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## Patent Eligibility of Disease Diagnosis

Shahrokh Falati

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## PATENT ELIGIBILITY OF DISEASE DIAGNOSIS

*Shahrokh Falati, Ph.D., J.D. \**

*The U.S. Supreme Court effectively redefined the scope of patent eligible subject matter when it decided Mayo.<sup>1</sup> This decision focused on medical diagnostic technology and has had a profound effect on the biotechnology and personalized medicine industries in the United States. Subsequent back-to-back decisions by the Supreme Court in Myriad<sup>2</sup> and Alice<sup>3</sup> have made it unequivocally clear that there is now wholesale broadening of the judicially created exceptions to statutory laws governing patent eligible subject matter. This has caused havoc in the biopharmaceutical industry by not only making it a near impossibility to obtain a patent in certain fields, but also by vastly increasing the number of medical diagnostic patents being invalidated based on Section 101 of Title 35 of the U.S. Code. This major change in law has had unintended consequences, discouraging research and development necessary for new medical diagnostic and therapeutic methods to come to market. This article analyzes the patent eligibility legal landscape and focuses on emerging medical diagnostic technologies to explain why the Supreme Court's recent rulings were made in error. I end by discussing how Congress could either abolish, as unnecessary, the non-statutory, Supreme Court-created, exceptions to*

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<sup>1</sup> Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012).

<sup>2</sup> Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

<sup>3</sup> Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208 (2014).

*Section 101, or to amend the statute. Only by doing so can our laws once again encourage and reward creative thinkers and entrepreneurs who take risk and innovate new medical diagnostic technologies in the U.S.*

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## I. INTRODUCTION

Patents drive technological innovation in our society. The mechanism by which they do this is to reward those who make a novel contribution in their field with a monopoly that can bring the patent owner a financial benefit. At the same time, patent law encourages inventors to ultimately disclose their inventions to the public, so that the public at large benefits from technological innovation and progress.

In the United States, for any technology or invention to be patentable, it must first be deemed to be a subject matter that is “patent eligible.”<sup>4</sup> If it is not a patent eligible subject matter, it will be impossible to obtain protection for that technology under U.S. patent law. Yet, even if it is subject matter that is deemed to be “patent eligible,” the technology must then also be found by the U.S.

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<sup>4</sup> 35 U.S.C. § 101 (2018) (outlining the requirements for patentability).

Patent and Trademark Office (“USPTO”) to be (1) useful, (2) novel, and (3) nonobvious before a patent can be issued.<sup>5</sup>

An invention is eligible for a patent under Section 101 only if it is a process or method, machine or apparatus, manufacture, or composition of matter, and only if it falls outside of three judicially created exceptions to patentability. These judicially created exceptions to the subject matter expressly stated in the statute include laws of nature, physical phenomena, and abstract ideas.<sup>6</sup> Natural phenomena embody anything that could be discovered in nature;<sup>7</sup> natural laws include correlations and laws determining how the natural world works;<sup>8</sup> and abstract ideas can be anything from mathematical formulas to fundamental economic practices.<sup>9</sup>

The Supreme Court had decades ago decided that Congress intended patent eligible subject matter, under Section 101, to “include anything under the sun that is made by man.”<sup>10</sup> Yet, in three recent back-to-back Supreme Court decisions,<sup>11</sup> the Court has effectively redefined the scope of patent eligible subject matter by greatly expanding the scope of the judicially-created exceptions to the statutory patent eligibility laws, thereby significantly narrowing the scope of subject matter that is patent eligible. Moreover, with this recent change, there are now two lines of Supreme Court cases

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<sup>5</sup> See *Novelty and Non-obviousness, Conditions for Obtaining a Patent*, USPTO (Oct. 2015), <https://www.uspto.gov/patents-getting-started/general-information-concerning-patents#heading-5> [<https://perma.cc/A2KW-9E48>].

<sup>6</sup> *Id.*

<sup>7</sup> *Myriad*, 569 U.S. 576 (contrasting the discovery of natural phenomena with invention).

<sup>8</sup> See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012) (deciding that the relation between certain blood metabolites and the likelihood a drug, thiopurine, being “ineffective or cause harm” was “a consequence of the ways in which thiopurine compounds are metabolized by the body” and therefore an ineligible natural law).

<sup>9</sup> Robert Sachs, *The Alice Guidance Categories of Potential Abstract Ideas*, BILSKI BLOG (Sept. 9, 2014), <https://www.bilskiblog.com/2014/09/day-3-example-categories-of-potential-abstract-ideas/> [<https://perma.cc/RSY2-7L8E>].

<sup>10</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (holding that a bacterium that had been genetically modified to effectively digest oil can be patented).

<sup>11</sup> *Mayo*, 566 U.S. 66; *Myriad*, 569 U.S. 576; *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208 (2014).

that are inconsistent and contradict each other.<sup>12</sup> The effect of this uncertainty has been profound, devastating the biotechnology, personalized medicine, and medical diagnostics industries in the United States.

The field of personalized medicine is fast evolving and now allows for tailored therapeutic strategies for both treatment and prevention purposes based on an individual's unique genomic and proteomic profile.<sup>13</sup> This is a rapidly growing field of technology that is proving to be transformational for medical interventions. The success of personalized medicine hinges on new and innovative medical diagnostic technologies. These medical diagnostic technologies are generally used in clinical medicine to identify the patient's condition and therefore provide for early and effective treatment of the particular disease at hand. Being able to accurately diagnose a disease with low chance of a missed diagnosis, an error in diagnosis, or a delayed diagnosis are all crucial features in the management of a disease, and all are dependent on newly emerging medical diagnostic technologies.

Unsurprisingly to many patent law practitioners with a biomedical background, the Supreme Court's recent *Mayo* decision resulted in a dramatic increase in patent offices rejecting applications related to personalized medicine and medical diagnostics fields. Indeed, according to one study, while prior to the *Mayo* decision only 15.9 percent of personalized medicine-related patent applications had rejections based on a lack of subject matter eligibility, this grew staggeringly to 86.4 percent post-*Mayo*.<sup>14</sup> In

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<sup>12</sup> See discussion of *Mayo* in view of *Diehr*, *infra* Sections III.b and IV.b; see also John M. Golden, *Flook Says One Thing, Diehr Says Another: A Need for Housecleaning in the Law of Patentable Subject Matter*, 82 GEO. WASH. L. REV. 1765, 1776 (2014). Historically, I would point out that there are four primary Supreme Court cases that showcase two separate approaches to patent eligibility. Current law is, in large part, an extension of *Funk Bros.* and *Flook* decisions, however, existing contrary approaches to patent eligibility by Supreme Court include the *Chakrabarty* and *Diehr* decisions.

<sup>13</sup> See discussion *infra* Part IV.a.

<sup>14</sup> Bernard Chao & Amy Mapes, *An Early Look at Mayo's Impact on Personalized Medicine*, 2016 PATENTLY-O PATENT L.J. 10 (2016). It should be noted that this study did not include any analysis of the ultimate outcome of these rejections in order to see if any rejections are withdrawn in view of attorney

another recent article,<sup>15</sup> the authors point out that the new patent eligibility legal framework resulted in no less than 830 patent applications being abandoned at the USPTO within the first six weeks of the Supreme Court's decision in *Mayo*.<sup>16</sup> Courts have used this new test to invalidate patent claims at a rate no less than 83 percent during that same period.<sup>17</sup> Two years after the Supreme Court changed the law in *Alice*, the numbers were largely similar, with the Federal Circuit using *Alice* to reject patent claims at a rate of more than 90 percent in both 2015 and 2016.<sup>18</sup>

By 2019, the Federal Circuit invalidated more than three quarters of cases it has heard on patent eligibility in those five years since the recent Supreme Court rulings.<sup>19</sup> Professor Osenga has nicely summarized by positing that “[t]he doctrine of patent-eligible subject matter is a mess, and it is weakening patent rights in this country. Nearly everyone, from the bar to the bench and from academia to industry, has called for reform.”<sup>20</sup> Indeed, other scholars

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arguments, something that would be important in assessing the ultimate practical effects of the Supreme Court's recent patent-eligibility decisions.

<sup>15</sup> Jasper L. Tran & J. Sean Benevento, *Alice at Five*, 2019 PATENTLY-O PATENT L.J. 25 (2019).

<sup>16</sup> *Id.*

<sup>17</sup> Jasper L. Tran, *Software Patents: A One-Year Review of Alice v. CLS Bank*, 97 J. PAT. & TRADEMARK OFF. SOC'Y 532, 545 (2015); *see also*, Tristan Gray-Le Coz & Charles Duan, *Apply It to the USPTO: Review of the Implementation of Alice v. CLS Bank in Patent Examination*, 2014 PATENTLY-O PAT. L.J. 1, 3 (2014).

<sup>18</sup> *Id.* (showing that the Federal Circuit used *Alice* as a basis to reject 94.1 percent of patent claims in 2015 and 92.3 percent of patent claims in 2016).

<sup>19</sup> Robert R. Sachs et al., *Benevolent Despot or Tyrant? Alice v CLS Bank Five Years on*, IAM (May 23, 2019), <https://www.iam-media.com/benevolent-despot-or-tyrant-alice-v-cl-s-bank-five-years> [<https://perma.cc/8LP4-CHYE>]. The data covers software and biotechnology/life science patents but excludes *Alice* challenges for covered business method (CBM) review. For a brief summary of post-*Alice* cases, *see Overview of Section 101 Patent Cases Decided After Alice v. CLS (as of March 1, 2019)*, GIBSON, DUNN, & CRUTCHER, <https://www.gibsondunn.com/wp-content/uploads/2019/03/Overview-of-Section-101-Patent-Cases-Decided-After-Alice-v-CLS-as-of-03-01-19.pdf> [<https://perma.cc/BQ9Y-GCF6>] (last visited Mar. 27, 2020).

<sup>20</sup> Kristen Osenga, *Institutional Design for Innovation: A Radical Proposal for Addressing § 101 Patent-Eligible Subject Matter*, 68 AM. U. L. REV. 1191, 1191 (2019).

have described the new Supreme Court test as one that “forces lower courts to engage in mental gymnastics,”<sup>21</sup> is “a foggy standard cloaked as a rule,”<sup>22</sup> a “crisis of confusion”<sup>23</sup> and others have seen the new patent eligibility law as so aggressive that “the penumbra around pure abstract ideas and natural phenomena is growing larger.”<sup>24</sup> Moreover, many judges on the Court of Appeals for the Federal Circuit have openly expressed their frustration with this new patent eligibility standard.<sup>25</sup>

The current legal framework has had particularly harmful consequences in the medical diagnostics industry. Existing biomedical patents are being struck down as invalid at the earliest pleading stages of litigations. The USPTO, confused on how to apply this new standard, has issued no less than five separate examination guidelines on how to apply the standard in as many years,<sup>26</sup> making it all but impossible to obtain any meaningful patent

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<sup>21</sup> Annal D. Vyas, *Alice in Wonderland v. CLS Bank: The Supreme Court’s Fantastic Adventure into Section 101 Abstract Idea Jurisprudence*, 9 AKRON INTELL. PROP. J. 1, 2 (2015). See also Brief of 19 Law Professors as Amici Curiae in Support of Petition for Writ of Certiorari, *Sequenom, Inc. v. Ariosa Diagnosis, Inc. et al.* (2016) [hereinafter *Sequenom* Amicus Brief].

<sup>22</sup> Michael Risch, *Nothing Is Patentable*, 67 FLA. L. REV. F. 45 (2015).

<sup>23</sup> David O. Taylor, *Amending Patent Eligibility*, 50 U.C. DAVIS L. REV. 2149, 2164 (2017).

<sup>24</sup> Risch, *supra* note 22.

<sup>25</sup> See discussion *infra* Part IV. Former Chief Judge of the U.S. Court of Appeals for the Federal Circuit (CAFC), Judge Michel, predicted that the new Supreme Court for patent eligibility would “create total chaos,” stating that it is “too vague, too subjective, too unpredictable and impossible to administer in a coherent, consistent way in the patent office or in the district courts or even in the federal circuit.” See Gene Quinn, *Judge Michel Says Alice Decision ‘will create total chaos,’* IPWATCHDOG.COM (Aug. 2, 2014), <https://www.ipwatchdog.com/2014/08/06/judge-michel-says-alice-decision-will-create-total-chaos/id=50696/> [https://perma.cc/57UC-GMPE]. Chief Judge of the CAFC, Judge Rader, referred to the CAFC’s inability to render a majority opinion in *Alice* as the greatest failure of his career. In his view, interpretation of Section 101 was simply settled law, based on *Diehr* and *Chakrabarty*.

<sup>26</sup> The latest version of the USPTO Subject Matter Eligibility guidelines was published in October of 2019. *Update on Patent Subject Matter Eligibility*, USPTO (Oct. 17, 2019), <https://www.uspto.gov/about-us/news-updates/update-patent-subject-matter-eligibility> [https://perma.cc/5Z53-DTU3].



protection for innovations in both the medical diagnostics and the wider life sciences and biotechnology industries.<sup>27</sup>

As just one example, the United States faces the unusual specter of having its patent laws render a new medical diagnostic method for non-invasively detecting abnormalities in the fetus of a pregnant woman as patent ineligible subject matter, while the highest courts in both the United Kingdom and Australia found the same technology to be eligible for patent protection.<sup>28</sup> Ceding ground to foreign countries in fostering new medical diagnostic technology development and talent retention issues aside, the less than desirable position we face today in the United States sees opportunistic free-riders taking advantage of this anomaly in current U.S. patent law to move in, copy innovative products, and gain market share at the expense of our innovators.

The reason the medical diagnostics industry is particularly sensitive to patent laws is because very large capital investments are necessary. It typically costs more than one billion dollars to develop a brand-new drug<sup>29</sup> or a medical diagnostic test.<sup>30</sup> Investors and company executives make decisions based on certainty and how the law can protect their investment from copycats. The argument raised by some that patents somehow block innovation and are ultimately of less value rings especially hollow when it is applied to the medical diagnostics industry.

This article argues that for the U.S. to regain its pole position in the arena of technological innovation within the medical diagnostics industry, Congress needs to act swiftly to amend the law

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<sup>27</sup> See discussion *infra* Part V.

<sup>28</sup> See discussion *infra* Part IV.b.

<sup>29</sup> Joseph A. DiMasi et al., *Innovation in the pharmaceutical industry: new estimates of R&D costs*, 47 J. HEALTH ECON. 20–33 (May 2016). This research and development cost study was published by Tufts Center for the Study of Drug Development.

<sup>30</sup> EUR. OBSERVATORY ON HEALTH SYST. & POL'Y, ENSURING INNOVATION IN DIAGNOSTICS FOR BACTERIAL INFECTION, EUROPEAN OBSERVATORY ON HEALTH SYSTEMS AND POLICIES 44 (Chantal Morel et al. eds., 2016). Rick Mullin, *Cost to Develop New Pharmaceutical Drug Now Exceeds \$2.5B*, SCI. AM. (Nov. 24, 2014), <https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/> [<https://perma.cc/EA4M-SGCK>].

highlighting that it disagrees with the Supreme Court's recent trilogy of patent eligibility decisions. As a mechanism for doing so and given where we are, this article proffers two strategies for Congress to decide between in order to better determine whether a subject matter is eligible for patent protection. Congress should act by either (1) amending Section 101, or (2) by abolishing, *in toto*, the non-statutory, Supreme Court-promulgated, exceptions to this statute. Either path will restore a balance to the laws that both fosters and encourages technology innovators to develop new medical diagnostic technologies that address patient needs of today and tomorrow.

Parts II and III of this article begin with the constitutional foundation of laws concerning patent eligibility and their legislative development. The focus then shifts to patent eligibility jurisprudence of the Supreme Court going back over a century, highlighting the Court's judicial activism in the recent trilogy of cases between 2012–2014, which effectively created its own expansive parallel set of laws alongside the statutory language concerning patent eligibility.

Parts IV and V introduce the field of personalized medicine and medical diagnostics, later focusing in depth on how these recent Supreme Court decisions on patent eligibility have affected medical diagnostic technologies and discussing how the non-statutory, Supreme Court-created, exceptions to patent eligibility laws have negatively affected the protection and the development of such key emerging biomedical technologies in the United States.

Scholars and stakeholders in the legal and biomedical community have begun to actively seek a fix from Congress because many in the biomedical community, especially those in the medical diagnostics industry, see the current status quo as being untenable. While some have proposed to keep the Supreme Court-created exceptions and have a “practical application” test, as thoughtfully proposed by other intellectual property (“IP”) law professors,<sup>31</sup> others, including the former Director of the U.S. Patent and

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<sup>31</sup> See *Sequenom* Amicus Brief, *supra* note 21 (focusing on arguments by Professors Lefstin & Menell).

Trademark Office, have argued for wholesale repeal of Section 101 from the Patent Act.<sup>32</sup>

In the penultimate section, part VI, this article concludes by encouraging Congress to act and bring certainty to this fundamental area of patent law in order to encourage innovators to once again invest and seek to develop new medical diagnostic technologies that have the potential to benefit the public. The article does not propose for the wholesale repealing of the statute, but advocates for avoiding yet another round of massaging a body of newly created law that has had more than five years to develop and has proved unworkable and difficult to apply in practice.

None of the Supreme Court created exceptions to the patent eligibility statute under Section 101 are in fact necessary because existing statutes under the Patent Act, unrelated to Section 101, will address the concerns the Supreme Court had when it created the exceptions. The Supreme Court's recent activism on this issue, which ironically the Court itself warned had the power to "swallow all of patent law"<sup>33</sup> and "eviscerate patent law,"<sup>34</sup> and the resulting mayhem it has now in fact caused, has greatly harmed the innovation ecosystem, especially damaging the medical diagnostics industry in the U.S.

If the reader is left unconvinced that abolishing, *in toto*, the non-statutory, Supreme Court-promulgated, exceptions to Section 101 is the way forward, this article also offers possible amendments to the law so as to defang these exceptions and bring them in line with

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<sup>32</sup> Steven Lundberg, *Dave Kappos Calls for Abolition of Section 101*, NAT'L L. REV. (Apr. 14, 2016), <https://www.natlawreview.com/article/dave-kappos-calls-abolition-section-101> [<https://perma.cc/3DDK-4YQF>]. David Kappos was the Director of the U.S. Patent and Trademark Office from 2009–2013. *Id.*

<sup>33</sup> The Supreme Court advised the lower courts in *Alice* to "tread carefully in construing *this exclusionary principle lest it swallow all of patent law.*" (emphasis added). *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014).

<sup>34</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012) (emphasis added). Two years prior to *Alice*, the Supreme Court in *Mayo* further warned that their own judicially created exceptions to the statute have the power to destroy Congress' patent law, stating: "The Court has recognized, however, that too broad an interpretation of *this exclusionary principle could eviscerate patent law.* For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." (emphasis added). *Id.*

what has been the intent of the Constitution and Congress for over 200 years. In so doing, for this latter part, this article will also draw on and review the European Patent Convention and its view on the patentability of diagnostic method claims in order to provide an extraterritorial context and possible direction lawmakers may wish to explore.

Part VI suggests ways in which this article might contribute to the scholarly debate by articulating the proposition that abolishing the non-statutory exceptions to patent eligibility laws under Section 101 will modernize and simplify the rules governing U.S. patent laws, and reverse the caustic effect of the new patent eligibility legal framework on the medical diagnostics industry. Such action would also bring back much sought-after certainty to current U.S. patent law, and would thereby also harmonize this feature of U.S. patent law with the patent laws of other industrialized societies much akin to how Congress harmonized important aspects of U.S. patent laws with patent laws of other industrialized countries when it passed the monumental America Invents Act in 2013. In the alternative, this part discusses how amendments to the existing statute could achieve a similar outcome.

