139. *Le Roy v. Tatham*, 55 U.S. 156, 160 (1852).

140. *Neilson v. Harford* (1841) 151 Eng. Rep. 1266, 1266-67.

by means of a mechanical apparatus to [the] furnace” and therefore a patent-eligible application.<sup>141</sup>

The principle-application distinction from *Neilson v. Harford*,<sup>142</sup> would influence the Supreme Court in *Le Roy*.<sup>143</sup> While the Court did not decide the case in *Le Roy* on subject matter grounds, it did import the distinction of non-patentable natural laws from the practical application of those principles.<sup>144</sup> The Court stated that while a principle cannot be patented, a “new property discovered in matter, when practically applied, in the construction of a useful article of commerce or manufacture, is patentable.”<sup>145</sup> As the court noted, “invention is not in discovering [the natural principles], but in applying them to useful objects.”<sup>146</sup>

However, by the 1970s personal computers were emerging and there was a recognition that these systems significantly blurred the lines between an unpatentable principle and a patentable application, and a considerable debate raged as to whether computer programs were patentable.<sup>147</sup> The Court confronted this issue head on in *Gottschalk v. Benson* when it considered a claim for a method to convert binary coded decimal numbers into pure binary numbers using a general purpose computer.<sup>148</sup> While the Court ruled the claim covered unpatentable subject matter, it did not rule the claim was for an abstract idea.<sup>149</sup> Rather, the Court ruled that the claim was “so abstract and sweeping” as to be in practical effect “a patent on the algorithm itself.”<sup>150</sup>

To reach this conclusion, the Court had to expand the judicial exceptions beyond the original three categories—abstract ideas, laws of nature, and natural phenomenon—to include the equivalents thereof. While *Benson* might have been considered on §112 grounds, the rejection on § 101 grounds reflected a skepticism as to whether computer programs were patentable in the first place.<sup>151</sup> Since *Benson*, the patent

141. *Id.*

142. *Neilson*, 151 Eng. Rep. 1266.

143. *See Le Roy v. Tatham*, 55 U.S. 156, 175 (1852).

144. *See id.* at 174-75.

145. *Id.* at 175.

146. *Id.*

147. *See Gottschalk v. Benson*, 409 U.S. 63, 72 (1972) (“Uncertainty now exists as to whether the statute permits a valid patent to be granted on programs. Direct attempts to patent programs have been rejected on the ground of nonstatutory subject matter. Indirect attempts to obtain patents and avoid the rejection, by drafting claims as a process, or a machine or components thereof programmed in a given manner, rather than as a program itself, have confused the issue further and should not be permitted.”).

148. *Id.* at 64.

149. *See id.* at 68-72.

150. *Id.*

151. *See id.* at 72-73.

system has become more accepting of such patents, but *Benson* has left a legacy of skepticism towards subject matter eligibility of software patents. As a result, the Court has relied on, and developed case law around invalidating suspect patents on subject matter grounds despite the fact other grounds may be more appropriate or manageable.

## 2. *Parker v. Flook*

In *Parker v. Flook*,<sup>152</sup> the Supreme Court built off of its original expansion of the scope of the judicial exceptions in *Benson*.<sup>153</sup> The claim in question was directed to a method for dynamically adjusting alarm limits in the catalytic conversion of hydrocarbons which relied on a mathematical formula.<sup>154</sup> What makes this case particularly fascinating, and quite distinct from *Benson*, is the claim did not “wholly preempt the mathematical formula” since it was only directed to the petrochemical and oil-refining industries.<sup>155</sup> Yet, despite this, the Court held the claim was directed to an unpatentable judicial exception.<sup>156</sup>

To reach its conclusion, the Court deviated substantially from precedent. Instead of asking whether the claim was so broad as to effectively be the mathematical formula, as was the case in *Benson*, the Court asked whether the “claim’s elements, individually and as an ordered combination, contain[ed] an ‘inventive concept’ sufficient to transform the claim into patent eligible subject matter.”<sup>157</sup> That is, after removing all that was well known and routine from the claim, if the only thing left was the mathematical formula, it covered ineligible subject matter.<sup>158</sup> In the case of *Flook*, the Court found that after removing the mathematical formula, the claim only consisted of well-known processes, techniques, and methods and, therefore, must cover ineligible subject matter.<sup>159</sup>

*Flook* has been criticized for its incorporation of elements of novelty and non-obviousness in its subject matter analysis.<sup>160</sup> Yet, more

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

153. *See generally id.*

154. *Id.* at 585-86.

