

# FINAL REPORT OF THE BERKELEY CENTER FOR LAW & TECHNOLOGY SECTION 101 WORKSHOP: ADDRESSING PATENT ELIGIBILITY CHALLENGES

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## ABSTRACT

Over the past five years, the Supreme Court has embarked upon a drastic and far-reaching experiment in patent eligibility standards. Since the founding era, the nation's patent statutes have afforded patent protection to technological innovations and practical applications of scientific discoveries. However, the Supreme Court's 2012 decision in *Mayo Collaborative Services v. Prometheus Laboratories* imposed a new limitation on the scope of the patent system: a useful application of a scientific discovery is ineligible for patent protection unless the inventor also claims an "inventive" application of the discovery. The following year, the Court ruled that discoveries of the location and sequence of DNA compositions that are useful in diagnosing diseases are ineligible for patent protection in *Association for Molecular Pathology v. Myriad Genetics, Inc.* Additionally, in its 2014 *Alice Corp. v. CLS Bank International* decision, the Court ruled that software-related claims are ineligible for patent protection unless the abstract ideas or mathematical formulas disclosed are inventively applied.

These decisions sent shock waves through the research, technology, business, and patent communities. Medical diagnostics companies experienced a dramatic narrowing of eligibility for core scientific discoveries. Reactions within the information technology community have been mixed, with some applauding the tightening of patent eligibility standards on software claims and the opportunity to seek early dismissal of lawsuits, particularly those filed by non-practicing entities, and others criticizing the shift in patent eligibility. Several members of the Federal Circuit bluntly criticized the Supreme Court's shift in patent eligibility standards on jurisprudential and policy grounds. Additionally, the Patent Office has struggled to apply the Supreme Court's new and rapidly evolving standards.

As this sea change unfolded, many patent practitioners, scholars, PTO officials, and jurists hoped that the Supreme Court would provide fuller and clearer guidance on patent eligibility standards. In the aftermath of the Supreme Court rejecting the invitation to reexamine its *Mayo* decision, many stakeholders have shifted their attention toward legislative reforms. This

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Report summarizes the presentations and discussion of a workshop that included leading industry representatives, practitioners, scholars, policymakers, and a retired jurist exploring the legal background and effects bearing on legislative action.

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## I. INTRODUCTION

Over the past five years, the Supreme Court has embarked upon a drastic and far-reaching experiment in patent eligibility standards. Since the beginning of the American patent system, the nation’s patent statutes have afforded patent protection to technological innovations and practical applications of scientific discoveries.<sup>1</sup> As the Supreme Court explained long ago, although no one can patent a natural phenomenon or “principle, *in the abstract*” (such as steam power, electricity, or “any other power in nature”), the patent system has recognized an invention in “*applying* [the processes used to extract, modify, and concentrate natural phenomena] to useful objects.”<sup>2</sup>

Notwithstanding the relative stability of this long-standing legal principle<sup>3</sup> and in the absence of any legislative change, the Supreme Court engrafted an additional substantive requirement for patent eligibility of scientific discoveries in its 2012 *Mayo Collaborative Services, v. Prometheus Laboratories* decision.<sup>4</sup> The Court unanimously held that a useful application of a scientific discovery is

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1. See Brief of Professors Jeffrey A. Lefstin & Peter S. Menell as Amici Curiae in Support of Petitioner for a Writ of Certiorari at 4–14, *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 136 S. Ct. 2511 (2016) (No. 15-1182), 2016 WL 1605520 [hereinafter Lefstin-Menell Sequenom Amicus Cert. Petition Brief].

2. *Le Roy v. Tatham*, 55 U.S. 156, 175 (1853) (emphasis added).

3. The Supreme Court’s decisions in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948) and *Parker v. Flook*, 437 U.S. 584 (1978) arguably strayed from this principle. However, *Funk Brothers* was largely ignored following the enactment of the 1952 Patent Act, and *Flook* was effectively overruled three years later in *Diamond v. Diebr*, 450 U.S. 175 (1981).

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

ineligible for patent protection unless the inventor has claimed an additional “inventive” application of the discovery.<sup>5</sup> The following year, the Court ruled that the discovery of an isolated DNA sequence useful in diagnosing diseases is ineligible for patent protection, regardless of whether the sequence would be novel or non-obvious over the prior art.<sup>6</sup> Additionally, in its 2014 *Alice Corp. v. CLS Bank International* decision,<sup>7</sup> the Court ruled that software-related claims are ineligible for patent protection unless the abstract ideas, algorithms, or mathematical formulas disclosed are inventively applied.<sup>8</sup>

These decisions have sent shock waves through the research, technology, business, and patent communities. Medical diagnostics companies have experienced a dramatic narrowing of eligibility for core scientific discoveries.<sup>9</sup> Reactions within the digital and high technology community have been mixed.<sup>10</sup> Many high technology companies that rely on software innovation—ranging from start-ups to Google—and their customers welcomed the tightening of patent eligibility standards on software claims and the opportunity to seek early dismissal of lawsuits, particularly those filed by non-practicing entities.<sup>11</sup> At the same time, other high technology companies that also rely on software innovation—ranging from start-ups seeking financing to IBM—have been sharply critical of the shift in the patent eligibility landscape.<sup>12</sup> Several members of the Federal Circuit have bluntly criticized the Supreme Court’s shift in patent eligibility standards on jurisprudential and policy grounds.<sup>13</sup> Additionally, the Patent Office has struggled to apply the Supreme

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5. *See id.* at 81.

6. *See Ass’n for Molecular Pathology v. Myriad Genetics*, 569 U.S. 576 (2013) (holding that synthetic derivatives of naturally occurring molecules may be patent-eligible under 35 U.S.C. § 101, seemingly without any requirement that the synthetic molecule represent an inventive advance over the naturally occurring species).

7. *See Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347 (2014).

8. *See id.* at 2359–60. The Court concluded that the representative method claim did no more than implement the abstract idea of intermediated settlement on a generic computer and that the system and media claims added nothing of substance to the underlying abstract idea.

9. *See* U.S. PATENT & TRADEMARK OFFICE, PATENT ELIGIBILITY SUBJECT MATTER: REPORT ON VIEWS AND RECOMMENDATIONS FROM THE PUBLIC 35–36 (July 2017), [https://www.uspto.gov/sites/default/files/documents/101-Report\\_FINAL.pdf](https://www.uspto.gov/sites/default/files/documents/101-Report_FINAL.pdf) [<https://perma.cc/XPX9-XW3Y>] [hereinafter USPTO REPORT].

10. *See id.* at 37.

11. *See id.* at 24–27, 37.

12. *See id.* at 37–38.

13. *See Ariosa Diagnostics Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1380–81 (Fed. Cir. 2015) (Linn, J., concurring) (noting that “[t]he Supreme Court’s blanket dismissal of conventional post-solution steps” bars patent eligibility to *Sequenom*’s “truly meritorious” invention and that the invention at issue would have been valid under the standards reflected in *Le Roy v. Tatham*, 63 U.S. 132, 135–36 (1859) (whether the claimed invention “effectuate[d] a practical result and benefit not previously attained”) (quoting *Househill Coal & Iron Co. v.*

Court's new and rapidly evolving standards.<sup>14</sup>

As this sea-change unfolded, many patent practitioners, scholars, PTO officials, and jurists hoped that the Supreme Court would provide fuller and clearer guidance on patent eligibility standards. After all, the Court's sudden shift in patent eligibility standards was neither squarely posed nor carefully briefed in the *Mayo* case.<sup>15</sup> With the exception of one amicus brief, based upon a questionable understanding of historical precedent,<sup>16</sup> none of the many briefs

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Neilson, 8 Eng. Rep. 616 (H.L. 1843), *reprinted in* 1 WEBSTER'S PATENT CASES 673, 683 (1844) and *Le Roy*, 55 U.S. at 175); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1286–87 (Fed. Cir. 2015) (Lourie, J., concurring in the denial of en banc rehearing) (noting that although the claims at issue “recite innovative and practical *uses* for the [law of nature] . . . [the *Mayo* decision] unfortunately obliged [us] to divorce the additional steps from the asserted natural phenomenon to arrive at a conclusion that they add nothing innovative to the process,” and commenting that “it is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps”) (emphasis in original); *id.* at 1289 (Dyk, J., concurring in the denial of en banc rehearing) (“[I]here is a problem with *Mayo* insofar as it concludes that inventive concept cannot come from discovering something new in nature—*e.g.*, identification of a previously unknown natural relationship or property. In my view, *Mayo* did not fully take into account the fact that an inventive concept can come not just from creative, unconventional application of a natural law, but also from the creativity and novelty of the discovery of the law itself. This is especially true in the life sciences, where development of useful new diagnostic and therapeutic methods is driven by investigation of complex biological systems. I worry that method claims that apply newly discovered natural laws and phenomena in somewhat conventional ways are screened out by the *Mayo* test.”); *id.* at 1294 (Newman, J., dissenting from the denial of en banc rehearing) (questioning *Mayo*'s breadth: “[p]recedent does not require that all discoveries of natural phenomena or their application in new ways or for new uses are ineligible for patenting”).

14. The USPTO has issued numerous guidance documents during the past several years in an effort to keep up with the shifting patent eligibility jurisprudence. *See infra* app. C (USPTO Patentable Subject Matter Guidance Documents).

15. *See generally* Brief for Petitioners, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012) (No. 10-1150), 2011 WL 3919717 [hereinafter Brief for Petitioners] (focusing brief on overbreadth of the Prometheus patent claims, not arguing for an inventive application test, and making no mention of the *Neilson v. Harford* decision); *see also* Brief for the United States as Amicus Curiae in Support of Neither Party at 9–11, *Mayo Collaborative Servs.*, 566 U.S. 66 (No. 10-1150), 2011 WL 4040414 [hereinafter Brief for the United States] (asserting that claims at issue were patent-eligible and do not preempt all practical uses of the law of nature, but are likely invalid under Sections 102 (novelty) and 103 (nonobviousness)). Moreover, the Supreme Court's 2010 *Bilski v. Kappos* decision, 561 U.S. 593 (2010), took a cautious, textual approach to patent eligibility and expressly “decline[d] to impose limitations on the Patent Act that are inconsistent with the Act's text.” *Id.* at 612. The breadth and analytical basis for the *Mayo* decision came as a shock to many practitioners and scholars.

16. The brief filed by Professor Joshua Sarnoff on behalf of nine law professors, Brief of Nine Law Professors as Amici Curiae in Support of Petitioners, *Mayo Collaborative Servs.*, 566 U.S. 66 (No. 10-1150), 2011 WL 4071921 [hereinafter Sarnoff *Mayo* Amicus Brief], contended that the English Court of the Exchequer's decision in *Neilson v. Harford*, 151 Eng. Rep. 1266 (Ex. 1841), <http://www.commonlii.org/uk/cases/EngR/1841/887.pdf>

submitted in *Mayo* framed the fundamental shift in patent eligibility doctrine that emerged.<sup>17</sup> When the Supreme Court later denied a petition for a writ of certiorari, without even requesting the views of the government through the Solicitor General,<sup>18</sup> in *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*—a case that many Federal Circuit jurists, scholars, and practitioners regarded as an ideal vehicle for clarifying patent eligibility standards<sup>19</sup>—attention turned toward the legislative arena.

In the aftermath of the Supreme Court rejecting the invitation to reexamine its earlier *Mayo* decision in *Sequenom*, we began planning a roundtable discussion among leading industry representatives, practitioners, scholars, policymakers, and retired jurists to explore the patent eligibility landscape and possible legislative solutions to the problems that have emerged. Drawing on the prior experience of the Berkeley Center for Law & Technology (BCLT) in

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[<https://perma.cc/7RNA-UZ85>], reprinted in 1 WEBSTER'S PATENT CASES 295 (1844), established the principle that scientific discoveries should be treated as part of the prior art and that this principle was brought into U.S. law through *O'Reilly v. Morse*, 56 U.S. 62 (1853). See Sarnoff *Mayo* Amicus Brief at 8–10. However, as Professor Lefstin's research demonstrates, the Court of Exchequer was not setting forth a broad principle that scientific discoveries or laws of nature are to be treated as known or in the prior art. See Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565, 580–87 (2015). Rather, the pertinent language from *Neilson v. Harford* quoted in the Sarnoff *Mayo* Amicus Brief and repeated in the *Mayo* decision addressed whether Neilson's invention—the preheating of air injected into a hot blast furnace—constituted a claim to a machine or an abstract principle. See *infra* text accompanying notes 80–88. Furthermore, as Professors Lefstin and Menell have revealed, neither the patent statutes nor the legislative history of these enactments dating back to the nation's founding contain any hint of a second, “inventive application” hurdle for patent eligibility of scientific discoveries. See Lefstin-Menell *Sequenom* Amicus Cert. Petition Brief, *supra* note 1, at 4–14.

17. Neither the Petitioners' opening brief nor the government's brief discussed the *Neilson v. Harford* decision. See Brief for Petitioners, *supra* note 15; Brief for the United States, *supra* note 15. The Respondent's brief noted that “the patent in *Neilson* wholly preempted the ‘natural phenomenon’ that ‘heating the blast, in a receptacle, between the blowing apparatus and the furnace’ would cause iron to smelt more rapidly in a furnace.” Brief for Respondent at 39, *Mayo Collaborative Servs.*, 566 U.S. 66 (No. 10-1150), 2011 WL 5189089. The Petitioners' reply brief argued that *Neilson v. Harford* is “irrelevant . . . because the patents . . . narrowly confined a scientific principle within a process that left other uses freely available.” See Reply Brief for Petitioners at 21, *Mayo Collaborative Servs.*, 566 U.S. 66 (No. 10-1150), 2011 WL 5562514 (stating only that “*Neilson* upheld a patent on a mechanical apparatus for blowing hot air into a furnace, having discovered that hot air worked better than cold”). None of these briefs addressed or explained the excerpt from *Neilson* on which the Supreme Court erroneously based the “inventive application” doctrine. See Lefstin-Menell *Sequenom* Amicus Cert. Petition Brief, *supra* note 1, at 15–20.

18. See *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 136 S. Ct. 2511 (2016).

19. See USPTO REPORT, *supra* note 9, at 11; see *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, SCOTUSBLOG (compiling certiorari petition party and 22 amici briefs), <http://www.scotusblog.com/case-files/cases/sequenom-inc-v-ariosa-diagnostics-inc/> [<https://perma.cc/9NVN-MFHP>].

hosting roundtables on salient intellectual property issues,<sup>20</sup> in the fall of 2016 we began planning this event with funding from Google and Intel Corporation. We insisted on and received complete independence from the funding organizations.