The enactment of America Invents Act in 2013 was a leap forward and so too would be significant congressional action concerning Section 101. This will have the knock-on effect of returning our laws to once again encouraging and rewarding entrepreneurial innovators, especially those operating in the personalized medicine and medical diagnostics industries, to develop and bring new biomedical technologies to the marketplace.<sup>35</sup>

## II. THE CONSTITUTIONAL FOUNDATION OF PATENT ELIGIBLE SUBJECT MATTER

The U.S. Constitution gives power to Congress to “promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective

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<sup>35</sup> Since the U.S. Constitution mandates Congress to enact laws to “promote the progress of science and the useful arts,” such action would be squarely within Congress’ mandate. U.S. CONST. art. I, § 8, cl. 8.

writings and discoveries.”<sup>36</sup> Thus, the U.S. Constitution not only grants Congress the power to create laws that promote the progress of science, but it also associates inventors with discoveries.<sup>37</sup> Since the power that Congress has is exclusive, only lawmakers decide the legal mechanism by which they will promote the progress in science and the useful arts. One way this can be done is to first define exactly what kind of subject matter the country wishes to see progress in, and then formulate laws that are tailored to promoting progress in those subject matters listed.<sup>38</sup> The focus of this paper is the patent eligibility statute under Section 101, with the ultimate question at the heart of this debate being: “what kind of subject matter is eligible for a patent?”<sup>39</sup>

#### *A. Legislative Development of Patent Eligibility Laws*

In 1790, Congress passed a law for the first time to codify what can and cannot be patent eligible subject matter.<sup>40</sup> Thomas Jefferson, who first drafted a statute to “promote the progress of science and useful arts,”<sup>41</sup> relied heavily on established English law that aimed “to promote the progress of science and useful arts . . . by giving the public at large a right to make, construct, use, and vend the thing invented, at as early a period as possible; having a due regard to the rights of the inventor.”<sup>42</sup> Next came the Thomas Jefferson-authored Patent Act of 1793, which repealed the Patent Act of 1790 and largely embodied the ideology of older English law and ultimately defined patent eligible subject matter to be “any new and useful

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<sup>36</sup> U.S. CONST. art. I, § 8, cl. 8 (capitalization omitted).

<sup>37</sup> See generally Sherry Knowles & Anthony Prosser, *Unconstitutional Application of 35 U.S.C. § 101 by the U.S. Supreme Court*, 18 J. MARSHALL REV. INTELL. PROP. L. 144 (2018).

<sup>38</sup> Indisputably, nowadays, Patent Law is intractably tied to new technology development and commercialization.

<sup>39</sup> The U.S. Constitution excludes the word “patent,” but there is also no explicit requirement for Congress to advance certain technologies to progress science.

<sup>40</sup> Pub. L. No. 1-34, 1 Stat. 109 (1790).

<sup>41</sup> *Id.*

<sup>42</sup> *Pennock v. Dialogue*, 27 U.S. 1, 18 (1829) (noting “it is obvious to the careful inquirer, that many of the provisions of our Patent Act are derived from the principles and practice which have prevailed in the construction of that of England.”).

process, machine, manufacture, or composition of matter, or any new or useful improvement thereof.”<sup>43</sup>

Between 1793 and 1952, other Patent Acts were passed by Congress, including the Patent Acts of 1794,<sup>44</sup> 1800,<sup>45</sup> 1832,<sup>46</sup> 1836,<sup>47</sup> 1837,<sup>48</sup> 1839,<sup>49</sup> 1842,<sup>50</sup> 1870,<sup>51</sup> and many more. Interestingly, vis-à-vis the patent eligibility laws, during this 160-year period the kind of subject matter eligible for patent protection remained largely unchanged. From the 1950s to the present day, the key legislation passed by Congress that affected patents were the 1952 Patent Act and the recently enacted America Invents Act. Although the 1952 Act added certain definitions, neither the 1952 Patent Act nor the recent America Invents Act changed the substance of patent eligibility laws as they existed in the 1790s.

Thus, for approximately the last 230 years, from the 1790s until today, the area of law affecting what subject matter is eligible for a patent has remained largely unchanged. The current version of the patent eligibility statute, 35 U.S.C. § 101, states:

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>52</sup>

The inclusion of the words “invents” and “discovers” in the statute has largely been deliberately consistent throughout the statutory language.<sup>53</sup> The reason this is important is that the Supreme Court in recent years has effectively ignored the word “discovers” to suit their new interpretation of the statute. As an example, the Supreme Court recently in *Myriad* stated that: “[g]roundbreaking, innovative, or even brilliant *discovery* does not by itself satisfy the

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<sup>43</sup> Patent Act of Feb. 21, 1793, § 1, 1 Stat. 319 (1793).

<sup>44</sup> Pub. L. No. 3-58, 2 Stat. 393 (1794).

<sup>45</sup> Pub. L. No. 6-25, 3 Stat. 37 (1800).

<sup>46</sup> Pub. L. No. 22-162, 4 Stat. 559 (1832).

<sup>47</sup> Pub. L. No. 24-357, 5 Stat. 117 (1836).

<sup>48</sup> Pub. L. No. 24-409, 5 Stat. 191 (1837).

<sup>49</sup> Pub. L. No. 25-292, 5 Stat. 353 (1839).

<sup>50</sup> Pub. L. No. 27-288, 5 Stat. 543 (1842).

<sup>51</sup> Pub. L. No. 41-230, 15 Stat. 198 (1870).

<sup>52</sup> 35 U.S.C. § 101 (2018) (emphasis added).

<sup>53</sup> Knowles & Prosser, *supra* note 37.

§ 101 inquiry.”<sup>54</sup> And yet, the express wording of the Section 101 statute says otherwise: “whoever invents *or discovers* . . . .”<sup>55</sup>

A key criticism of current patent eligibility laws, as articulated under the Supreme Court’s recent *Mayo* decision, is that it imports considerations of novelty of an invention under the patent eligible subject matter deliberation.<sup>56</sup> In order to make this reasoning work, the Supreme Court made statements that run directly against long standing express statutory language by saying, for example, that just by *discovering* something you do not necessarily satisfy the Section 101 inquiry.<sup>57</sup> That is even though the long-standing Section 101 statute expressly states that the inquiry is based on someone inventing or *discovering* any new and useful process, machine, manufacture or composition of matter.

Moreover, even after the Patent Act of 1793 defined statutory patent eligible subject matters as “any new and useful process, machine, manufacture, or composition of matter, or any new or useful improvement thereof,”<sup>58</sup> the many Patent Acts that were enacted in the ensuing 200 years decided to keep this express language of the statute unchanged. Indeed, it is also somewhat telling that when Thomas Jefferson authored the Patent Act of 1793, he had in mind that “ingenuity should receive a liberal encouragement.”<sup>59</sup> Thus, when the Supreme Court first created exceptions to what the statute explicitly states is patent eligible subject matter, and now their recent wholesale expansion of the scope of these exceptions, it has caused a shockwave. These exceptions run directly against not only long standing express statutory language, but also against the implicit intent of Congress to liberally encourage ingenuity, as Jefferson had intended.

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<sup>54</sup> *Ass’n for Molecular Pathology v. Myriad*, 569 U.S. 579, 591 (2013).

<sup>55</sup> 35 U.S.C. § 101 (2018) (emphasis added).

<sup>56</sup> See discussion *infra* Part IV.

<sup>57</sup> *Myriad*, 569 U.S. at 591 (“Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”).

<sup>58</sup> 35 U.S.C. § 101 (2018).

<sup>59</sup> THE WRITINGS OF THOMAS JEFFERSON 75–76 (Andrew A. Lipscomb ed., 1903). See Knowles & Prosser, *supra* note 37 for a more detailed and thorough discussion on the legislative history of § 101.

The statutory intent is and has been for over 200 years to set a low threshold to patent eligible subject matter. Indeed, the Supreme Court itself decades ago recognized this when stating that this includes “anything under the sun made by man.”<sup>60</sup> Yet, in direct contrast to the express statutory language found in Section 101, its legislative history and Congress’s intent, and past Supreme Court precedent, recent Supreme Court jurisprudence has evolved to now put a very high bar on a previously low threshold Section 101 inquiry as to what subject matter is even eligible for a patent.

### III. THE SUPREME COURT’S RECENT JUDICIAL ACTIVISM CONCERNING PATENT ELIGIBILITY LAWS

Article 1, Section 8 of the U.S. Constitution gives Congress the power “to promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”<sup>61</sup> With this as the backdrop, it may be counterintuitive to the non-patent scholar to learn that even if an invention is found to be novel, to be nonobvious, to have utility, and to meet all of the technical requirements for a patent, a patent will still not issue unless, as a preliminary threshold matter, the invention is directed to subject matter that the Patent Act, under Section 101, has defined to be *patent eligible subject matter*.<sup>62</sup> Thus, this topic of patent eligibility is of fundamental importance because of the direct nature in which it affects patent procurement and enforceability, and ultimately the progress of technological innovation in the United States.

#### A. 19<sup>th</sup> and 20<sup>th</sup> Century Decisions on Patent Eligible Subject Matter

*Le Roy v. Tatham*<sup>63</sup> is the oldest of three key patent eligibility cases handed down by the Supreme Court in the 19<sup>th</sup> century. A quote that is used regularly by more recent cases from both the

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<sup>60</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

<sup>61</sup> U.S. CONST. art. I, § 8, cl. 8 (capitalization omitted).

<sup>62</sup> See generally PETER S. MENELL ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* (2019) (providing a discussion of the evolution of the patentable subject matter doctrine).

<sup>63</sup> *Le Roy v. Tatham*, 55 U.S. 156 (1852).



Supreme Court and the Federal Circuit referencing this decision is that “a principle, in the abstract, is a fundamental truth; an original cause; a motive; and these cannot be patented, as no one can claim in either of them an exclusive right.”<sup>64</sup> In that same decade, the telegraph case *O’Reilly v. Morse*<sup>65</sup> was decided. There, Morse sued O’Reilly for patent infringement based on a technology that allowed for long distance transmission of a telegraph signal.<sup>66</sup> The Supreme Court noted that Morse’s broad patent claim was not enabled because he enabled only electromagnetic repeaters.<sup>67</sup> Drawing from the older *Neilson* decision from England,<sup>68</sup> the Supreme Court concluded that Morse’s patent claim addresses all possible applications of a physical principle, not a specific implementation of the principle. Thus, the Court found the patent claim to be ineligible subject matter.

The third notable case from the 19<sup>th</sup> century is *Tilghman v. Proctor*.<sup>69</sup> In *Tilghman*, the claim was to a method of making fatty acids and glycerin using hot water at a high pressure.<sup>70</sup> The Supreme Court, drawing on their earlier decision in *Morse*, clarified that a patent for a process is different from a patent to a scientific principle and that a scientific principle itself is not patent eligible subject matter.<sup>71</sup> The Court explained that a patent claim fails if it is not a claim to a particular machine, or a claim to a specific process for utilizing a scientific principle.<sup>72</sup>

In the 20<sup>th</sup> century, the Supreme Court decided three key cases related to patent eligibility in the 1970s, namely *Gottschalk v.*

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<sup>64</sup> *Id.* at 175.

<sup>65</sup> *O’Reilly v Morse*, 56 U.S. 62 (1853).

<sup>66</sup> *Id.*

<sup>67</sup> “Eighth. I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed for marking or printing intelligible characters, signs, or letters, at any distances, being a new application of that power of which I claim to be the first inventor or discoverer.” *Id.*

<sup>68</sup> *Neilson v. Harford*, 151 Eng. Rep. 1266 (1841).

<sup>69</sup> *Tilghman v. Proctor*, 102 U.S. 707 (1880).

<sup>70</sup> *Id.*

<sup>71</sup> *Id.* at 726–29.

<sup>72</sup> *Id.*

*Benson*,<sup>73</sup> *Parker v. Flook*,<sup>74</sup> and *Diamond v. Diehr*.<sup>75</sup> For the latter half of the 20<sup>th</sup> century, these three cases provided much of the framework for the Court's view on patent eligibility requirement under Section 101. That framework fundamentally changed when the Supreme Court decided a trilogy of patent eligibility cases within a three-year period between 2012–2014,<sup>76</sup> discussed *infra* in part IV.

In *Benson*,<sup>77</sup> the Supreme Court decided on the patentability of software, holding that a patent on a method for converting numbers from one binary format to another format was invalid. Justice Douglas, writing for the majority, articulated that “the mathematical formula involved here has no substantial practical application except in connection with a digital computer.”<sup>78</sup> Mathematical algorithms, according to the Court, were not eligible subject matter for patent protection because if a patent were allowed it would “wholly preempt the mathematical formula and in practical effect would be a patent on the algorithm itself.”<sup>79</sup> Although the Court had earlier distinguished scientific principles, such as laws of nature, from the *practical application* of those scientific principles,<sup>80</sup> the *Benson* decision was the first instance in which the Supreme Court described abstract ideas as a separate category of patent ineligible subject matter.<sup>81</sup>

Thus, after *Benson*, in contrast to *an invention*, algorithms were treated as laws of nature and the algorithm itself being treated as nothing more than a discovery of a fundamental truth and therefore making it ineligible subject matter for patenting. What to this day remains confusing about *Benson* is that although the Court found a mathematical algorithm (computer program) to be patent ineligible subject matter, the Court suggested it would allow a patent that

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<sup>73</sup> *Gottschalk v. Benson*, 409 U.S. 63 (1972).

<sup>74</sup> *Parker v. Flook*, 437 U.S. 584 (1978).

<sup>75</sup> *Diamond v. Diehr*, 450 U.S. 175 (1981).

<sup>76</sup> The *Mayo/Myriad/Alice* patent eligibility trio of cases from the Supreme Court, decided in 2012–14.

<sup>77</sup> *Benson*, 409 U.S. at 71–72.

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852).

<sup>81</sup> *Benson*, 409 U.S. at 63.

covered a “program servicing a computer.”<sup>82</sup> This is especially resonant since a computer program or software is nothing more than a complex mathematical algorithm, instructing a computer to solve a problem (thus akin to “servicing a computer” recited in *Benson*).

In *Flook*, a decision that was effectively overruled by the Court in two subsequent decisions, *Chakrabarty* and *Diehr*, the patent application was for a method of updating alarm limits.<sup>83</sup> *Flook*’s method was identical to previous systems, but for a mathematical algorithm.<sup>84</sup> Here, the *Flook* Court compared its own ruling in *Benson* some six years earlier to the specific application of the algorithm in *Flook* for catalytic conversion of hydrocarbons.<sup>85</sup> Relying on the English *Neilson*<sup>86</sup> decision and its progeny, the Court found *Flook*’s patent claim did not contain patent eligible subject matter because it was a “principle” or a “law of nature.”<sup>87</sup>

The Supreme Court in *Flook* took the controversial position and focused on the “inventive concept”<sup>88</sup> and not on the patent claim “as a whole.”<sup>89</sup> The Court opined that “even though a phenomenon of nature or mathematical formula may be well known, *an inventive application of the principle* may be patented. Conversely, the discovery of such a phenomenon cannot support a patent *unless there is some other inventive concept in its application.*”<sup>90</sup> Interestingly, although *Chakrabarty*<sup>91</sup> and *Diehr*<sup>92</sup> effectively overruled *Flook* later in the 20<sup>th</sup> century, the *Flook* holding and reasoning is making a strong revival as evidenced by how favorably recent Supreme Court decisions in *Bilski* in 2010 and *Mayo* in 2012 both looked upon and aligned with the *Flook* decision. Yet, in many

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<sup>82</sup> *Id.* at 71.

<sup>83</sup> *Parker v. Flook*, 437 U.S. 584, 585 (1978).

<sup>84</sup> *Id.*

<sup>85</sup> *Id.* at 588–90.

<sup>86</sup> *Neilson v. Harford*, 151 Eng. Rep. 1266 (1841).

<sup>87</sup> *Flook*, 437 U.S. at 592.

<sup>88</sup> *Id.* at 594.

<sup>89</sup> *Id.*

<sup>90</sup> *Id.* (emphasis added).

<sup>91</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

<sup>92</sup> *Diamond v. Diehr*, 450 U.S. 175, 186–87 (1981).

instances the lower courts continue to ignore *Flook* and follow *Diehr* and *Chakrabarty*, and the recently decided *Mayo* and *Alice* cases.<sup>93</sup>

The Supreme Court decided *Diehr* three years after *Flook*. *Diehr*'s invention used a computer program to determine the curing time for rubber, allowing better precision molded rubber products to be made.<sup>94</sup> The invention included a software algorithm to run a molding press, thereby achieving a specific result of curing rubber. The Court held that the computer program that executed the physical method was patent eligible subject matter, noting that although software algorithms could not be patented, the mere presence of a software element did not make an otherwise patent-eligible machine or process an ineligible subject matter for patenting.

Unlike the method claims in *Benson* and *Flook*, the *Diehr* Court found the method to be patent eligible subject matter because the claims did not “foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process”<sup>95</sup> when they were “considered as a whole.”<sup>96</sup> Thus, the *Diehr* Court focused on the implementation of the algorithm and how it applied in the method; more particularly, whether, as the Court noted, the mathematical algorithm “transform[s] and reduces . . . an article ‘to a different state or thing.’”<sup>97</sup> The Supreme Court reiterated its position in *Diehr* that abstract mathematical formulas are patent ineligible subject matter, and that using such a formula in a physical machine or process is different to a claim solely to the algorithm itself.

Interestingly, from each of *Benson*, *Flook* and *Diehr* decisions spanning a decade that focused on patent eligibility, a different interpretation emerged of the statutory law governing patent eligible subject matter, namely Section 101. However, from the most recently decided *Diehr* decision of this trilogy of cases, one could adduce the Court as highlighting two traditional understandings

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<sup>93</sup> See *infra* Part IV.

<sup>94</sup> U.S. Patent No. 4,344,142, directed to “Direct digital control of rubber molding presses” (filed Aug. 6, 1975).

<sup>95</sup> *Diehr*, 450 U.S. at 187.

<sup>96</sup> *Parker v. Flook*, 437 U.S. 584, 594 (1978).

<sup>97</sup> *Diehr*, 450 U.S. at 184.

concerning patent eligibility. First, that abstract principles are not patent eligible, even though practical applications of those principles are patent eligible,<sup>98</sup> and second that related issues, novelty, obviousness or inventiveness should play no role in determining patent eligibility under Section 101.<sup>99</sup>

Between 1981, when the *Diehr* decision was handed down, to 2010, the Supreme Court did not address a patent eligibility issue under Section 101. This resulted in stakeholders and patent professionals believing that the patent eligibility laws articulated in those cases had generally settled and could be relied upon. During this thirty-year period, the Court of Appeals for the Federal Circuit, interpreting the patent eligible subject matter under Section 101, began to interpret and rely on *Diehr* to broaden the scope of patent eligible subject matter. For example, in the years between the *Diehr* decision in 1981 and the *Bilski* decision in 2010, the Federal Circuit found business method claims that were previously patent ineligible subject matter were now patent eligible if the method achieved a “useful, concrete and tangible result.”<sup>100</sup>

This expansive radical move by the Federal Circuit in *State Street*<sup>101</sup> was eyebrow raising and although some commentators saw this as demonstrating the Federal Circuit’s ability to be nimble and flexible in the era of newly emerging innovative technologies and

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<sup>98</sup> *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.”).

<sup>99</sup> *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.”).

<sup>100</sup> *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1375 (Fed. Cir. 1998) (quoting *In re Alappat*, 33 F.3d 1526, 1544 (Fed. Cir. 1994)).

<sup>101</sup> *State Street* overruled the Freeman-Walter-Abele Test, noting it had “little, if any, applicability to determining the presence of statutory subject matter.” *Id.* at 1374. Yet, the court in *State Street* set forth a “‘useful, concrete, and tangible result[s]’” test. *Id.* at 1373 (quoting *In re Alappat*, 33 F.3d at 1544). The Supreme Court never accepted this test, questioning its viability. See *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 136 (2006).

all the while in keeping with the Supreme Court's *Diehr* decision, the reality of what transpired was completely different. Unfortunately, the Supreme Court denied *certiorari* in *State Street* to correct the mistake.<sup>102</sup> Therefore, what transpired after the Federal Circuit's expansion of what constitutes patent eligible subject matter in *State Street* was a surge in a plethora of business method patent applications on anything from offering legal services to even services aimed at booking lavatories. Relying on the Federal Circuit's interpretation of the Supreme Court's *Diehr* decision, the majority of IP stakeholders, between the 1999 *State Street* decision and 2010, regarded patent eligibility under Section 101 to be a "coarse filter"<sup>103</sup> through which the vast majority of patent applications pass with very few patent office rejections. Issues related to patent eligibility were simply not something to give too much attention to during that period.

