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## Why the Supreme Court Should Use *Ariosa v. Sequenom* to Provide Further Guidance on U.S.C. § 101 Patent Eligibility

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WHY THE SUPREME COURT SHOULD USE ARIOSAS V. SEQUENOM  
TO PROVIDE FURTHER GUIDANCE ON 35 U.S.C. § 101 PATENT  
ELIGIBILITY

NAIRA REZENDE SIMMONS<sup>1</sup>

ABSTRACT

*35 U.S.C. § 101 provides patent protection to “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” The Supreme Court previously concluded that Congress intended patentable subject matter to “include anything under the sun that is made by man.”<sup>2</sup> Nevertheless, over the past five years the U.S. Supreme Court has made a series of decisions that narrowed the scope of subject matter eligible for patent protection.*

*In Mayo<sup>3</sup> the court held that correlations between the concentrations of a metabolite in the blood and the concentration of a drug are not patent eligible because such correlations are “laws of nature.” In Alice<sup>4</sup> the Court not only limited the patent eligibility of computer-implemented methods and systems, but it articulated that the “Mayo framework” should be used in all cases in which the Court had to decide whether some category of technological innovation was inside or outside the scope of the patent system.*

*As a result of the overly broad, sweeping decisions made by the Supreme Court over the past five years, many important inventions that otherwise satisfy all statutory requirements for patent eligibility are no longer receiving proper patent protection. This paper discusses the context and implications of the holdings of Chakrabarty<sup>5</sup>, Diehr<sup>6</sup>, Bilski<sup>7</sup>, Mayo<sup>8</sup>,*

1. J.D. Candidate at the University of California Hastings College of the Law. I am grateful to professor Robin Feldman for her comments and guidance. Any mistakes or omissions are mine alone.

2. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (holding that genetically modified organisms can be patented).

3. See generally *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).

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

5. See generally *Chakrabarty*, 447 U.S. 303.

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

7. See generally *Bilski v. Kappos*, 561 U.S. 593 (2010).

*Myriad*<sup>9</sup>, and *Alice*<sup>10</sup>, and it uses the facts and posture of *Ariosa*<sup>11</sup> to illustrate that patent protection is being denied to remarkable inventions based on the newly created judicial exceptions to patent eligibility.

*This paper concludes by proposing that since judicial decisions rely on the facts which led to the dispute, judicially created exceptions to 35 U.S.C. § 101 should be narrowly applied to one or more classes in the Cooperative Patent Classification System (CPC). Because patents in the same class have similar technical features, the application of a judicial exception to patents in the same or similar classes would limit the possibility of unanticipated consequences for inventions in various fields that fall under the broad application of exceptions based on specific facts.*

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8. See generally *Mayo* 132 S. Ct. 1289.

9. See generally *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

10. See generally *Alice Corp.* 134 S. Ct. 2347 (2014).

11. See generally *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).

## I. OVERVIEW

### A. *The Constitutional Foundation for Patent Eligible Subject Matter under 35 U.S.C. § 101.*

For four months during the summer of 1787, the Constitutional Convention met “in order to form a more perfect union”<sup>12</sup> through the creation of the Constitution. One of the specific powers discussed and addressed was the governance of intellectual property in a national economy. The framers knew that society benefits from products of original and creative thought, and they included a legal framework for providing incentives to inventors and authors in the Constitution. Even during the Convention, while drafting the most important document ever written in the United States, the delegates adjourned one afternoon to watch an inventor named John Fitch demonstrate a trial of one of his inventions: a 45-foot steamboat on the Delaware River.<sup>13</sup> As Abraham Lincoln once said, “[t]he Patent System added the fuel of interest to the fire of genius.”<sup>14</sup>

The United States Constitution, on which U.S. Patent Law depends, was drafted in a pro-patent climate. Thomas Jefferson was directly involved in the patent system and drafted the statutory definition of what constitutes a patentable invention. In the Patent Act of 1793, Jefferson defined a patentable invention as “any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement thereof.”<sup>15</sup> Subsequent patent statutes in 1836, 1870, and 1874 employed the same broad language. In 1952, when the patent laws were recodified, Congress replaced the word ‘art’ with ‘process,’ but otherwise left Jefferson’s language intact. The Committee Reports accompanying the 1952 act inform us that Congress intended statutory subject matter to “include anything under the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled.”<sup>16</sup> The America Invents Act of 2011<sup>17</sup>, a law that represents

12. U.S. CONST. pmb1.

13. *John Fitch Was Granted a U.S Patent for the Steamboat, America’s Story from America’s Library*, AMERICA’S LIBRARY, [http://www.americaslibrary.gov/jb/nation/jb\\_nation\\_fitch\\_1.html](http://www.americaslibrary.gov/jb/nation/jb_nation_fitch_1.html) (discussing the grant of the U.S. patent for the steamboat in 1791) (last visited Apr. 21, 2016).

14. George F. Will, *Rev the scientific engine*, THE WASHINGTON POST (Jan. 2, 2011), <http://www.washingtonpost.com/wp-dyn/content/article/2010/12/31/AR2010123102007.html> (Lincoln’s quote is reportedly from a speech in Jacksonville, Illinois, delivered in February of 1859).

15. Patent Act of 1793, Ch. 11, 1 Stat. 318-23 (Feb. 21, 1793).

16. S. Rep. No. 1979, at 4 (1952); *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399. (The conditions of the title include also satisfying 35 U.S.C. §§ 102, 103, and 112) 16. S. Rep.

the most significant change to the U.S. patent system since 1952, did not change the statutory definition of what constitutes patentable inventions. As of today, the patent statute still provides that:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.<sup>18</sup>

The text of the statute still reflects the language drafted by Jefferson. However, the meaning of 35 U.S.C. § 101 has been severely curtailed by the United States Supreme Court, most notably in a quartet of contemporaneous cases - *Bilski*<sup>19</sup>, *Mayo*<sup>20</sup>, *Myriad*<sup>21</sup>, and *Alice*.<sup>22</sup>

It is possible, or even likely, that the decisions of our highest court – which have significantly narrowed the statutory definition of patent eligible subject matter – are a direct response to the failure of the patent system to properly address ethical, moral, socio-economic as well as inventiveness and obviousness issues raised by the emergence of new technologies.<sup>23</sup> For instance, many acknowledge that flaws in the patent system contributed to the rise of non-practicing entities (NPEs)<sup>24</sup>, and that NPEs in turn have wreaked economic havoc in many industries by enforcing weak or otherwise invalid patents.<sup>25</sup> Nonetheless, the broad application of the newly

17. See generally LEAHY-SMITH AMERICA INVENTS ACT, PUB.L. No. 112–29, 125 Stat. 284 (2011).

18. 35 U.S.C. § 101 INVENTIONS PATENTABLE.

19. See generally *Bilski v. Kappos*, 561 U.S. 593 (2010).

20. See generally *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).

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

22. See generally *Alice Corp. Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014).

23. Software, computers, or genetically engineered organisms, are not explicitly mentioned in statutory United States patent law. For an insightful analysis of some of issues raised by the failure of the patent system to properly address new technologies, see U.S. Gov’t Accountability Office, GAO-13-465, *Intellectual Property: Assessing Factors That Affect Patent Infringement Litigation Could Help Improve Patent Quality* (2013) (Congress required the Government Accountability Office (GAO) to study the consequences of patent litigation by NPEs or patent assertion entities (PAEs) in consultation with the USPTO. This study included the volume of litigation in the 20 years before enactment of the AIA, the volume of cases which are found to be without merit after judicial review, the impact of litigation on the time to resolve patent claims, the costs of such litigation, its economic impact on the U.S. economy and job creation, and any benefits created by NPEs or PAEs.).