155. *Id.* at 589-90.

156. *Id.* at 594-95.

157. IPOA, *supra* note 20, at 8.

158. *Flook*, 437 U.S. at 594 (“Here it is absolutely clear that respondent’s application contains no claim of patentable invention. The chemical processes involved in catalytic conversion of hydrocarbons are well known, as are the practice of monitoring the chemical process variables, the use of alarm limits to trigger alarms, the notion that alarm limit values must be recomputed and readjusted, and the use of computers for ‘automatic monitoring-alarming.’”).

159. *See id.* at 594-95.

160. IPOA, *supra* note 20, at 7-9.

fundamentally what *Flook* shows is the difficulties with intermixing preemption analysis with subject matter analysis. The Court having found that the claim in *Flook* did not fall into the same extreme category as *Benson*, it proceeded to develop a new test relying on the concept of inventiveness to distinguish an application from a principle.<sup>161</sup> However, this approach serves neither the purpose of subject matter eligibility nor of preemption. First, whether or not elements of a claim are “novel or independently eligible for patent protection is irrelevant to the question of whether the claims as a whole recite subject matter eligible for patent protection under § 101.”<sup>162</sup> Similarly, whether a claim element is inventive is immaterial as to whether the elements add meaningful limitations to a claims scope.

### 3. *Diamond v. Diehr*

Three years after *Flook*, the Supreme Court appeared to correct the subject matter analysis in *Diamond v. Diehr*,<sup>163</sup> but they would not provide any replacement for how to handle overly broad claims.<sup>164</sup> The patent in *Diehr* was directed to a process for molding rubber that relied on the Arrhenius equation to determine curing time.<sup>165</sup> As the Court pointed out, when determining subject matter eligibility, the claim should be “considered as a whole.”<sup>166</sup> It is “inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.”<sup>167</sup> Further, the fact that one or more of the steps “may not, in isolation, be novel or independently eligible for patent protection is irrelevant to the question of whether the claims as a whole recite subject matter eligible for patent protection under § 101.”<sup>168</sup>

Relying on this framework, the Court concluded that *Diehr*’s claim covered patent eligible subject matter. However, instead of overruling *Flook*, the Court distinguished *Diehr* from *Flook* by noting that, unlike

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161. *See id.* at 7-8.

162. *Diamond v. Diehr*, 450 U.S. 175, 193 n.15 (1981).

163. *Diamond*, 450 U.S. 175.

164. POA, *supra* note 20, at 9 (“The dissent in *Flook* became part of the majority in *Diehr*, where the Court correctly rejected *Flook*’s point of novelty approach and its incorporation of novelty considerations in the eligibility analysis.”); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1347 (Fed. Cir. 2019) (en banc) (“Mayo’s rationale thus follows the point of novelty/inventive concept reasoning of *Flook* and the *Diehr* dissent. As such, Mayo is in considerable tension with *Diehr*’s instruction to consider claims ‘as a whole’ and *Diehr*’s disapproval of dissecting claims into elements and ignoring non-novel elements in the § 101 analysis.”).

165. *Diehr*, 450 U.S. at 177.

166. *Id.* at 188.

167. *Id.*

168. *Id.* at 193 n.15.

*Flook*, the patent “do[es] not seek to pre-empt the use of that equation.”<sup>169</sup> But this distinction is rather unsettling as the *Flook* Court explicitly acknowledged that the patent did not “wholly preempt the mathematical formula.”<sup>170</sup> To get around this, the *Diehr* Court classified this limitation as a field limitation, not accorded any weight in determining claim scope.<sup>171</sup> However, the Court did not provide any explanation for why such a limitation should not carry any weight. One possibility is that these types of limitations do not distinguish known and unknown applications, and preemption would still occur, albeit in a narrower respect.<sup>172</sup> However, this is mere speculation as the Court did not articulate their rationale.