Yet, all this fundamentally changed when the Supreme Court, silent for thirty years on patent eligibility, rendered four patent eligibility decisions spanning 2010–2014, with *Bilski* being the first.<sup>104</sup>

*B. 21<sup>st</sup> Century Decisions on Patent Eligible Subject Matter:  
Expansion of the Judicially Created Exceptions*

The Supreme Court decided *Bilski* some thirty years after their *Diehr* decision. The patent claims at issue in *Bilski*<sup>105</sup> centered on a method for hedging risk in trading commodities. The Federal Circuit heard the case *en banc*, perhaps wishing to amend their *State Street* decision which had opened the flood gates for patenting a plethora of ways of doing business. The Federal Circuit agreed with the USPTO, and in tune with Supreme Court precedent, held that such methods can be patented only if they are implemented by a machine or transform something into a new or different thing. The Court found *Bilski*'s method was not patent eligible subject matter because "transformations or manipulations of . . . business risks or other such

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<sup>102</sup> See *State Street Bank and Trust Co.*, 525 U.S. 1093 (denying petition for writ of certiorari).

<sup>103</sup> *Res. Corp. Tech. Inc. v. Microsoft Corp.*, 627 F.3d 859, 869 (Fed. Cir. 2010).

<sup>104</sup> *Bilski v. Kappos*, 561 U.S. 593 (2010).

<sup>105</sup> *Id.*

abstractions cannot meet the test because they are not physical objects or substances.”<sup>106</sup> Although the Federal Circuit reaffirmed that business methods are still patentable, the Court rejected their own “useful concrete and tangible result” test in *State Street* on the basis that their earlier *State Street* decision had resulted in patents being issued on everyday activities that had no connection to innovation in new technologies.<sup>107</sup>

In *Bilski*, the Supreme Court issued a total of three opinions, consisting of a plurality opinion for the Court and two concurring opinions. In its plurality opinion, the Supreme Court affirmed the Federal Circuit’s rejection of Bilski’s patent claims, but for different reasons than the lower court. The Supreme Court in *Bilski* held that the Federal Circuit’s “machine-or-transformation” test is merely “a useful and important clue, an investigative tool” for patentability but not the sole or exclusive test for identifying patentable methods. Thus, the Supreme Court’s failure to provide a bright-line workable Section 101 framework effectively forced lower courts to decipher what is and is not patent eligible subject matter without a definitive test.<sup>108</sup>

The uncertainty of the *Bilski* decision did not last long because two years after deciding *Bilski*, the Supreme Court decided the seminal *Mayo* decision. In *Mayo*, the technology related to medical diagnostic technologies. Here, the Court used their *Mayo* decision<sup>109</sup> to fundamentally and radically change the scope of patent eligible subject matter, thereby substantially changing the foundation for how stakeholders in the personalized medicine, biotechnology and medical diagnostic fields would come to view the protectability of new developments and innovation in these technologies.

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<sup>106</sup> *In re Bilski*, 545 F.3d 943, 962–63 (Fed. Cir. 2008).

<sup>107</sup> *Id.* at 959–60 (citing *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998)).

<sup>108</sup> Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land: Bilski’s Superficial Textualism and the Missed Opportunity to Return Patent Law to Its Technology Mooring*, 63 STAN L. REV. 1289, 1304 (2011) (stating “the Supreme Court’s methodology and analysis for determining whether a process falls within the scope of patentable subject matter could hardly be more opaque.”).

<sup>109</sup> See discussion *infra* Part IV.b.

#### IV. PATENT ELIGIBILITY OF MEDICAL DIAGNOSTIC TECHNOLOGIES

##### A. *A Primer on Biotechnology, Personalized Medicine & Medical Diagnostic Technologies*

To give context to how the recent changes to patent eligibility laws discussed in this Article affect newly emerging technologies, I here focus on the field of personalized medicine, medical diagnostics and innovative technologies grounded in the field of biotechnology. One of the primary reasons why innovation in the biotechnology field is sensitive to and has been affected by the recent changes in patent eligibility laws is because, at its core, there is a close relationship between inventions in the biotechnological field, including those in medical diagnostics, and the laws of nature and natural phenomena they rely on. Thus, in order for the non-technical reader to appreciate the interplay between technology and law in this context, in this section, a brief overview of the medical technology is discussed.

Personalized medicine is an emerging model for treating and preventing disease that takes into account each person's genetic variations, environment, and lifestyle. Medical diagnostic tests now allow for the use of a patient's unique genetic profile to diagnose disease,<sup>110</sup> identify risk factors for genetic transmission of diseases,<sup>111</sup> assess possible future likelihood of a disease occurring,<sup>112</sup> and also intelligence in devising treatments.<sup>113</sup> Not long after the seminal *Mayo* decision, discussed in detail below, and recognizing this buzz around the field of personalized medicine and the emerging medical diagnostic technologies it relies upon,

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<sup>110</sup> See, e.g., *Testing For CF*, CYSTIC FIBROSIS FOUND., <https://www.cff.org/What-is-CF/Testing> [perma.cc/42NG-3NMX] (last visited Feb. 5, 2020).

<sup>111</sup> See, e.g., *Learning About Tay-Sachs Disease*, NAT'L HUM. GENOME RES. INST. (Mar. 17, 2011), <https://www.genome.gov/10001220> [perma.cc/U347-UGFC].

<sup>112</sup> *Genetic Testing FAQ*, NAT'L HUM. GENOME RES. INST., <https://www.genome.gov/FAQ/Genetic-Testing> [perma.cc/6GRN-J3RZ] (last visited Dec. 20, 2019).

<sup>113</sup> Margaret A. Hamburg & Francis S. Collins, *The Path to Personalized Medicine*, 363 NEW ENG. J. MED. 301, 301 (2010).



President Obama announced in his 2015 State of the Union address that the U.S. government would fund an “All of US” initiative<sup>114</sup> to enroll at least one million people into a personalized medicine initiative<sup>115</sup> in which ten years of medical information is captured and shared.<sup>116</sup>

The idea behind President Obama’s initiative has been to use the power of the collective data to better understand the biology and pathogenesis of a disease and be in a position to provide better patient care and outcomes. Various technologies developed over the last decade have made such an initiative possible, including for example low cost high throughput DNA sequencing technologies<sup>117</sup> and other genome-based technology platforms used to classify certain disease stages using medical diagnostic tests to predict the likelihood of future clinical outcomes, as prognostic tests.

The novel concept behind personalized medicine is to tailor therapeutic strategies, be they for treatment or prevention purposes, based on an individual’s genomic and proteomic profile. This rapidly evolving approach to medicine is proving to be transformational for medical interventions. With the ever increasing stratification of patients based on their molecular makeup, for example looking for mutations present in certain genes which would indicate a drug would not work on a given patient, and government support of initiatives such as the “All of US” mentioned previously,

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<sup>114</sup> National Institutes of Health, All of Us Research Program, <https://allofus.nih.gov/> [perma.cc/RS8V-K6NE] (last visited Dec. 12, 2019).

<sup>115</sup> *Digital Health Market Size Worth \$509.2 Billion By 2025*, GRAND VIEW RES. (May 2019), <https://www.grandviewresearch.com/press-release/global-digital-health-market> [perma.cc/7XD7-5WFD] (last visited Dec. 12, 2019).

<sup>116</sup> In 2015, President Obama announced in his State of the Union address the launch of the Precision Medicine Initiative, a bold new way to revolutionize how we improve health and treat disease (“Doctors have always recognized that every patient is unique, and doctors have always tried to tailor their treatments as best they can to individuals. You can match a blood transfusion to a blood type - that was an important discovery. What if matching a cancer cure to our genetic code was just as easy, just as standard? What if figuring out the right dose of medicine was as simple as taking our temperature?”). President Barack Obama, State of the Union Address (Jan. 30, 2015).

<sup>117</sup> *The Cost of Sequencing a Human Genome*, NAT’L HUM. GENOME RES. INST., <https://www.genome.gov/27565109/the-cost-of-sequencing-a-human-genome/> [https://perma.cc/VY2H-ZSLL] (last updated Oct. 30, 2019).

physicians are becoming increasingly more able to better tailor treatment strategies on a case by case basis. It is thus likely that the rise in the development of emerging new medical diagnostic technologies within the era of personalized medicine will result in the ability of physicians to select drugs based on a patient's underlying genetic makeup. Such tests will allow for periodic molecular profiling of people to move their health care strategies from acute intervention and disease management to proactive management of disease risk and prevention.

The success of personalized medicine hinges on new and innovative medical diagnostic technologies, involving for example genomic testing technologies.<sup>118</sup> Indeed, medical diagnostic technologies already play an important role in the practice of medicine, impacting as high as 70 percent of health care decision making.<sup>119</sup> The concept is to use such medical diagnostic tests in the field of personalized medicine, such that a patient receives the right drug at the right dose at the right time.<sup>120</sup> For example, in medicine, pharmacogenomics, a field that is highly relevant to personalized medicine, is increasingly being used in clinics to study genetic information of an individual before making drug choice and drug dose decisions.<sup>121</sup> Different mutations in certain genes can present similarly in patients, and yet each patient will only respond to different treatments (drug efficacy between patients with same gene mutation being different).<sup>122</sup>

Medical diagnostic tests are generally used in clinical medical practice to identify the patient's condition and therefore provide for early and effective treatment of the particular disease at hand. Being able to provide an accurate medical diagnostic test that has a small

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<sup>118</sup> Margaret A. Hamburg & Francis S. Collins, *The Path to Personalized Medicine*, 363 NEW ENG. J. MED. 301, 301 (2010).

<sup>119</sup> KEWAL K. JAIN, TEXTBOOK OF PERSONALIZED MEDICINE 91–96 (2d. ed. 2015).

<sup>120</sup> Wolfgang Sadée & Zunyan Dai, *Pharmacogenetics/Genomics and Personalized Medicine*, 14 HUM. MOL. GENET. 207 (2005).

<sup>121</sup> *What is Pharmacogenomics?*, NAT'L INSTS. HEALTH (Jan. 21, 2020), <https://ghr.nlm.nih.gov/handbook/genomicresearch/pharmacogenomics> [<https://perma.cc/X5TQ-GZZ7>].

<sup>122</sup> Williams E. Evans & Howard L. McLeod, *Pharmacogenomics: Drug Disposition, Drug Targets, and Side Effects*, 348 N. ENG. J. MED. 538, 546 (2003).

probability of missing a diagnosis, or making an error in the diagnosis, or a making a delayed diagnosis are all crucial features in the management of a disease.<sup>123</sup> These medical diagnostic tests help in better understanding a patient's condition, predict clinical outcomes, select personalized medical treatment protocols, and to determine if a treatment is working. Thus, the commercialization of molecular medical diagnostic technologies has greatly expanded the field of pharmacogenetics, the application of which is now increasingly adopted in personalized medicine to address a patient's condition.<sup>124</sup>

In a medical clinical setting, such medical diagnostic tests can be used to confirm/exclude, triage, monitor, prognose, or screen for a particular marker or condition. For example, a diagnostic test can confirm or exclude that a patient has a particular disease, or a test could be used repeatedly to monitor how effective a concurrent treatment is, or assess the progression and/or outcome of a disease, or screen for a disease condition in people who do not show outwardly any symptoms. Thus, the breadth and impact of the medical diagnostic field in being able to provide better patient care is enormous. Having a robust, accurate and precise medical diagnostic test that is readily repeatable and reproducible is a significant technological leap forward in the process of managing health outcomes in patients. In this emerging new technological era of advanced medical diagnostic technologies, the vision is to provide "the right drug, with the right dose at the right time to the right patient."<sup>125</sup> The question is: how does the new patent eligibility law interplay with innovations in this personalized medicine and medical diagnostics field?

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<sup>123</sup> G. D. Schiff et al., *Diagnostic Error in Medicine: Analysis of 583 Physician-Reported Errors*, 169 ARCHIVES OF INTERNAL MED. 1881–87 (2009).

<sup>124</sup> *Id.*

<sup>125</sup> *Id.*

*B. Patent Eligibility of Diagnostic Method Claims: The Problem with Mayo Expanding the “Law of Nature” Exception and Myriad Expanding the “Natural Phenomena” Exception*

Protecting medical diagnostic technologies by permitting their patenting is a desirable outcome, albeit one can understand the need to proceed with caution when establishing an overly inclusive system that allows a monopoly on such medical techniques. Medical diagnostic technologies can be used to capture a number of practical applications, including testing to identify certain characteristics that can then help deliver better health outcomes in patients.

The Supreme Court’s recent decisions in *Mayo* and *Myriad*, discussed *infra*, are two seminal decisions addressing the patent eligibility question of biotechnological innovations, including patent claims to emerging medical diagnostic technologies. After deciding *Bilski* in 2010, discussed *supra*, the Supreme Court turned its attention to a subcategory of innovative and financially lucrative technologies within the biomedical sector, namely the patent eligibility of emerging medical diagnostic technologies. In three short years, the Supreme Court decided three patent eligibility cases that would significantly impact this industry, starting with the decision in *Mayo*.<sup>126</sup> *Mayo* showcased the Court’s ill-advised radical shift away from its own precedent and away from the express language in the statute.

The Supreme Court created judicial exceptions to statutory language primarily to prevent patents from monopolizing “the basic tools of scientific and technological work.”<sup>127</sup> The context for the Supreme Court’s recent radical shift on this issue of patent eligibility is likely a result of several converging factors, including the fact that many on the patent bar had voiced an opinion that as a direct result of the Federal Circuit’s expansive interpretation of the Supreme Court’s *Diehr* decision over many years, a glut of superfluous low quality patents had issued and that this ultimately had a chilling effect on the advancement of technological innovation in America.

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<sup>126</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

<sup>127</sup> *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014) (quoting *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013)).

Some scholars have argued that well above 90 percent of patents are never actually commercialized in any way.<sup>128</sup> Although the lack of commercialization of the majority of patents does not necessarily damage the structure of incentives and rewards in the United States' patent system by themselves, the recent bundling of these superfluous patents and their assertion by non-practicing entities ("NPEs") against companies producing products has become cause for concern.<sup>129</sup> Moreover, the 2016 Federal Trade Commission report on Patent Assertion Entities also concluded that the high number of low quality patents and their assertion by NPEs is a nuisance business model.<sup>130</sup> Further still, the USPTO has faced criticism for enabling this landscape by granting poor quality patents, with a government report, issued by GAO during the same time as the Supreme Court decisions analyzed herein, specifically pointing out that a glut of poor quality issued patents was hurting the patent ecosystem,<sup>131</sup> and yet others highlighting that low quality

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<sup>128</sup> Robin Feldman, *Intellectual Property Wrongs*, 18 STAN. J.L. FIN. 250, 264 (2013) ("The vast majority of patents have never directly earned a return for the patent holder. Estimates suggest that the number is well above 90%."); *see also* Gideon Parchomovsky & R. Polk Wagner, *Patent Portfolios*, 154 U. PA L. REV. 1, 5 (2005) (estimating that less than 5 percent of patents hold any value).

<sup>129</sup> *Id.* at 254, 267–68 ("We need a mechanism for restraining inappropriate use of intellectual property and for signaling the difference between the acceptable pursuit of a return from your intellectual property and the inappropriate oppression of others, using the legal system and societally granted privileges as a weapon."); *see also* Mark A. Lemley & Robin Feldman, *Is Patent Enforcement Efficient?*, 98 B.U. L. REV. 649, 658 (2018).

<sup>130</sup> FED. TRADE COMM'N, PATENT ASSERTION ENTITY ACTIVITY: AN FTC STUDY 8 (2016) ("Ninety-three percent of reported Litigation [Patent Assertion Entity] licenses followed a lawsuit against the eventual licensee and 77% were valued at less than the estimated cost of defending a patent lawsuit through the end of discovery—a threshold below which litigation settlements might be considered nuisance value.").

<sup>131</sup> U.S. GOV'T ACCOUNTABILITY OFF., GAO-13-465, INTELLECTUAL PROPERTY: ASSESSING FACTORS THAT AFFECT PATENT INFRINGEMENT LITIGATION COULD HELP IMPROVE PATENT QUALITY 32 (2013) ("The prevalence of low quality patents was driving recent increases in litigation more than PME suits.").

patents in the biotechnology and medical diagnostic industries helped push up drug prices and cause public outrage.<sup>132</sup>

*i. Mayo and Expanding the “Law of Nature” Exception*

It is into this context that the first of the *Mayo* trilogy of cases was born, the ultimate result of which has been to make it much harder to obtain a patent. In *Mayo*, the Supreme Court drew on old case law, including from an old English case *Neilson*,<sup>133</sup> as well as from its own precedent in *O’Reilly*<sup>134</sup> and *Funk Brothers*<sup>135</sup> to propose that the real test for determining patent eligible subject matter under Section 101 was not whether the patent claim had a *practical application*, but rather whether the patent claim had an *inventive application* of an underlying principle.<sup>136</sup> As is explained *infra*,<sup>137</sup> this is seen by many as a radical shift and damaging to several technological industries, including being especially damaging to emerging medical diagnostics technologies.

In *Mayo*, the invention was directed to a method for optimizing the efficacy of a drug given to a patient. In particular, the patent claimed methods for calibrating the dosage of thiopurine drugs used for treating certain autoimmune diseases, including gastrointestinal disorders.<sup>138</sup> In effect, the method involved the doctor administering

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<sup>132</sup> Robin Feldman et al., *Empirical Evidence of Drug Pricing Games - A Citizen’s Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39, 42 (2017) (“Anecdotal evidence has percolated in recent years about new forms of strategic behavior designed to keep drug prices artificially inflated by blocking generic entry.”).

<sup>133</sup> *Neilson v. Harford*, 151 Eng. Rep. 1266 (1841).

<sup>134</sup> *O’Reilly v. Morse*, 56 U.S. 62 (1853).

<sup>135</sup> *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). In this case, the inventor did not create the strains of bacteria and the strains that were central to this invention, and therefore were ‘phenomena of nature’ and unpatentable. While mixing different strains into one product was an application of the natural phenomena, the invention was deemed unpatentable subject matter because it amounted to no more than an alternate way to package the product.

<sup>136</sup> See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72–73 (2012) (emphasis added).

<sup>137</sup> See discussion *infra* Part IV.b.ii.

<sup>138</sup> The independent patent claim at issue in *Mayo* recited 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;

the drug, waiting for the drug to be metabolized by the body, and then taking a blood sample to see if the metabolite of the drug was high or low. Based on this reading of the metabolite level, a decision was then made whether to administer more or less of the drug to the patient. Thus, the patent claimed measuring metabolites of the drug to optimize therapeutic efficacy and at the same time minimize toxicity and side effects.

However, the Supreme Court found Mayo's patent claims<sup>139</sup> "do nothing more than simply describe the natural relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm,"<sup>140</sup> stating further that correlating levels of a drug metabolite in blood with either an overdose or underdose of the drug is ineligible subject matter for patenting because it is a law of nature.<sup>141</sup> The *Mayo* Court went on to articulate its belief that, when a method involves a natural law or abstract idea, it must also contain "*an inventive concept*," which the Court defined as "other elements or a combination of elements . . . sufficient to ensure that the patent in practice amounts to *significantly more* than a patent upon the natural law itself."<sup>142</sup> The Court compared the *Mayo* patent claim to its past precedent in both *Diehr*<sup>143</sup> and *Flook*,<sup>144</sup> concluding that the patent claims provide mere "instructions" and that "because methods for

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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 8x10<sup>8</sup> 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 8x10<sup>8</sup> red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

<sup>139</sup> *Mayo*, 566 U.S. at 72–73.

<sup>140</sup> *Id.*

<sup>141</sup> *Id.* at 77 (the Court explaining that "The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.").