24. James Bessen, Jennifer Ford & Michael J. Meurer, *The Private and Social Costs of Patent Trolls* 2 1-33 (Boston Univ. School of Law, Working Paper No. 11-45, 2011) (raising the question: “Or are they “patent trolls” who exploit weaknesses in the patent system?”); accord, see generally Kirby Ferguson, *The Rise of the Patent Troll: An Animated Primer* by Kirby Ferguson, OPEN CULTURE (Apr. 14, 2014), <http://www.openculture.com/2014/04/the-rise-of-the-patent-troll.html>. Accord Sara Jeruss, Robin Feldman, Joshua Walker, *The America Invents Act 500: Effects of Patent Monetization Entities on Us Litigation*, 11 DUKE L. & TECH. REV. 357, 357-89 (2012).

25. See generally Chris Barry, Ronen Arad, Landan Ansell, Meredith Cartier, and HyeYun Lee, *2015 Patent Litigation Study: A Change in Patentee Fortunes*, PWC (May 2015),

created exceptions to patentability has damaged many innovators. Particularly, the recent decisions in *Myriad* and *Alice*, have provoked uncertainty in entire industries. In numerous cases, the current approach to what is patent eligible “seems to lead to the *reduction ad absurdum* that most biotechnology processes are patent-ineligible.”<sup>26</sup>

This paper first considers the historical context of select judicial opinions interpreting the meaning of 35 U.S.C. § 101, including *Chakrabarty*<sup>27</sup> and *Diehr*<sup>28</sup>. Thereafter, this paper considers the implications of the judicial framework created by the United States Supreme Court in the quartet of cases that outlined the current rules: *Bilski*<sup>29</sup>, *Mayo*<sup>30</sup>, *Myriad*<sup>31</sup>, and *Alice*<sup>32</sup>. This paper uses the facts and posture of *Ariosa v. Sequenom*<sup>33</sup> to illustrate the shortcomings of this broad framework. In doing so, it provides a practical, simple, readily applicable approach for applying the law to the facts, based on a patent classification system that could produce results which are more consistent with the purpose of patent law: to promote the progress of science and useful arts.

### *B. Issues Raised by the Application of 35 U.S.C. § 101 to New Technologies*

Throughout the existence of the patent system patents were, for the most part, seen by industry as shields to protect inventions from competition by “free riders” who simply copied such inventions. The broad language of 35 U.S.C. § 101 justified and protected the ideas and efforts of innovators in developing and improving “anything under the sun”<sup>34</sup>, as long

<https://www.pwc.com/us/en/forensic-services/publications/assets/2015-pwc-patent-litigation-study.pdf>. Accord David L. Schwartz, Jay P. Kesan, *Analyzing the Role of Non-Practicing Entities in the Patent System*, 99 CORNELL L. REV. 425, 425-50 (2014).

26. Jeffrey A. Lefstin, *Ariosa v. Sequenom and the Path Ahead for Subject-Matter Eligibility*, Patently-O, PATENTLYO (June 14, 2015), [patentlyo.com/patent/2015/06/sequenom-subject-eligibility.html](http://patentlyo.com/patent/2015/06/sequenom-subject-eligibility.html). Accord Brief of Professors Jeffrey A. Lefstin and Peter S. Menell as Amici Curiae, at 1, *Ariosa v. Sequenom*, 788 F.3d 1271 (2015) (No. 2014–1139, 2014–1144).

27. See generally *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

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

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

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

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

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

33. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *reh’g denied*, 809 F.3d 1282 (Fed. Cir. 2015).

34. S. REP. NO. 82-1979, at 5 (1952); as reprinted in 1952 U.S.C.C.A.N. 2394, 2399 (the full quote suggests that the other conditions of 35 U.S.C. §§ 102, 103, 112 need to be satisfied as well. It recites: “A person may have “invented” a machine or a manufacture, which may include anything under

as it satisfied all conditions for patentability. Throughout history, patents have also been used as “swords”, a term that refers to the offensive use of patent portfolios against a third-party.<sup>35</sup> Beginning in the early 2000s the practice of using patents as “swords” gained momentum.

A major trigger for this shift was the economic slowdown of 2001, while some industries recovered quickly and reached new heights in employment by 2008<sup>36</sup> (*e.g.*, most high-tech industries in the Silicon Valley grew more concentrated in the local economy relative to the United States from 2001 to 2008)<sup>37</sup> many companies that had developed intellectual property became bankrupt and their intellectual property was acquired by third parties looking for means to obtain a return on their investment. Frequently, NPEs were not actually involved in producing or marketing products themselves, so the most natural way to recover the investment was by licensing the intellectual property they had acquired or by suing for intellectual property infringement.

In due course, the successes and large recoveries obtained in infringement suits motivated some entities to acquire intellectual property solely for the purpose of enforcing it against third-parties.<sup>38</sup> Currently, the failure of a practitioner to advise a client to develop a patent portfolio that can be used both offensively and defensively could arguably be considered malpractice. The full impact of practicing patent owners and NPEs<sup>39</sup> using their patents as swords rather than shields has attracted the attention of the President’s Council of Economic Advisers, the National Economic Council, the Office of Science & Technology Policy, Scholars<sup>40</sup> and the

the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled”).

35. *See, e.g.*, Rajiv Patel, *Developing a Patent Strategy: A Checklist for Getting Started*, FENWICK & WEST LLP, [https://www.fenwick.com/FenwickDocuments/Patent\\_Checklist.pdf](https://www.fenwick.com/FenwickDocuments/Patent_Checklist.pdf) (succinctly outlines that a patent strategy should consider whether a patent portfolio is to be used offensively, defensively, or in another form).

36. *See*, Amar Mann & Tony Nunes, *After the Dot-Com Bubble: Silicon Valley High-Tech Employment and Wages in 2001 and 2008*, *Office of Publications & Special Studies, Regional Report*, BUREAU OF LABOR STATISTICS (August 2009), [http://www.bls.gov/opub/regional\\_reports/200908\\_silicon\\_valley\\_high\\_tech.htm](http://www.bls.gov/opub/regional_reports/200908_silicon_valley_high_tech.htm).

37. *Id.*

38. *See, e.g.*, *Patent Troll*, ELECTRONIC FRONTIER FOUNDATION, <https://www EFF.org/issues/resources-patent-troll-victims> (last visited Sept. 17, 2016) (Noting that the patent troll problem is not a new one, however they have created a troubling new trend where more and more small developers and companies are targeted by trolls).

39. NPEs are also known in the literature as patent monetization entities.

40. Sara Jeruss, Robin Feldman & Joshua Walker, *The America Invents Act 500: Effects of Patent Monetization Entities on Us Litigation*, 11 DUKE L. & TECH. REV. 357, 360 (2012), *See also*, Robin Feldman, *Patent Demands & Startup Companies: The View from the Venture Capital Community*, 16

Supreme Court of the United States.<sup>41</sup> Many believe that some of the limitations on patent eligible subject matter by the Supreme Court are a reaction to patent monetization.<sup>42</sup>

## II. ARGUMENTS

### *C. Existing Judicial Framework Limiting the Scope of Patent Eligible Subject Matter*

Judicial opinions, by their very nature are – or should be – fact specific. To better understand the current judicial framework limiting the scope of 35 U.S.C. § 101, one should consider how the courts have answered ethical, moral, economic, and technical challenges to the statute. In modern times, the most difficult biotechnology question before the Supreme Court was presented in a case dealing with whether genetically modified living organisms are patent eligible.<sup>43</sup> The facts of *Chakrabarty* are simple: while working for General Electric, a genetic engineer developed a bacterium that had the ability to break down crude oil. General Electric filed a U.S. patent application for the bacterium, listing Chakrabarty as the inventor and proposing to use the engineered bacterium in cleaning oil spills. The application was rejected by a patent examiner, who argued that living things were not patentable subject matter under 35 U.S.C § 101.<sup>44</sup>

YALE J.L. & TECH. 236, 239 (2014) (Examining the effects of the rising patent monetization market on startup companies).