We sought participants with significant knowledge and experience in the key industries affected by the shift in patent eligibility standards—principally the bioscience and software fields. To promote candid discussion among these participants, we established the following ground rules: (1) Participants would be free to use the information received, but neither the identity nor the affiliation of the speaker(s) could be revealed; (2) We would prepare a report describing the results of the workshop—and that report would not attribute statements or views to individuals (other than the co-convenors); and (3) The report would list the participants and be made available to the public through BCLT. Appendix A contains the Workshop Schedule. Appendix B contains the list of participants. Appendix C lists the preparatory materials that we distributed to the participants in advance of the workshop. This document constitutes the workshop report.

Part I contains a lightly edited version of the background document that we circulated to participants prior to the workshop. Part II summarizes the four workshop sessions leading up to the discussion of legislative proposals: (A) legal background; (B) effects on research and development (R&D); (C) effects on patent prosecution; and (D) effects on patent assertion, litigation, and case management. Part III summarizes the discussion of legislative proposals and sets forth a framework for seeking compromise on reform legislation.

## II. BACKGROUND MEMO

### A. LEGAL BACKGROUND AND WORKSHOP GOALS

Over the past several years, the Supreme Court has embarked on a dramatic experiment in patent eligibility jurisprudence. For most of American patent law history, the boundary of the patent system was drawn between abstract principles and practical applications of those principles as embodied in statutorily-defined categories of inventions. Although augmented by limitations to the technological arts and by the exclusion of mental steps and printed matter, the distinction between abstractions and practical applications remained the primary test of patent eligibility since the nation's founding era.

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20. See, e.g., Stuart Graham, Peter Menell, Carl Shapiro, & Tim Simcoe, *Final Report of the Berkeley Center for Law & Technology Patent Damages Workshop*, 25 TEX. INTELL. PROP. L.J. 115 (2018).



In *Gottschalk v. Benson* (1972),<sup>21</sup> *Parker v. Flook* (1978),<sup>22</sup> and *Diamond v. Diehr* (1981),<sup>23</sup> the Supreme Court charted an uncertain course as it confronted advances in information technologies. The Court's decisions vacillated among multiple rationales for the patent eligibility doctrine: a requirement of tangibility; hesitation to extend the reach of the patent system to areas unanticipated by Congress; and the exclusion of concepts that had "always existed" such as laws of nature and basic mathematical relationships. And while each case presented a different vision of 35 U.S.C. § 101—the statutory section governing patent eligibility—the Court maintained a pretense that each was consistent with its long-standing principles. Nonetheless, at the end of its path in *Diehr*, the Court reaffirmed two traditional foundations of the patent eligibility doctrine: that the boundary of eligible subject-matter lay between abstract principles and practical applications of those principles,<sup>24</sup> and that considerations of prior art play no role in determining eligibility under § 101.<sup>25</sup>

Nearly thirty years after *Diehr*, the Court reopened the interpretation of § 101 in *Bilski v. Kappos*.<sup>26</sup> *Bilski* acknowledged that Congress had not limited patent-eligible subject matter other than setting forth the eligible categories of inventions in § 101.<sup>27</sup> Nonetheless, the Court concluded that "as a matter of statutory *stare decisis* going back 150 years,"<sup>28</sup> its precedents demanded the exclusion of "laws of nature, physical phenomena, and abstract ideas."<sup>29</sup> *Bilski* declined to further explain the rationale for imposing extra-textual limitations on patent-eligible subject matter or explain how such limitations were to be applied in practice.

However, in *Mayo Collaborative Services v. Prometheus Laboratories*, the Court grounded the patent eligibility doctrine in the rationale that patents preempting

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

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

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

24. *See id.* at 187 ("It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."); *id.* at 191 ("We recognize, of course, that when a claim recites a mathematical formula (or scientific principle or phenomenon of nature), an inquiry must be made into whether the claim is seeking patent protection for that formula in the abstract.").

25. *See id.* at 188–89 ("The 'novelty' of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.").

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

27. *See id.* at 601.

28. *Id.* at 602.

29. *Id.* at 601. It was not until *Gottschalk v. Benson*, 409 U.S. 63 (1972), that abstract ideas were described as a separate category of excluded subject matter. *See id.* at 71–72; the Court's earlier precedents simply distinguished between principles (including laws of nature) in the abstract and practical applications. *See Le Roy v. Tatham*, 55 U.S. 156, 175 (1852).

access to fundamental principles would foreclose more innovation than they would promote.<sup>30</sup> At the same time, drawing on a markedly ahistorical reading of foundational nineteenth century cases such as *Neilson v. Harford*,<sup>31</sup> *O'Reilly v. Morse*,<sup>32</sup> and in Justice Douglas's 1948 opinion in *Funk Brothers*,<sup>33</sup> the *Mayo* Court suggested that the test for patent eligibility under § 101 was neither practical application nor the extent to which a claim preempted an underlying principle.<sup>34</sup> Instead, patent eligibility would depend on whether the claim represented an “inventive” application of that principle.<sup>35</sup> In *Alice Corp.*,<sup>36</sup> the Court extended the *Mayo* framework to computer-implemented inventions, confirming that *Mayo*'s requirement for an “inventive concept” in the claim represents the new test for patent-eligible subject matter under § 101.<sup>37</sup>

The *Mayo/Alice* decisions established a two-step inquiry for determining patent eligibility:

Step 1: Does the patent claim a patent-ineligible law of nature, natural phenomena, or abstract idea?

Step 2: If so, does the claim nevertheless contain an inventive concept sufficient to transform the ineligible law of nature, natural phenomena, or abstract idea into a patent-eligible application of the ineligible subject matter?

The *Alice* decision emphasized the preemption concerns (identified in *Mayo*) as central to patent eligibility and characterized step two as a search for an “inventive concept”—i.e., an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.”<sup>38</sup> In so doing, the *Mayo* and *Alice* decisions brought considerations of prior art and claim scope,

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

31. 151 Eng. Rep. 1266 (1841).

32. 56 U.S. 62 (1853); *see generally*, Lefstin-Menell Sequenom Amicus Cert. Petition Brief, *supra* note 1.

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

34. *See Mayo*, at 566 U.S. at 72.

35. *See id.* at 66, 72–73.

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

37. *See id.* at 2355, 2357. The Court's omission of any reference to “inventive concept” in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), in which the claims were directed to compositions of matter, had led some observers to question whether it was a universal requirement. While *Alice* confirmed that an “inventive concept” was required under § 101, the Court's analysis in *Alice* emphasized that the claims recited only a generic application of an abstract idea, rather than focusing on inventiveness per se.

38. *See Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 566 U.S. at 73) (alterations in original).

traditionally lodged in the statutory requirements of non-obviousness<sup>39</sup> and enablement or written description<sup>40</sup> into the patent eligibility determination.

Neither *Mayo* nor *Alice* addressed the legislative history of § 101's predecessor statutes, nor did they engage with the legislative text, history, or structure of the 1952 Act.<sup>41</sup> Moreover, the Court's decisions have left a raft of unanswered questions. Must a claim embodying an application of a newly discovered natural law satisfy a double requirement of both discovery and invention? Are inventive data-processing algorithms ineligible abstract ideas, or potentially eligible applications? What is the relationship between the underlying preemption rationale identified in *Mayo* and the actual test for patent eligibility? If the function of § 101 is to calibrate patent scope, how does that role relate to the other patentability doctrines of the 1952 Act?

The uncertainty and confusion resulting from the Court's recent jurisprudence create significant problems for many companies and investors contemplating research and development projects, as well as for patent prosecutors, patent examiners, and patent jurists.<sup>42</sup> In the decade prior to the *Mayo* decision, the USPTO rarely rejected patents on subject matter grounds, and one could count on one hand the number of judicial § 101 invalidity decisions in any year. Since *Mayo*, the number of § 101 invalidity rulings has skyrocketed, with more than one hundred invalidity determinations per year during the past two years.<sup>43</sup> Courts now routinely confront § 101 invalidity motions at the very outset of, and throughout, many patent cases. The USPTO has issued numerous guidance documents cataloging this rapidly evolving terrain.<sup>44</sup>

For some, the Supreme Court's rulings provide a ready means to eliminate some "unworthy" patents at an early stage of litigation. Yet given the lack of clarity in the test the Court has framed, do these rulings represent a return to the vague and subjective "I-know-it-when-I-see-it" standards for patentability that bedeviled the patent system before the 1952 Act? At the very least, we have witnessed an inversion of relative patent eligibility standards between the United States and other developed countries, some of which now maintain significantly more generous standards of patent-eligible subject matter.<sup>45</sup>

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39. See 35 U.S.C. § 103 (2013).

40. See 35 U.S.C. § 112(a) (2013).

41. See Lefstin-Menell Sequenom Amicus Cert. Petition Brief, *supra* note 1, at 26–28.

42. See generally David O. Taylor, *Confusing Patent Eligibility*, 84 TENN. L. REV. 157 (2016).

43. See *infra*, tbl.1

44. See *infra* app. C, USPTO Patentable Subject Matter Guidance Documents.

45. See Kevin Madigan & Adam Mossoff, *Turning Gold into Lead: How Patent Eligibility Doctrine Is Undermining U.S. Leadership in Innovation*, 24 GEO. MASON L. REV. 939, 941 n.10 (2017) (reporting that over 1,700 patent applications covering the same inventions that were

Many observers saw a chance for the Supreme Court to moderate or at least clarify *Mayo's* effect on patent eligibility in 2015. Relying on a narrow interpretation of *Mayo*, the Court of Appeals for the Federal Circuit held in *Ariosa Diagnostics v. Sequenom* that an innovative prenatal diagnostic test was ineligible under § 101, because the inventors, having discovered a natural phenomenon, had relied upon known means for its practical application.<sup>46</sup> Nonetheless, despite widespread support for reviewing the decision, the Court denied the writ of certiorari without even requesting the Solicitor General's views. The Court's refusal signals that the Court is not inclined to act on the serious challenges created by its recent jurisprudence and is unlikely to further refine its § 101 jurisprudence in the foreseeable future.<sup>47</sup> Responsibility now lies with Congress to bring greater clarity, consistency, and logic to patent eligibility.

The workshop aimed to: (1) identify areas of consensus and disagreement on the appropriate scope of patent eligibility; (2) understand the impact of the recent decisions on R&D, use of the patent system, and use of trade secret and copyright protection; and (3) explore potential legislative approaches to patent eligibility.

While various groups have been considering potential legislative reforms, there appears to be a substantial divide across the range of technology industries. The workshop aimed to provide a forum for discussing these perspectives and hopefully to bridge the divide through candid engagement.

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rejected in the U.S. as ineligible were considered eligible in both China and the European Union). The database identified the abandoned U.S. patent applications in the following fields (with the number of applications in each field shown in parentheses): Drug and Therapeutics (474); Molecular Biology and Microbiology (356); Amusement Devices (245); Combinatorial Chemistry (238); Measuring and Testing (83); Databases (80); Multicellular Living Organisms (38); Structural Design (35); Control Systems (21); Business Methods (18); Surgery (17); Chemistry (15); Immunology (15); Computer Graphics (14); Food Or Edible Materials (11); Agriculture (10); User Interfaces (9); Organic Compounds (8); Data Processing (5); Artificial Intelligence (3); Education And Demonstration (3); Electrolysis (3); Vehicle Navigation (3); Communications (2); Telecommunications (2); Coatings (2); Information Security (2); Cleaning & Compositions (2); Electro-Chemistry; (2) Marine Propulsion (1); Resins And Rubbers (1); Refrigeration (1); Compositions: Ceramic (1); Video Recording (1); Mineral Oils (1); Radiation Imagery (1); Dentistry (1); Registers (1); Image Analysis (1); Chemical Disinfecting (1); Digital Communications (1); Fluid Sprinkling (1); Power Plants (1); Radiant Energy (1); Error Detection (1); Adhesives (1); Evaporators (1).

46. See 788 F.3d 1371, 1377 (Fed. Cir. 2015). In a case decided after certiorari was denied in *Sequenom*, the Federal Circuit has seemingly placed less emphasis on the need for novelty in the inventor's means of application. See *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1051 (Fed. Cir. 2016).

47. See David O. Taylor, *Amending Patent Eligibility*, 50 U.C. DAVIS L. REV. 2149, 2157–64 (2017).

## B. SUMMARY OF LEGISLATIVE PROPOSALS

In the aftermath of the Court's denial of a writ of certiorari in *Sequenom*, various groups have proposed legislative reforms on patent eligibility.<sup>48</sup> The USPTO also has held workshops and solicited comments on patent eligibility.<sup>49</sup>

### 1. *Result of Human Effort*

The Intellectual Property Owners Association (IPO) proposal would amend the patent statute to replace the current two-part test with a test that would find a claim eligible if it describes something that is the result of human effort.<sup>50</sup> This approach harkens back to P.J. Federico's commentary<sup>51</sup> and the legislative history of the 1952 Patent Act, which suggested "anything under the sun made by man" might be eligible for patenting.<sup>52</sup>

### 2. *Physicality*

Another proposal would replace the current two-step test with a test that would find a claim eligible if it describes something that takes physical or tangible form. This approach excludes claims describing purely mental steps. The IPO proposal reflects this approach to the extent it recites that a "claimed invention is ineligible . . . if the claimed invention as a whole . . . exists solely

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48. For an overview of various potential legislative reforms, *see generally id.*

49. *See* USPTO REPORT, *supra* note 9 at 23.

50. *See* INTELLECTUAL PROPERTY OWNERS ASS'N, PROPOSED AMENDMENTS TO PATENT ELIGIBLE SUBJECT MATTER UNDER 35 U.S.C. § 101 (2017), [http://www.ipo.org/wp-content/uploads/2017/02/20170207\\_IPO-101-TF-Proposed-Amendments-and-Report.pdf](http://www.ipo.org/wp-content/uploads/2017/02/20170207_IPO-101-TF-Proposed-Amendments-and-Report.pdf) [<https://perma.cc/JE95-UBCW>]. The American Intellectual Property Law Association (AIPLA) proposal, which was released after our workshop, parallels this proposal. *See* AIPLA, AMERICAN INTELLECTUAL PROPERTY PROPOSAL AND REPORT ON PATENT ELIGIBLE SUBJECT MATTER (2017), <https://www.aipla.org/resources2/reports/2017AIPLADirect/Documents/AIPLA%20Report%20on%20101%20Reform-5-19-17-Errata.pdf> [<https://perma.cc/BPA7-4HQ7>].