<sup>142</sup> *Id.* at 72–73 (emphasis added).

<sup>143</sup> See *Diamond v. Diehr*, 450 U.S. 175, 192–93 (1981) (holding subject matter patent eligible).

<sup>144</sup> See *Parker v. Flook*, 437 U.S. 584, 596 (holding subject matter patent ineligible).

making such determinations were well known in the art, this step simply tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists in the field. Such activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.”<sup>145</sup>

Thus, in *Mayo*, the Supreme Court articulated that the test for determining patent eligible subject matter under Section 101 was not whether the patent claim had a *practical application*, but rather whether the patent claim had an *inventive application* of an underlying principle. The U.S. government had filed an *amicus curiae* in this case, advising the Court to adhere to the statutory language and to keep a low threshold for determining patent eligible subject matter, arguing that the higher bars to patentability in other parts of the Patent Act are best suited for the task for determining patentability,<sup>146</sup> namely novelty under Section 102 and obviousness under Section 103. Yet, the Supreme Court decided against the government’s position and by articulating their new position in *Mayo*, the Supreme Court effectively vastly increased the scope of the Court’s own created exceptions to the express language of the statute that outlines what is and is not patent eligible subject matter.

ii. *Myriad and Expanding the “Product of Nature” Exception*

Just one year after the controversial *Mayo* decision, the Supreme Court decided another patent eligibility case related to biomedical technologies when it decided *Myriad*.<sup>147</sup> In *Myriad*, the Court addressed the controversial issue of whether certain genomic inventions were patent eligible subject matter. The Supreme Court held that genomic DNA was subject matter that is ineligible for a patent under Section 101 because of the “product of nature” judicial exception. Prior to this decision, courts took the view that such claims would be patent eligible if the claim included significant

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<sup>145</sup> *Mayo*, 566 U.S. at 67.

<sup>146</sup> Patentability and patent eligibility are two different concepts, with the former focusing most on legal issues of novelty (Section 102 of the Patent Act) and non-obviousness (Section 103 of the Patent Act) and the latter focusing on patent eligible subject matter (Section 101 of the Patent Act).

<sup>147</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).



artificial changes made to the product of nature, perhaps by purifying, isolating or altering in any way.

This “product of nature” exclusion to patent eligible subject matter had previously denied patent protection to plant extracts,<sup>148</sup> naturally occurring metals,<sup>149</sup> and novel mixtures of existing bacteria.<sup>150</sup> Yet, the courts created a significant exception allowing an isolated and purified natural product to be patent-eligible. For example, Judge Learned Hand in *Parke-Davis* held that isolating and purifying adrenaline from animal glands made it patent eligible subject matter despite it being a natural product.<sup>151</sup> However, the contours of this exception all changed with the arrival of *Myriad*.

*Myriad* followed just one year after the alarming *Mayo* decision. In *Myriad*, the overarching technology related to the eligibility of isolated DNA sequences, namely BRCA1 and BRCA2 genes, methods for predicting the likelihood of cancer developing in a patient by examining mutations in those genes, and also methods to identify anti-cancer drugs using the isolated DNA sequences.<sup>152</sup> At its core, *Myriad* involved the discovery that certain mutations in these two genes are associated with a predisposition of a patient to developing breast and ovarian cancer.<sup>153</sup> *Myriad*’s invention represented a significant advancement in cancer treatment. Yet, as soon as *Myriad* began its commercialization strategy, there was widespread public outcry.<sup>154</sup> A group of medical professionals,

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<sup>148</sup> Ex parte Latimer, 1889 Dec. Comm’r Pat. 123.

<sup>149</sup> Gen. Elec. Co. v. De Forest Radio Co., 28 F.2d 641, 642 (3d Cir. 1928).

<sup>150</sup> Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

<sup>151</sup> *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911).

<sup>152</sup> See patent claims 1, 2, 5, 6, 7, and 20 of U.S. Patent No.: 5,747,282; and patent claims 1, 6, and 7 of U.S. Patent No.: 5,837,492.

<sup>153</sup> For example, claim 1 of U.S. Patent No. 5,747,282 recites: “An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the [following] amino acid sequence . . . .” For the sake of transparency, the author of this article was a member of the IP law group of a large international law firm in NYC that developed the patent portfolio for this innovator concerning their breast and ovarian cancer technology.

<sup>154</sup> E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS IN MEDICINES 38, S41, S43 (2010), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3037261/> [<https://perma.cc/QV7T-QCQX>].

joined by other entities, sued Myriad and sought to invalidate its patents on Section 101 grounds, arguing that isolated DNA is a product of nature and therefore is patent ineligible subject matter.<sup>155</sup>

On appeal, ignoring three decades of practice to the contrary, the Supreme Court held that while claims directed specifically to the complementary DNA (cDNA) for the breast cancer genes, BRCA1 and BRCA2, were patent-eligible, claims to an isolated nucleic acid encoding the BRCA1/2 genes were not patent eligible because they are “a natural product.”<sup>156</sup> Consistent with its previous decision in *Mayo*, in which the court expanded its “law of nature” exception<sup>157</sup> to patent eligible subject matter, in *Myriad* the Supreme Court expanded its “product of nature” exception<sup>158</sup> to patent eligible subject matter under Section 101.<sup>159</sup> With this *Myriad* decision, the Supreme Court reversed thirty years of USPTO practice of granting exactly that kind of patent for isolated nucleic acid sequences that now the Court was deciding was ineligible subject matter. To highlight the weight of this decision, the USPTO had issued over 50,000 U.S. patents relating in part to DNA<sup>160</sup> and all of these were now subject to this seesaw reversal because of this expansion to the “natural product” exception under this newly decided expansive *Myriad* decision.

Immediately following *Myriad*, the Federal Circuit began to invalidate patents en masse.<sup>161</sup> The problem with expanding the scope of the judicially created exceptions to statutory patent eligible subject matter can be seen by assessing, for example, the effect of this radical change in patent law on the medical diagnostic

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<sup>155</sup> See *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 186–89 (S.D.N.Y. 2010).

<sup>156</sup> *Id.*; see generally Evan H. Tallmadge, *Patenting Natural Products After Myriad*, 30 HARV. J.L. & TECH. 569 (2017).

<sup>157</sup> *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 189.

<sup>158</sup> In this paper, “product of nature” and “natural phenomena” are used interchangeably.

<sup>159</sup> See *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.* 569 U.S. 576, 579 (2013).

<sup>160</sup> Guyan Lian, *Molecules or Carriers of Biological Information: A Chemist’s Perspective on the Patentability of Isolated Genes*, 22 ALBANY L.J. SCI. AND TECH. 133 (2012).

<sup>161</sup> *Genetic Tech. Ltd. v. Merial LLC*, 818 F. 3d 1369 (Fed. Cir. 2016).

technologies. In one example, when Professor Dennis Lo and colleagues at Oxford University discovered that cell-free fetal DNA (cffDNA) could be detected in the plasma and serum of pregnant women, they obtained U.S., European and Australian patents for their novel methods of detecting this cffDNA using standard techniques.<sup>162</sup> The center piece of this new medical diagnostic technology was the ability to now more accurately and less invasively detect abnormalities and characteristics of unborn children by taking a simple blood test from the pregnant mother, without having to risk complications to the unborn fetus and pregnant mother by inserting a needle into the mother's uterus and puncturing the amniotic sac by amniocentesis to take a sample of amniotic fluid for further testing.<sup>163</sup> In the U.S., the Federal Circuit in *Ariosa* invalidated claims for these non-invasive methods of detecting cffDNA from a blood sample of a pregnant woman.<sup>164</sup> According to the court, the only new and useful subject matter in the method “was the discovery of the presence of cffDNA in maternal plasma or serum.”<sup>165</sup> In contrast to the legal position in the United States, this same technology, as will be discussed further *infra*,<sup>166</sup> was recently found to be patent eligible subject matter by both the High Courts of the United Kingdom and also Australia.<sup>167</sup>

Judge Linn indicated that *Ariosa* “represents the consequence—perhaps unintended—of that broad language in [*Mayo*] excluding a meritorious invention from the patent protection it deserves.”<sup>168</sup> Indeed, he indicated that he concurred “only because” he was bound by the breadth of *Mayo*.<sup>169</sup> Moreover, once a hearing *en banc* was denied in *Ariosa*, several Judges on the Federal Circuit also used the opportunity to express concern that such discoveries were not able to overcome the Supreme Court's very high new bar to what the

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<sup>162</sup> See Y. M. Dennis Lo et al., *Presence of Fetal DNA in Maternal Plasma and Serum*, 350 THE LANCET 485 (1997).

<sup>163</sup> *Id.*

<sup>164</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).

<sup>165</sup> *Id.* at 1377

<sup>166</sup> See discussion *infra* Part VI.b.

<sup>167</sup> See Part VI.b on harmonizing patent eligibility laws.

<sup>168</sup> *Ariosa*, 788 F.3d at 1380 (Linn, J., concurring).

<sup>169</sup> *Id.*

Court unilaterally had opined is and is not patent eligible subject matter. For example, Judge Lourie stated that “it is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility.”<sup>170</sup> Similarly, Judge Dyk contended that “we are bound by the language of *Mayo*, and any further guidance must come from the Supreme Court.”<sup>171</sup> On appeal, the Supreme Court passed on the opportunity to correct its decision in *Mayo* by denying *certiorari* in *Ariosa* in 2016, a decision that disappointed many observers because even though there were 23 amicus briefs filed encouraging the Court to grant *certiorari* in *Ariosa*, the Supreme Court did not even ask the Solicitor General’s opinion.<sup>172</sup>

Some scholars have argued that the impact of *Myriad* raises serious questions about the patent eligibility of biotechnological products, including diagnostic methods.<sup>173</sup> However, other scholars have disagreed, at least in regards to the extent to which the *Myriad* decision upends the biotechnological sector.<sup>174</sup> What most scholars agree with is that the *Mayo* decision was inelegantly decided and poses a serious threat to the biotechnology industry.<sup>175</sup>

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<sup>170</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* 809 F.3d 1282, 1287 (Fed. Cir. 2015) (Lourie, J., concurring).

<sup>171</sup> *Id.* (Dyk, J., concurring).

<sup>172</sup> Albeit, that stance may be changing since the Supreme Court recently asked for the Solicitor General’s decision on two patent eligibility appeals currently pending before the Court. Currently pending opportunities for the Supreme Court to grant *certiorari* include in *Berkheimer*, *Vanda*, and *Athena Diagnostics*. It remains to be seen; it is interesting that this time, unlike in *Ariosa*, the Supreme Court has indeed invited the Solicitor General to submit a brief in both *Berkheimer* and in *Vanda*; for *Athena Diagnostics*, a petition for *certiorari* is expected to be filed within weeks.

<sup>173</sup> Robert Schwartz & Timo Minssen, *Life After Myriad: The Uncertain Future of Patenting Biomedical Innovation and Personalised Medicine in an International Context*, 3 INTELL. PROP. Q. 189–241 (2015).

<sup>174</sup> Christopher M. Holman, *Mayo, Myriad, and the Future of Innovation in Molecular Diagnostics and Personalized Medicine*, 15 N.C. J.L. & TECH. 639 (2014).

<sup>175</sup> INTELL. PROP. 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/P4MW-G24Z>] (stating that recent decisions “have dramatically narrowed the scope of patent protection

One year after its *Myriad* decision, came *Alice*.<sup>176</sup> In *Alice*, the Supreme Court considered the patentability of a computer-implemented financial trading exchange system.<sup>177</sup> Here, the Supreme Court underlined its two-part test for identifying patent ineligible subject matter.<sup>178</sup> First, a claim is analyzed to see if any of the exceptions to the statute apply.<sup>179</sup> If so, then the patent claim is reviewed to determine whether the claim recites additional elements that transform the claim into a patent-eligible application of any of those three exceptions to the statute.<sup>180</sup> In this second step of the test, it is necessary to determine whether the claim incorporates an “inventive concept” that amounts to more than merely applying the law of nature, natural phenomenon, or abstract idea to a particular technological environment.<sup>181</sup> The Court determined that the method claims in *Alice* were drawn to the abstract idea of intermediated settlement, and that this amounted to nothing more than implementation of an abstract idea on a computer.<sup>182</sup>

*Alice* thus confirms that *Mayo*’s test should be used to determine patent eligibility questions under Section 101, namely that it is not whether a patent claim has a *practical application*, but rather whether it has an *inventive application* of an underlying principle.<sup>183</sup> The *Alice* decision underscored the Court’s concern with preemption, recognizing that abstract ideas are not patentable because granting a monopoly to an abstract idea would stifle innovation.<sup>184</sup> Thus, a claim that recites an abstract idea must include “additional features” that amount to an “inventive concept” to be

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for life sciences and software technology by significantly expanding the judicially-created exceptions to patent-eligible subject matter”).

<sup>176</sup> *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208 (2014).

<sup>177</sup> *Id.* at 208.

<sup>178</sup> *Id.* at 217–18.

<sup>179</sup> *Id.* at 218.

<sup>180</sup> *Id.* at 221.

<sup>181</sup> *Id.*

<sup>182</sup> *Id.* at 225.

<sup>183</sup> *Id.* at 222.

<sup>184</sup> *Id.* at 216.

patent eligible subject matter.<sup>185</sup> *Alice* also confirms that *Mayo*'s two-step analysis should be applied to all types of claims.<sup>186</sup>

In *Mayo*<sup>187</sup> and *Alice*,<sup>188</sup> the Supreme Court thus adopted a two-step test for determining patent-eligibility under Section 101, giving rise to the expansion of the Supreme Court created exceptions to what is patent eligible subject matter. These exceptions are exceptions to the four categories of subject matter explicitly listed in the Section 101 statute as being patent eligible.<sup>189</sup> That is, even if an invention falls within one of the four categories of patent eligible subject matter under the statute, it can still be found to be ineligible subject matter because of the Supreme Court-created exceptions to this statutory language. Under this new *Mayo/Alice* two step test, one begins with determining whether the claimed invention is to one of the four statutory categories.<sup>190</sup> If not, to qualify for patent eligible subject matter, the patent claim must not be directed to a judicial exception unless the claim as a whole includes additional limitations amounting to significantly more than the exception.<sup>191</sup>

This new *Mayo/Alice* test has been very difficult for patent stakeholders, including examiners, inventors, patent owners, patent lawyers and judges alike, to implement and/or interpret because it remains unclear what the boundaries of Section 101 are.<sup>192</sup> As the IP

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<sup>185</sup> *Id.* at 221.

<sup>186</sup> *Id.* at 216.

<sup>187</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

<sup>188</sup> *Alice*, 573 U.S. at 208.

<sup>189</sup> The current version of the patent eligibility statute, 35 U.S.C. § 101 (2018), states: "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>190</sup> *Alice*, 573 U.S. at 217–18; *see Mayo*, 566 U.S. at 77; *see also* 35 U.S.C. § 101 (2018).

<sup>191</sup> *See Mayo*, 566 U.S. at 72.

<sup>192</sup> *See Synchronoss Techs., Inc. v. Dropbox Inc.*, No. 16-cv-00119-HSG (N.D. Cal. Dec. 22, 2016) ("This Court agrees with those judges who have observed that even post-*Enfish*, the *Mayo/Alice* test provides limited practical guidance for distinguishing software and computer patents that are valid under § 101 from those that are not."); *Amdocs (Isr.) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288 (Fed.Cir. 2016) ("[A] search for a single test or definition [of what an 'abstract idea' encompasses] in the decided cases concerning § 101 from this court, and

Law Section Chair of the American Bar Association conservatively put it recently “the Supreme Court has injected ambiguity into the subject matter eligibility determination.”<sup>193</sup> The President of the American IP Law Association agreed with that sentiment in his own letter to the government on behalf of his law association.<sup>194</sup> The patent bar and the USPTO remain lost on how to implement this new patent eligibility test, even five years after the Supreme Court decided *Alice*.<sup>195</sup> Interestingly, even the Supreme Court itself seems lost in how to apply the test, as evidenced by the major inconsistencies between its patent eligibility decisions.<sup>196</sup> Scholars also noticed that the Court provided minimal guidance regarding the boundaries of its new test.<sup>197</sup>

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indeed from the Supreme Court, reveals that at present there is no such single, succinct, usable definition or test.”); *Intell. Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1329 (Fed. Cir. 2016) (Mayer, J., concurring) (describing the “semantic gymnastics” entailed in applying the *Mayo/Alice* test); *BASCOM Glob. Internet Servs. V. AT&T Mobility LLC*, 827 F.3d 1341, 1352–54 (Fed. Cir. 2016) (Newman, J., concurring) (“I have come upon no guide to when a claim crosses the boundary between unacceptable abstractness and acceptable specificity.”); *Device Enhancement LLC v. Amazon.com, Inc.*, 189 F. Supp. 3d 392 (D. Del. 2016) (discussing the “still difficult-to-discern requirements of the Alice analysis,” and the resulting “difficult exercise” under § 101).

<sup>193</sup> Letter from Donna P. Suchy, Section Chair, Section of Intell. Prop. Law, Am. Bar Ass’n., to Michelle K. Lee, Under Sec’y of Com. for Intell. Prop. and Dir. of the USPTO (Jan. 18, 2017), [https://www.americanbar.org/content/dam/aba/administrative/intellectual\\_property\\_law/advocacy/advocacy-20170117-comments.authcheckdam.pdf](https://www.americanbar.org/content/dam/aba/administrative/intellectual_property_law/advocacy/advocacy-20170117-comments.authcheckdam.pdf) [<https://perma.cc/99CM-KVSQ>] (stating “the Supreme Court has injected ambiguity into the subject-matter eligibility determination”).

<sup>194</sup> Letter from Mark L. Whitaker, President, Am. Intell. Prop. Law Ass’n., to Michelle K. Lee, Under Sec’y of Com. for Intell. Prop. and Dir. of the USPTO (Jan. 18, 2017), [https://www.uspto.gov/sites/default/files/documents/comments\\_aipla\\_jan182017.pdf](https://www.uspto.gov/sites/default/files/documents/comments_aipla_jan182017.pdf) [<https://perma.cc/Y2EE-2UJ5>] (outlining how the Supreme Court’s recent patent eligibility decisions have caused “uncertainty and inefficiency for patent applicants and litigants[.]”).

<sup>195</sup> *Id.*; see generally Tran & Benevento, *supra* note 15.

<sup>196</sup> Donald R. Dunner, *The Supreme Court: A Help or a Hindrance to the Federal Circuit’s Mission?*, 17 J. MARSHALL REV. INTELL. PROP. L. 298 (2018). See Donald R. Dunner, *Response to Judge Timothy B. Dyke*, 16 CHI.-KENT J. INTELL. PROP. 326 (2017); see also Golden, *supra* note 12, at 1770.

<sup>197</sup> Christopher M. Holman, *Patent Eligibility Post-Myriad: A Reinvigorated Judicial Wildcard of Uncertain Effect*, 82 GEO. WASH. L. REV. 1796, 1798 (2014)

Prior to reaching the Supreme Court, there was a highly divided *en banc* decision at the Federal Circuit in *Alice*.<sup>198</sup> The Chief Judge of the Court of Appeals for the Federal Circuit (“CAFC”) at the time, Judge Rader, referred to the CAFC’s inability to render a majority opinion in *Alice* as “the biggest failure of his career.”<sup>199</sup> In his view, interpretation of Section 101 was simply settled law, based on *Diehr* and *Chakrabarty*. Another former Chief Judge of the CAFC, Judge Michel, predicted that *Alice*’s new test for patent eligibility would “create total chaos,” stating that the test is “too vague, too subjective, too unpredictable and impossible to administer in a coherent, consistent way in the patent office or in the district courts or even in the federal circuit.”<sup>200</sup>

Further still, Judge Moore’s dissent in *Alice*, in which she was joined by three other Federal Circuit judges, took a negative view of reading judicial exceptions expansively.<sup>201</sup> As yet another indication of how split the Federal Circuit was when it decided *Alice*, Judge Newman stated in her own dissent that the court should return to the express statutory language of Section 101 and Congress’s intent.<sup>202</sup>

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(“Unfortunately, the Court has provided little guidance with respect to the readjusted contours of the newly invigorated doctrine, and as a consequence, judges and the PTO have been thrown into a state of confusion with respect to the proper application of the doctrine; the high degree of uncertainty is even more problematic for patent attorneys and their clients.”).

