

# Patent Eligibility Post-*Myriad*: A Reinvigorated Judicial Wildcard of Uncertain Effect

Christopher M. Holman\*

## ABSTRACT

*In the 1970s and early 1980s, the U.S. Supreme Court issued several landmark decisions establishing the contours of patent eligibility—a judicially created doctrine that serves as a gatekeeper to prevent the patenting of subject matter deemed so fundamental as to be better left unpatented. Over the course of the next twenty-five years, the Court of Appeals for the Federal Circuit oversaw a progressive expansion in the scope of subject matter deemed patent eligible, highlighted by the adoption in the 1990s of a “useful, concrete, and tangible” test for patent eligibility, which for all practical purposes seemed to subsume the patent eligibility inquiry with the requirement of utility. However, in 2006 the Supreme Court actively reengaged the doctrine, and since that time the Court has granted certiorari in five patent eligibility cases, resulting in four decisions (the first case was dismissed after oral argument). In every case in which the Court reached a decision, all of the patent claims at issue were ruled invalid for covering patent-ineligible subject matter. Unfortunately, these decisions provide little guidance for the lower courts and the Patent Office with respect to the criteria to be applied in assessing patent eligibility—and little coherent insight into exactly what the Court is trying to accomplish. This Essay identifies some of the critical open questions that have been raised by the Supreme Court’s reinvigoration of patent eligibility, and it reviews some of the early efforts by lower courts to apply the heightened standard in a manner that maintains adequate incentives for innovation while addressing the legitimate policy concerns underlying the Supreme Court’s current obsession with the doctrine.*

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\* Christopher M. Holman, Ph.D., J.D., is a Professor of Law at the University of Missouri–Kansas City.

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## INTRODUCTION

When I began teaching patent law to law students in 2005, I would spend close to two class sessions covering the doctrine of patent eligibility,<sup>1</sup> which was consistent with the extensive coverage afforded the topic by the casebook I was using at the time.<sup>2</sup> But after teaching the course a couple of years, I began to seriously consider scaling way back on the amount of class time I devoted to the subject. Patent eligibility was no doubt an appealing subject for contemplation by law professor-types, being as it was an abstract, policy-driven creation of the Supreme Court, untethered in any meaningful way to the language of the patent statute.<sup>3</sup> But from a practical perspective, the doctrine seemed to have little, if any, real significance to the vast majority of contemporary patent practice. With the Federal Circuit’s adoption in the 1990s of a “useful, concrete, and tangible” test for patent eligibility, for all practical purposes patent eligibility seemed to have been subsumed by the utility requirement.<sup>4</sup> Indeed, in 2008, Professor Michael Risch was able to argue quite plausibly that “everything is patentable.”<sup>5</sup>

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<sup>1</sup> The terms “patentable subject matter” and “patent eligibility” are used interchangeably by courts and commentators to refer to the same doctrine; for the most part I prefer “patent eligibility,” because it seems to me to be the more contemporary of the two.

<sup>2</sup> ROBERT MERGES & JOHN DUFFY, *PATENT LAW & POLICY: CASES AND MATERIALS* (2002).

<sup>3</sup> 35 U.S.C. §§ 1–390 (2012).

<sup>4</sup> See *infra* Part I.

<sup>5</sup> See Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591 (2008).

However, by the time Professor Risch published his article, events had begun to transpire that would cause a dramatic shift in the status quo, thrusting the once moribund doctrine of patent eligibility front and center in the nation's patent policy debate. Of particular significance was a strongly worded dissent penned by Justice Breyer in the Supreme Court's 2006 decision to dismiss *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*,<sup>6</sup> which expressed the view of three of the Justices that the expansion in the recognized scope of patentable subject matter that had occurred under the watch of the Federal Circuit had resulted in substantial negative public policy consequences.<sup>7</sup> The dissenting Justices essentially called for a more vigorous enforcement of the patent eligibility requirement as a significant doctrinal tool for weeding out ill-advised and unwarranted patents.<sup>8</sup> Justice Breyer's dissent opened the door, resulting in an explosion of patent eligibility litigation that has birthed four Supreme Court decisions and two highly fractured en banc Federal Circuit decisions.<sup>9</sup>

The Supreme Court clearly views patent eligibility as an important gatekeeper to patentability, and it has issued marching orders to the judiciary and the U.S. Patent and Trademark Office ("PTO") to interpret the requirement more strictly and in a robust manner that addresses what the Court sees as a problem with over-patenting.<sup>10</sup> This doctrine has awoken from its near dormant state of a decade ago, and patent infringement defendants are increasingly turning to it as a pragmatic tool for economically disposing of an adversary's allegedly infringed patent.<sup>11</sup> 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. The issue of patent eligibil-

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<sup>6</sup> *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006).

<sup>7</sup> *See id.* at 137–39 (Breyer, J., dissenting).

<sup>8</sup> *See id.*

<sup>9</sup> *See Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012); *Bilski v. Kappos*, 130 S. Ct. 3218 (2010); *CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269 (Fed. Cir. 2013) (en banc), *aff'd*, 134 S. Ct. 2347 (2014); *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), *aff'd sub nom. Bilski v. Kappos*, 130 S. Ct. 3218 (2010). The Supreme Court decided *Alice Corp.* after this Essay was written, and the substance of that decision is not addressed.

<sup>10</sup> *See infra* Part III.