51. *See* Pasquale J. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. 1 (1954 ed.), *reprinted in* 75 J. PAT. & TRADEMARK OFF. SOC'Y 161 (1993).

52. *See* S. REP. No. 82-1979, at 5 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399 (noting that "[a] person may have 'invented' a machine or a manufacture, which may include anything under the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of [this] title are fulfilled.") That phrase first surfaced in patentable subject matter jurisprudence in *In re Bergy*, 596 F.2d 952, 961 (C.C.P.A. 1979). It was then picked up in *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980), and *Diamond v. Diebr*, 450 U.S. 175, 182 (1981), without its full context or ellipses. *See* Brief of Professors Peter S. Menell & Michael J. Meurer as Amici Curiae in Support of Respondent at 10–22, *Bilski v. Kappos*, 130 S. Ct. 3218 (2009) (No. 08-964), 2009 WL 3199629 (providing comprehensive analysis of the legislative history of the 1952 Patent Act).

in the human mind.”<sup>53</sup>

### 3. *Practical Application or Embodiment*

A different proposal would not wholly replace the existing two-step test, but rather modify only the second part of that test. This proposal would replace the current search for an “inventive concept” or “inventive application” of an abstract idea, natural law, or physical phenomenon with a search for a “practical application” of an abstract idea, natural law, or physical phenomenon, assuming the claim falls within one of the § 101 categories.<sup>54</sup> The Lefstin-Menell Sequenom Amicus Cert. Petition Brief contends that this approach comports with the core principles of pre-*Mayo* jurisprudence.<sup>55</sup> The ABA’s Section of Intellectual Property Law (ABA-IPL) submitted comments to the USPTO that are consistent with a “practical application” test.<sup>56</sup>

### 4. *List of Exclusions*

Another proposal would replace the existing two-step test with a list of eligibility exclusions, where subject matter would be excluded when claimed “as such.” This proposal is modeled on the European Patent Convention.<sup>57</sup> Paragraph 2 of Article 52 of the European Patent Convention states that “(a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; [and] (d) presentations of information” “shall not be regarded as inventions.” Paragraph 3 notes, however, that “Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a . . . patent application or . . . patent relates to such subject-matter or activities as such.”<sup>58</sup>

### 5. *Technological Arts*

Drawing on the constitutional clause authorizing Congress to grant patent

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53. INTELLECTUAL PROPERTY OWNERS ASS’N, *supra* note 50, at 1.

54. For a discussion of this approach, *see* Taylor, *supra* note 47, at 2205–07.

55. *See* Lefstin-Menell Sequenom Amicus Cert. Petition Brief, *supra* note 1, at 27–28.

56. *See* Letter from Donna P. Suchy, Section Chair, Section of Intellectual Prop. Law, Am. Bar Ass’n, to The Honorable Michelle K. Lee, Under Secretary of Commerce for Intellectual Prop. & Dir. of the USPTO (Jan. 18, 2017). The ABA submitted a formal reform proposal in May 2017. *See* Letter from Donna P. Suchy, Section Chair, Section of Intellectual Prop. Law, Am. Bar Ass’n, to The Honorable Michelle K. Lee, Under Secretary of Commerce for Intellectual Prop. & Dir. of the USPTO (Mar. 28, 2017).

57. European Patent Convention art. 52, Nov. 29, 2001, 1065 U.N.T.S. 199, <http://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar52.html> [<https://perma.cc/TU3M-VLQ3>].

58. *Id.*

protection (“[t]o promote the Progress of . . . useful Arts . . .”<sup>59</sup>), a technological arts test would ask whether the claimed invention contributes to the technological arts, solves a technological problem, or otherwise falls within the technological arts. This test has some similarities with Article 52 of the European Patent Convention, which provides that European patents are available for inventions in all technologies susceptible of industrial application while excluding certain fundamental principles claimed as such. A group of patent professionals organized by Ken Sonnenfeld, Hans Sauer, and Margaret Brivanlou (the “Banbury group”) has released a statement favoring a technological arts requirement.<sup>60</sup> For more information, see the Banbury Statement listed in Appendix C.

#### 6. *Elimination of Eligibility in Favor of Other Statutory Doctrines*

Another proposal is to eliminate the doctrine of patent eligibility as a separate patentability requirement in favor of the other existing statutory patentability requirements: utility, novelty, non-obviousness, written description, enablement, and definiteness.<sup>61</sup>

In conjunction with at least some versions of this proposal, some have advocated for amending existing statutory doctrines outside of the eligibility requirement to address the inability of those doctrines to deal with relevant concerns. For example, *Mayo* raised concerns that claims encompassing fundamental principles may impede further research. Yet, many have called for overruling the Federal Circuit’s narrow conception of the common law experimental use exception in favor of codifying a broader experimental use exception. A broader statutory experimental exception might allow, for example, experimentation on patented technology to improve upon it. Alternatively, if the limitation of patent-eligible subject matter under § 101 is a response to the concern that § 112 insufficiently limits the patentee’s reach into after-arising technologies, the enablement or written description doctrines might be revised to directly address those concerns.<sup>62</sup> Professor Taylor has

59. U.S. CONST. art. I, § 8, cl. 8.

60. Statement by Kenneth H. Sonnenfeld et al, A Proposed Path Forward for Legislatively Addressing Patent Eligibility Law, from the Conference: Patenting Genes, Natural Products and Diagnostics: Current Status and Future Prospects, (Nov. 9–11, 2016), <https://www.uspto.gov/sites/default/files/documents/Updated%20Banbury%20Statement.pdf> [<https://perma.cc/Q2QV-PZAJ>].

61. See, e.g., Brief for Eli Lilly and Company, Eisai Inc., Upsher-Smith Labs., Inc., Pfizer Inc., and Etiometry, Inc. as Amici Curiae in Support of Petitioner, Sequenom, Inc. v. Ariosa Diagnostics, Inc., 136 S. Ct. 2511 (2016) (No. 15-1182), 2016 WL 1298192. For a discussion of this approach, see Taylor, *supra* note 47, at 2207–11.

62. See Rebecca S. Eisenberg, *Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After In re Bilski*, 3 CASE W. RES. J.L. TECH. & INTERNET 1, 59 (2012); Mark A. Lemley et al., *Life After Bilski*, 63 STAN. L. REV. 1315, 1331 (2011).

proposed modifying the utility requirement to require that claims, rather than merely specifications, identify the relevant utility.<sup>63</sup> Requiring claims to identify utility would address concerns that claims are not sufficiently clear, over-broad, and inappropriately prevent the use of basic tools of science and technological development.<sup>64</sup>

### 7. *No Change*

Another proposal is not to amend the patent statute, but to instead allow the courts to continue to apply the current law to develop relevant distinctions between eligible and ineligible claims. In particular, this proposal rejects both the view that current eligibility law is unduly confusing or problematic and the view that the existing statutory doctrines adequately address the problem of poor quality patents. Two groups opposing change to the patent statute are the Internet Association and the Computer & Communications Industry Association.<sup>65</sup>

## C. GUIDING PRINCIPLES FOR ANALYSIS OF LEGISLATIVE PROPOSALS

If the workshop participants conclude that some statutory amendment would be appropriate to address problems with the current state of eligibility law, the next question is what the best approach might be for such an amendment. It might be helpful to think about potential guiding principles for analyzing and comparing proposals.<sup>66</sup>

### 1. *Scope of Eligibility*

The scope of eligibility may be thought of in general or specific terms. That is, as a general matter, many may think that broad but not unlimited eligibility is the appropriate lens. In terms of particular technologies, like software or diagnostic technologies, however, there will no doubt be differing views. Each proposal ought to be analyzed in terms of whether it strikes the correct balance in terms of the scope of eligibility and takes future, unforeseen technologies into account.

### 2. *Clarity*

To the extent that patent law is meant to induce investment in research

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63. See Taylor, *supra* note 47, at 2189.

64. See *id.*

65. See generally William G. Jenks, Comments of the Internet Association and the Computer & Communications Industry Association Regarding the USPTO Patent Subject Matter Eligibility Guidelines (Part I) (Jan. 18, 2017) (unpublished comment), [https://www.uspto.gov/sites/default/files/documents/comments\\_jenkins\\_jan182017.pdf](https://www.uspto.gov/sites/default/files/documents/comments_jenkins_jan182017.pdf) [<https://perma.cc/E8E9-LPX7>].

66. See Taylor, *supra* note 47, at 2189–97.



and development, as with any property-type right, the governing law and the governing legal instrument ought to be relatively clear. Thus, patent eligibility ought to provide a relatively clear demarcation between eligible and ineligible claims.

### 3. *Constraint on Judicial Intervention*

The Supreme Court has decided eight cases in the last forty years (and four cases in the last seven years) on the issue of patent eligibility, far more than on any other patent law doctrine. This indicates that the Supreme Court has been unable to identify a workable standard despite numerous attempts to do so. Thus, one guiding principle for a statutory amendment may be constraint on judicial intervention and, in particular, constraint on the Supreme Court's opportunity to treat patent eligibility as a common law doctrine subject to repeated interpretation as a matter of legal doctrine (rather than application).

### 4. *Flexibility*

Flexibility refers to the ability of any proposal to be applied meaningfully to new, unforeseen, and even unimagined human activity. In other words, one may ask whether a proposal may be meaningfully applied to new claimed inventions or, instead, whether it is only backward-looking.

### 5. *Technological Zoning*

Thinking more broadly along "scope of eligibility" lines, Professor Menell, among others, has long advocated a *sui generis* approach for computer software.<sup>67</sup> Beyond administrative considerations, there is no economic basis for uniform patent duration across vastly different technologies. Prior to the emergence of software protection, patent eligibility had not been such a divisive aspect of patent protection. Furthermore, there is relatively little evidence indicating that computer software developers need robust patent protection to thrive. For many applications, computer software receives effective protection under trade secrecy law. In addition, copyright law affords software protection against piracy. There is relatively strong empirical evidence that patent protection for computer software has caused more harm than good. Much of the controversy over patent assertion entities relates to software-related patents.

Thus, another principle for guiding patent eligibility policy would be to explore putting software-related technologies into a separate regime that is tailored to the distinctive economic needs and technological attributes of computer software. This could involve a system with a much shorter duration

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67. See Peter S. Menell, *Tailoring Legal Protection for Computer Software*, 39 STAN. L. REV. 1329, 1371 (1986).

and tailored remedies. It could also exclude pure business methods and other non-technological fields from patent eligibility. Such compromises could defuse the apparent impasse between discovery-based and information-based industries.

### III. WORKSHOP PROCEEDINGS

We convened the BCLT patent eligibility workshop at the University of California at Berkeley on March 17, 2017. Substantially all of the invitees were able to attend. The participants are listed in Appendix B. In order to understand the range of views about patent eligibility law and policy, we organized the day around two principal areas: (1) the legal background and the effects of the Supreme Court's shift in patent eligibility standards; and (2) the need for and design of legislative reform.

As reflected in the workshop agenda contained in Appendix A, we devoted the morning and early afternoon to a first set of issues: (A) the statutory and jurisprudential basis for patent eligibility limits and the effects of the recent Supreme Court cases (*Mayo/Myriad/Alice*) on the lower courts' handling of patent cases; (B) the effects of the shift in patent eligibility law on research and development in the most affected industries; (C) the effects of shifting patent eligibility jurisprudence on USPTO activity and patent prosecution; and (D) the effects of the changed landscape on patent assertion activity, litigation strategy, and case management. This Part summarizes these four sessions, each of which ran for approximately 90 minutes. Part III summarizes the second major discussion area: views on the need for and design of legislative reform of patent eligibility standards.

#### A. LEGAL FOUNDATION

The first session was intended to assess the degree of consensus regarding the legal foundation for patentable subject matter limitations and to summarize empirical data on how district courts and the Federal Circuit have applied the Supreme Court's recent patentable subject matter rulings.

##### 1. Patentable Subject Matter Limitations: Patent Act and Jurisprudence

Professors Lefstin and Menell opened the workshop by exploring how the Supreme Court arrived at the *Mayo* decision and scrutinizing the decision's legal basis.<sup>68</sup> Their presentation began by noting that in the absence of any indication that Congress intended to limit the scope of the patent system beyond the categories it enumerated in § 101, the Supreme Court has based its

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68. The presentation largely summarized the analysis in Lefstin-Menell Sequenom Amicus Cert. Petition Brief, *supra* note 1.

subject matter jurisprudence on a particular view of history—in *Bilski*'s words, “a matter of statutory *stare decisis* going back 150 years.”<sup>69</sup> In particular, *Mayo* relied on a passage from *Neilson v. Harford*,<sup>70</sup> a case decided by the Court of Exchequer in 1841, which had also been central to the Supreme Court's decisions in *Le Roy v. Tatham*,<sup>71</sup> *O'Reilly v. Morse*,<sup>72</sup> and *Tilghman v. Proctor*.<sup>73</sup> The passage quoted in *Mayo* referred to the challenge raised to Neilson's patent on the hot blast iron smelting process, and *Mayo* concluded that Neilson's patent had been sustained only because his apparatus represented an inventive and unconventional means of applying Neilson's discovery that preheating the blast dramatically increased the efficiency of the smelting process. According to *Mayo*:

The English court concluded that the claimed process did more than simply instruct users to use the principle that hot air promotes ignition better than cold air, since it explained how the principle could be implemented in an inventive way. Baron Parke wrote (for the court):

“It is very difficult to distinguish [Neilson's claim] from the specification of a patent for a principle, and this at first created in the minds of some of the court much difficulty; but after full consideration, we think that the plaintiff does not merely claim a principle, but a machine embodying a principle, and a very valuable one. We think the case must be considered as if the principle being well known, the plaintiff had first invented a mode of applying it by a mechanical apparatus to furnaces; and his invention then consists in this—by interposing a receptacle for heated air between the blowing apparatus and the furnace. In this receptacle he directs the air to be heated by the application of heat externally to the receptacle, and thus he accomplishes the object of applying the blast, which was before of cold air, in a heated state to the furnace.” *Neilson v. Harford*, Webster's Patent Cases, at 371.

Thus, the claimed process included not only a law of nature but also several unconventional steps (such as inserting the receptacle, applying heat to the receptacle externally, and blowing the air into the furnace) that confined the claims to a particular, useful

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69. *Bilski v. Kappos*, 561 U.S. 593, 602 (2010).

70. 151 Eng. Rep. 1266 (1841).

71. 55 U.S. 156 (1853).

72. 56 U.S. 62 (1853).