<sup>198</sup> CLS Bank Int’l v. Alice Corp. Pty, 717 F.3d 1269 (Fed. Cir. 2013).

<sup>199</sup> Dan Levine, *Insight: Rocker Judge Juggles Tech Policy, Supreme Court and the Stones*, REUTERS (Dec. 11, 2013) <https://www.reuters.com/article/us-usa-judge-rader-insight/insight-rocker-judge-juggles-tech-policy-supreme-court-and-the-stones-idUSBRE9BA06D20131211> [<https://perma.cc/4HVG-GD9K>].

<sup>200</sup> See Quinn, *supra* note 25.

<sup>201</sup> In her dissent in *Alice*, Judge Moore stated: “*I am concerned that [in] the current interpretation of § 101 . . . The Supreme Court has taken a number of our recent decisions and, in each instance, concluded that the claims at issue were not patent-eligible. See Bilski, Prometheus, Myriad (under consideration) . . . holding that [all claims] are all patent-ineligible under § 101 . . . Holding that all of these claims are directed to no more than an abstract idea gives staggering breadth to what is meant to be a narrow judicial exception.*” *Alice*, 717 F.3d at 1313 (Moore, J., dissenting) (emphasis added).

<sup>202</sup> Judge Newman also wrote separately in *Alice*: “I propose that the court return to the statute, and hold that when the subject matter is within the statutory classes in section 101, eligibility is established. This conforms with legislative intent.” *Alice Corp.*, 717 F.3d at 1326 (Newman, J., concurring in part, dissenting



The discontent among Federal Circuit judges vis-à-vis the new patent eligibility test continues, and it is clear from the past year that the judges are unhappy with the status quo. For example, in *Berkheimer v HP Inc.*, Judge Lourie concurred, noting that “the law needs clarification by higher authority, perhaps by Congress, to work its way out of what so many in the innovation field consider are Section 101 problems.”<sup>203</sup> In another patent eligibility decision from last year, Judge Plager criticized the process of finding abstract ideas as an elusive search for *inventiveness*, and asked “[i]s it any wonder that the results of this process are less than satisfactory.”<sup>204</sup>

That said, the Federal Circuit has tried to find a way to dampen the toxic effect of recent Supreme Court decisions on patent eligibility on key industries such as medical diagnostics and software-driven bioinformatics. The Circuit provided guidance on step one of *Alice* in *Enfish*,<sup>205</sup> stating that “focus[ing] on a specific means or method that improves the relevant technology” is patent eligible to validate protection for technologies in the software industry,<sup>206</sup> and also provided some guidance on step two of *Alice* in

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in part). *See also* *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (“In choosing such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.”).

<sup>203</sup> *Berkheimer v. HP Inc.*, 890 F.3d 1369, 1374–75 (Fed. Cir. 2018) (*per curiam*) (Lourie, J., concurring) (stating that § 101 “needs clarification by higher authority, perhaps by Congress” and opining that “the Supreme Court whittled away at the § 101 statute in *Mayo* by analyzing abstract ideas and natural phenomena with a two-step test . . . thereby bringing aspects of §§ 102 and 103 into the eligibility analysis”), *petition for cert. filed*, No. 18-415 (U.S. Oct. 3, 2018).

<sup>204</sup> *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1354–55 (Fed. Cir. 2018).

<sup>205</sup> *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016). The case stands for the proposition that software inventions may be patent-eligible, if the innovation does not pertain to an abstract idea for which a computer is used “merely as a tool.” This decision bucks the trend of invalidating software patents as mere abstract ideas based on *Alice*.

<sup>206</sup> *See, e.g., McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299 (Fed. Cir. 2016); *Thales Visionix Inc. v. United States*, 850 F.3d 1343 (Fed. Cir. 2017); *Visual Memory LLC v. Nvidia Corp.*, 867 F.3d 1253 (Fed. Cir. 2017).

*Bascom*.<sup>207</sup> Yet, although a few cases have survived the patent eligibility challenge, many more such patents have been invalidated under this new patent eligibility test.<sup>208</sup>

Thus, the main problem with expanding the scope of the exceptions to patent eligibility is that inventions/discoveries in biotechnology, and in particular medical diagnostics technologies, tend to be intertwined with what occurs in nature. As described above, this sector has been hit hard by the change in patent eligibility laws with the Federal Circuit invalidating medical diagnostic claims at an alarmingly high rate. For example, patent claims to methods for determining a patient's risk of developing cardiovascular disease by detecting the myeloperoxidase enzyme in the patients' blood and making a correlation from the results to cardiovascular risk was found to be patent ineligible subject matter.<sup>209</sup> Interestingly, in this recent *Cleveland Clinic* decision,<sup>210</sup> the Federal Circuit aligned itself with its problematic earlier ruling in *Ariosa*,<sup>211</sup> concluding that claim limitations directed to standard techniques will fail to pass the Section 101 patent eligibility hurdle.<sup>212</sup> Five years on from *Alice*, there are now many opinions by Federal Circuit judges expressing

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<sup>207</sup> *Bascom Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016).

<sup>208</sup> *See, e.g., Secured Mail Sols. LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 909 (Fed. Cir. 2017), cert. denied, 138 S. Ct. 2000 (2018); *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121 (Fed. Cir. 2018); *In re Marco Guldenaar Holding B.V.*, 911 F.3d 1157 (Fed. Cir. 2018); *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363, 1365 (Fed. Cir. 2018); *BSG Tech. LLC v. Buyseasons, Inc.*, 899 F.3d 1281 (Fed. Cir. 2018); *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1343 (Fed. Cir. 2018).

<sup>209</sup> *Clev. Clinic Found. v. True Health Diagnostics*, 859 F.3d 1352 (Fed. Cir. 2017).

<sup>210</sup> *Id.*

<sup>211</sup> Discussed further *infra* Part VI.

<sup>212</sup> *Clev. Clinic*, 859 F.3d at 1360 (noting that “each limitation Cleveland Clinic raises, however, merely recites known methods of detecting MPO or MPO derivatives and applies the correlation between these biomarkers and cardiovascular health”); *id.* at 1361 (“Indeed, Cleveland Clinic has not created a new laboratory technique; rather, it uses well-known techniques to execute the claimed method.”).

frustration by their inability to avoid the handcuffs of the Supreme Court's Section 101 jurisprudence.<sup>213</sup>

Thus, the new patent eligibility test under *Mayo/Alice* is badly suited for medical diagnostic tests that rely on newly discovered laws of nature. The patent bar and all stakeholders in the technology industry, especially in the medical diagnostics industry, are in dire need of a clear test to use for determining whether a diagnostic test that has its basis in a law of nature is patent eligible. There are options for greatly improving the current status quo.<sup>214</sup>

*C. Disarray in Biomedical Industry Caused by the Supreme Court's New "Inventive Application" Standard for Determining Patent Eligibility and the Misclassification of Innovations in Medical Diagnostics as Laws of Nature or Products of Nature*

As defined in Section 101, the four categories of patent eligible subject matter are: processes, machines, manufactures and compositions of matter,<sup>215</sup> with the first category defining "actions" and the latter three categories defining "things."<sup>216</sup> The Supreme Court created exceptions to these four statutory categories, finding laws of nature, natural products of nature, and abstract ideas to be patent ineligible subject matter.<sup>217</sup> In the Court's view, inventions that encompass these exceptions are "basic tools of scientific and technological work"<sup>218</sup> that should be "free to all men and reserved exclusively to none,"<sup>219</sup> and that this "reflects a basic judgment that

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<sup>213</sup> *Id.*; see Dunner, *The Supreme Court*, *supra* note 196.

<sup>214</sup> See discussion *infra* Part VI.c.

<sup>215</sup> For more detailed information on the four categories, see Manual of Patent Examining Procedure § 2106.03.

<sup>216</sup> Pursuant to 35 U.S.C. § 100(b), "The term 'process' means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." See also 35 U.S.C. § 100(b) (2018); *Corning v. Burden*, 56 U.S. 252, 267–68 (1854); *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

<sup>217</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013); *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014).

<sup>218</sup> *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

<sup>219</sup> *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

protection in such cases, despite its potentially positive incentive effects, would too often severely interfere with, or discourage, development and the further spread of useful knowledge itself.”<sup>220</sup> For example, under this principle, Einstein may have discovered that anything having mass has an equivalent amount of energy, but he would not have been able to patent his celebrated formula,  $E=mc^2$ , that shows this relationship, nor could Newton patent his discovery of the law of gravity, or a lay person patent his/her discovery of a new mineral in the earth. These kinds of discoveries are “manifestations of laws of nature, free to all men and reserved exclusively to none.”<sup>221</sup>

The problem with *Mayo* expanding the boundaries of the law of nature exception to patent eligible subject matter is that it fails to recognize that the very nature of molecular medical diagnostics means that new discoveries in this field, more so than other fields, are meshed with what occurs in nature. Whereas until now, most medical treatments have taken the “average patient” into account, personalized medicine using innovative medical diagnostics technologies allows for a different approach and this includes ultimately measuring how each patient’s body works and drawing clinical conclusions. Thus, the very nature of these types of medical diagnostic technologies easily trigger the exceptions expounded by the *Mayo* trilogy.<sup>222</sup> Hence, unsurprisingly, the *Mayo* decision resulted in a dramatic increase in rejections of patent applications related to genetics and personalized medicine.<sup>223</sup> Moreover, in the courts, the Federal Circuit rejected patent claims based on patent ineligibility at an eye-popping rate of 94.1 percent in 2015 and 92.3

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<sup>220</sup> Lab. Corp. of America Holdings v. Metabolite Laboratories, Inc., 548 U.S. 124, 128 (2006).

<sup>221</sup> *Funk Bros.*, 333 U.S. at 130.

<sup>222</sup> Referring to the three back-to-back Supreme Court cases: *Mayo*, *Myriad* and *Alice*.

<sup>223</sup> Bernard Chao and Amy Mapes, *An Early Look at Mayo’s Impact on Personalized Medicine*, 2016 PATENTLY-O PAT. L. J. 10. It should be noted that this study did not include any analysis of the ultimate outcome of these rejections in order to see if any rejections are withdrawn in view of attorney arguments, something that would be important in assessing the ultimate practical effects of the Supreme Court’s recent patent-eligibility decisions.

percent in 2016,<sup>224</sup> with the number of Federal Circuit Section 101 opinions rising from just 19 in the five years before *Alice* to 156 in the five years after *Alice*, an increase of 732 percent.<sup>225</sup>

One recent case that demonstrates how difficult the lower courts are finding *Mayo*'s implementation is *Vanda*.<sup>226</sup> In *Vanda*, the Federal Circuit decided that the “method of treatment” patent claims were not directed to a judicial exception and thus were patent eligible subject matter, even though the claims appeared very similar to the method of treatment claims at issue in *Mayo*. In *Vanda*, the patent was directed to a medical diagnostic technology related to treating schizophrenic patients with iloperidone.<sup>227</sup> The treatment method involved first genotyping the patient to assess a gene called CYP2D6, and then based on that assessment and extrapolation concerning the schizophrenic patient's metabolism, giving the patient a low dose of iloperidone so as to decrease cardiovascular side-effects if the genotyping step indicated it necessary.<sup>228</sup> Here, the Federal Circuit in effect circumvented *Mayo* by sidestepping the first step of the test, even though the “inventive concept” in *Vanda* was ultimately, like in *Mayo*, a natural law.

Although the Federal Circuit was split in *Vanda*, the majority decision tried to take the edge off of the destructive effect of *Mayo* on the medical diagnostic industry by looking to find a way to parse *Vanda* to be distinct from *Mayo* when not enough room existed between the underlying medical diagnostic technologies to make that distinction. As such, what we are left with is the uninspiring position of having to draft patent claims to mirror the seemingly patent eligible method of treatment steps in *Vanda*. That specter leaves us with a position, for example, of having to just cosmetically reword diagnostic method patent claims to recite a *treatment* based

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<sup>224</sup> Jasper L. Tran, *Two Years After Alice v. CLS Bank*, 98 J. PATENT & TRADEMARK OFF. SOC'Y 354, 358–59 (2016); see also Tran & Benevento, *supra* note 15.

<sup>225</sup> See Sachs, *supra* note 19.

<sup>226</sup> *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1133 (Fed. Cir. 2018).

<sup>227</sup> *Id.* at 1121.

<sup>228</sup> *Id.*

on the diagnosis, such that the claim only “touches upon” a law of nature but is directed to a particular method of treatment.<sup>229</sup>

Indeed, at least presently, the best chance of success on such medical diagnostic method claims appears to be one in which practitioners draft claims to recite an application of a natural law specifically enough, such that the claim does not have to satisfy the “significantly more” hurdle of the test in *Mayo*.<sup>230</sup> To draw on the parallel abstract idea exception where claims are eligible if they “recite a specific improvement over prior systems”<sup>231</sup> or enable a computer or device “to do things it could not do before,”<sup>232</sup> patent claims related to an overarching natural law, as medical diagnostic claims commonly are, can sidestep the *Alice* and *Mayo* scrutiny by including language in the claims to particular applications, for example by including a treatment step of the natural law.

Most recently, in another medical diagnostic technology case, the Federal Circuit upheld the eligibility of a claim involving an assessment of a patient’s metabolic characteristics before a dosing regimen is given to the patient.<sup>233</sup> In *Endo Pharma*, the Federal Circuit deemed the claims to be “legally indistinguishable” from those in *Vanda*.<sup>234</sup> Both *Vanda* and *Endo Pharma* recite method of treatment claims to “steps of carrying out a dosage regimen based on the results of . . . testing,” and both “require specific treatment steps.” In both these recent biotechnology decisions, the Federal Circuit points out that the inventors in both *Vanda* and *Endo Pharma* identified a natural law and claimed an application of the relationship they identified, not the natural law itself,<sup>235</sup> and as such both claims were “directed to more than just reciting the natural

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<sup>229</sup> *Id.* at 1136 (“At bottom, the claims here are directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome. They are different from *Mayo*.”).

<sup>230</sup> *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1342 (Fed. Cir. 2018).

<sup>231</sup> *Core Wireless Licensing S.A.R.L. v. LG Elecs., Inc.*, 880 F.3d 1356, 1363 (Fed. Cir. 2018).

<sup>232</sup> *Finjan, Inc., v. Blue Coat Sys., Inc.*, 879 F.3d 1299, 1305 (Fed. Cir. 2018).

<sup>233</sup> *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, 919 F.3d 1347, 1348 (Fed. Cir. 2019).

<sup>234</sup> *Id.* (citing *Vanda Pharm. v. West-Ward Pharm. Int’l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018)).

<sup>235</sup> *Id.* at 1353–54 (citing *Vanda*, 887 F.3d at 1135).

relationship.”<sup>236</sup> Indeed, the Federal Circuit distinguished these cases from *Mayo* by highlighting that the patent claims in *Mayo* “as a whole [were] not directed to the application of a drug to treat a particular disease.”<sup>237</sup> As discussed above, although these may be seen as *Mayo* working, the vast majority of stakeholders in the biotechnology industry see *Mayo* as being destructive and hard to implement and work with.

*Mayo* requires a determination of what is routine conventional activity and what would be “significantly more” and “inventive.”<sup>238</sup> These are all subjective determinations and certainly not one that a person not having ordinary skill in the art should be making. For one, all other key sections of the Patent Act dealing with determining what is new, obvious and whether an invention has been described in sufficient detail, make these key patentability determinations based on the skill level of an ordinary artisan in that field.<sup>239</sup> In the current initial threshold finding of what subject matter is even eligible for a patent, the view of the ordinary skilled artisan is excluded. That is, another problem with the new patent eligibility test is not only the subjectivity of having to determine what is an “inventive concept” in a given technology (traditionally the exclusive domain of Section 102), and what amounts to “significantly more,” is “routine and conventional,” and what “sufficiently transforms,”<sup>240</sup> but that all of this is taking shape without the necessity of having the views of a person of ordinary skill in the art take central role.

The test in *Mayo* is too subjective. It disregards the efforts of skilled innovators and instead allows someone, typically an examiner or judge with no skill in the art, to determine what is

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<sup>236</sup> *Id.* The Court found the combination of the “administering step” and the “wherein clause” “identified the appropriate schedule and dose . . . to administer,” so the claims did “more than just recognize the need to lower or decrease a dose.” *Id.* at 1355.

<sup>237</sup> *Id.* (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 74 (2012)).

<sup>238</sup> *Mayo*, 566 U.S. at 72–73.

<sup>239</sup> See 35 U.S.C. § 112 (2018).

<sup>240</sup> All concepts that are required under the new patent eligibility test under *Mayo* and *Alice*.

“inventive,” “significantly more” and “conventional” in a given field of art.<sup>241</sup> A court determines who the person of ordinary skill in the art is, using relevant factors,<sup>242</sup> however, the patent eligibility determination should involve the person having ordinary skill and not be left to the courts. In the field of medical diagnostic technologies, that ordinary skilled person is typically a doctor who either developed the test as a researcher or one who applies the test in a medical clinical setting, not individuals who have less than ordinary training in that medical diagnostic technology.

What makes the new patent eligibility test all the more terse is that such subjective determinations on patent eligibility are threshold determinations, meaning the invention is not even looked at for true inventiveness or obviousness under the more established objective tests of different parts of the Patent Act, if it is deemed as a preliminary matter to be ineligible under section 101.<sup>243</sup> Furthermore, as discussed above, these determinations have invalidated patents at the early stages of patent litigation, before any substantive deliberations on whether the invention is new or obvious.

Setting aside *Mayo* would be a step in the right direction by restoring the Supreme Court’s older *Diehr* legal framework. Indeed, if the Supreme Court had taken its own approach in *Chakrabarty* and *Diehr* and asked in its deliberations in *Mayo* and *Myriad* whether a claimed invention (considered as a whole and taking into account the contribution of all elements) is found in nature, it would have arrived at a different conclusion regarding these medical diagnostic technologies being essentially a feature of nature. One can only surmise why the Supreme Court decided to follow its much older *Flook* and *Funk Bros.* approach than its own recent reasoning in *Chakrabarty* and *Diehr* and the reliance in industry on these more recent decisions. However, all is not lost as there are legislative options to correct this error.

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<sup>241</sup> *Mayo*, 566 U.S. at 72–73.

<sup>242</sup> *Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007).

<sup>243</sup> See discussion *infra* Part VI.c.



*D. The U.S. Supreme Court's Parallel Law on Patent Eligibility is Inconsistent with Express Statutory Language, and Runs Against the U.S. Constitution*

In situations where the U.S. Constitution has given sole authority to Congress to create laws consistent with that granted authority, the judicial branch's highest court, namely the U.S. Supreme Court, is then limited to that statutory construction.<sup>244</sup> In this context, when the Supreme Court accepts to address a question of patent law related to patent eligible subject matter, the Supreme Court is required to construe the literal meaning of Section 101. However, the Supreme Court's recent jurisprudence, discussed *supra*, has departed from the literal meaning of the statute, instead introducing its own law in the area of patent eligibility by creating broad exceptions to the statute. In so doing, it has become clear to many stakeholders that the Court has conflated, whether intentionally or not, other existing statutory regimes concerning patentability with the threshold issue of patent eligibility.<sup>245</sup> For example, the new law for determining patent eligibility requires an "inventive application" which is traditionally a concept dealt with under the novelty provisions in Section 102 of the Patent Act.<sup>246</sup>

Congress has been consistent with their intent concerning patent eligible subject matter. Indeed, based on the legislative history of Section 101, discussed above, and the fact that multiple Patent Acts passed by Congress over a period of some 200 years, including the

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<sup>244</sup> *Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253–54 (1992). Indeed, the Supreme Court in *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000) has stated that "when the statute's language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms." (citation omitted). The Supreme Court further states in *Connecticut Nat'l Bank*, 503 U.S. at 253–54 that "courts must presume that a legislature says in a statute what it means and means in a statute what it says . . ." and going even further in its *Connecticut Nat'l Bank* decision to be clear that "when the words of a statute are unambiguous, then, this first canon is also the last . . . judicial inquiry is complete." (citation omitted).