41. The United States Supreme Court has attempted to impose direct barriers on litigation driven by patent monetization entities when it lowered the bar for a defendant to recover its legal costs if the judge sees the plaintiff's suit as frivolous. *See* *Octane Fitness, LLC v. Icon Health & Fitness, Inc.*, 134 S. Ct. 1749, 1757-58 (2014).

42. James Bessen, *What the Courts Did to Curb Patent Trolling—for Now*, THE ATLANTIC (Dec. 1, 2014), <http://www.theatlantic.com/business/archive/2014/12/what-the-courts-did-to-curb-patent-trolling-for-now/383138/> (Arguing that the number of lawsuits has been declining since the Supreme Court decision in *Alice*).

43. *Diamond v. Chakrabarty*, 447 U.S. 303, 303-07 (1980). *Cf.*, *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014) (The second most difficult biotechnology question considered by the Supreme Court). In *Roslin*, the institute was the first group to successfully produce the first mammal ever cloned from an adult somatic cell: Dolly the Sheep. In the opinion, the Federal Circuit affirmed a determination by the Patent Trial and Appeal Board affirming the rejection of claims 155-159 and 164 of U.S. Application No. 09/225,233 (filed Apr. 4, 1999) as being directed to unpatentable subject matter under 35 U.S.C. § 101.

44. *See generally*, prosecution history of U.S. Patent No. 4,259,444 (issued Mar. 31, 1981).

Two former administrative bodies within the USPTO came to opposite conclusions with regards to the patent eligibility of living organisms<sup>45</sup>, and this compelled the Commissioner of Patents and Trademarks to seek guidance from the Supreme Court on the interpretation of 35 U.S.C § 101.<sup>46</sup> Chief Justice Warren Burger delivered a split 5-4 ruling in favor of General Electric.<sup>47</sup> In his opinion, Chief Justice Burger noted that:

The question before us in this case is a narrow one of statutory interpretation requiring us to construe 35 U.S.C. § 101, which provides: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” Specifically, we must determine whether respondent’s micro-organism constitutes a “manufacture” or “composition of matter” within the meaning of the statute.<sup>48</sup>

Chief Justice Burger concluded that an engineered bacterium was eligible for patent protection under the statute. In reaching that conclusion, the Chief Justice reminded everyone that the statute was authored by Thomas Jefferson and embodied Jefferson’s philosophy that “ingenuity should receive a liberal encouragement.”<sup>49</sup> Furthermore, the Chief Justice noted that subsequent patent statutes enacted in 1836, 1870, and 1874 “employed the same broad language”, and that the recodification of the statute in 1952 by Congress merely replaced the word “art” with “process.”

*Chakrabarty* was consistent with decades of legal practice, but shortly thereafter the Supreme Court became more active in questioning the breadth of 35 U.S.C. § 101.<sup>50</sup> The patents that concerned the Supreme

45. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). The Board of Patent Appeals and Interferences (BPAI) agreed with the original decision; however, the United States Court of Customs and Patent Appeals (CCPA) overturned the case in *Chakrabarty*’s favor, writing that “the fact that micro-organisms are alive is without legal significance for purposes of the patent law.” The BPAI has since been replaced with the Patent Trial and Appeal Board (PTAB) and the CCPA ceased to exist in 1982.

46. See generally, prosecution history of U.S. Patent No. 4,259,444 (issued Mar. 31, 1981).

47. See generally *Chakrabarty*, 447 U.S. 303. Chief Justice Warren E. Burger wrote the decision, and was joined by Potter Stewart, Harry Blackmun, William Rehnquist, and John Paul Stevens. The dissenting opinion was written by William J. Brennan, who was joined by Byron White, Thurgood Marshall, and Lewis Franklin Powell.

48. *Id.* at 307 (emphasis added).

49. *Id.* at 308.

50. The original trilogy of patent cases by the Supreme Court discussing the patent eligibility of computer software related invention elaborated on the theory of preemption. In *Gottschalk v. Benson* 409 U.S. 63 (1972) the Court ruled that a process claim directed to a numerical algorithm, as such, was not patentable because “the patent would wholly pre-empt the mathematical formula.” In *Parker v. Flook*, 437 U.S. 584 (1978) the Court ruled that an invention that departs from the prior art only in its use of a mathematical formula is patent-eligible only if the implementation is novel and nonobvious. The algorithm itself must be considered as if it were part of the prior art. In *Alice*, the current controlling opinion, the court elaborates that the risk of preemption must be “disproportionate.” *Alice*, slip op. at 5.

Court the most were patents related to laws of nature<sup>51</sup> and abstract ideas.<sup>52</sup> In *Diamond v. Diehr*, the Supreme Court outlined a third exception to patent eligible subject matter: natural phenomena. *Diehr*<sup>53</sup> forced the justices to consider the application of their own precedents, which notably discussed the possibility of preemption by a broad reading of 35 U.S.C. § 101 to advances in computer technology.<sup>54</sup> The patent at stake in *Diehr* disclosed an invention that provided improvements to the process of curing synthetic rubber.<sup>55</sup> The improvements incorporated the use of embedded thermocouples into existing machinery to constantly monitor temperatures inside a pressing mold.<sup>56</sup> The embedded thermocouples fed the measured values into a computer and used a well-known mathematical equation to calculate when the molding process should be finished.<sup>57</sup>

Individually, the components of the *Diehr* patent were entirely known in either the rubber industry or technology circles.<sup>58</sup> As a whole, the invention improved the efficiency of the process and the quality of the product, and the significance of the improvements and value of the invention were not disputed by any court.<sup>59</sup> To acknowledge the

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

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

53. *Diehr* produced another 5-4 split opinion by the Supreme Court. The majority wrote an opinion by Rehnquist, joined by Burger, Stewart, White, Powell. Justice Stevens wrote a dissenting opinion joined by Brennan, Marshall, Blackmun.

54. For discussion of preemption in dicta, see the two original cases in the software patent eligibility trilogy: (1) *Gottschalk v. Benson*, 409 U.S. 63 (1972) (explaining that that holding the patent at issue as valid “would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself”); and (2) *Parker v. Flook*, 437 U.S. 584 (1978) (holding that the claims involved statutory subject matter because they included recitation of post-solution activity and did not preempt the formula or algorithm used). The adjective “disproportionate” was recently added by the Courts in *Alice*.

55. The claimed invention was a process for molding raw, uncured synthetic rubber into cured precision products. The process uses a mold for precisely shaping the uncured material under heat and pressure and then curing the synthetic rubber in the mold so that the product will retain its shape and be functionally operative after the molding is completed. Before the invention was made, there was no disclosed way to improve the measure of the temperature without opening the press. The invention solved this problem by using embedded thermocouples to constantly check the temperature, and then feeding the measured values into a computer. The computer then used the Arrhenius equation to calculate when sufficient energy had been absorbed so that the molding machine should open the press.

56. *Diamond v. Diehr*, 450 U.S. 175, 177-78 (1981).

57. *Id.*

58. Basics of rubber curation have been published as early as the 1900’s, see, e.g., *Rubber, (Peeps at industries)* by Edith A. Browne, London: A&C Black, 1912. The Arrhenius equation was first published by Arrhenius in 1889, see generally, Arrhenius, S.A. (1889). “Über die Dissociationswärme und den Einfluß der Temperatur auf den Dissociationsgrad der Elektrolyte.” *Z. Phys. Chem.* 4: 96–116.