73. 102 U.S. 707 (1880).

application of the principle.<sup>74</sup>

The same passage had been cited by *Parker v. Flook* in support of the notion (later rejected by *Diehr*) that discoveries should be treated as part of the prior art.<sup>75</sup> However, in the briefing for *Mayo*, only one brief, filed by Professor Joshua Sarnoff on behalf of nine law professors,<sup>76</sup> quoted and discussed the language from *Neilson*. Professor Sarnoff's brief connected the supposed "requirement for prior art treatment of new discoveries" with a strong distinction between inventions and discoveries, the latter being ultimately creations of the divine rather than the human.<sup>77</sup>

Professors Lefstin and Menell pointed out the close relationship between this line of analysis and the Supreme Court's reasoning in *Mayo*. The Court's opinion quoted the referenced passage from the *Neilson* case, and grounded its inventive application requirement on the same interpretation of that case raised in *Flook* and offered in Professor Sarnoff's brief.<sup>78</sup>

Professors Lefstin and Menell then highlighted three critical errors with the Supreme Court's *Mayo* analysis. First, the Court provided no analysis of the statutory text, which refers repeatedly to patent protection for "inventions" or "discoveries." Every major patent statute since the nation's founding has afforded patent protection to technological innovations *and* scientific discoveries.<sup>79</sup> Thus, the dual "invention *or* discovery" thread runs through the fabric of U.S. patent law. Furthermore, the very constitutional clause empowering Congress to establish patent protection expressly refers to "Discoveries."<sup>80</sup>

Second, the legislative history of the patent statutes has consistently endorsed patent protection for *applied scientific discoveries*, whether or not they

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74. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 83–84 (2012).

75. *Parker v. Flook*, 437 U.S. 584, 592 (1978).

76. See Sarnoff *Mayo* Amicus Brief, *supra* note 16.

77. See *id.* at 8, 10 ("[D]iscoveries were not thought to be human creations that were the proper objects of exclusive property rights.").

78. See *Mayo*, 566 U.S. at 83–84.

79. See Patent Act of 1790, ch. 7, 1 Stat. 109–12, § 1 (authorizing granting of patents to any person who "invented or *discovered* any useful art, manufacture, engine, machine, or device . . . if they shall deem the invention or *discovery* sufficiently useful and important . . .") (emphasis added); Patent Act of 1793, Stat. 318, § 1 (retaining the dual eligibility structure, referring to "said invention or discovery"); *id.* at § 10 (referring to the patentee as the "inventor or discoverer"). Currently, § 100 defines "invention" to mean "invention or discovery," and § 101 authorizes one who "invents or discovers" one of the enumerated categories of subject matter to apply for a patent. See 35 U.S.C. §§ 100(b), 101 (2013).

80. See U.S. CONST. art. I, § 8, cl. 8 (authorizing Congress "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and *Discoveries*?" (emphasis added)).

are *inventively* applied. The legislative history of the 1836 Patent Act, perhaps the most important patent statute in the nation's history,<sup>81</sup> expresses Congress's fervent hope that patent protection would encourage *scientific discovery*:

Whoever imagines that, because so many inventions and so many improvements in machinery have been made, there remains little else to be discovered, has but a feeble conception of the infinitude and vastness of mechanical powers, or of the unlimited reach of science. Much as has been discovered, infinitely more remains unrevealed. The ingenuity of man is exploring a region without limits, and delving in a mine whose treasures are exhaustless. "Neither are all the mysteries of nature unfolded, nor the mind tired in the pursuit of them."

The first conceptions of ingenuity, like the first suggestions of science, are theories which require something of experiment and practical exemplification to perfect.<sup>82</sup>

The timing of this pronouncement coincides with the *Neilson v. Harford* (1841), *LeRoy v. Tatham* (1853), and *O'Reilly v. Morse* (1854) era, indicating that jurists from this critical formative era would have seen applications of scientific discoveries to be comfortably within the scope of patentable subject matter.

Professors Lefstin and Menell showed that the dual eligibility framing—*inventions or discoveries*—continued through to the present statute.<sup>83</sup> In particular, the legislative history of the 1930 Plant Patent Act explicitly stated

81. The 1836 Patent Act established the Patent Office. From 1790 to 1793, Congress authorized any two of the "Patent Board," comprised of the Secretary of State, the Secretary for the Department of War, and the Attorney General to grant patents. That system proved unworkable, and the 1793 Act shifted to a patent registration system with validity decisions left to courts enforcing patents. The lack of an examination system led to the proliferation of "unrestrained and promiscuous grants of patent privileges," JOHN RUGGLES, SELECT COMMITTEE REPORT ON THE STATE AND CONDITION OF THE PATENT OFFICE, S. DOC. NO. 24-338, at 4 (1836), eroding faith in the patent system and ultimately leading to the Act of 1836 which instituted examination in a newly constituted Patent Office. *See* S. REP. ACCOMPANYING S. BILL NO. 239, 24th Cong. (Apr. 28, 1836).

82. S. REP. ACCOMPANYING S. BILL NO. 239, 24th Cong. (Apr. 28, 1836).

83. *See* Patent Act of 1870, ch. 230, 16 Stat. 198 (Jul. 8, 1870) (referring to "invention or discovery" and "inventor or discoverer" throughout the statute. *See* REVISED STATUTES OF THE UNITED STATES, 946–53 (2d ed. 1878) (reproducing Rev. Stat. §§ 4884, 4886, 4887, 4888, 4890, 4891, 4892, 4893, 4895, 4896, 4897, 4899, 4902, 4908, 4916, 4917, 4920, 4922, 4923, 4924, 4926, 4927)); Plant Patent Act of 1930, 46 Stat. 703 (amending Rev. Stat. § 4886); Patent Act of 1952 § 100(a) (restates the traditional definition of "invention" as "invention or discovery"), § 100(b) (defining "process" to include "a new use of a known process, machine, manufacture, composition of matter, or material"), § 101 ("Whoever invents or discovers . . .").

Congress's view that the patent statutes embrace the act of discovery. In that Act, Congress sought to provide patents for the work of the plant breeder, who might do nothing more than discover a naturally occurring bud mutant on a cultivated plant, and then propagate that mutant by conventional techniques. The proposed scheme raised questions whether the patent system could embrace discoveries with such minimal human intervention in their application. Congress was emphatic that the patent laws could, and in fact did, extend to such discoveries:

Present patent laws apply to "any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . ." *It will be noted that the laws apply both to the acts of inventing and discovery* and this alternative application has been true of the patent laws from their beginning. See, for instance, the Patent Act of 1790 (1 Stat. 109).<sup>84</sup>

Notably, Congress implemented patents for plants by adding them as a new category of inventions or discoveries protectable under the basic patentability statute, R.S. § 4886, indicating that Congress saw no distinction between plant and utility patents in the nature of the inventive act. Congress specifically rejected a proposal by the Patent Office that would have had the statute distinguish between the quantum of invention or discovery required for plant patents versus utility patents.<sup>85</sup>

Third, Professor Lefstin explained that neither the Court of Exchequer in *Neilson*, nor the U.S. Supreme Court in *O'Reilly*, had required *inventive* application of scientific discoveries.<sup>86</sup> The statement emphasized in the Sarnoff brief and quoted in the *Flook* and *Mayo* decisions—" [w]e think the case must be considered as if the principle [of preheating air prior to injection into a hot-blast smelter] being well known"—was a declaration that Neilson's patent claimed a machine rather than an abstract scientific principle. While American precedent of the era (such as *O'Reilly*) understood the Exchequer's holding clearly, *Flook* and *Mayo* took that passage out of its proper context and misinterpreted it drastically.

Professor Lefstin explained that Neilson's specification had disclosed next

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84. H.R. REP. NO. 71-1129, at 7 (1930); S. REP. NO. 71-315, at 6 (1930) (quoting Rev. Stat. § 4886) (emphasis added).

85. See *A Bill to Provide for Plant Patents: Hearing on H.R. 11372 Before the H. Comm. on Patents*, 71st Cong. 7 (1930). The Office's proposal would have had the statute define "invented" and "discovered" specifically for plant patents. That rejected language stated: "finding a thing already existing and reproducing the same as well as in the sense of creating."

86. See generally Lefstin, *supra* note 16 (explicating the history of the *Neilson* litigation).

to nothing about his heating apparatus, yet claimed that his patent covered every hot-blast smelter no matter what means of heating were employed. Beyond a challenge on enablement grounds, Neilson's refusal to be limited to a particular heating apparatus laid his patent open to the challenge that he had claimed an abstract scientific principle, rather than a patentable machine.<sup>87</sup>

The Exchequer recognized that the defendant's challenge was exactly the same raised by the defendant in a case it had decided seven years earlier, *Minter v. Wells*<sup>88</sup>—except that Neilson's case involved a newly discovered principle, rather than one well-known.

Minter's patent had claimed a reclining chair embodying the principle of self-adjusting leverage.<sup>89</sup> Like Neilson, Minter had declared that his claim was not limited to any precise shape or form of chair. The defendants therefore attacked the patent on the ground that Minter had merely claimed a well-known principle of mechanics in the abstract.<sup>90</sup> The Exchequer rejected the challenge, holding that Minter's claim was not to the well-known principle, but to the application of that principle in the construction of a chair.<sup>91</sup> Thus, Minter's claim was not to a well-known principle, but rather it applied a well-known principle to a chair to produce a patent-eligible *machine*. The critical passage in *Neilson* refers to this doctrine—relating to what constitutes a *machine*. *Neilson* holds that the same doctrine governing applications of well-known principles should govern applications of newly discovered principles. It does not declare that scientific discoveries are to be treated as well-known or prior art for purposes of patent eligibility.<sup>92</sup>

Reinforcing this point, the English courts have never interpreted *Neilson v. Harford* to require inventive application of scientific discoveries.<sup>93</sup> Conventional application of newly discovered scientific principles is all that

87. Processes were not recognized as patentable at the time.

88. 149 Eng. Rep. 1180 (Ex. 1834), <http://www.commonlii.org/uk/cases/EngR/1834/222.pdf> [<https://perma.cc/7WCV-RMNB>], reprinted in 1 CARPMAEL'S PATENT CASES 622 (1834).

89. *Id.* at 622.

90. *Id.* at 644.

91. *Id.* at 646.

92. This conclusion is also apparent from the sentence preceding the passage on which the Supreme Court derives the inventive application doctrine. That sentence reads: "[A]fter full consideration, we think that the plaintiff does not merely claim a principle, but a machine embodying a principle, and a very valuable one." *Neilson v. Harford*, 151 Eng. Rep. 1266, 1273 (Ex. 1841), <http://www.commonlii.org/uk/cases/EngR/1841/887.pdf> [<https://perma.cc/7RNA-UZ85>], reprinted in 1 WEBSTER'S PATENT CASES 295, 371 (1844). The Exchequer was assessing whether a broad claim to all manner of pre-heating air, like the broad claim in *Minter v. Wells* to a wide range of chair shapes, was to an abstract principle or a machine.

93. See Lefstin, *supra* note 16, at 591–93.

English law has ever required.<sup>94</sup>

The *Mayo* decision compounded its misinterpretation of early English law to require *inventive* application of newly discovered laws of nature by asserting that Neilson had inventively applied the pre-heating principle. The *Mayo* opinion states that “the claimed process included not only a law of nature but also several unconventional steps (such as inserting the receptacle, applying heat to the receptacle externally, and blowing the air into the furnace) that confined the claims to a particular, useful application of the principle.”<sup>95</sup> But Neilson’s patent was sustained precisely because he employed well-understood, routine, and conventional means in the application of a new scientific discovery.<sup>96</sup> In rejecting the defendant’s argument that Neilson had not disclosed enough about the heating means to enable practice of the invention, the Exchequer relied on the fact that Neilson’s means of preheating were routine and well-known in the art. As Baron Parke’s opinion acknowledged and accepted, the patentee argued that:

[t]he mode of heating air was perfectly well known; it was no discovery of Mr. Neilson’s, everybody knew it. Air had been heated, and there had been different shaped vessels employed for heating the air; for heating the air economically, and for heating it to a higher or lesser degree of temperature; all that was perfectly well known.<sup>97</sup>

Given the lack of historical foundation for an inventive application requirement, Professors Lefstin and Menell noted that it was particularly surprising that the Supreme Court, which has increasingly emphasized textualist modes of interpretation, would overlook the unbroken chain of references to patent protection extending to both “inventions” and “discoveries.” Moreover, by intermingling nonobviousness (§ 103) and

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94. See *Genentech, Inc.’s Patent*, (1989) RPC 147, 213–17; *Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd.*, (2004) UKHL 46.

95. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 84 (2012).

96. As the Supreme Court recognized in *O’Reilly v. Morse*, Neilson’s patent had been attacked for inadequate disclosure, what modern practitioners refer to as enablement, as well as for subject matter grounds. See *O’Reilly v. Morse*, 56 U.S. 62, 115 (1853). (“[T]he defendant among other defences [sic] insisted—that the machinery for heating the air and throwing it hot into the furnace *was not sufficiently described* in the specification, and the patent void on that account—and also, that a patent for throwing hot air into the furnace, instead of cold, and thereby increasing the intensity of the heat, was a patent for a principle, and that a principle was not patentable.”) (emphasis added).

97. *Neilson*, 1 WEBSTER’S PATENT CASES at 344. That the Exchequer acknowledged and accepted this fact is shown by the judges’ repetition of this point. See *id.* at 337 (Alderson, B.) (stating that Neilson’s heating means were “perfectly well known”). *Neilson* even became the authority for the proposition that practical applications of discoveries were patentable without any invention in the means of application. See Lefstin, *supra* note 16, at 592, 606–08.



enablement or written description (§ 112) considerations into the subject matter inquiry, the *Mayo/Alice* decisions short-circuited the factual inquiries and structure mandated by the 1952 Act. Professors Lefstin and Menell surmised that the Court's failure to engage these critical issues likely resulted from a lack of adequate briefing. The questions presented did not signal to the litigants or amicus community that the Court might venture into such a radical reconsideration of patentable subject matter limitations.

Professors Lefstin and Menell concluded their review of the *Mayo/Myriad/Alice* decisions by highlighting the decisions' impacts on several key technology industries. For the bioscience industries, the *Mayo/Myriad* decisions exclude from patent protection path-breaking discoveries unless they are inventively applied. This in effect requires scientists working in diagnostics and other discovery-based fields to make two breakthroughs in order to obtain patent protection: (1) they must "discover" a law of nature or natural phenomenon; and (2) they must "inventively" apply that discovery. Conventional application of even a Nobel Prize-worthy discovery no longer suffices to obtain a patent. The rule is nominally clear, but excludes subject matter that has been patentable since the creation of the patent system: conventional applications of scientific discoveries.