<sup>245</sup> Paxton M. Lewis, *The Conflation of Patent Eligibility and Obviousness: Alice's Substitution of Section 103*, 1 UTAH ONLAW: UTAH L. REV. ONLINE SUPP. 13 (2017).

<sup>246</sup> See e.g. *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1334 (Fed. Cir. 2016).

recently passed America Invents Act, have kept the concise language of Section 101 largely unchanged, it is clear that no exceptions were contemplated or intended. In particular, even where Congress recently passed the America Invents Act,<sup>247</sup> the biggest fundamental change in patent law in sixty years, major changes were made to the law on patentability while those on patent eligibility were left largely untouched.<sup>248</sup>

These judicially created exceptions represent a direct affront to the statute and run contrary to Congress's express and implicit intent, as well as their constitutionally mandated task of "Promot[ing] the useful arts."<sup>249</sup> Moreover, the statute clearly states, "[w]hoever *invents or discovers* any new and useful process, machine, manufacture or composition of matter . . . may obtain a patent . . . ."<sup>250</sup> Thus, the Supreme Court's fascination with "inventive concept" fails to consider the word "discovers" in the statute. Not only should there be no exceptions to the four statutory categories of patent eligible subject matter as adumbrated in the Section 101 statute,<sup>251</sup> but that any "invention *or discovery*" related to these four listed categories should suffice to pass this intentionally low threshold finding of whether a subject matter is deemed patent eligible. The Supreme Court fails to acknowledge or discuss, and indeed omits, any focus on the word "discovers" in their patent eligibility jurisprudence. This can reasonably be deduced to be because it does not fit the Supreme Court's test, and yet there is a reason that the statute includes this word. If anything, there is nothing to indicate that the word "discovers" ought to have anything less than equal weight to the word "invents" when the statute expressly recites "invents *or discovers*." And yet, the Supreme Court recently in *Myriad* boldly undermined this, stating

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<sup>247</sup> Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended in scattered sections of 35 U.S.C.).

<sup>248</sup> The current version of the patent eligibility statute, 35 U.S.C. § 101 (2018), states: "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>249</sup> U.S. CONST. art. I, sec. 8, cl. 8.

<sup>250</sup> 35 U.S.C. § 101 (2018) (emphasis added).

<sup>251</sup> *Id.*

“groundbreaking, innovative, or even brilliant *discovery* does not by itself satisfy the § 101 inquiry.”<sup>252</sup>

Moreover, the Supreme Court has itself stated in *Chakrabarty*,<sup>253</sup> “Congress has intended patentable subject matter to include anything under the sun that is made by man.”<sup>254</sup> The Court further explained Section 101 eligibility and its scope by stating that “[w]e have cautioned that courts should not read into the patent laws limitations and conditions which the legislature has not expressed.”<sup>255</sup> In choosing such expansive terms as the four listed statutory patent eligible subject matters modified by the comprehensive “*any*”, “*Congress plainly contemplated that the patent laws would be given wide scope.*”<sup>256</sup> No exceptions were contemplated, so long as any invention or discovery falls within the four categories of patent eligible subject matter that have been listed in the statute for over two hundred years. Contrary to the Supreme Court’s recent interpretation, it is clear from both the express language of the statute and its legislative history, discussed *supra*, that patent eligible subject matter, under the Section 101 statute, should be given wide scope.

The Supreme Court’s recent trilogy of cases on patent eligibility runs counter to the plain meaning of Section 101 and its legislative intent,<sup>257</sup> and is inconsistent with past Supreme Court precedent.<sup>258</sup> Tellingly, these past decisions provide very little analysis of statutory construction or legislative intent.<sup>259</sup> Instead, seemingly out of thin air, the Supreme Court created, and recently greatly expanded the scope of, the “judicial exceptions” to the federal statute that outlines the requirements to patent eligibility. This contrarian jurisprudence by the Supreme Court has caused disarray

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<sup>252</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 577 (2013) (emphasis added).

<sup>253</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

<sup>254</sup> *Bilski v. Kappos*, 561 U.S. 593, 642 (2010) (noting Congress’s intention for statutory subject matter to “include anything under the sun that is made by man”) (quoting *Chakrabarty*, 447 U.S. at 309) (citation omitted).

<sup>255</sup> *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933).

<sup>256</sup> *Chakrabarty*, 447 U.S. at 308 (emphasis added).

<sup>257</sup> See discussion *supra* Part II.

<sup>258</sup> *Golden*, *supra* note 12, at 1770.

<sup>259</sup> *Holman*, *supra* note 197, at 1798.

in technology-driven industries, harming especially innovation in biotechnology and medical diagnostics fields in the United States.

## V. INHIBITION OF BIOTECHNOLOGICAL INNOVATION CAUSED BY EXISTING PATENT ELIGIBILITY LAWS

The U.S. Constitution requires Congress to promote innovation.<sup>260</sup> Developing innovative new biotechnological products takes much time and money; and depends on robust and predictable patent protection, as an inducer for those who wish to take risks and develop new innovative technologies. In the biotechnology, drugs, and medical diagnostics field, the process for developing a new disease therapy begins with basic research done to elucidate the underpinnings of a disease, find potential targets and diagnostic methods to detect various stages of the disease and ways to manage it.<sup>261</sup> The developmental process can take many years and cost between \$2 and \$3 billion.<sup>262</sup> Thus, any radical changes in patent laws that disrupt this enticement of a reward for companies, can greatly affect innovation by technology-driven companies. Sadly, the radical change in patent eligibility laws has greatly affected the medical diagnostics and personalized medicine industries.

In a recent elegant study researchers examined U.S. patent applications that received patent ineligibility rejections.<sup>263</sup> The study then compared that same technology to see if it was also rejected as patent ineligible subject matter in Europe or in China.<sup>264</sup> In their

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<sup>260</sup> U.S. CONST. art. I, sec. 8, cl. 8 recites “promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their *respective writings and discoveries*.” (emphasis added).

<sup>261</sup> Andrea D. Eckhart et al., *Metabolomics as a Key Integrator for “Omic” Advancement of Personalized Medicine and Future Therapies*, 5 *CLINICAL & TRANSLATIONAL SCI.* 285, 285 (2012).

<sup>262</sup> See e.g. Ricky Mullin, *Tufts Study Finds Big Rise in Cost of Drug Development*, *CHEMICAL & ENGINEERING NEWS* (Nov 20, 2014), <https://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html> [<https://perma.cc/TDT9-SX9H>].

<sup>263</sup> 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 (2017).

<sup>264</sup> *Id.*

empirical analysis, the authors questioned whether the impact of the newly adopted patent eligibility laws are resulting in the U.S. surrendering its long-held position as the world leader in new technology development and commercialization.<sup>265</sup> The results should speak volumes to law and policy makers: over 1,700 U.S. patent applications spanning multiple technologies, including everything from drugs and therapeutics, molecular biology, combinatorial chemistry databases, immunology, microbiology, telecommunications, artificial intelligence, to name a few, were all found to be ineligible subject matter for patenting in the U.S. because of the recently expansive Supreme Court patent ineligibility regime. And yet, those very same technologies were all found to be patent eligible subject matter in both the European Union and in China.<sup>266</sup>

In yet another recent study, 4.4 million office actions mailed from 2008 through mid-July 2017 covering 2.2 million unique patent applications were studied using a novel technology identification strategy.<sup>267</sup> The results showed a spike in patent eligibility rejections, especially in the medical diagnostics and software patent applications following the Supreme Court's recent decisions in *Alice* and *Mayo*.<sup>268</sup> Interestingly, although this study did not find a major impact on other fields, it did find that among the patent applications directed to medical diagnostic technologies, the patent eligibility rejection rate grew from 7 percent to 32 percent in

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<sup>265</sup> *Id.*

<sup>266</sup> *Id.* at 941 (reporting that over 1,700 patent applications covering the same inventions were rejected as patent ineligible subject matter in the U.S., and yet were considered eligible in both China and the European Union). Abandoned U.S. patent applications included in fields such as (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); and others.

<sup>267</sup> Colleen Chien & Jiun Ying Wu, *Decoding Patentable Subject Matter*, 2018 PATENTLY-O PATENT LAW J. 10, 10 (2018).

<sup>268</sup> *Id.*

the month after *Mayo* and continued to climb to a high of 64 percent and to 78 percent among final office actions just prior to abandonment.<sup>269</sup>

Moreover, many patent stakeholders have recognized this negative effect of current patent eligibility jurisprudence, especially on the medical diagnostics and personalized medicine field. For example, Senator Coons recently commented that “[t]oday, U.S. patent law discourages innovation in some of the most critical areas of technology, including artificial intelligence, medical diagnostics, and personalized medicine.”<sup>270</sup> To give further context to this statement, a diagnosis of a disease generally occurs *before* treatments and cures can be developed. As such, new medical diagnostic tests typically precede the invention of new innovative medical devices, with the latter typically trailing discovery of new diagnostic tests by about a decade.<sup>271</sup>

It follows that as a result of the negative impact the new patent eligibility laws have on the medical diagnostics industry, far fewer medical devices will be developed in the decade to come. This is yet another unintended consequence of the Supreme Court’s interpretation of Section 101, especially as it relates to the development of newly emerging medical diagnostic technologies and follow-on development of new medical devices. Moreover, as other commentators have pointed out, the recently promulgated legal test for patent eligible subject matter in the U.S. is so opaque as to create substantial doubt on the longevity of long-term research and development and the growth of technological innovation in general, including innovation in the medical diagnostics technologies.<sup>272</sup>

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<sup>269</sup> *Id.*

<sup>270</sup> *Sens. Coons and Tillis and Reps. Collins, Johnson, and Stivers Release Section 101 Patent Reform Framework* CHRIS COONS (Apr. 17, 2019), <https://www.coons.senate.gov/news/press-releases/sens-coons-and-tillis-and-reps-collins-johnson-and-stivers-release-section-101-patent-reform-framework> [<https://perma.cc/HA6Y-U5QZ>].

<sup>271</sup> See Brief for Medtronic, Inc. as Amici Curiae Supporting Neither Party, *Bilski v. Doll* 556 U.S. 1268 (2009) (No. 08-964), Lexis 728.

<sup>272</sup> *Sequenom* Amicus Brief, *supra* note 21, at 13 (describing the Supreme Court’s new test for patent eligibility as overly restrictive).

A. *Profound Uncertainty Precipitated by the Supreme Court's New Patent Eligibility Jurisprudence Has Caused a Downturn in the Biotechnology Industry*

Some have highlighted that because of the recent changes in patent eligibility laws “many inventions are improperly being denied protection and there is significant uncertainty among patentees and patent applicants as to the breadth of the judicially created exclusions from patent eligibility.”<sup>273</sup> Biomedical innovation and in particular medical diagnostics technologies appear to be severely affected, with one Federal Circuit judge commenting that “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>274</sup> Moreover, according to the Biotechnology Industries Organization and the Pharmaceutical Research & Manufacturers of America, this trend presents a “dark cloud overshadowing thousands of issued and maintained biotechnology patents,” which “affects future investment decisions.”<sup>275</sup> Indeed, research has shown that “the courts invalidated more patents in the 14 months since *Alice*, than they did in the five years previous to *Alice*.”<sup>276</sup> This fundamental change in patent eligibility laws has resulted in a disproportionate impact on certain fields, including in medical diagnostic and biotechnology industries.<sup>277</sup>

Moreover, a recent study focused on the fundamental question of whether the Supreme Court’s new patent eligibility legal

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<sup>273</sup> Amy Landers, *The Interconnections Between Entrepreneurship, Science and the Patent System*, 2016 UTAH L. REV. 631, 631–32 (2016) (citation omitted).

<sup>274</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1285 (Fed. Cir. 2015) (Lourie, J., concurring) (denying a petition for rehearing *en banc*).

<sup>275</sup> Brief for the Biotechnology Indus. Org. (BIO) & Pharm. Research & Mfrs. of Am. (PhRMA) as *Amici Curiae* Supporting Appellants and in Favor of *En Banc* Reconsideration at 3, *Ariosa Diagnostics*, 809 F.3d 1282 (Nos. 2014-1139, 2014-1144).

<sup>276</sup> Robert R. Sachs, *#AliceStorm: The Summertime Blues Continue*, FENWICK & WEST (Aug. 29 2015), <http://www.bilskiblog.com/blog/2015/08/alicestorm-summertime-blues-continue.html> [<https://perma.cc/JCA4-AX5G>].

<sup>277</sup> VOICES OF THE BAR, *Where Do We Stand One Year After Alice?* LAW 360 (June 17, 2015), <https://www.law360.com/articles/668773> [<https://perma.cc/34NY-NDEU>] (discussing the impact of *Alice* on industries such as the computer and biotechnology).

framework actually impacted decisions to invest in new technology development and commercialization.<sup>278</sup> A survey of 475 venture capital and private equity investors studied the impact of the Court's patent eligibility cases on their firms' decisions to invest in companies developing technology.<sup>279</sup> This study found that investors overwhelmingly believe patent eligibility is an important consideration when their firms decide whether to invest in companies developing technology. These results are in tune with the notion that patents are an absolutely integral part of capital investment decisions being made to develop newly emerging innovative technologies, including those in the biotechnology and medical diagnostic field. Interestingly, investors view patent eligibility as affecting different industries to different levels and factor this into their capital investment decisions. For example, whereas capital investment in construction related technologies is only minimally affected by the new patent eligibility laws, the new legal landscape is having a huge impact for these same venture capital and private equity firms when they view a potential investment opportunity in biotechnology and medical diagnostics industries.<sup>280</sup>

The investors have been turning away from investing in certain innovation-focused industries, such as biotechnology and software-driven innovations, as a direct result of the Supreme Court's recent decisions on this issue. In particular, about 200 venture capital and private equity investors indicated that the Supreme Court's recent patent eligibility laws had a somewhat negative or very negative effects on their firm's existing investments.<sup>281</sup> 33 percent of investors who focus on technologies reported that the new patent eligibility laws impacted their firms' investment behavior, with

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<sup>278</sup> David O. Taylor, *Patent Eligibility and Investment* (Feb. 24, 2019), Cardozo L. Rev., Forthcoming; SMU Dedman School of Law Legal Studies Research Paper No. 414, <https://ssrn.com/abstract=3340937> [<https://perma.cc/BG8F-WTK3>].

<sup>279</sup> *Id.* (showing that with 74 percent of investors agreed that patent eligibility issue is a key reason to invest or not to invest, and 14 percent disagreeing).

<sup>280</sup> *Id.*

<sup>281</sup> Jason Rantanen, *Guest Post on Patent Eligibility and Investment: A Survey*, PATENTLYO (Mar. 6, 2019), <https://patentlyo.com/patent/2019/03/patent-eligibility-investment.html> [<https://perma.cc/82T8-VVV3>].



these investors reporting that they shifted their capital investments away from companies that were developing new technology related to biotechnology, medical diagnostics and pharmaceutical industries.<sup>282</sup> This 2019 report adds to the data emerging regarding how the Supreme Court's recent decisions on patent eligibility are harming the medical diagnostics industry and innovation economy in the U.S.

Similar statements made by no less than the current acting Director of the USPTO that the *Mayo/Myriad/Alice* test is damaging technological innovation and economic competitiveness by giving stakeholders very significant reason to pause when looking to take risks to develop new emerging technologies because of the *Mayo/Myriad/Alice* framework making for a weak patent protection landscape. Indeed, this data supports recent study by other scholars who highlighted for the first time empirical data to support the fears of many stakeholders that the Supreme Court's recent patent eligibility decisions have set forth a dark future for the U.S. innovation economy, especially as it relates to newly emerging innovative medical diagnostic technologies. Those same technologies that are being routinely rejected in the U.S. as being patent ineligible subject matter are being found to be patent eligible subject matter under the laws in Europe, Australia, and China.<sup>283</sup>

Since the *Alice* decision, it has become much harder to obtain patents in certain industries, especially in the medical diagnostics and software industries. Unfortunately, this has stymied the development of specialized software related to medical diagnostics, such as artificial intelligence (AI) for better deciding and diagnosing disease based on rapid readings and extrapolations of large data sets. The practical results of which have been that innovation goes where it has the best chance to grow. For example, it should be a warning to our law and policy makers that Chinese AI start-ups are now receiving more funding than American AI start-ups. According to a review published in 2018 by MIT Technology Review, of the \$15.2 billion invested in AI startups globally in 2017, 48 percent went to

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<sup>282</sup> *Id.*

<sup>283</sup> *Id.*

China and just 38 percent to America.<sup>284</sup> The U.S. is starting to lose out in capital investments in key industries, such as artificial intelligence which has interconnections to newly emerging medical diagnostic technologies, highlighted by the fact that while the U.S. accounted for 77 percent of such investment before the *Alice* decision, that investment fell to 50 percent three years after the *Alice* decision.<sup>285</sup>

A study published in 2019 that surveyed close to 500 venture capital and private equity firms about how their investment decisions in new technologies changed since the new Supreme Court created patent eligibility laws came into effect, provided critical data for an evidence-based evaluation of how the havoc caused by the Supreme Court has affected investments in new technology development.<sup>286</sup> Professor Taylor makes a compelling evidence-based argument, highlighting the negative impact of the Supreme Court's recent patent eligibility cases, namely *Mayo/Myriad/Alice*, has had on capital investment, and especially so on investment decisions being made on emerging innovative new technologies in the biotechnology, medical diagnostics and pharmaceutical industries. The study points out that these medicine related technologies, even though they are the most impactful in terms of public health, are the most impacted by reduced investments in these industries directly because of the Supreme Court's recent decisions on patent eligibility.<sup>287</sup>

These findings further support the position that Congress should act to overturn the Supreme Court's new eligibility standard to prevent additional lost investment in technological development in the United States. Indeed, given the results of at least the above two

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<sup>284</sup> Jackie Snow, *China's AI startups scored more funding than America's last year*, MIT TECH. REV. (Feb. 14, 2018), <https://www.technologyreview.com/f/610271/chinas-ai-startups-scored-more-funding-than-americas-last-year/> [<https://perma.cc/XT8R-HTKD>].

<sup>285</sup> *Id.*

<sup>286</sup> *The State of Patent Eligibility in America: Testimony of David O. Taylor before the United States Senate Judiciary Committee*, SUBCOMMITTEE ON INTELLECTUAL PROPERTY (June 4, 2019), <https://ssrn.com/abstract=3399699> [<https://perma.cc/U3NN-KMCZ>].

<sup>287</sup> *Id.*

comprehensive recent surveys,<sup>288</sup> it seems likely that the Supreme Court's eligibility decisions have resulted in lost investment in the biotechnology and medical diagnostics fields and that this has delayed or altogether prevented the development of new medicines and diagnostics tests. This coupled with China taking market share from the U.S. in emerging new technologies ought to spur lawmakers to turn their attention to this pressing issue.

## **VI. TO ENCOURAGE PROGRESS OF SCIENCE AND THE USEFUL ARTS, CONGRESS SHOULD REVISIT PATENT ELIGIBILITY LAWS**

The Supreme Court's uprooting of patent eligibility laws by redrawing the boundaries of the judicial exceptions to statutory language has now had several years to settle, and the effects have been devastating. What biotechnology patent experts had predicted has come to pass, with many diagnostic method claims falling within the newly enlarged law of nature exception. Thus, in effect, entities engaged in the research necessary to discover a disease biomarker are now told their work is not even *eligible* for patent protection, a determination with huge business, investment and financial implications. Similarly, the expansion of the product of nature and abstract ideas exceptions have encapsulated a wide breadth of inventions, especially impacting methods used by biotechnology and software companies, for example those running medical diagnostic and bioinformatics technological applications to assess gene expression.