59. *Diehr*, 447 U.S. 303 at 179 (1981). Noting that “[r]espondents characterize their contribution to the art to reside in the process of constantly measuring the actual temperature inside the mold.”

significance of the discovery in its totality the Supreme Court explained that patent claims have to be considered as a whole. In the words of Justice Rehnquist:

When a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101.<sup>60</sup>

Reading the claims as a whole provided an effective way for the Supreme Court to address concerns of preemption by broad patents while acknowledging the innovative contributions of an invention to a particular technical field.<sup>61</sup> *Diehr* outlined a logical path for claim construction under 35 U.S.C. § 101, but subsequent cases have limited the meaning of the statute.

Shortly after *Diehr* was decided, Congress passed the Federal Courts Improvement Act of 1982.<sup>62</sup> The Act which merged the United States Court of Customs and Patent Appeals and the appellate division of the United States Court of Claims, making the judges of the former courts into circuit court judges.<sup>63</sup> The goal of the creation of the Federal Circuit was to promote greater uniformity in certain areas of federal jurisdiction, *i.e.* patent law, and relieve the pressure on the dockets of the Supreme Court and the courts of appeals for the regional circuits.<sup>64</sup> The Federal Circuit is particularly known for its decisions on patent law, as it is the only appellate-level court with the jurisdiction to hear patent case appeals.<sup>65</sup> The Federal Circuit attempted to apply some of the patent eligibility tests previously articulated by the Supreme Court, and it also created some of its own tests. However, all of these tests were created to address specific questions arising in particular fact-patterns and they have proven difficult to apply in even slightly different scenarios across various areas of

Further noting that “[t]he patent examiner rejected the respondents’ claims on the sole ground that they were drawn to nonstatutory subject matter under 35 U. S. C. § 101.”

60. *Id.* at 175, 192.

61. Under a legal theory of preemption, “a mathematical formula, like a law of nature, cannot be the subject of a patent, *cf.* *Gottschalk v. Benson*, 409 U.S. 63; *Parker v. Flook*, 437 U.S. 584.” *See* *Gottschalk v. Benson*, 409 U.S. 63 (1972) (holding that a process claim directed to a numerical algorithm, as such, was not patentable because “the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.”)

62. *Landmark Judicial Legislation*, FEDERAL JUDICIAL CENTER, [http://www.fjc.gov/history/home.nsf/page/landmark\\_22.html](http://www.fjc.gov/history/home.nsf/page/landmark_22.html) (last visited Apr. 21, 2016).

63. PUB.L. 97-164 §165, 96 Stat. 50. *Public Law 97-164, § 165 (1982)* (enacted).

64. *See*, *Landmark Judicial Legislation*, *supra* note 62.

65. Roger Meiners, Al H. Ringleb, & Frances L. Edwards, *THE LEGAL ENVIRONMENT OF BUSINESS* Chapter 12. (12th ed. 2016).

technology. A notable example is the disparate interpretation of the “machine-or-transformation”<sup>66</sup> test of patent eligibility by different judges within the Federal Circuit and within the Supreme Court seen in *Bilski v. Kappos*.<sup>67</sup> *Bilski* is a case about the patentability under 35 U.S.C. § 101 of an abstract idea: a method of hedging risk in the field of commodities trading in the energy market.<sup>68</sup> In *Bilski*, The Board of Patent Appeals and Interferences the Federal Circuit, and the Supreme Court all concluded that the claims were invalid, but they did so using irreconcilable legal reasoning and different interpretations of the machine-or-transformation test.

In delivering the majority opinion in *Bilski*<sup>69</sup>, Justice Kennedy framed the legal question as one of statutory interpretation pertaining to the breadth of 35 U.S.C. § 101.<sup>70</sup> He noted that the Federal Circuit “produced five

66. The “machine-or-transformation” test was first articulated under its present form in the government’s brief in *Gottschalk*.

67. See A. Mark Lemley et al., *Life After Bilski*, 63 STAN. L. REV. 1315 (2011). (discussing *Bilski*, the machine-or-transformation test, and concerns with patentability of “natural laws”).

68. The first claim consists of the following steps: “(a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumers;” (“(b) “identifying market participants for said commodity having a counter-risk position to said consumers;”; and “(c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.” In *Bilski*, The patent examiner rejected the application on the grounds that the invention is not implemented on a specific apparatus, merely manipulates an abstract idea, and solves a purely mathematical problem. The Board of Patent Appeals and Interferences agreed and affirmed. The Federal Circuit, in turn, affirmed. The *en banc* court rejected its prior test for determining whether a claimed invention was a patentable “process” under Patent Act, 35 U.S.C. § 101—i.e., whether the invention produced a “useful, concrete, and tangible result,” see, e.g., *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998)—holding instead that a claimed process is patent eligible if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. Concluding that this “machine-or-transformation test” is the sole test for determining patent eligibility of a “process” under § 101, the [Federal Circuit] applied the test and held that the application was not patent eligible. See *Bilski v. Kappos*, 561 U.S. 593 (2010). The Supreme Court affirmed the holding, but clarified the machine-or-transformation test was an important clue, but not the only test.

69. In *Bilski*, Kennedy delivered the majority opinion, joined by Roberts, Thomas, Alito; Scalia (except Parts II-B-2 and II-C-2). A concurrence was written by Justice Stevens, joined by Ginsburg, Breyer, Sotomayor. A separate concurrence was written by Justice Breyer, joined by Scalia (Part II).

70. Justice Kennedy reiterated the dicta of *Chakrabarty* noting that “Congress plainly contemplated that the patent laws would be given wide scope” and summarized what the Supreme Court considers to be the three specific exceptions of patent eligible subject matter under 35 U.S.C. § 101. In Justice Kennedy’s words: “This Court’s precedents provide three specific exceptions to § 101’s broad principles: “laws of nature, physical phenomena, and abstract ideas.” “While not required by the statutory text, these exceptions are consistent with the notion that a patentable process must be new and useful.” And, in any case, the exceptions have defined the statute’s reach as a matter of statutory stare decisis going back 150 years. See *Le Roy v. Tatham*, 55 U.S. 156 (1853). The § 101 eligibility inquiry is only a threshold test. Even if a claimed invention qualifies in one of the four categories, it must also

different opinions” in interpreting the machine-or-transformation test and that “students of patent law would be well advised to study these scholarly opinions.”<sup>71</sup> With regards to the different opinions produced by the Federal Circuit, Justice Kennedy highlights that different justices would have used distinct rationales for finding the *Bilski* claim invalid under 35 U.S.C. § 101<sup>72</sup> and “[o]nly Judge Newman disagreed with the court’s conclusion that petitioners’ application was outside of the reach of § 101.”<sup>73</sup> “She did not say that the application should have been granted but only that the issue should be remanded for further proceedings to determine whether the application qualified as patentable under other provisions.”<sup>74</sup> Specifically, Justice Kennedy articulates that the entire Federal Circuit erred in their interpretation of the machine-or-transformation test. In Justice Kennedy’s words:

Three arguments are advanced for the proposition that the [*Bilski*] invention is outside the scope of patent law: (1) it is not tied to a machine and does not transform an article; (2) it involves a method of conducting business; and (3) it is merely an abstract idea. The Court of Appeals ruled that the first mentioned of these, the so-called machine-or-transformation test, was the **sole** test to be used for determining the patentability of a “process” under the Patent Act, 35 U.S.C. § 101 . . . . Adopting the machine-or-transformation test as the sole test for what constitutes a “process” (as opposed to just an important and useful clue) violates these statutory interpretation principles.<sup>75</sup>

After *Bilski*, we started to see many examples of the difficulties presented by the broad application of specific judicial exceptions to new, non-analogous art. *Mayo* is a good example of a case where the USPTO, the Federal Circuit, and the Supreme Court arrived at entirely disparate results.<sup>76,77</sup> Many agree that the *Mayo* claims captured an important

satisfy “the conditions and requirements of this title, § 101(a), including novelty, see § 102, nonobviousness, see § 103, and a full and particular description, see § 112.”