By contrast, for the software industries there is tremendous uncertainty regarding what constitutes an inventive application of abstract ideas and algorithms. While pure business methods that do not improve the functioning of a computer are no longer patent-eligible, there remains substantial subjectivity surrounding the patent eligibility of computer-implemented processes in general.

## 2. § 101 Invalidation Rates—Courts

Robert Sachs presented data on changes in § 101 invalidity rates in the courts.<sup>98</sup> In the decade preceding the *Mayo* decision (in March 2012), there were only a handful of district court decisions that found patents invalid under § 101.<sup>99</sup> Table 1, however, summarizes a significant increase in district court

98. The data was current as of February 28, 2017.

99. See *Climax Molybdenum Co. v. Molychem, LLC*, No. 02-cv-00311, 2007 WL 3256698 (D. Colo. Nov. 1, 2007); *Perfect Web Techs., Inc. v. Infousa, Inc.*, 89 U.S.P.Q.2d 2001 (S.D. Fla. 2008), *aff'd on other ground*, 587 F.3d 1324 (Fed. Cir. 2009); *CyberSource Corp. v. Retail Decisions, Inc.*, 620 F. Supp. 2d 1068 (N.D. Cal. 2009), *aff'd*, 654 F.3d 1366 (Fed. Cir. 2011); *DealerTrack, Inc. v. Huber*, 657 F. Supp. 2d 1152 (C.D. Cal. 2009), *aff'd in part, vacated in part, rev'd in part*, 674 F.3d 1315 (Fed. Cir. 2012); *Fort Props., Inc. v. Am. Master Lease LLC*, 609 F. Supp. 2d 1052 (C.D. Cal. 2009), *aff'd*, 671 F.3d 1317 (Fed. Cir. 2012); *Bancorp Servs., L.L.C. v. Sun Life Assurance Co. of Can.*, 771 F. Supp. 2d 1054 (E.D. Mo. 2011), *aff'd*, 687 F.3d 1266 (Fed. Cir. 2012); *Glory Licensing LLC v. Toys "R" Us, Inc.*, 2011 WL 1870591 (D.N.J. May 16, 2011); *VS Techs., LLC v. Twitter, Inc.*, 2012 WL 1481508 (E.D. Va. Apr. 27,

§ 101 invalidity decisions both in the 32 months preceding the Supreme Court's *Alice* decision (in June 2014) and in the 32 months following.

**Table 1**  
**All District Court Decisions on § 101 Related Motions**

	After <i>Mayo</i> but Before <i>Alice</i> (24 months, June 2012 to June 2014)				After <i>Alice</i> (32 months, June 2014 to February 2017)				
	<i>Invalid</i>	Not invalid	<i>Total</i>	Percent Invalid	<i>Invalid</i>	Not invalid	<i>Total</i>	Percent Invalid	% Change Post- Alice
<i>Decisions</i>	16	21	37	<b>43.2%</b>	222	137	359	<b>61.8%</b>	<b>+19%</b>
<i>Patents</i>	26	55	81	<b>32.1%</b>	324	454	778	<b>41.6%</b>	<b>+10%</b>

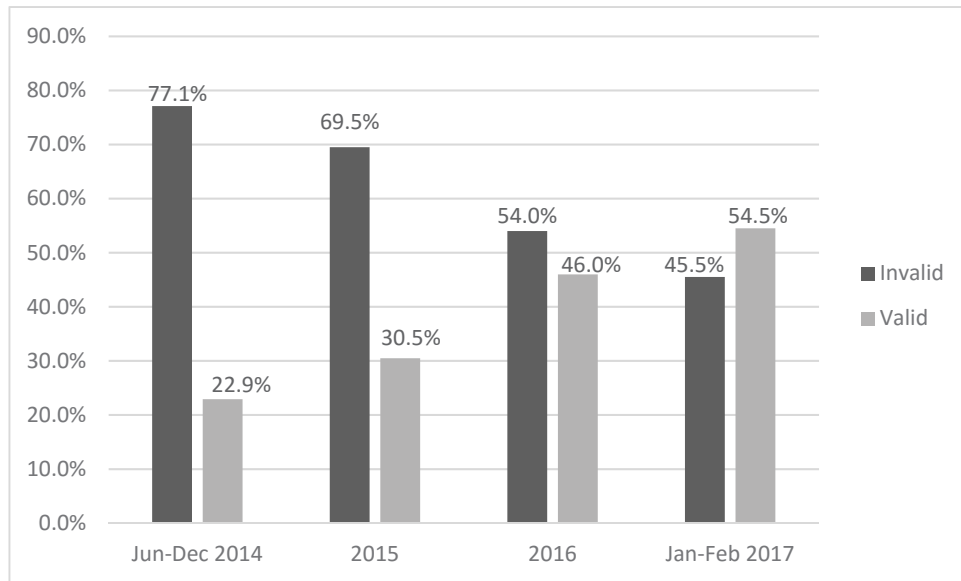
We see a dramatic rise in the number of district court § 101 invalidity decisions following the *Mayo* decision, with no more than three in any year prior to 2012 to an average of 8 per year in the two years following the *Mayo* decision. That number increases 10-fold after the *Alice* decision.

Furthermore, the rate at which patents were found invalid increased significantly as well. Figure 1 shows the district court outcomes on § 101 invalidity determinations over time.

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2012); *CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 768 F. Supp. 2d 221 (D.D.C. 2011), *aff'd*, 717 F.3d 1269 (Fed. Cir. 2013) (en banc), *aff'd* 134 S. Ct. 2347 (2014); *Ass'n for Molecular Pathology v. USPTO*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010), *aff'd in part, rev'd in part*, 689 F.3d 1303 (Fed. Cir. 2012), *aff'd in part, rev'd in part*, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013); *King Pharms., Inc. v. Eon Labs, Inc.*, 593 F. Supp. 2d 501 (E.D.N.Y. 2009) (ruling four claims ineligible), *aff'd on other grounds, vacated in part*, 616 F.3d 1267 (Fed. Cir. 2010) (reversing § 101 invalidity determination). In addition, the Federal Circuit struggled with several patentable subject matter disputes appealed from USPTO § 101 rejections. The Federal Circuit also upheld a few PTO patent rejections on eligibility grounds. *See In re Comiskey*, 554 F.3d 967 (Fed. Cir. 2009); *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), *aff'd on different reasoning*, *Bilski v. Kappos*, 561 U.S. 593 (2010); *In re Nuijten*, 500 F.3d 1346 (Fed. Cir. 2007).

**Fig. 1**  
**Section 101 Outcomes in District Courts**  
**June 2014 to February 2017**



The number of decisions rose sharply from 35 in the second half of 2014 to 141 in 2015, and to 161 in 2016. As shown, the percentage of invalidity determinations fell from a high of 77.1% in 2014 to less than 50% for the first two months of 2017.

Table 2 shows the § 101 invalidity decisions by court and litigation stage.

**Table 2**  
**Section 101 Decisions by Court and Litigation Stage**  
**June 2014 to February 2017**

<b>Tribunal</b>	<b>§ 101 Invalidity Decisions</b>	<b>% Invalid</b>	<b>Total § 101 Decisions</b>
<b>District Court</b>	<b>222</b>	<b>62%</b>	<b>359</b>
Motion for attorney fees	1	100%	1
Motion for Judgment on the Pleadings (JOP)	63	68%	92
Motion to Dismiss (MTD)	94	60%	157
Motion for Summary Judgment (MSJ)	62	64%	97
Post-Trial Motion (PTM)	2	17%	12
<b>Federal Circuit</b>	<b>70</b>	<b>91%</b>	<b>77</b>
Appeal-PTAB-Covered Business Method Review (CBM)	7	100%	7
Appeal-JOP	14	88%	16
Appeal-MSJ	24	92%	26
Appeal-MTD	20	95%	21
Appeal-Prelim Inj. (PI)	1	100%	1
Appeal-PTAB	4	100%	4
Appeal-PTM	0	0%	2
<b>Grand Total</b>	<b>292</b>	<b>67%</b>	<b>436</b>

District courts have resolved the majority of § 101 controversies early in case management—on the pleadings, motion to dismiss, and summary judgment stages. The Federal Circuit has affirmed a high percentage of invalidity determinations.

Table 3 summarizes the Federal Circuit’s review of § 101 invalidity decisions.

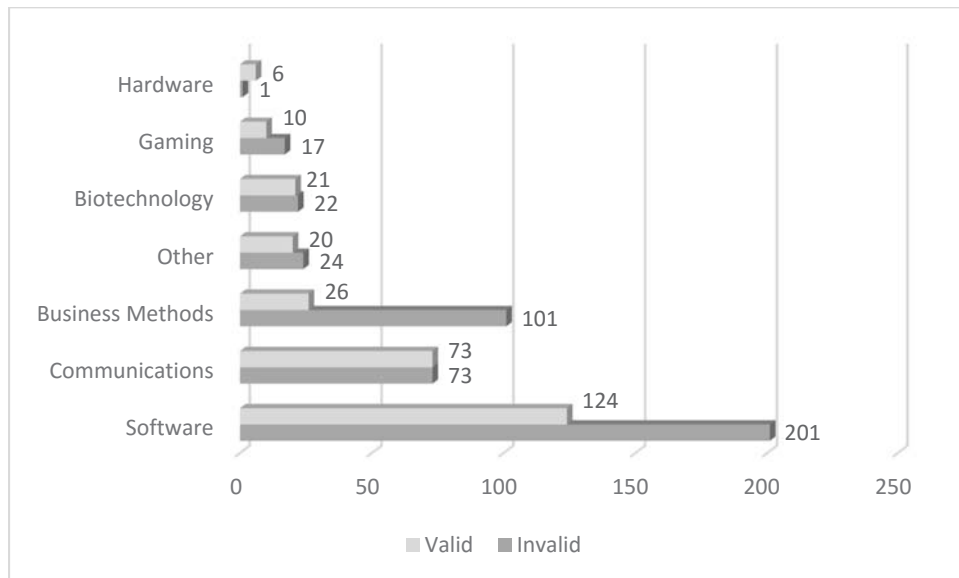
**Table 3**  
**Federal Circuit Review of § 101 Determinations**  
**June 2014 to February 2017**

	Invalid			Not Invalid		Total
	Affirmed	Affirmed <i>Per Curiam</i>	Reversed	Affirmed	Reversed	
Appeal-CBM	2	1	-	-	-	3
Appeal-JOP	2	12	-	-	2	16
Appeal-MSJ	10	13	1	-	2	26
Appeal-MTD	10	10	-	-	1	21
Appeal-PI	1	-	-	-	-	1
Appeal-PTAB	1	7	-	-	-	8
Appeal-PTM	-	-	-	2	-	2
<b>Total</b>	<b>26</b>	<b>43</b>	<b>1</b>	<b>2</b>	<b>5</b>	<b>77</b>

The Federal Circuit has affirmed substantially all district court invalidity determinations. Nearly two-thirds of affirmances have been with opinion. By contrast, the Federal Circuit reversed five of the seven district court findings of no invalidity.

Figure 2 shows the distribution of invalidated patents across technology fields.

**Fig. 2**  
**Patents Challenged under § 101 by Technology Field**  
**June 2014 to February 2017**



### 3. Discussion

None of the workshop participants questioned the core points in the legal presentation. One scholar noted that Professor Sean O'Connor's research suggests that the term "discoveries" in the U.S. Constitution reflected a heightened level of inventiveness.<sup>100</sup> While acknowledging Professor O'Connor's research, Professor Menell noted that the 1790 Patent Act and all subsequent Patent Acts refer to the patentability of "inventions or discoveries." Professor Lefstin noted that the legislative history of the Plant Patent Act of 1930 and the 1952 Act make clear that Congress has supported broad coverage of both inventions and discoveries, bearing in mind that patentable "discoveries" have always been practical applications embodied in

100. See Sean M. O'Connor, *The Overlooked French Influence on the Intellectual Property Clause*, 82 U. CHI. L. REV. 733, 739 (2015) (suggesting that the French *Encyclopédie* defines "discoveries" as "the most important inventions, rather than the uncovering of existing facts").

one of the statutory classes of subject matter, not discoveries in the abstract. And there was broad consensus among the participants that the basis for the Supreme Court's "inventive application" requirement was flawed and that patent law had long afforded protection for applied discoveries.

One participant commented on the undesirable effects of the Supreme Court's recent patentable subject matter jurisprudence on district judges. That participant noted that docket pressures already motivate judges to reduce their trial burdens and that the Supreme Court's "inventive application" jurisprudence, which can be wielded at early stages of litigation, invites cursory analysis of patentable subject matter. Based on the clear text of the Patent Act and jurisprudence, that participant expressed the view that § 101 should be liberally and broadly construed, and that §§ 103 and 112 provide the appropriate tools for curtailing dubious and overbroad patents.

The discussion turned to participants' views about what was driving the Supreme Court's renewed interest in and approach to patentable subject matter limitations. Several participants viewed the Supreme Court's recent foray into patent eligibility as a misdirected effort to address other problems in the patent system, notably broad, vague, and inadequately-supported claims. Others noted perceptions that the non-obviousness standard remains uncertain and too low with regard to software-related patents. The proliferation of "low quality" patents in conjunction with the emergence of patent assertion entities has raised the salience of the patent system, and perhaps the Supreme Court saw § 101 as a tool for reining in these problems.

One participant focused on jurisprudential philosophy, noting that the Supreme Court views patentable subject matter limitations as a common law enterprise.

Other participants emphasized broader moral concerns that might animate the Court's jurisprudence, such as public perceptions about bioscience companies claiming "ownership" of people's genetic information. One participant noted that the Court's patentable subject matter cases may reflect discomfort with intellectual property protection for fundamental tools or knowledge building blocks, such as laws of nature and mental steps. Others noted the intuition that patents are for technology, not business strategies. The Court's recent focus on diagnostics, software, and business methods reflects these considerations.

## B. EFFECTS ON RESEARCH AND DEVELOPMENT

The second session focused on the effects of the shift in patentable subject matter eligibility on research and development activity. One scholar opened the session by framing key questions. An industry practitioner then discussed the relationship between patent protection for diagnostics and advances in personalized medicine. We then opened the discussion and concluded with

perspectives from software industry representatives.

1. *Framing*

The patent system aims to promote innovation by providing time-limited exclusive rights in exchange for disclosure of useful inventions and discoveries. Without patents, we would expect many inventors to rely on trade secrets to appropriate return on their research and development investments.