This judicially created high threshold to what is patent eligible subject matter was created out of thin air and directly conflicts with the statutory language of Section 101 and its legislative intent.<sup>289</sup> No better place can this uncertainty be seen than by looking at how the USPTO, the practicing patent bar, the district courts, and the Federal Circuit have interpreted and implemented the Supreme Court's new test for determining patent eligibility.

Patent office examiners were faced with no less than five sets of very detailed USPTO-promulgated guidelines in as many years. The

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<sup>288</sup> *Id.*

<sup>289</sup> *Id.*

latest version of these guidelines reminded examiners that Section 101 is not the sole tool for determining patentability. The Supreme Court similarly has stated that “[t]he § 101 patent-eligibility inquiry *is only a threshold test*”<sup>290</sup> and that the lower courts should “tread carefully in construing this *exclusionary principle lest it swallow all of patent law*.”<sup>291</sup> The Court also warned in *Mayo* that it “has recognized, however, that too broad an interpretation of this *exclusionary principle could eviscerate patent law*. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.”<sup>292</sup> Indeed, Section 101 was not written or intended to forego an analysis under different statutory sections of the Patent Act of whether, for example, major breakthrough medical diagnostics discoveries are new and non-obvious.

Another problem with the Supreme Court’s jurisprudence on this issue is that when coming up with their *Mayo/Alice* framework for determining the contours of their own created exceptions to the explicit statutory language of Section 101, neither of the *Mayo* nor *Alice* decisions addressed the legislative history of Section 101, nor the legislative text or history of the 1952 Patent Act.<sup>293</sup> With *Mayo*, *Myriad*, and *Alice*, all being decided within three years in the past decade, it is clear that there is now wholesale expansion of the scope of the exclusions to patent eligible subject matter. Ironically, several years on, we are exactly where the Supreme Court warned we could be: a situation in which the judicial exceptions to Section 101 have all but “swallowed all of patent law,” and “eviscerated patent law,” as the Court itself warned in both *Mayo* and *Alice*.<sup>294</sup>

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<sup>290</sup> See *Bilski v. Kappos*, 561 U.S. 593, 602 (2010). (emphasis added).

<sup>291</sup> *Alice Corp. Pty Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014) (emphasis added).

<sup>292</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012) (emphasis added).

<sup>293</sup> See *Sequenom* Amicus Brief, *supra* note 21 at 26–28.

<sup>294</sup> *Id.*

*A. Exceptions to Patent Eligibility Laws Are Unnecessary  
Because Existing Statutory Patentability Requirements Prevent  
Patenting a Law of Nature or a Natural Phenomenon*

The Supreme Court decided eight cases in the last forty years concerning the patent eligibility issue, which is far more than on any other patent law doctrine, and it is noteworthy that four of those eight cases were decided recently back-to-back. However, even after these four recent decisions, the Supreme Court has been unable to provide a workable standard that comports with the legislative framework. If anything, as discussed *supra*, the current status of how the Supreme Court views patent eligibility law is directly inconsistent with statutory language and intent and has proved to be unworkable, causing havoc in industries focused on technological innovation such as the medical diagnostics industry.

After the *Mayo* trilogy, the maw of subsequent patent eligibility rulings has greatly restricted the ability to patent certain technologies, including medical diagnostic technologies, and created inconsistency and uncertainty in the patent system. This is no less reflected by the fact that the Supreme Court has recently heard four patent eligibility cases in four years, and two more—*Vanda* and *Berkheimer*—are currently pending *certiorari*, with the Supreme Court inviting the Solicitor General's view.<sup>295</sup> This has all contributed to a harder environment for obtaining a patent, especially since the threshold to assessing whether a subject matter is even patent eligible has been fundamentally raised. This uncertainty has even reached the point where the Supreme Court recently decided that a U.S. patent was merely a “public franchise,”<sup>296</sup> which shocked observers because such a government franchise can technically later be withdrawn.

While the judicial exceptions to Section 101 have had the effect of making it much harder to obtain a patent in certain technologies, and while these judicial exceptions are aligned with the policy of having a smaller number of high-quality patents as opposed to many weak patents, the method with which the Supreme Court has done

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<sup>295</sup> *Id.*

<sup>296</sup> *Oil States Energy Servs., LLC v. Greene's Energy Group, LLC, et al.*, 584 U.S. 1365, 1368 (2018).

this, namely Section 101, has had unintended consequences for the biotechnology and software industries in the United States. For example, the highly regarded Cleveland Clinic and other major public and private research and development institutions are beginning to refrain from researching and developing certain types of innovative technologies directly because they cannot gain meaningful patent protection.<sup>297</sup> Further, no patent protection means investors are unwilling to provide the capital necessary to develop innovative R&D to develop medical and software-driven technologies that can be deployed in hospitals and laboratories.<sup>298</sup>

Thus, the Supreme Court was misguided to so fundamentally change patent eligibility laws. If the concern of the Court has been issues related to preemption as the Court indicated in *Alice*, and if the goal therefore has been to not allow patents for the judicially-created exceptions, the Supreme Court should have refrained from so vastly expanding the scope of these exceptions in their three recent back-to-back cases. Instead, the focus should have remained on other statutes, namely Section 102 (requiring the invention to be *new*), Section 103 (requiring the invention to be *nonobvious*), and Section 112 (requiring a detailed *description* of the invention) to evaluate patent claims at issue.<sup>299</sup> Indeed, this article advances the position that this strategy would simplify the subject matter eligibility analysis for the USPTO, courts, patent owners, practitioners and the public alike by prohibiting any determination of “inventiveness”<sup>300</sup> and patentability issues under Sections 102, 103, and 112 from the Section 101 analysis. As is developed *infra*,<sup>301</sup> there are possible fixes to the current untenable status quo.

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<sup>297</sup> Brenden Gingrich & Simone Ward, *Cleveland Clinic II: Has the Federal Circuit Undermined Patent Office Guidance and Eliminated an Important Tool for Patenting Diagnostics?*, JDSUPRA (May 9, 2019), <https://www.jdsupra.com/legalnews/cleveland-clinic-ii-has-the-federal-23420/> [<https://perma.cc/SLC9-U6B6>].

<sup>298</sup> *Id.*

<sup>299</sup> 35 U.S.C. §§ 102–03, 112 (2018) (emphasis added).

<sup>300</sup> Or “inventive concept” as is required under the *Mayo/Alice* framework.

<sup>301</sup> See discussion *infra* Part VI.c.

Indeed, the Supreme Court itself has made this clear: “[t]he § 101 patent-eligibility inquiry is *only a threshold test* . . . the claimed invention must also satisfy ‘the conditions and requirements of this title.’ Those requirements include that the invention be novel, see § 102, nonobvious, see § 103, and fully and particularly described, see § 112.”<sup>302</sup> In *Mayo*, the U.S. government urged the Supreme Court not to depart far from the statutory language and to keep a low threshold for determining patent eligibility. They urged the Court to leave it to the parts of the Patent Act best suited to determine patentability, namely novelty under Section 102 and obviousness under Section 103.<sup>303</sup> Indeed, others have also pointed out that provisions in the Patent Act should be used as the tool for invalidating claims, not Section 101.<sup>304</sup>

Yet, in its *Mayo* decision, the Supreme Court disagreed with the U.S. government’s position, stating that it would make the “law of nature” exception to Section 101 a “dead letter” and is not consistent with *Bilski*, *Diehr*, *Flook*, and *Benson*.<sup>305</sup> With the exception of *Chakrabarty*, the Supreme Court has hardly ever discussed the legislative history of Section 101,<sup>306</sup> and instead has backed its more activist current jurisprudence on Section 101 under *Mayo* by merely referencing some of their own case law. The Court in *Mayo* refused “the Government’s invitation to substitute §§ 102, 103, and 112 inquiries for the better-established inquiry under § 101,” and resisted calls by the government in *Mayo* to heavily reduce the influence of Section 101 and rely more on the traditional patent-eligibility inquiry under Sections 102, 103, and 112. In the Court’s view, shifting the inquiry to the other provisions of the Patent Act “risks creating significantly greater legal uncertainty, while

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<sup>302</sup> *Bilski v. Kappos*, 561 U.S. 593, 602 (2010) (emphasis added).

<sup>303</sup> See generally Brief for the United States as Amici Curiae Supporting Neither Party at 10, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

<sup>304</sup> Jeremy C. Doerre, *Is There Any Need to Resort to a § 101 Exception for Prior Art Ideas*, PATENTLY-O PATENT L.J. 10 (2019).

<sup>305</sup> *Mayo*, 566 U.S. at 89.

<sup>306</sup> See generally *Diamond v. Chakrabarty*, 477 U.S. 303 (1980) (referring to the legislative history of 35 U.S.C. § 101, it is only limited to interpreting the word “manufacture” and “composition of matter” since this case related to a modified bacterium that could process and break down hydrocarbons).

assuming that those sections can do work that they are not equipped to do.”<sup>307</sup>

However, many scholars, including the present author, disagree, instead believing that Section 101 is not the “better established inquiry.” As the Supreme Court itself has stated in *Bilski*, “[t]he § 101 patent-eligibility inquiry is only a threshold test.”<sup>308</sup> Justice Rehnquist, writing for the court in *Diehr*, even explained that considering novelty under Section 101 was wholly inappropriate.<sup>309</sup> Seven years after the radical *Mayo* decision, the results are now self-evident and point to uncertainty in this area of patent law. There is no question that this stifles technological innovation and the development of new technology and commercialization, especially in the medical diagnostics industry in the United States.<sup>310</sup> Sadly, the *Mayo* decision has resulted in considerations of novelty, non-obviousness and the description of an invention, all being made under the Section 101 patent eligibility umbrella. The result has greatly elevated the importance of Section 101, while diminishing the other traditionally more stringent statutory requirements of the Patent Act. This is made even more problematic by the fact that while the other key provisions of the Patent Act, for example novelty and obviousness, take into consideration the ordinary level of skill in the art in an effort to have an objective test, the new patent eligibility test is very subjective and does not require the involvement of the ordinary skilled artisan. Practically, this can result in judges and examiners who have less than ordinary skill in a particular technology, for example a medical diagnostic for liver cancer, making subjective determinations of what the “inventive concept” is, what amounts to “significantly more,” and what qualifies as “conventional and routine activity” in that given field of art.

Another problem of the current *Mayo/Alice* patent eligibility test is that newly emerging breakthrough technologies, especially those in the medical diagnostic field, fail at this preliminary threshold step

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<sup>307</sup> *Mayo*, 566 U.S. at 66.

<sup>308</sup> See *Bilski v. Kappos*, 561 U.S. 593, 602 (2010).

<sup>309</sup> See *Diamond v. Diehr*, 450 U.S. 175, 188–89 (1981).

<sup>310</sup> Taylor, *supra* note 23, at 2155.



and therefore are never commercialized or brought to market. This is because the Supreme Court, contrary to the statute, made the threshold of what is patent eligible subject matter so high. The test fails to make substantive determinations of the technology in view of a single prior art reference or what others have done to render any such breakthrough obvious. Also, the current *Mayo/Alice* patent eligibility framework does not factor in claim construction to any great level. This is even though such claim construction, including using intrinsic and extrinsic evidence, is a key feature of a patentability analysis.

If the Supreme Court is adamant about maintaining its judicial exceptions to Section 101, a potential way forward would be for the Supreme Court to go back to the law of patent eligibility that existed before it unilaterally expanded the scope of patent ineligible subject matter in its *Mayo/Myriad/Alice* trilogy of cases. Indeed, by disrupting a quietly settled area of law through their 21<sup>st</sup> century Section 101 jurisprudence, the Supreme Court has magnified the focus on Section 101 and exposed the strident inconsistencies on how even the Court itself views patent eligible subject matter.<sup>311</sup> So much so, that the Federal Circuit in their first decision involving biotechnology and medical diagnostics after the Supreme Court's *Mayo* decision, ruled that an improved method of cryopreserving hepatocytes obtained from liver surgery or organ donors is patent eligible subject matter.<sup>312</sup> In so doing, interestingly, the Federal Circuit chose to largely ignore the Supreme Court's *Mayo*, *Myriad* and *Alice* line of cases and instead follow the Supreme Court's *Chakrabarty* and *Diehr* decisions.

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<sup>311</sup> In *Mayo*, the Court held that if the concept is not inventive and otherwise ineligible, the addition of conventional steps will not overcome a patent ineligibility rejection. 566 U.S. at 66. In direct contrast, in *Diehr*, the Court held that "it is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constitutes of the combination were well known and in common use before the combination was made." 450 U.S. at 188.

<sup>312</sup> *Rapid Litigation Mgmt., Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016).

The uncertainty on what the patent eligibility test is and how to apply it has sadly resulted in the invalidation of some breakthrough inventive technologies,<sup>313</sup> reflected, for example, by how the Federal Circuit recently viewed the breakaway medical diagnostic innovation in *Ariosa*.<sup>314</sup> For example, in that case discovering unique fetal DNA in the blood of a pregnant mother and inventing a new method for non-invasively determining important fetal characteristics, as discussed below, should not fail the patent eligibility test under Section 101, as it has recently.<sup>315</sup> Such a medical diagnostic test may not be patentable if routine methods were used to develop it, but the mere discovery itself ought to pass the Section 101 threshold inquiry. The patentability requirements of novelty and non-obviousness as listed in the other statutes of the Patent Act, for example, ought to be what determines whether such a discovery should obtain a U.S. patent or not. That is, patent eligibility and patentability are not the same concept.

Judge Linn stated in a concurring opinion in *Ariosa* that prior to the invention, prenatal diagnosis involved invasive techniques that could potentially harm the fetus and increase the chance of a miscarriage. In his view, “[b]ut for the sweeping language in the Supreme Court’s *Mayo* opinion,” he saw “no reason, in policy or statute . . . why this breakthrough invention should be deemed patent ineligible.”<sup>316</sup> After *Ariosa* was decided the same invention was found in November 2017 to be patent eligible subject matter by the highest court of the United Kingdom and, as recently as in August 2019, that same invention was also found to be patent eligible by the highest court of Australia. With the U.S. Supreme Court refusing to grant *certiorari* in *Ariosa*, this technology, and many other medical diagnostics technologies like it, remain patent *ineligible* subject matter under current law in the U.S.

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<sup>313</sup> Michael A. Sanzo, *Patent Eligibility in Biotechnology: a Look Under the Hood*, 45 AIPLA Q.J. 1 (2017); see also Michael A. Sanzo, *The Patenting Of Gene Based Diagnostic Assays In A Post Mayo And Myriad World*, 16 J. MARSHALL REV. INTELL. PROP. L. 1 (2016).

<sup>314</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375–76 (Fed. Cir. 2015).

<sup>315</sup> *Id.*

<sup>316</sup> *Id.* (emphasis added).

As it stands, the four recent Supreme Court decisions—*Bilski*, *Mayo*, *Myriad*, and *Alice*—have dramatically narrowed the scope of patent protection for innovation-dependent industries, such as medical diagnostics, by significantly expanding the judicially created exceptions to subject matter that is listed as patent eligible in the statute. Thus, there is growing discord among patent stakeholders, precipitated by the lack of clarity regarding the scope of subject matter that is eligible for a patent under Section 101. For example, David Kappos, the former Director of the USPTO, called for Congress to repeal the entire Section 101 statute from the Patent Act on the basis that it is unworkable. Additionally, the current acting Director of the USPTO, as recently as in 2019 and after releasing a dizzying fifth set of guidelines to patent examiners in as many years,<sup>317</sup> indicated that the landscape of patent eligible subject matter remains troubling. Several senior judges have also voiced their concern with current jurisprudence on Section 101, as discussed above.<sup>318</sup> Some propose amending the statute so as to not be out of line with the Supreme Court’s promulgated exceptions to the statute.<sup>319</sup>

The time is ripe for Congress to revisit the Section 101 statute of the Patent Act. This article proposes a middle ground that does not repeal the statute that has largely remained unchanged for over 200 years, but equally, does not propose amendments to the statute in order to keep the Supreme Court’s parallel jurisprudence in place. Instead, it advocates for a return to the statutory language and intent and suggests an option for Congress to do away with the three exceptions that the Supreme Court has unilaterally foisted upon Section 101. This position is very similar to the one taken by Judge Newman of the Federal Circuit in *Alice*.<sup>320</sup> In some ways it is also similar to the position of the Intellectual Property Owners

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<sup>317</sup> See U.S. PATENT & TRADEMARK OFF., SUBJECT MATTER ELIGIBILITY EXAMPLES: ABSTRACT IDEAS (Jan. 7, 2019), [https://www.uspto.gov/sites/default/files/documents/101\\_examples\\_37to42\\_20190107.pdf](https://www.uspto.gov/sites/default/files/documents/101_examples_37to42_20190107.pdf) [<https://perma.cc/EF62-HVQZ>].

<sup>318</sup> See discussion *supra* Part IV.b.

<sup>319</sup> See discussion *infra* Part VI.c.

<sup>320</sup> See *CLS Bank Int’l v. Alice Corp. Pty*, 717 F.3d 1269, 1321–27 (Fed. Cir. 2013) (Newman, J., concurring in part and dissenting in part).

Association (“IPO”) which encourages an amendment to the statute, stating that the “proposed legislation will: (a) reverse the Supreme Court ruling and restore the scope of subject matter eligibility to that intended by Congress; (b) define subject matter eligibility more clearly and in a technology-neutral manner; . . . and (d) simplify the subject matter eligibility analysis.”<sup>321</sup>

Although the Supreme Court has previously overruled its own interpretation of patent eligibility,<sup>322</sup> it appears the Court is unwilling to overrule or at least revise its recent incoherent decisions, most notably in *Mayo*, evidenced by the fact that the Court denied *certiorari* in *Ariosa*, an opportune moment for the Court to correct itself.<sup>323</sup> In this latter example, over twenty amicus briefs from a variety of interested parties and industries were filed and yet the Supreme Court did not even ask for the Solicitor General’s view. Jurisprudence on patent-eligible subject matter, governed by Section 101, has currently entered a “maw” and the situation will only get worse as new technologies advance because these new advances will challenge courts’ interpretations of certain aspects of patent law.<sup>324</sup> There is no question that current law governing patent-eligibility under Section 101 is uncertain and in upheaval, and as many stakeholders argue, there is a need for action from Congress.<sup>325</sup>

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<sup>321</sup> INTELL. PROP. OWNERS ASSOC., PROPOSED AMENDMENTS TO PATENT ELIGIBLE SUBJECT MATTER UNDER 35 U.S.C. § 101, 2 (Feb. 7, 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/W6YA-26F3] (emphasis added).

<sup>322</sup> See *Diamond v. Chakrabarty*, 447 U.S. 303, 316–17 (1980); *Diamond v. Diehr*, 450 U.S. 175, 191–92 (1981). These decisions effectively overruled *Flook*. See *id.*

<sup>323</sup> *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 136 S. Ct. 2511, 2511 (2016) (denying petition for writ of certiorari).

<sup>324</sup> See Bernard Chao, *Finding the Point of Novelty in Software Patents*, 28 BERKELEY TECH. L.J. 1217, 1224 (2013); Jeremy D. Roux, *The Supreme Court and Section 101 Jurisprudence: Reconciling Subject-Matter Patentability Standards and the Abstract Idea Exception*, 2014 U. ILL. L. REV. 629, 658 (2014).

<sup>325</sup> Shahrokh Falati, *To Promote Innovation, Congress Should Abolish the Supreme Court Created Exceptions To 35 U.S. Code § 101*, 28 TEX. INTELL. PROP. L.J. 1 (2019).

*B. Need for Harmonization: U.S. Laws on Patent Eligibility at Odds with Other Industrialized Nations' Laws*

There are no statutes in the U.S. that have defined the kind of inventions or discoveries that would fall outside the ambit of patentable subject matter.<sup>326</sup> Indeed, the only category of invention explicitly excluded by statute as patent ineligible subject matter is the more recent recitation of nuclear weapons as a category for which it is impermissible to obtain a patent.<sup>327</sup> This contrasts European law where patent legislation explicitly lists the exceptions to patentable subject matter.<sup>328</sup> Thus, unlike in Europe where there is clear explicit legislation, in the United States it is left to the courts to outline what kind of subject matter can and cannot be eligible for a patent.