#### 4. Modern Preemption and Subject Matter Eligibility

After *Diehr*, the Supreme Court did not decide another subject matter eligibility case for thirty years, and left the development of the law to the Federal Circuit.<sup>173</sup> During that period, the Federal Circuit, building off of *Diehr*, significantly expanded the scope of subject matter eligibility to such an extent that invalidation due to subject matter ineligibility was rare.<sup>174</sup> However, this changed in 2010 when the Supreme Court decided four cases in five years, starting with *Bilski v. Kappos* and eventually culminating into the *Alice/Mayo* two-step analysis.<sup>175</sup>

In *Bilski*, the Court concluded that claims directed to the concept of hedging and its applications were unpatentable subject matter.<sup>176</sup> But despite *Diehr*'s guidance,<sup>177</sup> the *Bilski* Court imported from *Flook* the concept of inventiveness noting that well known techniques do not transform patentable ineligible subject matter into eligible subject

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169. *Id.* at 176.

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

171. *Diehr*, 450 U.S. at 191 (“A mathematical formula as such is not accorded the protection of our patent laws . . . and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.”).

172. *See infra* Section IV.B.

173. *Diehr* was decided in 1981 and the Court would not decide *Bilski* until 2010.

174. Mark A. Lemley et al., *Life After Bilski*, 63 STAN. L. REV. 1315, 1318 (2011) (“[A]fter 1998, patentable subject matter was effectively a dead letter.”); *see also* HICKEY, *supra* note 22, at 15.

175. HICKEY, *supra* note 22, at 16.

176. *Bilski v. Kappos*, 561 U.S. 593, 611-12 (2010).

177. *Diamond v. Diehr*, 450 U.S. 175, 193 n.15 (1981) (“The fact that one or more of the steps . . . may not, in isolation, be novel or independently eligible for patent protection is irrelevant to the question of whether the claims as a whole recite subject matter *eligible* for patent protection under § 101.”).

matter.<sup>178</sup> The Court further embraced this approach in *Mayo v. Prometheus*.<sup>179</sup> In *Mayo*, after the Court first quickly concluded that the claim in question was directed to an unpatentable law of nature, it then dissected the claims into their component parts and held that each claim element consisted of “well-understood, routine, conventional activity already engaged in by the scientific community” that add nothing to the law of nature.<sup>180</sup> The modern framework for subject matter eligibility analysis was finalized in *Alice* by the Court implementing a two-step test.

Under *Alice*, the first step of the framework is to ask whether the claim is directed to patent ineligible subject matter.<sup>181</sup> To be directed to a patent ineligible subject matter, the claim as a whole must focus on the ineligible subject matter, and not just involve the subject matter.<sup>182</sup> However, this determination is done in consideration of the state of art.<sup>183</sup> If the claims are directed to ineligible subject matter, the Court then searches for an “inventive concept” that “‘transform the nature of the claim’ into a patent-eligible application.”<sup>184</sup>

The *Alice/Mayo* framework suffers from the same flaws as *Flook* and seems to ignore *Diehr*’s guidance to view the claim as a whole.<sup>185</sup> While “[t]he Court indicated that it had considered the claim ‘as a whole,’ . . . it did so by reviewing the claim on an element-by-element basis in search of something new and inventive, discounting the formula as ‘assumed to be within the prior art.’”<sup>186</sup> What this approach does is ignore meaningful limitations on the application of an abstract idea or

178. *Bilski*, 561 U.S. at 612 (“These claims attempt to patent the use of the abstract idea of hedging risk in the energy market and then instruct the use of well-known random analysis techniques to help establish some of the inputs into the equation”).

179. See generally *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

180. *Id.* at 79-80.

181. *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 218 (2014) (“We must first determine whether the claims at issue are directed to a patent-ineligible concept.”).

182. *Id.* at 217 (“At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law. At some level, ‘all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.’ Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept.”).