71. *Bilski v. Kappos*, 561 U.S. 593, 600 (2010).

72. Judge Mayer argued that petitioners’ application was “not eligible for patent protection because it is directed to a method of conducting business.” *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008). He urged the adoption of a “technological standard for patentability.” *Id.* at 1010. Judge Rader would have found petitioners’ claims were an unpatentable abstract idea. *Id.* at 1011. *Bilski v. Kappos*, 561 U.S. 593, 600-01 (2010.)

73. *Bilski v. Kappos*, 561 U.S. 593, 601 (2010).

74. *Id.*

75. *Id.* at 597-98 (emphasis added).

76. Petitioners Mayo Collaborative Services and Mayo Clinic Rochester (Mayo) bought and used diagnostic tests based on Prometheus’ patents. But in 2004 Mayo announced that it intended to sell and market its own, somewhat different, diagnostic test. Prometheus sued Mayo contending that Mayo’s test infringed its patents. The District Court found that the test infringed the patents but granted summary judgment to Mayo, reasoning that the processes claimed by the patents effectively claim natural laws or natural phenomena—namely, the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drugs—and therefore are not patentable. The Federal Circuit reversed, finding the

discovery that was inventive, non-obvious, and fully described in the patent specification,<sup>78</sup> *i.e.*, it satisfied all statutory requirements for patent eligibility outside of 35 U.S.C. § 101.<sup>79</sup> The invention required administering a drug to a patient, measuring the level of a metabolite of the drug in the blood of the patient, and determining whether the level of the metabolite in the blood is above or below a threshold level associated with toxicity.<sup>80</sup> A significant amount of research and development was employed by the inventors to determine what constitutes a safe and what constitutes a toxic level of the metabolite. Interestingly, because every person metabolizes the drug in a different way, the Mayo invention gave a physician the required tools to assess how a patient was individually metabolizing the drug<sup>81</sup> This provided invaluable guidance to a physician in determining what dose of the drug should be prescribed to a patient. This also allowed a physician to adjust the dose of the drug that is prescribed depending on individual patient responses<sup>82</sup>

The patent examiner(s) who issued the *Mayo* claims had been trained to recognize inventiveness but was not necessarily exposed to recent developments in patent law.<sup>83</sup> When the *Mayo* patent was challenged in

processes to be patent eligible under the Circuit's "machine or transformation test." On remand from the [Supreme Court] for reconsideration in light of *Bilski v. Kappos*, 561 U.S. 593, 130 S.Ct. 3218, 177 L.Ed.2d 792, which clarified that the "machine or transformation test" is **not a definitive test of patent eligibility**, *id.* at –, 130 S.Ct. at 3226–3227, the Federal Circuit reaffirmed its earlier conclusion. The Supreme Court reversed and found that the claims were patent ineligible. *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S.Ct. 1289, 1291 (2012).

77. The sitting justices included Justice Breyer, who delivered the opinion for the majority, Chief Justice J. Roberts, Justice Scalia, Justice Kennedy, Justice Thomas, Justice Ginsburg, Justice Alito, Justice Sotomayor, and Justice Kagan.

78. See Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565 (2015) (discussing the Supreme Court's recent cases on patent-eligible subject matter and the inventive character of *Mayo*).

79. The exemplary claim of *Mayo* recites: "A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising: (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject." U.S. Patent No. 6,355,623, (issued Mar. 12, 2002).

80. See generally, specification of U.S. Patent No. 6,355,623 (issued Mar. 12, 2002) and U.S. Patent No. 6,680,302 (issued Jan. 20, 2004) (describing the use of thiopurine drugs).

81. *Id.*

82. See, *e.g.*, Claim 1 of U.S. Patent No. 6,355,623 (issued Mar. 12, 2002) which teaches a required level of 6-thioguanine that indicates a need to increase the amount of drug being administered to a subject.

83. Patent Examiners are not required to be lawyers, often, Patent Examiners are engineers and scientists. For a description of the qualification requirements for a patent examiner position see *Patent*

District Court, the court hesitated in interpreting the judicial precedent.<sup>84</sup> The district court judges provided a complete infringement analysis under the presumption of validity of the issued patent, but they proceed to grant summary judgment against *Mayo*, reasoning that the patents effectively claim natural laws or natural phenomena.<sup>85</sup> On appeal, the Federal Circuit reversed relying on the machine-or-transformation test that had previously caused significant controversy in *Bilski*.<sup>86</sup> Partially relying on guidance from the Supreme Court holding in *Bilski*, which held that the machine-or-transformation test is “not the only test but an useful clue”, the Federal Circuit concluded that the *Mayo* claims required the transformation of the drug by the human body.<sup>87</sup> Perhaps a bit precociously, and without completing a full analysis, the Federal circuit concluded that the *Mayo* patents satisfied the Circuit’s “machine-or-transformation test,” which the Federal Circuit thought to be sufficient to “confine the patent monopoly within rather definite bounds.”<sup>88</sup>

The Supreme Court granted a writ of certiorari and overturned the prior ruling unanimously, and reminded everyone, that the “machine-or-transformation test” is not a definitive test of patent eligibility, but only an important and useful clue.<sup>89</sup> Yet, somehow, the Federal Circuit understood that the machine-or-transformation test led to the “clear and compelling conclusion . . . that the . . . claims . . . do not encompass laws of nature or preempt natural correlations.”<sup>90</sup> Unanimously, the Supreme Court held that the right question to be asked was “do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to

*examiner positions, U.S. PAT. AND TRADEMARK OFF.,*  
<https://www.uspto.gov/web/offices/pac/exam.htm> (last modified Dec. 3, 2016 12:29:34 PM).

84. See generally, *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 2005 WL 7985065 (S.D. Cal. Nov. 22, 2005).

85. The District Court found that Mayo’s test infringed claim 7 of the ‘623 patent. App. to Pet. for Cert. 110a–115a. In interpreting the claim, the court accepted Prometheus’ view that the toxicity-risk level numbers in Mayo’s test and the claim were too similar to render the tests significantly different. The number Mayo used was too close to the number the claim used to matter given appropriate margins of error. Nonetheless the District Court ultimately granted summary judgment in Mayo’s favor. The court reasoned that the patents effectively claim natural laws or natural phenomena—namely the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drug dosages—and so are not patentable. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 2008 WL 878910 (S.D. Cal. Mar. 28, 2008)

86. See *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1339 (Fed. Cir. 2009), *cert. granted, judgment vacated*, 561 U.S. 1040.

87. *Id.* at 1343.

88. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1345–47 (2009) (internal quotation marks omitted).

89. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1296 (2012).

90. *Id.*

qualify as patent-eligible processes that *apply* natural laws?” “We believe that the answer to this question is no.”<sup>91</sup> In answering the aforementioned question in the negative, the Supreme Court significantly curbed the patent protection available to diagnostic inventions. This is important because one of the alternatives to patent protection, keeping a technology a trade secret, does not provide proper protection to technologies and diagnostic tools that need to be fully disclosed to the public during the regulatory approval process.