To highlight that the time is ripe for the U.S. Congress to act to reign in the caustic harm that the judicially created exceptions to Section 101 are causing to U.S. businesses and position on the global innovation economy, one can review how other industrialized countries' patent laws address the same legal question. To make this point, I focus on one recent example of a new medical diagnostic method and discuss its treatment by patent laws of three industrialized nations, namely the United States, the United Kingdom and Australia.

In this example, the technology concerned whether the discovery that there are fragments of fetal DNA in the blood a pregnant woman and that this can be used to provide a non-invasive way to determine fetal characteristics was patent eligible subject matter or not. The test itself has applications of great value, namely

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<sup>326</sup> Even though the language of Section 101 has largely remained the same for over 200 years, there reference to “invents or discovers” focuses on what category is allowable subject matter, but there is no reference to what would not be allowed as patent eligible subject matter in any U.S. statute, including Section 101. *See* 35 U.S.C. § 101 (2018).

<sup>327</sup> Perhaps tellingly, the Patent Act does not actually include this exclusion. The exclusion is codified in the Atomic Energy Act, at 42 U.S.C. § 2181(a) (2018).

<sup>328</sup> European Patent Convention art. 52(3)–53, Oct. 5, 1973 (reciting the exceptions to patentability, albeit the Europeans have strong views on their own system of providing these exceptions).

it is an improved technique that does not require taking fetal or placental samples for screening for chromosomal abnormalities that could affect a baby's health and development, such as trisomy 21 (Down syndrome), sex chromosome aneuploidies, determining the gender of a baby and the like. Since the commercial potential for the prenatal diagnostic market is enormous, patent litigation ensued between the innovator and copycats for this same technology in several international jurisdictions, including in the United States, United Kingdom, and Australia.

The U.S. position has been that this diagnostic method is patent ineligible subject matter under Section 101 because the presence of the cell free fragments of fetal DNA in maternal blood was *a natural phenomenon* and the claims did not contain *an inventive concept* sufficient to "transform" the natural phenomenon into a patent eligible subject matter.<sup>329</sup> Thus, the invention is patent ineligible because it falls under the judicially created exception to patent eligible subject matter for being "naturally-occurring."<sup>330</sup>

Yet, in direct contrast to the U.S. position, Australia's High Court decided in August 2019 that this same discovery *is* patent eligible subject matter.<sup>331</sup> Additionally, the High Court of Justice in

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<sup>329</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015). Here, a U.S. patent governing a method of detecting fetal DNA in the pregnant mother's serum was found to be directed to patent ineligible laws of nature and natural phenomenon, and thus the patent was deemed to be invalid. The Federal Circuit decided that the patent claims were generally directed to detecting the presence of a naturally occurring thing or a natural phenomenon, cell-free fetal DNA in maternal blood. Moreover, the Federal Circuit found that the other elements of the claim, including using PCR to amplify the DNA from blood, did not transform the ineligible patent claim into a patent-eligible application of the natural phenomenon, reasoning that those additional elements were well-understood, conventional activities.

<sup>330</sup> *Id.*

<sup>331</sup> *Sequenom, Inc. v. Ariosa Diagnostics, Inc.* [2019] F.C.A. 1011 (Austl.) (*Ariosa* suggested that the Australian Court should follow the U.S. position. Justice Beach's response was an emphatic, "I hardly think so." In fact, in considering the Australian High Court *Myriad* decision, Justice Beach stated that "in nature, the presence of cffDNA in the maternal blood has not and cannot be detected without human action. Accordingly, unlike the claims considered in *Myriad*, the invention claimed adds to human knowledge and involves the suggestion of an act to be done which results in a new result, or a new process.").

the United Kingdom, similar to Australia's High Court, recently also heard this same legal issue, involving the same technology.<sup>332</sup> There, in 2017, Justice Henry Carr of the U.K. High Court, similar to Justice Beach's August 2019 decision from Australia's High Court, found that such a patent claim *is* patent eligible subject matter.<sup>333</sup>

The consistency between the U.K.'s highest court's decision in November 2017 and Australia's highest court's decision in August 2019 on this same legal issue involving the same technology, finding the technology to be patent eligible subject matter in both U.K. and A.U., greatly contrasts current U.S. law and puts the U.S. position directly at odds with positions taken on the same legal issue by other industrialized nations with well-developed legal systems. Practically, this difference has had negative results for the U.S. leadership role in innovation, especially so in the biotechnology and medical diagnostics field as evidenced by a recent study.<sup>334</sup> Further, as Judge Randall Rader, recently retired former Chief Judge at the CAFC noted recently, "[f]rankly, there is no country in the world

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<sup>332</sup> *Illumina, Inc. v. Premaitha Health PLC* [2017] EWHC 2930 (Pat). Although they did not receive their typical top-billing in this England and Wales Patent Court case, Ariosa and Sequenom were still named as claimants.

<sup>333</sup> Justice Henry Carr of the High Court of Justice in Great Britain wrote: "I do not accept that, properly construed, claim 1 is a claim to a discovery as such. The claims are not directed to information about the natural world, but rather to a practical process, namely a 'detection method' which uses information about the natural world. Claim 1 is directed to the detection of foetal DNA in a sample of plasma or serum. Such samples do not exist in the natural world and must be artificially created. The claimed method of detection is also an artificial process which does not exist in the natural world. The claim is to a practical process of implementing a discovery, for practical applications. The actual contribution, as a matter of substance, does not fall solely within the excluded subject matter and is technical in nature."

<sup>334</sup> Madigan & Mossoff, *supra* note 263, at 953 (reporting that over 1700 patent applications covering the same inventions were rejected as patent ineligible subject matter in the U.S., and yet were considered eligible in both China and the European Union). Abandoned U.S. patent applications included in fields such as (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); and others.

that does what we do here. We have once again, set ourselves on a course which is out of harmony with the rest of the world's intellectual property standards."<sup>335</sup>

### C. *Legislative Options and Ripe Time for Congress to Act*

The impact of the new patent eligibility legal regime the Supreme Court has ordered has been very negative. Although patent defendants may rejoice, the consequences on U.S. private and public enterprises conducting biomedical research, including those aiming to commercialize new medical diagnostics, has been seismic. This radical change in law has deterred the commercialization of certain biomedical inventions because of the weakened patent protection for those technologies and a disruption of the business ecosystem in which they and their partners operate, including having a direct negative effect on capital investment into such projects, as discussed above.<sup>336</sup> As a result, there have been recent proposals to legislate and change the laws governing patent eligible subject matter.

As of the beginning of 2020, the U.S. Congress is considering making changes to patent eligibility laws. As an indication of forthcoming changes to the law, Senator Chris Coons (D-DE) recently said in at a conference that subject matter eligibility is “an area where the jurisprudence is insufficiently clear, and which may necessitate congressional action to provide clarity and consistency.”<sup>337</sup>

As 2020 begins, since the Federal Circuit has been unable or unwilling to define the contours of what is and is not patent eligible subject matter in view of the Supreme Court's recent jurisprudence on the issue, a group of Senators and House of Representatives are presently considering fixing the Supreme Court-created patent

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<sup>335</sup> Eli Mazour, *The Most Interesting Man in the Patent World Fights to Improve America's Patent System*, IPWATCHDOG (Sept. 19, 2017), <https://www.ipwatchdog.com/2017/09/19/most-interesting-man-patent-world/id=87983/> [<https://perma.cc/26YE-QFH9>].

<sup>336</sup> *Id.*

<sup>337</sup> Chris Coons, *A Few Thoughts on the Supreme Court's Section 101 Jurisprudence*, IPWATCHDOG (Feb. 8, 2017), <https://www.ipwatchdog.com/2017/02/08/thoughts-supreme-courts-section-101-jurisprudence/id=78166/> [<https://perma.cc/9J3G-2BGM>].



eligibility problem<sup>338</sup> and they have released a bipartisan framework for Section 101 reform in which they outline specific goals.<sup>339</sup> The lawmakers seek to come up with legislative language, with the anticipation being that bills will be introduced in 2020 in both the House and the Senate. Many major patent stakeholders are also encouraging Congress to act; for example, both the Intellectual Property Owners Association and the American Intellectual Property Law Association, both well-regarded professional IP associations, have written to Congress asking the lawmakers to undo the *Mayo/Alice* framework through legislation.<sup>340</sup> This is an opportune time for Congress to do so because the time is ripe and it is necessary. The time may be ripe, but what should Congress do regarding patent eligibility?

Professors Lefstin and Menell have proffered a legislative proposal of focusing on a “practical application” of an abstract idea, natural law, or natural phenomenon.<sup>341</sup> The proposal would be to align with pre-*Mayo* jurisprudence. This position also has some backing from the ABA’s Section of Intellectual Property Law, evidenced by their submission of comments to the USPTO that

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<sup>338</sup> As of Winter 2019, Senator Chris Coons (D-DE), Senator Thom Tillis (R-NC), Congressman Doug Collins (R-GA) and Congressman Hank Johnson (D-GA) currently have a four-principle framework for legislatively fixing patent eligibility laws. *Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Bill Text to Reform Section 101 of the Patent Act*, THOM TILLIS, U.S. SEN. FOR N.C. (May 22, 2019), <https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act> [<https://perma.cc/LM3A-GPAU>].

<sup>339</sup> Warren Woessner, *Senate Committee Releases Outline for Section 101 Reform*, PATENTS4LIFE (Apr. 18, 2019), <https://www.patents4life.com/2019/04/senate-committee-releases-outline-section-101-reform/> [<https://perma.cc/QE7Y-FLDW>].

<sup>340</sup> Dennis Crouch, *AIPLA On Board with Statutory Reform of 101*, PATENTLYO (May 16, 2017), <https://patentlyo.com/patent/2017/05/aip-la-statutory-reform.html> [<https://perma.cc/946B-RDXK>]. For an analysis of the different proposals from the Intellectual Property Owners Association (IPO), the American Intellectual Property Law Association (AIPLA), and the American Bar Association Section of IP Law (ABA), see Brett Winborn, *Patent Owners Versus The Supreme Court: Changing The Law Underlying Patent Eligible Subject Matter*, 44 J. CORP. L. 187 (2018).

<sup>341</sup> *Sequenom Amicus Brief*, *supra* note 21.

largely agree with this “practical application” test.<sup>342</sup> Moreover, Professors Lefstin and Menell, well-known patent law scholars, submitted a supplementary statement, as recent as in Summer of 2019, to the Committee on the Judiciary, Subcommittee on Intellectual Property Hearings on “The State of Patent Eligibility in America.”<sup>343</sup>

Yet, as reasonable and elegant as this “practical application” test is to other IP scholars, including the present author who is a fan of the proposal, from a pure practical standpoint, it may be hard to effectively and universally implement. This would likely be exasperated by the fact that patent examiners look for a test to easily apply when examining patent applications in the trenches with little time and many Office Actions to write. Indeed, to have some 10,000 patent examiners of all education and work backgrounds and over 200 Administrative Patent Judges at the USPTO, all trained to effectively and uniformly examine patent eligibility issues based on what would remain a convoluted subjective legal framework may be asking too much. The reality is that it is likely overly ambitious to expect patent examiners to perform this examination process consistently, in a technology-neutral, objective manner.

In contrast, a recent article took an empirical approach and found that the two-step test for patent eligibility may not be as impossible to administer as many have suggested and in fact the test may be clearer for certain types of claims than for others.<sup>344</sup> However, it is noteworthy that this study used a survey of 231 patent attorneys, which may not be reflective of the over 10,000 patent examiners, the majority of which do not have a formal legal background.<sup>345</sup> Thus, how clear the test is and how easy it is to apply remains up for

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<sup>342</sup> See Letters dated January 18, 2017 and March 28, 2017, from Donna P. Suchy, Section Chair, Section of Intell. Prop. Law, Am. Bar Ass’n, to the Under Sec’y of Commerce for Intell. Prop. & Dir. of the USPTO. The ABA submitted a formal reform proposal in May 2017.

<sup>343</sup> Peter S. Menell & Jeffrey A. Lefstin, *Reforming Patent Eligibility: Supplementary Statement of Professors Jeffrey A. Lefstin and Peter S. Menell*, UC HASTINGS RESEARCH PAPER NO. 336 (2019).

<sup>344</sup> See generally Jason D. Reinecke, *Is the Supreme Court’s Patentable Subject Matter Test Overly Ambiguous? An Empirical Test*, 2019 UTAH L. REV. 581 (2019).

<sup>345</sup> *Id.*

debate, with majority of stakeholders finding it more cumbersome and unpredictable than not.

It may be noteworthy here to state that there are a minority group of scholars who argue to the contrary on this issue. For example, Professor Landers' recent article studying the interconnections between entrepreneurship, science and patents proposes a more nuanced view than the linear model of innovation that directly links patent law's importance to basic science and innovation, and that the recent restrictive nature of the patent eligibility laws has the potential to maximize available information for entrepreneurship and thereby promote innovation and not stifle it as the majority of scholars have argued.<sup>346</sup> However, most scholars recognize the need for action, describing the current test in a variety of ways, including it being "too philosophical and policy based to be administrable"<sup>347</sup> and "a foggy standard cloaked as a rule."<sup>348</sup>

There is a clear chorus amongst the patent bar, drumming for change to the current patent eligibility laws. Other proposals, including one from former USPTO Director Kappos, have included the wholesale repealing of the entire Section 101 statute from the Patent Act on the basis that it is unworkable and is outdated since it has virtually remained unchanged since the 18th century. And although the Intellectual Property Owners Association's position may have evolved, they proposed amending the statute and that the

proposed legislative language would address patent-eligibility concerns by reversing the Supreme Court decisions and restoring the scope of subject matter eligibility to that intended by Congress . . . ; defining the scope of subject matter eligibility more clearly and in a technology-neutral manner; and simplifying the . . . eligibility analysis.<sup>349</sup>

This article respectfully presents yet another option, and one I rank highly on available options, and that is to encourage the lawmakers to look at Europe or even Japan, both equally

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<sup>346</sup> Landers, *supra* note 273.

<sup>347</sup> Dennis Crouch, *Eligibility: Explaining the IPO Legislative Proposal*, PATENTLYO (Feb. 9, 2017), <https://patentlyo.com/patent/2017/02/eligibility-explaining-legislative.html> [<https://perma.cc/7F5H-2T4H>].

<sup>348</sup> Michael Risch, *Nothing Is Patentable*, 67 FLA L. REV. F. 45, 45 (2015).

<sup>349</sup> *Id.*; see also Michael Woodward, *Amending Alice: Eliminating the Undue Burden of "Significantly More,"* 81 ALB. L. REV. 329 (2017).

industrialized nations with developed legal frameworks, and analyze their patent laws as a model framework on this patent eligibility issue.

At the outset, the European Patent Office (“EPO”), much like the USPTO, considers that the discovery of a natural phenomenon not to be patent eligible. However, unlike U.S. law, the EPO takes the view that a patentable invention can derive from a practical use of that discovery,<sup>350</sup> such as its use in a method of diagnosis. As an example, discovering a naturally occurring correlation between a biomarker for cancer X can focus on the use of that discovery in a new method to diagnose cancer X. Thus, in Europe, method claims directed at diagnosing a disease by first detecting the presence or levels of a biomarker in a patient *are* patentable, even if the correlation itself is naturally occurring and not patentable.

Moreover, under their framework, the EPO determines patentability based on two factors: a patent eligibility hurdle<sup>351</sup> (akin to our Section 101) which requires the claimed subject matter to have a technical character; and a patentability hurdle<sup>352</sup> (akin to our sections 102 and 103), which requires the claimed subject matter to contribute a technical solution to a technical problem. Moreover, instead of undergoing a *Mayo* trilogy analysis as discussed above, any application claiming an invention that falls into a category prohibited by the European Patent Convention is expressly rejected by the EPO.<sup>353</sup> In drawing parallels, any legislative fixes to current U.S. patent eligibility laws, could model itself to be a “threshold,” like Article 52 of the European Patent Convention, and thereby list subject matter that doesn’t possess technical character, such as mathematical methods, methods for performing mental acts or doing business, and presentations of information.

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<sup>350</sup> *Guidelines for Examination Part G-II 3.1*, EUR. PAT. OFF., [https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g\\_ii\\_3\\_1.htm](https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_3_1.htm) [<https://perma.cc/6JR9-RFUH>] (last visited Mar. 22, 2020).

<sup>351</sup> Eur. Pat. Convention arts. 52, 54, Nov. 29, 2001, 1065 U.N.T.S. 199.

<sup>352</sup> *Id.*, arts. 54, 56.

<sup>353</sup> The European Patent Convention specifically excludes programs for computers, methods of treatment or diagnosis of the human or animal body, and plant and animal varieties. Notably, the list of unpatentable categories is considered non-exhaustive.

This may be an easier approach to implement in practice, especially by the very large number of patent examiners at the USPTO. Indeed, it appears that as 2020 begins, a bipartisan framework for Section 101 reform is under consideration by a number of Senators and House Representatives, and one of their goals is indeed to name a short exclusive list of categories, much like in Europe. Under consideration are to list and thereby explicitly exclude mental activities, pure mathematical formulas, products that exist solely and exclusively in nature, fundamental scientific principles and economic principles.<sup>354</sup>

Instead of focusing on the idea of abolishing *in toto* the Supreme Court created exceptions to the statute, other options include amending the Section 101 statute itself in order to focus on the word “useful” by deleting the word “new”. The aim here would be to clearly highlight that Section 101 is separate from and different to the “new” requirement of Section 102, thereby obviating the most common criticism of the *Mayo* test. This would avoid having to determine what is routine conventional activity and what would be “significantly more” and “inventive” (or how *new* the claimed invention is), thereby setting aside the highly disruptive Supreme Court’s recent *Mayo* decision and restoring the Supreme Court’s older *Diehr* legal framework.

Indeed, other options would be to go a step further and codify *Diehr* and expressly state that in order to determine patent eligibility under Section 101, novelty under Section 102 and obviousness under Section 103, must not be considered, and thus also highlighting that subjectively determining what is and is not routine and conventional activity has no place in a Section 101 patent eligible subject matter analysis. Finally, to harmonize Section 101 with other parts of the Patent Act, namely the Section 102 novelty section, the Section 103 obviousness section, and the Section 112 definiteness section, Section 101 could be amended to include parallel language that focuses on the person having ordinary skill in the art, much like all the other sections of the Patent Act. This would help to remove the presently subjective patent eligibility question out of the hands of patent examiners at the USPTO and judges in the

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<sup>354</sup> See discussion *supra* Part I.

courts and make it more an objective analysis in parallel fashion to other sections of the Patent Act.

It remains up for discussion what the final bills will say and how lawmakers will attempt to remedy the current status of affairs. One thing remains obvious: Section 101 cannot remain as is because America's leadership position on innovation and entrepreneurial new technology development and commercialization is at stake.

## VII. CONCLUSION

The Patent Act defines four independent categories of subject matter that are eligible for patent protection, namely processes, machines, manufactures, and compositions of matter.<sup>355</sup> The express statutory language and its legislative history make it clear that Congress intended to give a wide scope to patent eligible subject matter. Yet, from these four broad categories that are listed in the statute, the Supreme Court has judicially created three exceptions and the Court recently vastly expanded the scope of these exceptions.

This article advances the proposition that the biotechnology industry and in particular entities developing the medical diagnostic technologies of the future would stand to benefit from abolishing the non-statutory, Supreme Court-promulgated, exceptions to Section 101 altogether, or at least by making certain clear amendments to the statute, so as to bring certainty to this fundamental basic question of the patent ecosystem: what subject matter is eligible for a patent. These Supreme Court-created exceptions to the statutory language have no constitutional or legislative foundation and have caused great uncertainty in patent laws, harming the biotechnology, personalized medicine and medical diagnostics industries. The Supreme Court's decisions on patent eligibility of the past decade have damaged America's standing as a leader in new technology development and commercialization. The time is ripe for Congress to act to correct the patent eligibility legal landscape and thereby promote technological innovation, especially in the medical diagnostics field.

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<sup>355</sup> *Id.*