183. IPOA, *supra* note 20, at 15 (“In its analysis of step one, the Court supported its conclusion that the claims in *Alice* were directed to an abstract idea by considering the state of the art.”).

184. *Alice Corp. Pty.*, 573 U.S. at 217.

185. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1347 (Fed. Cir. 2019) (Chen, J., concurring) (“As such, *Mayo* is in considerable tension with *Diehr*’s instruction to consider claims ‘as a whole’ and *Diehr*’s disapproval of dissecting claims into elements and ignoring non-novel elements in the § 101 analysis.”).

186. *Id.* at 1344.

natural principle, and claim that by an application becoming known it can no longer serve as a claim limitation.

There is no better example of the difficulties that have been caused by the *Alice/Mayo* framework than with *Athena Diagnostics, Inc. v. Mayo Collaborative Services* (“*Athena*”).<sup>187</sup> The claim in *Athena* was directed to a method for diagnosing neurological disorders by detecting antibodies to the muscle specific tyrosine kinase (MuSK) protein.<sup>188</sup> As Justice Chen noted, this class of patents “intuitively seem to be the kind of subject matter the patent system is designed for: to encourage the risky, expensive, unpredictable technical research and development.”<sup>189</sup> Yet, following the *Mayo* framework, “after setting aside the law of nature, ‘any additional steps consist[ed] of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add[ed] nothing significant beyond the sum of their parts taken separately.’”<sup>190</sup> That is, once you remove the natural phenomenon from the equation, all the reviewer is left with is “well-understood, routine, conventional activities.”

The question is, how do you distinguish cases such as *Athena* from cases that simply “implement an abstract idea using a computer,” such as in *Benson*? Subject matter alone is wholly inoperative to serve as a distinguishing factor as both cases are directed to judicial exceptions.<sup>191</sup> Further, *Athena* shows that inventiveness is insufficient as once the court removes the judicial exception from the analysis, the claims contain only routine and well-known tools and steps. The distinguishing factor seems to be one of claim breadth. Does the claim cover both known and unknown uses so as to prevent future development? In the case of *Athena*, the claim is directed to a particularly narrow application for diagnosing neurological disorders related to MuSK, which, unlike *Flook*, intuitively seems to only cover uses known to the inventor.<sup>192</sup> The next section sets forth a framework for analyzing claim breadth and provides examples of the framework in action.

#### IV. PATH FORWARD

Most of the focus driving the recent changes to subject matter eligibility is to combat aggressive enforcement of overly-broad, low-

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187. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743 (Fed. Cir. 2019).

188. *Id.* at 747.

189. *Athena Diagnostics, Inc.*, 927 F.3d at 1352 (Chen, J., concurring).

190. *Id.* at 1347.

191. See generally IPOA, *supra* note 20.

192. See *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 747 (Fed. Cir. 2019).

quality patents by non-practicing entities.<sup>193</sup> However, the Court has struggled with creating reliable and predictable tests to invalidate such low-quality patents.<sup>194</sup> As discussed above, the Court has relied on subject matter eligibility to address issues of claim breadth, with the rationale being that patents should not be awarded for claims that cover both the known and unknown. However, to determine when a claim preempts an unknown application, the Court has relied on inventiveness concepts, which confuses the issue by mixing in elements of novelty and obviousness in the analysis.<sup>195</sup> Whether a claim is novel or obvious is irrelevant to whether it claims known and unknown uses. This section discusses the relevant considerations in developing a new framework for analyzing claim subject matter eligibility and determining when a claim is overly broad.