The Supreme Court outlined another challenge to the validity of diagnostic patents in *Myriad*.<sup>92</sup> *Myriad* is an unusual case largely driven by advocacy organizations.<sup>93</sup> In *Myriad*, medical organizations, researchers, genetic counselors, and patients brought action against patentee and the United States Patent and Trademark Office (USPTO), challenging the validity of patents for isolated deoxyribonucleic acid (DNA) sequences associated with predisposition to breast cancers and ovarian cancers, and patents for diagnostic methods of identifying mutations in those DNA sequences. Myriad had obtained several such patents, covering the sequence of the BRCA1 and BRCA2 genes.<sup>94</sup> Myriad’s knowledge of the BRCA1 and BRCA2 mutations typically involved in disease progression allowed it to reverse engineer the genes’ normal nucleotide sequence and to develop medical tests useful for detecting mutations in these genes in a particular patient and for assessing the patient’s cancer risk.<sup>95</sup> If valid, Myriad’s patents would give it the exclusive right to isolate an individual’s BRCA1 and BRCA2 genes, and would give Myriad the exclusive right to synthetically create BRCA cDNA.<sup>96</sup> Justice Thomas delivered the opinion

91. *Id.* at 1297.

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

93. *See* A Lane Baldwin & Robert Cook-Deegan, *Constructing narratives of heroism and villainy: case study of Myriad’s BRCAAnalysis® compared to Genentech’s Herceptin®*, 5 GENOME MED. 1 (2013).

94. The patents include U.S. Patent No. 5,747,282 (issued May 5, 1998); U.S. Patent No. 5,837,492 (issued Nov. 17, 1998); U.S. Patent No. 5,693,473 (issued Dec. 2, 1997); U.S. Patent No. 5,709,999 (issued Jan. 20, 1998); U.S. Patent No. 5,710,001 (issued Jan. 20, 1998); U.S. Patent No. 5,753,441 (issued May 19, 1998); and U.S. Patent No. 6,033,857 (Mar. 7, 2000).

95. *See generally*, specifications and claims of U.S. Patent No. 5,747,282 (issued May 5, 1998); U.S. Patent No. 5,837,492 (issued Nov. 17, 1998); U.S. Patent No. 5,693,473 (issued Dec. 2, 1997); U.S. Patent No. 5,709,999 (issued Jan. 20, 1998); U.S. Patent No. 5,710,001 (issued Jan. 20, 1998); U.S. Patent No. 5,753,441 (issued May 19, 1998); and U.S. Patent No. 6,033,857 (issued Mar. 7, 2000).

96. *See* claims of U.S. Patent No. 5,747,282 (issued May 5, 1998); U.S. Patent No. 5,837,492 (issued Nov. 17, 1998); U.S. Patent No. 5,693,473 (issued Dec. 1997); U.S. Patent No. 5,709,999 (issued Jan. 20, 1998); U.S. Patent No. 5,710,001 (issued Jan. 20, 1998); U.S. Patent No. 5,753,441 (issued May 19, 1998); and U.S. Patent No. 6,033,857 (issued Mar. 7 2000).

of the court in *Myriad*<sup>97</sup>, which partially reiterated the previous Supreme Court analysis of patent eligible subject matter in *Mayo*, but introduced new limitations to patent eligibility of natural products. The opinion did not deny the magnitude of *Myriad*'s discoveries, but surprisingly Justice Thomas indicated that “[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”<sup>98</sup> This statement is contrary to the very purpose of 35 U.S.C. § 101 to provide protection to “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” It is also contrary to what Thomas Jefferson intended to protect when he drafted the statute describing patent eligible subject matter.<sup>99</sup>

To decide *Myriad*, the majority of the Supreme Court parsed the genetic code of the BRAC1 and BRAC2 genes into components that were “naturally occurring” versus components that were not “naturally occurring.”<sup>100</sup> In doing so, it concluded that the sequences of BRAC1 and BRAC2 genes were not patent eligible because they were products of nature.<sup>101</sup> However, the synthetic intermediate used in an *in-vitro* reaction to amplify BRAC1 and BRAC2, namely the complementary DNA (cDNA)

97. Thomas, Roberts, Kennedy, Ginsburg, Breyer, Alito, Sotomayor, and Kagan joined the majority opinion. Scalia joined in part and filed an opinion concurring in part and concurring in the judgment. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2110 (2013).

98. *Id.* at 2117. To support that reasoning, Justice Thomas evoked the line of reasoning discussed in a much older Supreme Court Case: “*In Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 68 S.Ct. 440, 92 L.Ed. 588 (1948), this Court considered a composition patent that claimed a mixture of naturally occurring strains of bacteria that helped leguminous plants take nitrogen from the air and fix it in the soil. *Id.*, at 128–129, 68 S.Ct. 440. The ability of the bacteria to fix nitrogen was well known, and farmers commonly “inoculated” their crops with them to improve soil nitrogen levels. But farmers could not use the same inoculant for all crops, both because plants use different bacteria and because certain bacteria inhibit each other. *Id.*, at 129–130, 68 S.Ct. 440. Upon learning that several nitrogen-fixing bacteria did not inhibit each other, however, the patent applicant combined them into a single inoculant and obtained a patent. *Id.*, at 130, 68 S.Ct. 440. The Court held that the composition was not patent eligible because **the patent holder did not alter the bacteria in any way.** *Id.*, at 132, 68 S.Ct. 440 (“There is no way in which we could call [the bacteria mixture a product of invention] unless we borrowed invention from the discovery of the natural principle itself”). His patent claim thus fell squarely within the law of nature exception. So do *Myriad*'s. *Myriad* found the location of the BRCA1 and BRCA2 genes, but that discovery, by itself, does not render the BRCA genes “new . . . composition[s] of matter,” § 101, that are patent eligible.” *Id.*

99. Letter from Thomas Jefferson to James Madison, 28 August 1789, in PTJ, 15:368. Transcription available at Founders Online. Jefferson articulates his intention of providing protection for monopolies by stating: “monopolies may be allowed to persons for their own productions in literature and their own inventions in the arts for a term.” <http://founders.archives.gov/documents/Jefferson/01-15-02-0354>.

100. See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2108 (2013) (“Held: A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring.”).

101. *Id.* at 2117.

created in vitro, was “not a “product of nature” and is patent eligible under § 101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA.” “In that situation, a short strand of cDNA may be indistinguishable from natural DNA.”<sup>102</sup> The logic applied by the Supreme Court in deciding *Myriad* surprised many because the synthetic intermediate is designed to be a functional mirror image of the natural product.<sup>103</sup> The reasoning applied by the Supreme Court to reach the decision, which was established as precedent for interpreting patent eligible subject matter, baffles almost anyone that has been taught to think of an invention as a ground breaking, innovative or even brilliant discovery.

The last case in this quartet of opinions is *Alice Corp. v. CLS Bank Int'l* (2014).<sup>104</sup> *Alice* is the first Supreme Court case on the patent eligibility of software-related inventions since *Diehr*, and it is fraught with a number of different issues, including extortion of practicing entities by non-practicing entities and the patentability of inventions that have existed for many years in the form of trade secrets. In *Alice*, a consortium of banks (collectively “CLS Bank”) developed a computer system that used proprietary technology to facilitate trillions of dollars in transactions every

102. *Id.* at 2119.

103. Justice Scalia deserves credit for articulating in his concurrence that he was unable to affirm the molecular biology details of the discovery. In his words: “I join the judgment of the Court, and all of its opinion except Part I-A and some portions of the rest of the opinion going into fine details of molecular biology. I am unable to affirm those details on my own knowledge or even my own belief. It suffices for me to affirm, having studied the opinions below and the expert briefs presented here, that the portion of DNA isolated from its natural state sought to be patented is identical to that portion of the DNA in its natural state; and that complementary DNA (cDNA) is a synthetic creation not normally present in nature.” *Id.* at 2120 (Scalia, J., dissenting). Ct. Justice Thomas attempted to explain what was not being decided in *Myriad*. In his words: “It is important to note what is *not* implicated by this decision. First, there are no method claims before this Court. Had *Myriad* created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent. But the processes used by *Myriad* to isolate DNA were well understood by geneticists at the time of *Myriad*’s patents “were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach,” 702 F.Supp.2d, at 202–203, and are not at issue in this case. Similarly, this case does not involve patents on new applications of knowledge about the BRCA1 and BRCA2 genes. Judge Bryson aptly noted that, “[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, *Myriad* was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications.” 689 F.3d, at 1349. Nor do we consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of § 101 to such endeavors. We merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.” *Id.* at 2119-20.

104. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014). For a detailed discussion of Post-*Alice* Jurisprudence see Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence of Abstractions*, 16 N.C.J. OF L. AND TECH. 647 (2015) (for a discussion of the current jurisprudence on patent-eligibility).

day.<sup>105</sup> Alice Corporation (“Alice”), widely believed by many to be a non-practicing entity or patent troll, owned several patents that disclosed a scheme for mitigating “settlement risk,” *i.e.*, that covered the proprietary methods used by the banks to facilitate the aforementioned transactions. Alice attempted to enforce its patents against CLS and CLS challenged the validity the patents in court.<sup>106</sup> The district court held that all of the claims were ineligible for patent protection under 35 U.S.C. § 101 because they were directed to an abstract idea.<sup>107</sup> The Federal Circuit affirmed, sitting *en banc*.<sup>108</sup> The Supreme Court held that the claims were drawn to a patent ineligible abstract idea.<sup>109</sup> Yet, when explaining the legal framework that needs to be used to determine patent eligible subject matter, Justice Thomas explained that the “*Mayo* framework” must be applied to: distinguish patents that claim the buildin[g] block[s] of human ingenuity, which are ineligible for patent protection, from those that integrate the building blocks into something more, thereby transform[ing] them into a patent-eligible invention.”<sup>110</sup> Alice concludes by applying the framework of *Mayo* to **all judicial exceptions** and **all claim types**.<sup>111</sup>

#### *D. The Facts and Posture of Ariosa v. Sequenom*

*Alice* was decided on March 20, 2014. Shortly thereafter, the USPTO began to update their interim guidance on subject matter eligibility and to retrain patent examiners on how to evaluate patent claims reciting natural phenomena and abstract ideas.<sup>112</sup> If the courts are struggling with what exactly is enough to render a claim that partly recites a natural law patent

105. Roger Parloff, *Supreme Court to decide when ideas become too ‘abstract’ to patent*, FORBES MAGAZINE (Mar. 28, 2014, 9:00 AM EDT), <http://fortune.com/2014/03/28/supreme-court-to-decide-when-ideas-become-too-abstract-to-patent/>.

106. *See* CLS Bank Int’l v. Alice Corp. Pty. Ltd., 768 F. Supp. 2d 221, 223 (D.D.C. 2011), *rev’d*, 685 F.3d 1341 (Fed. Cir. 2012), *reh’g en banc granted, opinion vacated*, 484 F. App’x 559 (Fed. Cir. 2012), and *aff’d*, 717 F.3d 1269 (Fed. Cir. 2013), *aff’d*, 134 S. Ct. 2347, 189 L. Ed. 2d 296 (2014) (The facts of the case describe Alice as an Australian company that: 1) owns four United States patents; and 2) asserts that CLS infringes these four patents).

107. CLS Bank Int’l v. Alice Corp. Pty. Ltd., 768 F. Supp. 2d 221 (D.D.C. 2011) *rev’d*, 685 F.3d 1341 (Fed. Cir. 2012) *reh’g en banc granted, vacated*, 484 F. App’x 559 (Fed. Cir. 2012) and *aff’d*, 717 F.3d 1269 (Fed. Cir. 2013) *aff’d*, 134 S. Ct. 2347 (2014).

108. CLS Bank Int’l v. Alice Corp. Pty., 717 F.3d 1269 (Fed. Cir. 2013) *aff’d*, 134 S. Ct. 2347, 189 L. Ed. 2d 296 (2014).

109. Alice Corp. Pty. Ltd. v. CLS Bank Int’l, 134 S. Ct. 2347, 2349-50, (2014).

110. *Id.* at 2350 (internal citations omitted) (alterations in original).

111. *Id.* at 2349-50.

112. 2014 *Interim Guidance on Subject Matter Eligibility*, U.S. PAT. AND TRADEMARK OFF., <https://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0> (last modified Nov. 2, 2016).

eligible, so are patent examiners, patent practitioners, and investors considering the possibility of financing the development of a discovery. The Interim Guidance on Patent Subject Matter Eligibility from the USPTO to patent examiners that explains how to consider the breadth of 35 U.S.C. § 101 has been updated approximately eight times since August 2009.<sup>113</sup> *Ariosa v. Sequenom*<sup>114</sup> is a case that clearly illustrates why the newly created judicial framework fails to protect many inventions in biotechnology.

The patents at issue in *Ariosa* detail the discovery of cell-free fetal DNA (“cffDNA”) in the maternal blood. Current estimates suggest that between 11-13.4% of the DNA in the maternal blood is fetal in origin.<sup>115</sup> The invention, commercialized by Sequenom as its MaterniT21 test, created an alternative for prenatal diagnosis that avoids the risks of widely-used techniques that obtain samples from the fetus or placenta.<sup>116</sup> Sequenom, Inc. licensed the patent<sup>117</sup> from the inventors and began to commercialize the technology. A dispute arose when two competitors of Sequenom, Ariosa Diagnostics, Inc. and Natera, Inc. sought a declaration that their own test using cffDNA did not infringe on the patent licensed by Sequenom. Sequenom counterclaimed for patent infringement.<sup>118</sup> At this point the District Court determined that the Sequenom patent was invalid under 35 U.S.C. § 101. Sequenom appealed but the Federal Circuit affirmed the district court<sup>119</sup> and denied a rehearing in banc.<sup>120</sup>

113. See *Current Subject Matter Eligibility Guidance and Training Materials*, U.S. PAT. AND TRADEMARK OFF., (<http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0>) (last modified July 20, 2016) (listing eligibility standards for December 2014 with July 2015 update); *Past Subject Matter Eligibility Guidance and Training Materials*, U.S. PAT. AND TRADEMARK OFF., (<http://www.uspto.gov/patent/laws-and-regulations/examination-policy/past-subject-matter-eligibility-guidance-and-training>) (last modified July 29, 2016) (listing links for eligibility materials for June 2014, Mar. 2014, Aug. 2012, 2010, Aug. 2009.)

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

115. E. Wang, A. Batey, C. Struble, T. Musci, K. Song, O., & A. Oliphant, *Gestational age and maternal weight effects on fetal cell-free DNA in maternal plasma*, 33 *PRENATAL DIAGNOSIS* 663, (2013).

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

117. U.S. Patent No. 6,258,540 (issued Jul. 10, 2001) (“the ‘540 patent’”).

118. *Aria Diagnostics, Inc. v. Sequenom, Inc.*, No. C 11-06391 SI, 2013 WL 5701532, at 1 (N.D. Cal. Oct. 16, 2013).

119. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1380 (Fed. Cir. 2015).

120. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1284 (Fed. Cir. 2015) (denying hearing *en banc*).