The efficacy of the patent system is often difficult to measure. Some innovation occurs without the need for exclusive rights and some inventors are able to gain patent protection without providing critical information. Due to the risks of being liable for willful infringement, engineers and scientists in some fields, such as software, steer clear of reading patents. Patents in other fields, such as pharmaceuticals, provide critical security needed for the large capital expenditures and risk of research and development.

The shift in patentable subject matter eligibility suggests several questions for understanding the effects on research and development activities:

- a) Are research institutions and companies shifting their research agendas?
- b) Are research institutions and companies relying more significantly on trade secrecy and reducing public disclosure of scientific discoveries, technological inventions, and technical knowledge?
- c) Is there greater opportunity for follow-on innovators without patents on fundamental building blocks?

2. *Diagnostics, Personalized Medicine, and Biosciences*

An industry practitioner then discussed the relationship between patent protection for diagnostics and personalized (or precision) medicine. According to this representative, precision medicine uses a patient's individual clinical characteristics to tailor medical intervention. Examples include detecting the patient's genotype with increased drug response, measuring drug metabolites in the patient's blood, and observing the patient's clinical response to a drug as means of modifying and optimizing drug dosage.

Molecular diagnostics play a central role in driving precision medicine research and development. It provides the clues for determining disease predisposition, diagnosing disease, assessing disease prognosis, predicting drug response, and targeting prescriptions and diagnostics. Precision medicine depends critically upon balanced regulation, robust reimbursement, and intellectual property rights.

The representative asserted that while few scholars question the need for strong patents in drug research, there is less understanding of the role of



patents in medical diagnostics. Such research is more akin to conventional drug development than software or electronics in terms of its investment patterns and research life cycles.

Notwithstanding that there have been no significant substantive changes to patent eligibility and validity standards in the patent statute, patent protection for diagnostics has significantly eroded over the past decade due to judicial decisions. While these shifts have had negative impacts on all of life science research and development, they have been particularly severe for the diagnostics sector. Reagents and many processes are seen as ineligible for patent protection. Diagnostic kits can also be more difficult to patent under the murky standards relating to “abstract ideas.”

Furthermore, trade secret protection for diagnostics research can be difficult to maintain. Diagnostics companies must publish most details of their tests in peer-reviewed journals to be eligible for reimbursement. Other forms of intellectual property—trademark protection for branding and copyright for instructions—do not provide effective protection to support appropriability, i.e., the ability to derive a return on research and development investment, for diagnostics research.

Ultimately, research and development incentives for medical diagnostics depends critically on the balance among regulation, reimbursement, and patent rights. There is currently no regulatory framework balancing innovator and follow-on generic entrants as there is in the prescription drug sector (Hatch-Waxman legislation). A robust regulatory framework, such as FDA regulation of laboratory-developed diagnostic tests, would increase quality and safety of medical diagnostics but would add to the validation and investment burdens on diagnostics companies to bring their tests to market. Furthermore, the reimbursement rules governing diagnostics play a critical and uncertain role for evaluating diagnostics investments. Patent protection can be an important factor in negotiating reimbursement with health care payers. The shift in patent eligibility for diagnostics threatens research and development investment in medical diagnostics.

Other participants elaborated on the adverse effects of the *Mayo* and *Myriad* decisions on the bioscience industries more generally. One participant noted that venture capitalists and other investors pay significant attention to whether the fruits of research and development expenditures can be internalized by their creators. Ultimately, most investors are indifferent between investing in bioscience, software, or commodities—whichever offers the higher return will attract more capital. The difficulty of protecting advances in scientific discoveries has, in that person’s view, tilted investment away from areas that are more difficult to protect and toward research where trade secrets are more viable.

Participants also discussed how the loss of patent protection for isolated and purified natural products further limits the range of bioscience advances where investors cannot expect rewards from their investments. An attorney with a strong bioscience background provided several concrete examples of important scientific research that was experiencing funding difficulties as a result of the shift in patent eligibility standards: cytotoxins derived from sea organisms (purified natural products) that could be used in treating tissue sarcoma; genes relating to particular genetic mutations; and snake toxins used for treating multiple sclerosis. That participant also noted that bio-analytical data, which can in theory be protected by trade secrecy, is often very difficult to commercialize without disclosure.

One participant drew attention to the Supreme Court's definition of "law of nature" in *Mayo* as a cause of the incoherence across multiple technological fields. That participant noted that the relationship between biomarkers and diseases may be naturally occurring, but they are not "laws of nature." It would be better, in that participant's view, to characterize such relationships as contingent outcomes of evolution. From that perspective, they are no different in kind from other natural relationships that are discovered in chemistry, metallurgy, and semiconductors and could be extrapolated to software and information technologies.

### 3. *Software and Information Technologies*

Attorneys working in the software field provided a more mixed view of the shift in patent eligibility jurisprudence. While not defending the Supreme Court's recent decisions on interpretive or jurisprudential grounds, several in-house counsels in the information technology sector noted that the *Alice* decision has not materially affected their companies' research and development levels, project choice, or start-up acquisition decisions. One participant noted that some boards of directors pay attention to whether potential acquisition targets have patents, but such patents are not typically determinative in the acquisition decision.

While recognizing that software technology should be patentable, several technology industry participants commended the *Alice* decision for weeding out numerous bad patents, reducing litigation risks and costs, and providing a means for resolving litigation over weak patents earlier in the process.

One participant noted that software patents continue to be filed, although patents for analytics are more difficult to pursue. Some of these technologies, however, can be protected by trade secrecy, especially as more and more of the software industry shifts to cloud-computing, software as a service, and enterprise computing business models. This participant noted that algorithmic technologies are being replaced by neural networks and machine learning, which are also vulnerable under *Alice*, but can be protected by trade secrets.

Another participant noted that software development is more collaborative and open today. Many platforms rely on open source software, with competition occurring through implementations and cloud-based services.

An attorney working at a company that has a large research division commented that distinctions across scientific and technological fields are often artificial. Many of the most important breakthroughs happen when researchers cross-germinate methods and findings to open up fertile new research fields. This is increasingly happening in the digital age in fields such as analytics, diagnostics, drug development, bioinformatics, and medical imaging. Although it is sometimes difficult to link patents to products, patents nonetheless are critical to the investment process. This participant noted that concerns about basic building blocks being monopolized and royalty stacking can be exaggerated. Research companies license and cross-license technological advances. Patents often promote openness and sharing, whereas trade secrecy can stand in the way. A bigger impediment to research and development is the commodification of technology, which reduces profit margins. Many research enterprises are looking for areas where breakthroughs can produce significant returns on investment.

### C. EFFECTS ON PATENT PROSECUTION

The third session explored the effects of the Supreme Court's recent patentable subject matter decisions on patent prosecution. A representative from the USPTO began by highlighting the agency's difficulty handling the changes to the law of patent eligibility. We then heard a presentation by Robert Sachs on patent prosecution invalidity rates at the USPTO. Participants then engaged in a general discussion about patent prosecution relating to patent eligibility, followed by more particular discussion of § 101 prosecution in the life sciences and information technology sectors.

#### 1. *The USPTO's Experience*

The session began with remarks from Robert Bahr, the USPTO's Deputy Commissioner for Patent Examination Policy, who described the USPTO's efforts to keep up with the rapidly evolving patentable subject matter jurisprudence. He noted that patentable subject matter emerged as a major area of uncertainty in 2009 surrounding the *Bilski* patent. He then summarized the workload challenges and the efforts to update guidance documents.

Since the Supreme Court decided *Bilski* in 2010, the USPTO has struggled to provide guidance to its patent examiners regarding the law governing eligibility. The Supreme Court did not articulate any eligibility test in *Bilski*, and the Court limited its decision to the particular facts of that case.

When the Supreme Court later introduced the "inventive concept" test in *Mayo*, it was not immediately clear if this test applied beyond claims related to

laws of nature. Moreover, *Myriad* seemed to indicate that a more traditional eligibility test—one asking whether a claim described something different than what exists in nature—applied even after *Mayo*. In *Alice*, the Court finally made clear that the “inventive concept” test applied broadly to all of the judicial exceptions (laws of nature, natural phenomena, and abstract ideas), but the Court did not clarify whether the more traditional eligibility test applied in *Myriad* has any continuing applicability. As a result, *Alice* represented a significant shift in the framework to be applied by patent examiners, but still did not clearly eliminate other approaches to the question of eligibility. Moreover, the “inventive concept” test itself does not provide significant direction to resolve eligibility disputes.

In the face of these Supreme Court decisions—all along the way and even after *Alice*—the USPTO has issued a series of guidance documents for examiners. The preparation of these guidance documents has been increasingly challenging given both the changes in the governing law and the lack of clarity associated with application of the “inventive concept” test. Indeed, despite the issuance of numerous guidance documents examiners have expressed concerns with how they should apply the Supreme Court’s “inventive concept” test. The guidance documents provide the examiners with a framework for determining eligibility. The documents, for example, include flow charts to guide the examiners in terms of the process. But the documents do not provide answers in terms of how the test applies in particular cases. They emphasize particular examples based on judicial opinions.

## 2. § 101 Invalidation Rates—Prosecution

Robert Sachs presented data on § 101 invalidity rates at the USPTO.<sup>101</sup> Table 4 presents the percentage of patents that the USPTO has rejected under § 101 in the period preceding the *Alice* decision and intervals following other developments: following the issuance of the 2014 Preliminary Guidance Document;<sup>102</sup> following the issuance of the 2014 Interim Guidance Document;<sup>103</sup> following the issuance of the July 2015 Guidance Update;<sup>104</sup>

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101. The data was current as of February 28, 2017.

102. See Memorandum from Andrew H. Hirshfeld, Deputy Comm’r for Patent Examination Policy, USPTO, on Preliminary Examination Instructions for Determining Subject Matter Eligibility in view of *Alice Corp. v. CLS Bank, et al.* (June 25, 2014), [https://www.uspto.gov/sites/default/files/patents/announce/alice\\_pec\\_25jun2014.pdf](https://www.uspto.gov/sites/default/files/patents/announce/alice_pec_25jun2014.pdf) [<https://perma.cc/3KBG-9L6D>].

103. See 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74618 (Dec. 16, 2014) (to be codified at 37 C.F.R. pt. 1), <https://www.uspto.gov/sites/default/files/documents/training%20-%202014%20interim%20guidance.pdf> [<https://perma.cc/W4PP-WVV6>].

104. See USPTO, JULY 2015 UPDATE: SUBJECT MATTER ELIGIBILITY 1

following the Federal Circuit's *Enfish* decision (overturning a district court § 101 invalidation decision);<sup>105</sup> and following the Federal Circuit's 2016 *McRO* decision (overturning a district court § 101 invalidation decision).<sup>106</sup>

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<https://www.uspto.gov/sites/default/files/documents/ieg-july-2015-update.pdf>  
[<https://perma.cc/CYS7-ZZ6P>].

105. See Memorandum from Robert W. Bahr, Deputy Comm'r for Patent Examination Policy, USPTO, on Recent Subject Matter Eligibility Decisions (*Enfish, LLC v. Microsoft Corp.* and *TLI Commc'ns. LLC v. A.V. Automotive, LLC*) 2 (May 19, 2016), [https://www.uspto.gov/sites/default/files/documents/ieg-may-2016\\_enfish\\_memo.pdf](https://www.uspto.gov/sites/default/files/documents/ieg-may-2016_enfish_memo.pdf) [<https://perma.cc/C8LM-KBCN>].

106. See Memorandum from Robert W. Bahr, Deputy Comm'r for Patent Examination Policy, USPTO, on Recent Subject Matter Eligibility Decisions (Nov. 2, 2016), <https://www.uspto.gov/sites/default/files/documents/McRo-Bascom-Memo.pdf> [<https://perma.cc/C8LM-KBCN>].

**Table 4**  
**USPTO § 101 Invalidation Rates by Technology Center**  
**June 2012 to February 2017**

Tech Center	Tech Subtype	Before <i>Alice</i> (%)	Prelim Guidance 2014 (%)	Interim Guidance 2014 (%)	July 2015 Update (%)	<i>Enfisb</i> May 2016 (%)	<i>McRO</i> Nov. 2016 (%)
1600	<i>Agriculture</i>	24.0	24.2	24.5	21.6	22.1	21.2
	<i>Biotech</i>	16.9	22.2	21.6	18.4	16.0	15.5
	<i>Healthcare</i>	3.2	4.6	4.7	3.1	2.8	3.3
1700	<i>Chemistry</i>	2.0	2.1	2.1	4.5	1.1	1.1
2100	<i>Computers</i>	21.5	22.0	20.9	17.3	15.7	17.3
2400	<i>Communications</i>	13.2	13.3	17.3	21.8	17.3	16.4
	<i>Computers</i>	19.7	19.4	23.6	25.5	19.7	21.0
2600	<i>Communications</i>	12.4	12.5	14.8	14.2	13.9	12.5
	<i>Computers</i>	10.2	9.9	10.3	9.5	9.1	8.1
2800	<i>Electrical Systems</i>	3.1	4.3	4.8	4.3	5.1	5.3
3600	<i>Civil Engineering</i>	3.0	4.1	4.2	3.9	3.1	3.2
	<i>Manufacturing</i>	1.8	1.9	2.0	1.9	1.7	1.5
	<i>Transportation</i>	12.4	15.6	13.4	13.9	14.3	13.8
3600 Business Methods	<i>Ecommerce</i>	43.3	83.0	92.5	90.7	92.1	90.9
3700	<i>Civil Engineering</i>	2.5	3.8	4.4	3.0	2.7	2.4
	<i>Gaming &amp; Education</i>	19.7	39.8	50.0	43.3	38.1	35.6
	<i>Healthcare</i>	6.2	8.6	10.7	10.0	9.2	9.5
	<i>Manufacturing</i>	1.3	1.5	1.3	0.7	0.5	0.4

The most dramatic effects have been in business methods and

gaming/education, although the § 101 invalidity rates in biotechnology and agriculture have also been high.