#### *A. Preemption Analysis Should Be Removed from Subject Matter Analysis*

The major issue with preemption and the judicial exceptions is that the Court has intermixed the two analyses in subject matter eligibility law. The distinct objectives of the preemption doctrine and judicial exceptions make it difficult to create a predictable law capable of reasonably advancing both objectives. At the heart of preemption analysis is the question of whether the claim covers both known and unknown applications of a principle. The preemption doctrine recognizes that by awarding an exclusive right to unknown applications of an invention, the progress of science is impeded as the inventor controls the rights of any future developments.<sup>196</sup> In contrast, the objective of the judicial exceptions is to ensure that the fundamental building blocks of science are not exclusive to any person.<sup>197</sup>

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193. *Athena Diagnostics, Inc.*, 927 F.3d at 1337 (Hughes, J., concurring) (“I, for one, would welcome further explication of eligibility standards in the area of diagnostics patents. Such standards could permit patenting of essential life saving inventions based on natural laws while providing a reasonable and measured way to differentiate between overly broad patents claiming natural laws and truly worthy specific applications.”); *id.* (Dyk, J., concurring) (“The *Mayo/Alice* framework has thus proven to be both valuable and effective at invalidating overly broad, non-inventive claims that would effectively ‘grant a monopoly over an abstract idea.’”); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 85 (2012) (“The Court has repeatedly emphasized [claim breadth] concern, a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature.”).

194. See generally IPOA, *supra* note 20.

195. *Id.* at 10.

196. See HICKEY, *supra* note 22, at 24-25.

197. See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1366 (Fed. Cir. 2018); *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014).

While preemption analysis, as embodied in subject matter eligibility, has found utility in distinguishing an ineligible judicial exception from patent-eligible application in extreme cases, in its current form it does not establish whether the claim covers unknown uses. What it does in these extreme cases is to short-circuit the subject matter analysis and conclude whether the claim is a principle or application is irrelevant if the claim is so broad that failing for preemption is a foregone conclusion. While the Court has tried to extend this analysis to cover cases that deviate from these extreme examples, it has failed to create a reliable framework.

Subject matter analysis is rooted in 35 U.S.C. § 101, which states “[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 the conditions and requirements of this title.”<sup>198</sup> This language has remained virtually unchanged since the Patent Act of 1793.<sup>199</sup> At the heart of the language is Thomas Jefferson’s view that inventiveness should be liberally rewarded.<sup>200</sup> The Court has explicitly recognized that the Congressional intent of § 101 is for subject matter eligibility to be given a wide scope.<sup>201</sup> The judicial exceptions provide an important counterbalance to this role by recognizing that some subject matter is so fundamental that providing such an award does not promote the progress of science.<sup>202</sup>

There is an important debate to be had as to how broad the judicial exceptions should be.<sup>203</sup> For example, should the judicial exceptions cover not only abstract ideas, natural phenomenon, and laws of nature but also equivalents thereof?<sup>204</sup> However, this debate is independent of determining whether society should award a patent for claims that cover

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198. U.S.C. § 101 (1952).

199. *In re Bilski*, 545 F.3d 943, 966 (Fed. Cir. 2008), *aff’d but criticized sub nom.* *Bilski v. Kappos*, 561 U.S. 593 (2010) (“The criteria for patentability established by the 1793 Act remained essentially unchanged until 1952, when Congress amended § 101 by replacing the word ‘art’ with ‘process’ and providing in § 100(b) a definition of the term ‘process.’ The Supreme Court has made clear that this change did not alter the substantive understanding of the statute; it did not broaden the scope of patentable subject matter.”).

200. *In re Bilski*, 545 F.3d at 1011.

201. *Bilski*, 561 U.S. at 601 (“In choosing such expansive terms . . . modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope. Congress took this permissive approach to patent eligibility to ensure that ‘ingenuity should receive a liberal encouragement.’”).

202. *See Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1366 (Fed. Cir. 2018); *Alice Corp. Pty. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014).

203. *See Lemley et al.*, *supra* note 174, at 1330 n.79.

204. *See supra* Section III.C.

both known and unknown applications. While preemption may serve a useful justification for classifying a claim as covering a principle, intermixing the two in the subject matter analysis confuses the independent role that each one plays.