The reluctance of the Patent Trial and Appeal Board<sup>121</sup> and of the Federal Circuit to deny the validity of the Sequenom patent on its merits is illuminating. In denying a petition for rehearing en banc filed by Sequenom, Circuit Judge Lourie noted that:

I concur in the court's denial of rehearing en banc in this case, based on the precedent of *Mayo* . . . I do so because I find no principled basis to distinguish this case from *Mayo*, by which we are bound. . . Appellants and amici have argued before us in briefs that a broad range of claims of this sort appear to be in serious jeopardy. It is said that **the whole category of diagnostic claims is at risk**. It is also said that a crisis of patent law and medical innovation may be upon us, and **there seems to be some truth in that concern**.<sup>122</sup>

Judge Lourie further elaborated that “[t]he claims in the [Sequenom] case perhaps should be in jeopardy, not because they recite natural laws or abstract ideas, but because they may be indefinite or too broad.”<sup>123</sup> But they should not be patent-ineligible on the ground that they set forth natural laws or are abstractions.”<sup>124</sup> Justice Lourie then notes that the discovery of cffDNA “has led to an important new development: diagnosis of possible birth defects without using highly intrusive means.”<sup>125</sup> Citing *Diehr*, Justice Lourie concluded by making the statement that even though he was bound by the *Mayo* precedent “[a]pplications of natural phenomena or laws to a known process ‘may well be deserving of patent protection.’”<sup>126</sup>

In addition to Lourie other circuit justices noted their concerns with the *Mayo* framework in denying rehearing of *Ariosa* en banc. Circuit Judge Timothy Dyk explicitly explained the need for further guidance and why the guidance needs to be provided directly by the Supreme Court. In his words:

In my view the framework of *Mayo* and *Alice* is an essential ingredient of a healthy patent system, allowing the invalidation of improperly issued and highly anticompetitive patents without the need for protracted and expensive litigation. Yet I share the concerns of some of my colleagues that a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature (**reflected in some of the language in *Mayo***) may discourage

121. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, No. IPR2012-00022, 2014 WL 4381564 (P.T.A.B. Sept. 2, 2014) (The P.T.A.B. found the '540 patent to be invalid in part, based on an anticipation analysis under 35 U.S.C. § 102. It affirmed several dependent claims as valid).

122. *Ariosa*, 809 F.3d at 1284-85 (internal citation removed) (emphasis added).

123. I have interpreted “too broad” to mean that Judge Lourie agreed with the interpretation of the PTAB in the IPR of the '540 patent.

124. *Ariosa*, 809 F.3d at 1285.

125. *Id.* at 1285.

126. *Id.* at 1285-86.

development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena. **This leads me to think that some further illumination as to the scope of Mayo would be beneficial in one limited aspect.** At the same time I think that we are bound by the language of Mayo, and **any further guidance must come from the Supreme Court, not this court.**<sup>127</sup>

Only Judge Newman demonstrated any willingness to attempt to distinguish the claims at stake in *Sequenom* from the claims challenged in *Mayo*.<sup>128</sup> In pointing to the white elephant in the room, Judge Newman states that as the other judges recognized, the *Sequenom* discovery represents a breakthrough, and provides important diagnostic information without the risks of the previously required invasive procedures of penetrating the amniotic sac.<sup>129</sup> Judge Newman concludes by stating that: “I respectfully dissent from my colleagues’ conclusion that Supreme Court precedent on Section 101 excludes this invention from eligibility for patenting. . . . The subject matter should be reviewed for compliance with Sections 102, 103, and 112, and any other relevant provisions of the patent law.”<sup>130</sup>

### III. CONCLUSION

*E. The Supreme Court should use the facts and posture of Ariosa v. Sequenom to provide further guidance on patent eligibility and perhaps limit the scope of judicially created exceptions to patent eligibility to select classes of patents.*

Most appellate courts understand that sometimes a legal test is too difficult, too subtle, too ambiguous, or too ephemeral to be usefully applied by lower courts. In patent law, the Federal Circuit and the Supreme Court are not only creating precedent that guides lower courts, but they are also creating precedent that guides patent examiners, many of whom are trained solely in a technical field. The subtleties of a legal analysis can be lost on the engineers and scientists who have been trained to recognize new and useful processes, machines, manufactures, or any improvements thereof. In March 2016, Sequenom filed a Petition for *writ of certiorari* in the

127. *Id.* at 1287 (emphasis added).

128. *Id.* at 1294.

129. See *MaterniT® 21 PLUS*, SEQUENOM, INC., <https://www.sequenom.com/tests/reproductive-health/maternit21-plus> (last visited Sept. 17, 2016).

130. *Ariosa*, 809 F.3d at 1294.

Supreme Court of the United States, challenging the decision of the United States Court of Appeals for the Federal Circuit in *Ariosa*.<sup>131</sup> Considering the complexity of the rules and the difficulties in correctly applying the judicial exceptions across various areas of technology, it would be appropriate for the Supreme Court to provide further guidance on patent eligibility. The Supreme Court should grant cert, reconsider the “overwhelming breadth and scope of [its] prior ruling in *Mayo*”<sup>132</sup>, and possibly consider a more effective approach for applying exceptions of patent eligible subject matter.

The single question presented by Sequenom in the petition for certiorari is as follows:

Whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery?<sup>133</sup>

To address some of the points raised by this question, some have suggested that the Supreme Court should reconsider the legal principles applied in *Chakrabarty* and *Diehr*.<sup>134</sup> Others believe that the Supreme Court should consider the path proposed by Circuit Justice Pauline Newman: the invalidity of certain claims is more appropriately pursued under the other sections of the patent statute, namely 35 U.S.C. §§ 102, 103, or 112.<sup>135</sup> Another approach is to consider that different areas of technology have different views as to what constitutes a natural phenomena. Thus, if the Supreme Court chooses to elaborate on a definition of a “natural phenomena” it should consider narrowly applying its guidance to only one or more technology classes in the CPC.

Adopted by the USPTO as of January 1, 2013, the CPC is a system for organizing all U.S. patent documents into collections based on common

131. Petition for Writ of Certiorari, *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 788 F.3d 1371 (2015) (No. 15-1182).

132. Gene Quinn, *SCOTUS Blog founder asks Supreme Court to reconsider Mayo ruling in Sequenom v. Ariosa*, IPWATCHDOG (Mar. 21, 2016), <http://www.ipwatchdog.com/2016/03/21/scotus-supreme-court-reconsider-mayo-sequenom-ariosa/id=67333/>.

133. Petition for Writ of Certiorari, *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 788 F.3d 1371 (2015) (No. 15-1182).

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

135. See, e.g., *Ariosa*, at 1294 (where J. Newman explains that invalidity of the claims would have been more appropriately pursued under the other sections of the patent statute, namely 35 U.S.C. §§ 102, 103, or 112).

subject matter and there are over 400 classes in the U.S. patent classification system, further divided into subclasses. A class generally delineates one technology from another. Subclasses delineate processes, structural features, and functional features of the subject matter encompassed within the scope of a class. Because patents in the same patent class have similar technical features, the application of a judicial exception to patents in the same, or in a similar class, limits the possibility of unanticipated consequences of broadly applying exceptions based on specific facts to inventions in different fields. For example, the two patents challenged in the *Mayo* case were reviewed by examiners in the patent technology center that specializes in biotechnology and organic chemistry inventions. This same technology center reviewed the patent at issue in *Ariosa*. In both *Mayo* and *Ariosa*, district and appellate courts relied on an *In re Bilski* type of analysis to evaluate the claims regardless of the fact that the “natural phenomena” or “laws of nature” at the core of *Bilski* are remarkably different than the “natural phenomena” at the heart of *Mayo* and *Ariosa*. In contrast, some the patents challenged in *Bilski* were reviewed by a technology center that focuses on patents that are classified as: “Computer Architecture, Software, and Information Security.” The patents challenged in *Alice* were reviewed by examiners in the technology center that reviews, among other things, electronic commerce.

Applying judicial exceptions to select classes of patents could promote consistency across the USPTO and consistent decision-making in judging a patent’s validity. This could also remove some of uncertainty that has been created by the broad application of the *Mayo* and *Alice* rulings, which outlined overly broad tests for the patent eligibility of abstract ideas and natural products based on vastly different fact patterns and technologies. This path could also make it easier for our appellate courts to produce tailored tests for patent eligibility that should only be applicable in some fields.