### 3. *General Discussion*

Even with the USPTO's various guidance documents, several participants noted that the Supreme Court's eligibility test is difficult to apply consistently, and there is great variance from examiner to examiner in how the test applies. One characterization of the effect on patent prosecution is the view that patent examiners and administrative patent judges in many instances could easily write official actions or opinions related to the same claims coming out either way—either finding eligibility or finding no eligibility. Examiners are sensitive to signals from management, so whether there is a signal to lean against issuance or lean toward issuance makes a difference in how examiners decide close cases. The impact of this sensitivity to management's signals has particular impact on patent eligibility given the subjectivity of the “inventive concept” test. One participant noted that some patent examiners appear to have a new attitude that they simply will not find eligibility, at least “not on [their] watch.” In terms of the Patent Trial and Appeal Board, likewise, one participant expressed the view that if a patent applicant or owner takes a patent eligibility case to that tribunal, it is “not likely to end well.” And while the Federal Circuit in the past served as a “savior” in terms of reversing the USPTO in appropriate circumstances, it has recently been less inclined to rescue deserving claims.

One participant noted that examiners were more likely to uphold claims if they analyzed validity under §§ 102, 103, and 112 prior to analyzing eligibility under § 101. Thus, the confusing nature of the “inventive concept” test might be undermining careful analysis and understanding of patent applications.

### 4. *Bioscience*

Several participants who specialize in prosecuting life sciences applications noted that it is now very difficult to obtain patents in particular inventive fields, such as purified products, methods of treatment using purified molecules, purified enzymes for industrial processes, enzyme variants, and personalized medicine diagnostics—fields where advances had been patentable for decades, or even centuries. Patent examiners seem less likely to allow claims focusing on the structures of these molecules, and more likely to allow claims focusing on the functions of these molecules. Examples of related types of claims not being allowed include purified strains, purified enzymes for industrial applications, and even enzyme variants. It is particularly problematic that the market seeks purified substances to eliminate, for example, contamination, but the patent law requires changes or even marked differences to be present. This is an example of the law diverging from market and technology demands.

Moreover, it is not clear under the law how substantial changes to natural substances must be to warrant patentability.

As a result, companies are not pursuing such claims, are abandoning applications, and are not filing continuations. Such companies believe that patent protection for these inventions and discoveries are critically important, and they are biding their time in the hope that the law of patent eligibility will shift back to broader eligibility.

There has been a dramatic decrease in the ability to patent personalized medicine claims. One participant noted a perverse situation reflecting the apparent view that diagnostic inventions are not eligible as a category: a claim otherwise eligible appears now to be ineligible if it includes a method of diagnosing a disease or other problem or characteristic. As a result, more specific, narrower, and more useful claims have been denied patent eligibility, again merely because they include a step of diagnosis. It is also notable that the standard for patent eligibility for diagnostics has moved in the opposite direction of the underlying technology. Just as inventors have made significant advancements improving the ability to provide targeted medical information to patients, the Supreme Court has eliminated the eligibility of these inventions for patents. The Supreme Court has created a test for eligibility that stands in the way of the creation of new personalized medical inventions.

The effect on companies operating in the life sciences area has been dramatic. In the past, these companies invested very large sums of money (perhaps more than \$2.5 billion) on research and development and, simultaneously, filed patent applications to protect their investments. These patent applications, when issued as patents, complied with the standards of patent eligibility as those standards existed at the time the patents issued. Now, sometimes 10 to 15 years later, the Supreme Court has changed those standards and there is no recourse available. There is no opportunity to amend the claims of the patents to comply with the new eligibility test.

##### 5. *Information Technology*

Participants agreed that the *Bilski* and *Alice* decisions have substantially eliminated patent eligibility for pure business methods claims—claims that do not improve the functioning of computers. The viability of software claims is hazier. Several practitioners noted that art units addressing encryption and optical networks are not predictable.

One participant noted “almost no luck” in overcoming eligibility rejections with pre-*Alice* patent applications. The only available strategy is to file a Request for Continuing Examination and try to get a different examiner. Notably, the data indicates that patent applications filed after *Alice* show no significant improvement in terms of ability to overcome eligibility rejections. Moreover, the data shows that sometimes the only rejection preventing a



patent application from issuing as a patent is a rejection based on § 101. One participant relayed how difficult it is to explain to a client that a patent application has no prior art rejections under §§ 102 or 103, and yet the patent examiner has finally rejected the application as claiming something that is conventional or routine.

Patent prosecutors noted that a key determinant of whether a software claim will issue is how the patent is classified. If the patent is categorized within the ecommerce area, there is little chance that its claims will be found eligible. Thus, applicants focus a lot of their strategic effort in drafting their patents so that they will be assigned to a technology center with a higher eligibility proclivity. Prosecutors noted that most pre-*Alice* software-related filings are lost and not worth pursuing.

#### A. EFFECTS ON PATENT ASSERTION/LITIGATION/CASE MANAGEMENT

The fourth session focused on the effects of the shift in patent eligibility jurisprudence on patent litigation activity and judicial case management.

##### 1. Framing

An experienced patent litigator launched the session by summarizing the key shifts in patent assertion strategy. This participant noted that patent owners today are far less likely to assert dubious patents. The cases being filed in the post-*Alice* era more frequently relate to patents on networking technologies and other machine-related claims as opposed to business methods. Nonetheless, there remains a substantial gray area due to the vagueness of § 101 jurisprudence.

As a result of this uncertainty, plaintiffs are likely to assert more patents and more claims. Prior to the *Mayo* decision, a typical filing would assert no more than four to six patents because of limitation of trial time and jury's cognitive capacity. Following *Mayo*, plaintiffs are more likely to assert ten or more patents as a hedge against the risks of patents being invalidated during early case management on ineligibility grounds. This has raised the complexity and potentially the cost of patent cases.

The other major effect of the shift in patent-eligibility standards has been to front-load patent case management in the software and bioscience fields. Defendants invariably seek early dismissal of claims under § 101. This puts the judge in the difficult position of applying the vague “inventive application” framework to patent claims that have already survived scrutiny under §§ 102, 103, and 112 at the Patent Office. Nonetheless, many district courts have been receptive to these motions, resulting in cursory assessment of patent eligibility—often before claim construction. These district judges may be deciding what is well-understood, routine, and conventional in technical fields without a well-developed record, although for some patents they are able to

find these admissions in the patent specification.

## 2. *Discussion*

While acknowledging that the *Mayo/Alice* standards lack coherence—often boiling down to a subjective “I know it when I see it” standard—several participants commented that the *Alice* decision has allowed defendants to get particularly weak patent cases dismissed early in the litigation process, resulting in substantial savings and effectively eliminating many dubious patents from the system. These participants see the jurisprudence becoming somewhat more predictable. In their view the decisions effectively exclude pure business methods and emphasize technical solutions to technical problems.

Several bioscience industry participants noted that companies have been reluctant to bring test cases, especially after the Supreme Court declined review in the *Sequenom* case. They have lost faith in the Supreme Court and no longer see the Federal Circuit as having the courage to percolate eligibility standards.

## IV. LEGISLATIVE PROPOSALS

The final workshop session focused on whether legislation is needed to address the shift in patentable subject matter jurisprudence, as well as reactions to various proposals. The session began with a brief summary of the pending proposals and the various evaluative criteria set forth in Section I.C. We then went around the table to afford all participants an opportunity to express their perspectives and react to views of others.

### A. SUMMARY OF DISCUSSION

Building upon the prior presentations and discussions, the participants engaged in a wide-ranging discussion of the current status of the law governing patent eligibility, as well as the potential avenues for reform, including recent legislative proposals. Several themes developed. On the one hand, a consensus emerged that the current state of the law is indefensible as a matter of legal principle and is causing particular difficulties for bioscience fields. Participants largely agreed that the Supreme Court did not appear poised to make further significant pronouncements about the scope of patentable subject matter in the foreseeable future. As a result, participants largely agreed that legislation would be necessary to address the problems that have emerged for bioscience researchers. On the other hand, there was disagreement on the need for legislative reform of patentable subject matter relating to computer software. Moreover, there was a lack of agreement on the best solution to current problems, and none of the current proposals listed in Section I.B. garnered consensus. This Section summarizes the areas of consensus and disagreement, with particular attention to the bioscience and software fields. We then

summarize the participants' views regarding the existing legislative proposals and other potential approaches.

1. *The Need for a Legislative Solution*

The discussion repeatedly returned to the need for legislation to address the problems plaguing patent eligibility. A consensus emerged that key aspects of the Supreme Court's *Mayo*, *Alice*, and *Myriad* decisions were indefensible as a matter of statutory interpretation or fidelity to prior case law. Significantly, this consensus spanned the range of industry representatives and legal scholars. No one, for example, disputed Professors Lefstin and Menell's critique of the Supreme Court's *Mayo/Alice* two-part test focusing on the search for an "inventive" rather than merely a "practical" application of a natural law or physical phenomenon.

More generally, there was consensus that a test requiring a search for an "inventive" application of a natural law or physical phenomenon does not provide adequate objective guidance to patent examiners, jurists, practitioners, or the inventive community. As one participant explained, the current state of affairs is "awful" because investors look for patents, which are critical to their investment decisions. And yet under the current law, patent lawyers cannot provide clear or reliable guidance about eligibility.

The manifestation of these concerns differs markedly across fields. Patent prosecutors and examiners do not know what to do when confronted with a question of software eligibility. In the words of one participant, prosecutors in particular are "pulling their hair out." By contrast, bioscience research representatives and many legal scholars worry that the Supreme Court's standards relating to breakthrough scientific advances are far too clear and clearly wrong. They believe that the Supreme Court has eliminated patent protection for important useful research discoveries that are conventionally applied. They emphasized that the major research challenge is often in scientific discovery, not application. Once scientists discover scientific laws, they can use routine, conventional, and well-understood techniques to make such discoveries useful for improving public health, safety, and welfare.

Many participants viewed patent eligibility doctrine as incoherent. It lacks the clarity needed for a property-based incentive regime to function effectively. The lack of clarity has led the USPTO to restrict patent eligibility even beyond what some participants believe the case law requires.

Although software companies that are defendants welcome the opportunity to challenge vague and uninventive claims on eligibility grounds, several participants noted that the lack of coherence presents problems. As one participant noted, the "sky was falling" after the Federal Circuit's *State*

*Street Bank* decision,<sup>107</sup> when the Federal Circuit opened the patent-eligibility door to all software and business methods claims. While the Supreme Court has brought an end to that problem, “the sky is falling again now” because the Supreme Court has gone too far in the opposite direction in *Mayo* and *Alice*.

Many, but not all, participants agreed that legislation would be appropriate to solve problems caused by the current state of the law. The challenge is in finding a balanced compromise—which might be characterized as a separating equilibrium in which bioscience researchers can once again pursue patent protection for applications of new scientific discoveries, without unleashing a wave of assertions of dubious software and business method patents. Some others, particularly those from software companies that are frequently sued by non-practicing entities, however, expressed a preference for letting the current regime play out in the lower courts, even while recognizing the problems with the current state of the law.

Many participants highlighted the need for a clear legislative solution over the existing common law scheme. One participant expressed concern that the United States is not leading the world with respect to patent eligibility; that “things have gotten pretty bad” with respect to reaching the right result in cases, particularly in the field of biotechnology; and, in response to the argument that “we should just let the courts figure this out because it is too hard,” one participant retorted that “we did, and [the courts] screwed it up really badly.” Many participants bemoaned the prospects of Supreme Court correction.

As several participants noted, the Supreme Court has now heard several cases in this area since 2010 and has been unable to identify a coherent test that comports with the legislative framework. Moreover, while the Supreme Court’s *Flook* decision diverged from the traditional approach for patent eligibility, the Court effectively overruled *Flook* in its decisions in *Chakrabarty* and *Diehr* within a few years. The current Supreme Court, by contrast, does not appear to be interested in revisiting the *Mayo* test (which resurrected aspects of *Flook*), as evidenced by the denial of certiorari in *Sequenom*, where the Court did not even ask for the Solicitor General’s view of the case despite over twenty amicus briefs from a wide range of industries and scholars advocating review. In the end, many participants, particularly those in bioscience fields but also some in software fields, expressed an urgent need for a legislative solution. Some participants thought case law development on whether a software claim recited a technical effect could lead to a more predictable and useful body of law.

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107. See *State St. Bank & Tr. Co. v. Signature Fin. Grp., Inc.*, 149 F.3d 1368 (Fed. Cir. 1998).

## 2. *Field-Specific Concerns*

Many participants directed their comments to challenges facing the bioscience and software fields. In this Section, we summarize their comments and identify particular areas of consensus and disagreement within these fields. We also identify support for particular proposals from participants with expertise in these fields.

### a) Bioscience

Participants from the bioscience industries as well as several academics strongly advocated for legislative reform of patent eligibility. As they explained, the case law is not developing in the biotechnology area because of fear that the courts will expand the ineligibility zone. Stakeholders are fearful of bringing test cases. One participant expressed the concern that the Supreme Court can take the next case (as it did in *Mayo*) and eliminate all of the intervening case law development. According to another participant, every § 101 case “makes your heart stop” because of the ability of courts to invalidate bioscience patents after so much money is invested in research and development predicated on the patentability of the underlying technology. Furthermore, according to several participants, the USPTO has shown little appetite for exercising its patent law expertise to confront new challenges. The agency has been largely reactive, or has adopted rigid interpretations of cases such as *Myriad*, interpretations that arguably restrict eligibility even beyond what the Supreme Court requires.

Several participants expressed that the case for legislative reform is particularly salient in particular areas of bioscience research such as medical diagnostics. There was broad agreement among bioscience industry representatives that the Supreme Court’s eligibility framework fundamentally misapprehends the research challenges in the medical diagnostic field and that a legislative solution is the only effective way to restore confidence in patent protection for applied scientific advances in this area. The USPTO’s interpretation of *Myriad* was another area of significant concern, because of the loss of investment and development necessary to bring treatments based on natural products to the public. One participant suggested that legislators should focus on how best to provide incentives for optimal investment in research and development. According to this participant, Congress needs to confront the challenges of curing cancer. This participant advocated erring on the side of patent eligibility so as to “provide a strong incentive for invention.”

In terms of specific proposals, some participants agreed that newly discovered laws of nature should not be considered to be prior art, and that practical applications of discoveries should be eligible for patenting. Other participants noted concerns about the effects of overbroad protection on

cumulative innovation—efforts by follow-on inventors and concerns about licensing impediments and costs. Several participants expressed willingness to expand 35 U.S.C. § 287 to protect doctors and/or to expand the experimental use exception to protect individuals and companies who improve patented technology from being subject to patent infringement liability. Others favored expanding patent law’s experimental use exception to infringement liability so as to balance the interest in providing an incentive for the original discovery and the interest in encouraging follow-on inventors who desire to improve upon practical applications of the discovery.