In many ways, the preemption approach is remarkably similar to the written description framework of 35 U.S.C. § 112:

[t]he purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to ‘recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.’<sup>205</sup>

The Federal Circuit has at least once suggested the role of the written description requirement is to prevent the applicant from preempting future development.<sup>206</sup> Yet, with what seems to be a fluke of history, the Court has not relied on § 112 for preemption analysis but rather intermixed it with subject matter eligibility.<sup>207</sup> Worse yet, because § 101 is a threshold question,<sup>208</sup> determining claim breadth as part of subject matter eligibility has resulted in § 112 to not develop the necessary framework to analyze these claims.<sup>209</sup> Therefore, it is crucial that any framework used to analyze a claim recognizes each doctrine’s distinct role and clearly establishes that preemption analysis is independent of subject matter analysis.

One concern about removing preemption from the subject matter analysis is that it risks turning § 101 into a dead letter law, which can simply be overcome by crafty claim drafting.<sup>210</sup> Given the low invalidation rates for subject matter eligibility during the 1990s, that concern would seem plausible.<sup>211</sup> However, what this ignores is the role

205. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991)).

206. *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993) (“Claiming all DNA’s that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived.”).

207. *See Gottschalk v. Benson*, 409 U.S. 63, 63 (1972). *Benson* was the first supreme court case covering computer technology and the Court chose to invalidate on subject matter grounds instead of written description grounds. *Id.*

208. *Diamond v. Diehr*, 450 U.S. 175, 188 (1981) (“[T]hat process is at the very least not barred at the threshold by § 101.”); *Bilski v. Kappos*, 561 U.S. 593, 602 (2010) (“The § 101 patent-eligibility inquiry is only a threshold test.”).

209. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1338 (Fed. Cir. 2019) (Dyk, J., concurring) (“Those sections [§ 102, § 103] and § 112 do not adequately address ‘the risk that a patent on the [natural] law would significantly impede future innovation.’”).

210. Lemley et al., *supra* note 174, at 1318 (“[A]fter 1998, patentable subject matter was effectively a dead letter.”); *see also HICKEY*, *supra* note 22, at 15.

211. *See HICKEY*, *supra* note 22, at 15.

that subject matter eligibility plays. That is, to act as a rough filter to weed out those claims that cover subject matter that is not suitable for receiving patent protection—such as principles—and, in many ways, to guide the innovator towards claims suitable for protecting—application of those principles. This is a role that is well suited for the USPTO to fulfill, and one in which they were fulfilling long before *Mayo* and *Alice*.<sup>212</sup> In addition, this concern ignores the court's role in counterbalancing the breadth of subject matter eligibility with the judicial exceptions. Removing preemption from the subject matter analysis does not remove judicial exceptions. Rather, it clarifies that the two are distinct doctrines with their own objectives.

### *B. A New Framework*

After removing preemption analysis from subject matter eligibility, the challenge becomes how to determine when a claim is so broad as to not deserve a patent. *Benson* provides the obvious extreme. That is, where a claim covers both all known and unknown uses it is too broad to receive patent protection.<sup>213</sup> But beyond this extreme, the answer is less clear. To arrive at an answer, there needs to be clarity around what is meant by not patenting unknown uses.

One interpretation is that an innovator should not receive protection for what they did not invent prior to the claimed invention's effective filing date. There is some merit to this interpretation as it seems particularly unfair to grant an exclusive right to an innovator for something that they did not create. However, this approach is flawed in two significant ways. First, it is challenging to reasonably establish all uses known to the innovator at the time of filing an application. This would likely require an enormous disclosure, making examination potentially unworkable. Second, and most importantly, the approach focuses on what the inventor knows and not what would impede the progress of science, which is the preemption's actual objective.<sup>214</sup> Whether or not an inventor knows of all uses is irrelevant to whether the exclusion would prevent future innovations. As a result, this interpretation would very likely be underinclusive, potentially leading to absurd results in the courtroom with the court invalidating claims because an innovator did not establish they knew of an obvious modification covered by the claim, as well as potentially never-ending

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212. See Chien, *supra* note 72.

213. *Gottschalk v. Benson*, 409 U.S. 63, 68-72 (1972).

214. See *O'Reilly v. Morse*, 56 U.S. 62, 113 (1853).

specifications that claim every possible combination or uses to prevent such absurd results.