Several participants indicated a willingness, through legislative reform if necessary, to treat the biotechnology industry differently than the software industry. For example, if patenting of broad generic solutions is unacceptable to the software industry or if it is not possible to identify an elegant, omnibus solution, these participants were open to legislative reforms targeting bioscience fields. One participant suggested looking outside of patent law for a solution that would fund the biotechnology and life sciences industries, such as medical reimbursements for diagnostics.

b) Software

Participants broadly agreed that the current eligibility regime fails to provide predictability, although some in the software field expressed the view that case law is improving predictability. Many commented that patent eligibility jurisprudence is too blunt a tool to invalidate many software-related claims, while noting many of these claims would likely fail §§ 102, 103, and/or 112. Some participants noted that the current regime calls into question some software-related claims that should be eligible, although unlike in the bioscience area where participants generally favored patent eligibility for conventional applications of scientific discoveries, it was more difficult to articulate particular software areas that are being erroneously, categorically excluded. In short, the current software eligibility regime causes inefficient redundancy, a cloud of suspicion on all software-related patents, and incorrect outcomes with respect to some software-related claims.

Some software industry representatives favored the current regime on the purely instrumental ground that it provides a shortcut to invalidating many dubious software patents and can save litigation resources. Others favored a more open-ended framework that affords protection for applications of discoveries, including algorithms. One participant expressed concern that this latter approach is similar to the “useful, concrete and tangible result” test most commonly associated with the Federal Circuit’s decision in *State Street Bank*.<sup>108</sup>

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108. *Id.* at 1373–75.

Several participants, moreover, expressed the view that pure business methods should not be patent eligible, even if they are implemented on computers, because of low development cost, deleterious effects on free market competition, and the absence of any need to provide an incentive to ensure their development. One participant defended the eligibility of pure business methods on the ground that all processes meeting the §§ 102, 103, and 112 requirements should be patentable.

Several participants expressed support for a technological arts test as a way of excluding eligibility for business methods (even if they use computers in non-technologically inventive ways), while preserving eligibility for software claims that improve the functioning of computers and computing technology. One participant noted, however, that it is unclear how the technological arts test applies to new technologies. That participant noted that European patent examiners initially considered artificial intelligence to be ineligible. Another participant suggested that the difficulty of determining eligibility of software relates to the broad statutory term “process,” and so a legislative solution might focus on narrowing that particular statutory category.

Other participants emphasized that software patents are plagued by overbroad scope resulting in significant part from functional claiming. They advocated addressing these concerns through applying § 112(b) and (f) in a rigorous way, including early in litigation. Others similarly suggested that the primary concern is lack of enablement or written description under § 112(a), and similarly encouraged applying these doctrines earlier in litigation.

Some, but not all, participants involved with software nevertheless indicated a desire for a wait-and-see approach to allow the case law to develop with respect to software-related claims. Others similarly expressed concern about the political feasibility of amending patent eligibility at a time when many software companies are concerned about abusive patent assertion. Several participants suggested that any legislative reform to patent eligibility that eliminates this early dispute resolution mechanism would need to be paired with other reforms that help reach similarly efficient results. We address this interest in more detail below. We note, however, that several other participants responded that we should not impair innovation in the pursuit of judicial efficiency.

### *3. Evaluation of Existing Legislative Proposals and New Proposals*

In the previous Section, we summarized comments on the impact of particular proposals on the bioscience and software industries. In this Section, we summarize more general comments as well as comments directed to particular proposals but not limited in scope to either bioscience or software industry concerns. We also summarize new proposals identified in the workshop.

Most participants agreed that eligibility should be a “coarse filter” or “minimal hurdle.” Furthermore, several participants expressed the desire to prevent deconstruction of patent claims, which involves ignoring claim elements.

Many participants expressed support or concern with particular proposals. One participant, for example, favored the IPO proposal as a constructive starting point, but also thought that a test focusing on whether the claimed invention is in the technological arts might find broader support. Another participant favored a test that focused on whether claims are specific and patentable under §§ 102, 103, and 112. Another participant suggested adopting a technological arts test, but at the same time making it clear that technology includes practical applications of discoveries. Such a technological arts test might be neutral facially, but have differential impact in different industries (in particular biotechnology versus software). Yet another participant suggested that a technological arts test, without some definition, is ambiguous and might be seen as consistent with what courts are doing now. This participant suggested that technological arts be defined as human-directed efforts to harness natural laws and physical phenomena to achieve practical end results. This definition, it was posed, would exclude purely mental processes.

What this discussion highlighted is that none of the proposals, at least in their current form, provides an effective test for distinguishing between the bioscience and software fields. Some participants advocated developing a test that expressly distinguishes between bioscience and software eligibility. Several participants saw merit in a test that restored the practical application of a discovery standard in conjunction with expressly limiting patent eligibility to the technological arts. Some questioned whether “technological” could be clearly delineated. Other participants, however, expressed a desire for a trans-technology approach. They noted the convergence of bioscience and software fields through, for example, advances in bioinformatics.

Some participants expressed reluctance to depart from the current standards because of the litigation cost savings and speed advantage of being able to challenge patent validity early in litigation through a motion pursuant to Federal Rule of Civil Procedure 12(b)(6). Several participants, however, recommended that courts allow early 12(b)(6) motions on more appropriate patent law doctrines that have extensive historical pedigrees that have produced objective guidelines, including the written description and enablement requirements. In this regard, several participants expressed a desire to preserve the ability early in litigation to eliminate poor quality patent assertions made by patent assertion entities (which occurs primarily in the software industry), while recognizing that the current test unfortunately undermines research and development incentives and investment in bioscience.



Rather than have Congress fashion legislation adopting a new test for patent eligibility, some participants suggested Congress give the USPTO the authority to do so. One participant, for example, noted the inherent difficulty in predicting technological advances and the patent system's purpose in bringing the unknown into the known. For this participant, these considerations suggested it might be better to defer to the USPTO rather than courts given the USPTO's expertise and ability to coordinate and update standards. Another participant noted the tension between maintaining flexibility to allow for accurate results (particularly in different industries) and constraining judicial intervention. This participant questioned whether courts should be making these distinctions at all, or instead whether the USPTO should make eligibility determinations without having courts revisit the question. This participant suggested that Congress should give the USPTO rulemaking authority to decide what is and what is not eligible.

B. TOWARDS A COMPROMISE PROPOSAL: THE NEED FOR CONSENSUS-BUILDING

The workshop revealed broad agreement that the Supreme Court's patent eligibility jurisprudence has diverged from the Patent Act's text and legislative history as well as long-standing jurisprudential standards. The participants also agreed that the Supreme Court's stated rationale and formulation lacks a sound foundation and misapprehends the *Neilson v. Harford* decision on which it grounds the inventive application standard. Furthermore, the workshop revealed a consensus that it is unlikely that the Supreme Court will reconsider the patent eligibility issue in the foreseeable future. Conferees also doubted that the Federal Circuit will confront the core concerns surrounding patent eligibility. Thus, legislative reform will be necessary to effect significant change in patent-eligibility standards.

While nearly all of the conferees recognized that this state of the law poses serious concerns for bioscience research and development, there existed substantial reluctance on the part of some software industry representatives about pursuing legislative reform that could increase patent assertion activity and raise defense risks and costs in the software field. Some participants also thought that the courts should be given time to develop an appropriate screen for the eligibility of software patents and saw some progress in the developing case law.

This suggests to the workshop convenors and authors of this report (Jeffrey Lefstin, Peter Menell, and David Taylor) that the most fruitful approach to reform legislation would restore the traditional patent-eligibility standard at least for bioscience advances—that is, establishing that conventional application of scientific discoveries are eligible for patent protection—while addressing concerns about cumulative creativity and

abusive patent assertion. Such additional provisions could include the following: (1) an expanded experimental use exception at least for doctors and medical researchers; (2) exclusion of non-technological subject matter, notably pure business methods (a technological arts test); (3) a mechanism to encourage courts to consider 12(b)(6) motions directed to § 112 issues (as opposed to § 101 issues) early in patent case management; (4) fee-shifting aimed at discouraging nuisance value patent lawsuits; (5) higher thresholds for enhanced damages in the software field; and/or (6) shorter duration for algorithm-based inventions—i.e., where the point of non-obviousness is a computer-implemented algorithm. We also note that compromise legislation might also address distinctive issues relating to affected industries that lie outside of the patent field, such as reimbursement policies relating to medical diagnostics.

We recognize, however, that there are differing views regarding each of these compromise elements. We therefore call for consensus-building among the interested constituencies. In this regard, we recognize that the IPO, AIPLA, and ABA-IPL proposals were approved by the governing boards of those organizations, which include representatives of various constituencies, including parties having significant interests in the bioscience and software industries. There was no consensus among our participants, however, that any of these proposals should be the exclusive focus of a legislative effort going forward. In short, there was a consensus that more discussion is necessary. In this regard, in particular, we recommend a future workshop aimed at developing a compromise package.

**APPENDIX A: PATENTABLE SUBJECT MATTER WORKSHOP  
AGENDA**

9:00 am	Breakfast
9:30 am	Introduction
10:00 am	Legal Background
11:15 am	Break
11:30 am	Effects on R&D
12:15 pm	Lunch Buffet
12:45 pm	Working Lunch: Effects on Prosecution
1:45 pm	Effects on Patent Assertion/Litigation/Case Management
2:30 pm	Break
2:45 pm	Legislative Proposals
3:30 pm	Discussion of Proposals
5:00 pm	Next Steps
5:30 pm	Reception
6:15 pm	Dinner

## APPENDIX B: PARTICIPANT LIST

<b>Academics</b>	<b>Affiliation</b>
Menell, Peter (convenor)	UC-Berkeley
Lefstin, Jeff (convenor)	UC-Hastings
Taylor, David (convenor)	SMU
Collins, Kevin	Wash U (St. Louis)
Cotter, Thomas	Minnesota
Eisenberg, Rebecca	Michigan
Holbrook, Timothy	Emory
Lemley, Mark	Stanford
Morris, Emily	Univ. of Maine
Narechania, Tejas	UC-Berkeley
Rai, Arti	Duke
Samuelson, Pamela	UC-Berkeley
<b>Practitioners</b>	
Hubbard, Marc	Hubbard Johnston
Kappos, David	Cravath, Swaine & Moore
Powers, Matthew	Tensegrity Law Group
Noonan, Kevin	McDonnell Boehnen Hulbert & Berghoff
Fu, Diana	Van Pelt, James & Yi
Sachs, Robert	Fenwick & West
Sonnenfeld, Ken	King & Spalding
<b>Industry/In-House</b>	
Sauer, Hans	Deputy GC (IP), BIO
Armitage, Robert	former Senior VP and General Counsel of Eli Lilly & Co.
Jackson, Benjamin	Myriad
Pleasure, Irene	Genentech
Michel, Suzanne	Google
Meehan, Michael	Uber
Jones, David	Microsoft
Underweiser, Marian	IBM
Skabrat, Steven	Intel
Rao, Dana	Adobe
Sarboraria, Matthew	Oracle

Simon, David	Salesforce
<b>Government/Other</b>	
Whyte, Ronald M.	U.S. District Judge, N.D. Cal. (retired)
Simpson, Jamie	Staff, Senator Christopher Coons (D. Del.)
Givens, Alexandra Reeve	Executive Director, Institute for Technology Law & Policy, Georgetown University Law Center, former Chief Counsel for IP and Antitrust on the Senate Judiciary Committee, working for senior Democrat Senator Patrick Leahy (D-Vt)
Bahr, Robert	Deputy Commissioner for Patent Examination Policy, USPTO
Kelley, Nathan	Deputy General Counsel for Intellectual Property Law and Solicitor, USPTO
Munck, Suzanne	Deputy Director and Chief Counsel for Intellectual Property, Office of Policy Planning, Federal Trade Commission

### APPENDIX C: PREPATORY MATERIALS

Brief of Professors Jeffrey A. Lefstin & Peter S. Menell as Amici Curiae in Support of Petition for a Writ of Certiorari, *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, pp. 4-14, No. 15-1182 (Apr. 29, 2016), [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2767904](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2767904) [<https://perma.cc/ZZB9-Q4JA>].

David O. Taylor, *Amending Patent Eligibility*, 50 U.C. DAVIS L. REV. 2151 (2017).

#### Legislative Proposals

- A Proposed Path Forward for Legislatively Addressing Patent Eligibility Law: Patenting Genes, Natural Products and Diagnostics: Current Status and Future Prospects, Conference Held at The Banbury Center, Cold Spring Harbor Laboratory (Nov. 9-11, 2016) (Banbury Statement) (available at <https://www.uspto.gov/sites/default/files/documents/Updated%20Banbury%20Statement.pdf>) [<https://perma.cc/YX8T-3BF3>].
- Intellectual Property Owners Association (IPO), Proposed Amendments To Patent Eligible Subject Matter Under 35 U.S.C. § 101 (Feb. 7, 2017).
- European Patent Convention, Art. 52, Patentable Inventions.
- ABA-IPL, Comments Related to Patent Subject Matter Eligibility (submitted to USPTO) (Jan. 18, 2017).
- Google Inc., Comments Related to Patent Subject Matter Eligibility (submitted to USPTO) (Jan. 18, 2017).
- Internet Association and Computer & Communications Industry Association (CCIA), Comments Related to Patent Subject Matter Eligibility (submitted to USPTO) (Jan. 18, 2017).
- Robert A. Armitage, Presentation Slides for USPTO Roundtable 2—Patent Eligibility Contours, Can We Find a Rational, Principled, Expansive, and Politically Palatable Approach to Statutorily Defining Patent Eligibility? (Dec. 5, 2016).
- Ryan Davis, Kappos Calls for Abolition of § 101 of Patent Act, *Law 360* 360 (Mar. 2, 2017), <https://www.law360.com/articles/783604/print?section=ip> [<https://perma.cc/UAQ4-YL4N>].

**USPTO Patentable Subject Matter Guidance Documents**

- 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74618 (Dec. 16, 2014).
- July 2015 Update: Subject Matter Eligibility.
- Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant's Response to a Subject Matter Eligibility Rejection (May 4, 2016).
- Recent Subject Matter Eligibility Decisions (*Enfish, LLC v. Microsoft Corp.*, and *TLI Communications LLC v. A. V. Automotive, LLC*) (May 19, 2016).
- Recent Subject Matter Eligibility Rulings (*Rapid Litigation Management v. CellzDirect* and *Sequenom v. Ariosa*) (Jul. 14, 2016).
- Recent Subject Matter Eligibility Decisions (Nov. 2, 2016).
- December 2016: Interim Eligibility Guidance Quick Reference Sheet.
- Training materials on subject matter eligibility (Mar. 3, 2017).