The proper interpretation seems to be that under the doctrine of preemption a claim is overly-broad and should not be afforded protection if it covers more than what the inventor can reasonably establish they created, and any modifications that would be obvious to a person having ordinary skill in the art (PHOSITA). This approach's main advantage is it removes the subjective nature of measuring what is known to the inventor, which is often amorphous and hard to define and relies on an objective measure for determining claim breadth.<sup>215</sup> Another advantage is that the approach brings greater certainty to the applicant that the court will not invalidate their claims due to failing to establish they knew all potential applications of what the claim covers without impeding science's progress. It is important to note that while this approach does leverage the PHOSITA standard of § 103, this standard merely provides an objective measure to determine claim breadth and is not meant to intermix the obviousness analysis with the preemption analysis.

### *C. Applications of the New Framework*

As discussed above, there are striking similarities between § 112 and the preemption doctrine. There is an important debate beyond the scope of this Article as to whether the claim breadth analysis should form part of the § 112 framework, and whether that analysis is compatible with that framework.<sup>216</sup> However, what this Article has established is the analysis should not form part of subject matter analysis. Further, the analysis should be measured using an objective standard. For example, in *Flook* the Court was concerned with a claim that automatically updated an alarm limit in the field of catalytic conversion of hydrocarbons using a mathematical formula.<sup>217</sup> Under this new framework, the Court would first consider whether the claim as a whole, irrespective of any issues of novelty, non-obviousness, or claim breadth, is a patent-ineligible abstract idea, or a patent-eligible application. As the claim was directed to applying a mathematical formula to adjust an alarm limit in a chemical process, the Court would likely find the claim is directed to a patent-eligible application.

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215. IPOA, *supra* note 20, at 3 (“In part as a reaction to this subjective ‘invention’ standard, Congress passed the Patent Act of 1952 with the intent that the scope of patent-eligible subject matter be broad and that patentability would be determined on objective basis. This approach was codified in section 103, which bases patentability on non-obviousness, using the objective standard of a person of ordinary skill in the art.”).

216. See Lemley et al., *supra* note 174, at 1330 n.79.

217. *Parker v. Flook*, 437 U.S. 584, 585-86 (1978).

Once patent eligibility is established, the Court then considers novelty, non-obviousness, written description, and claim-breadth. Under the claim-breadth analysis, the Court compares the claim against the specification and determines whether the claim only covers what the inventor has established they knew at the time of filing and any obvious modifications. Under this analysis, it is easy to see why the field limitation in *Flook* does not save it from invalidation. The field limitation not only would cover the intended scope of catalytic converters for removing pollutants,<sup>218</sup> but would also cover any catalytic conversion of hydrocarbons including the production of fuels, synthesis of commodity chemicals, and any other process that involves converting hydrocarbons using any particular catalyst. Modifications of *Flook*'s claimed invention to cover these fields would be far beyond obvious to one having ordinary skill in the art and, therefore, the claim would be correctly invalidated as overly broad.

*Diehr* provides a nice counterexample to *Flook*. *Diehr*'s claim was directed to “[a] method of operating a rubber-molding press for precision molded compounds aided by a digital computer” employing the Arrhenius equation for determining curing time.<sup>219</sup> As the claim is for applying the Arrhenius formula to molding rubber, the Court would (and did) find the claim is patent-eligible.<sup>220</sup> The question then is whether the claim is overly broad. What makes *Diehr* distinct from *Flook* is the claim in *Diehr* is directed to a specific application of operating a rubber-molding press for precision molded compounds, versus *Flook* that is directed to updating alarm limits in the field of catalytic conversion of hydrocarbons. Where the claim in *Flook* conceivably covers applications in many areas beyond the intended application of catalytic converters, *Diehr* is specific in its application, and any modifications the claim covers would conceivably be obvious to those of ordinary skill. As a result, the Court would likely find the claim does not extend beyond the bounds of what the inventor knew or obvious modifications.

Finally, in *Athena*, the claim was directed to a method for diagnosing certain neurological disorders by detecting antibodies to the muscle-specific tyrosine kinase (MuSK) protein.<sup>221</sup> What is particularly interesting about *Athena* is it is very likely that the claim covers all

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218. *Parker v. Flook*, OYEZ, <https://www.oyez.org/cases/1977/77-642> (last visited Apr. 10, 2021) (“Dale R. Flook applied for a patent on a method of adjusting alarm limits in response to changes that occur during the catalytic conversion process [of a catalytic converter]”).

219. *Diamond v. Diehr*, 450 U.S. 175, 177, 179 n.5 (1981).

220. *Id.* at 192-93.

221. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d. 743, 746-47 (Fed. Cir. 2019).

conceivable applications. However, it is hard to imagine any non-obvious application of an antibody's correlation to a disease, other than to diagnose the disease. The inability to find an inventive concept for applying the natural law is why medical diagnostic patents have struggled to find patent eligibility.<sup>222</sup> Yet many agree that the progress of science is hindered by not affording such invention protection.<sup>223</sup> What *Athena* reflects is the balance between hindering the progress of science by providing protection for overly broad claims and hindering the progress of science by not providing any protection. It is irrelevant whether the claim or patent covers all conceivable applications of a principle, so long as it only covers what is known to the inventor and obvious modifications. While science may not progress any further in that particularly narrow field by granting the patent, there is likely no more progress to be had in the field and science more generally will be hindered by failing to grant the patent.

By framing the analysis in terms of what is known to the inventor, the new framework properly addresses *Athena's* issues. Under the new framework, a reviewer would likely find the claim as patent-eligible as it covers an application of a natural law—applying the correlation of the antibody to the disease to diagnose the disease—and not the natural law itself. A reviewer would also likely find the claim is not overly broad, as it is directed to the specific application of diagnosing neurological disorders related to MuSK. Even though the claim likely covers all potential applications of the natural law, it is not necessarily overly broad as all potential modifications of the application established by the inventor would be obvious to one skilled in the art.

## V. CONCLUSION

In conclusion, with what seems to be a fluke of history, the Court has developed a subject matter analysis framework that relies on the preemption doctrine to justify invalidation. However, this Article has established that preemption has a distinct objective that is more closely aligned with the written description framework of § 112 than it is with the subject matter eligibility framework of § 101. This Article suggests that the intermixing of preemption analysis with subject matter eligibility likely originated from the Court's initial suspicion of subject

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222. See Sanjeev Mahanta, *Patent Eligibility of Medical Diagnostic Inventions: Where Are We Now, and Where Are We Headed?*, IPWATCHDOG (Apr. 14, 2019), <https://www.ipwatchdog.com/2019/04/14/patent-eligibility-of-medical-diagnostics-inventions-where-are-we-now-and-where-is-there-to-go/id=108263/>.

223. *Id.*; see also *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1352 (Fed. Cir. 2019) (Chen, J., concurring).

matter eligibility of computer programs in *Gottschalk v. Benson*, which was further exacerbated in *Parker v. Flook* through the introduction of an inventiveness test. While the Court would start to correct the record in *Diamond v. Diehr*, it would later reverse course and further embrace the inventive concept approach in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, and *Alice Corp. v. CLS Bank*. As a result, the Court has created an arbitrary and difficult to apply test, creating a chasm between the USPTO and courts reminiscent of the period leading up to the 1952 Act.

To address the issues the patent system currently faces, this Article proposes a new framework that separates the preemption analysis from the subject matter eligibility analysis. Under this new framework, subject matter eligibility would revert to its pre-*Benson* approach where judicial exceptions only cover natural phenomenon, natural laws, and abstract ideas but not their equivalents. Further, the preemption analysis would be based on an objective standard where a claim is determined to be overly broad if it covers more than what the inventor has established they invented or modifications that are obvious to a person having ordinary skill in the art. After establishing the new framework, this Article shows that this new framework provides a reasonable explanation for why the field limitation in *Flook* is not sufficient for satisfying claim breadth which was unclear in the Court's decision. Finally, this Article contends that under this new framework the claim in *Athena* would likely be found to be patent eligible, and not overly broad, a result that many agree is reasonable given the nature of the technology.