<sup>11</sup> *See infra* Part II.

ity appears to remain of little significance for some categories of invention—particularly in the mechanical, electronic, and chemical arts. It has, however, become an important element of infringement litigation and PTO examination in certain important areas of innovation—particularly those relating to so-called “business methods,” computer-implemented processes, and the next generation of cutting-edge medicine, molecular diagnostics, and personalized medicine.<sup>12</sup>

The Supreme Court’s recent interest in the development of the patent eligibility doctrine appears to have raised more questions than it has answered. The Court’s decisions provide little guidance with respect to the criteria to be applied in assessing a patent claim for eligibility, and little coherent insight into exactly what the Court hopes to accomplish. This Essay identifies some of the critical open questions that have been raised by the Supreme Court’s recent reinvigoration of patent eligibility, and it reviews some of the early efforts by lower courts to apply the heightened standard in a manner that maintains adequate incentives for innovation while addressing the legitimate policy concerns underlying the Supreme Court’s recent obsession with the doctrine.

## I. THE DEVELOPMENT OF THE DOCTRINE OF PATENT ELIGIBILITY

What policy concerns have piqued the Supreme Court’s recent interest in patent eligibility, after essentially putting the doctrine aside for a quarter of a century?<sup>13</sup> To my knowledge, the Supreme Court has never focused so much concentrated attention on any single doctrine of patent law, at least in modern history.<sup>14</sup> For comparison, consider the relatively scant attention that the Court has paid to other fundamental doctrines of patent law. Prior to its recent decision in *Nautilus, Inc. v. Biosig Instruments, Inc.*,<sup>15</sup> the Court had not addressed the definiteness doctrine since 1942 in *United Carbon Co. v. Binney & Smith Co.*<sup>16</sup> It has not addressed the utility requirement

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<sup>12</sup> See *supra* note 9 and accompanying text.

<sup>13</sup> The only patent eligibility decision decided by the Supreme Court in the twenty-five years between *Diamond v. Diehr*, 450 U.S. 175 (1981), and the grant of certiorari in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006), was *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124 (2001), a case that focused on the specific question of whether plants and seeds are eligible for utility patent protection.

<sup>14</sup> For the purposes of this Essay, I treat “modern history” as beginning with the passage of the Patent Act of 1952.

<sup>15</sup> *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014).

<sup>16</sup> *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228 (1942).

since its 1966 decision in *Brenner v. Manson*.<sup>17</sup> Even the nonobvious doctrine, which many consider to be the fundamental requirement of patentability, has been the subject of only a single Supreme Court decision in recent decades.<sup>18</sup> The Supreme Court has not addressed the issue of adequate disclosure under 35 U.S.C. § 112—i.e., the enablement, written description, and best mode requirements—since the inception of Section 112 in the 1952 patent statute.<sup>19</sup>

Prior to the 1952 patent statute, patent eligibility did not exist as a distinct doctrine. To the extent the Supreme Court addressed the bounds of patentable subject matter, the discussion was framed in terms of a requirement of inventiveness, a concept which incorporated elements of what under the modern statute falls under the rubric of nonobviousness.<sup>20</sup> I think it can be helpful to think of the Supreme Court's patent eligibility jurisprudence in terms of three discrete periods of focused judicial intervention in the development of patent law. The first intervention resulted in the creation of patent eligibility as a distinct requirement of patentability, the second substantially reined in the doctrine to accommodate important new areas of technology, and the third intervention (of which we are currently in the midst) is an attempt to reinvigorate the doctrine.<sup>21</sup>

The first Supreme Court intervention occurred in the 1970s, with the Court's creation of nonstatutory exceptions to patent eligibility in *Gottschalk v. Benson*<sup>22</sup> and *Parker v. Flook*.<sup>23</sup> These decisions appear to have been prompted by the increasing importance of computer programming as an important arena of technological innovation. The fundamental question before the Supreme Court was whether this sort of innovation was the type that should (or could) be protected by patents.<sup>24</sup> This was an important and controversial topic in the 1970s,

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<sup>17</sup> *Brenner v. Manson*, 383 U.S. 519 (1966).

<sup>18</sup> *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

<sup>19</sup> The modern incarnations of these critical disclosure requirements of patentability trace their origins to Section 112(a) as it first appeared in the 1952 patent statute, although the language of the statute and the doctrines themselves trace their origins back to earlier iterations of the patent statute. See Act of July 19, 1952, Pub. L. No. 82-593, § 112, 66 Stat. 792, 798.

<sup>20</sup> See *CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1295–97 (Fed. Cir. 2013) (Rader, C.J., concurring in part and dissenting in part).

<sup>21</sup> *J.E.M. Ag Supply, Inc.* is, in my opinion, an outlier, directed towards the very specific question of whether utility patent protection is available for plants, and is not addressed in this recounting of the evolution of the patent eligibility doctrine. See *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001); *supra* note 13.

<sup>22</sup> *Gottschalk v. Benson*, 409 U.S. 63 (1972).

<sup>23</sup> *Parker v. Flook*, 437 U.S. 584 (1978).

<sup>24</sup> See *Flook*, 437 U.S. at 585; *Benson*, 409 U.S. at 64.

with many arguing that patent protection should be available for software.<sup>25</sup> However, the Supreme Court of the 1970s disagreed, at least with respect to the computer programming claims at issue in *Benson* and *Flook*, essentially finding that the claimed computer programs came too close to the sorts of activities that can be accomplished by human thought processes, and thus were outside of the realm of what constituted a patentable “process” under Section 101.<sup>26</sup> The significance of the *Benson-Flook* intervention was that it established patent eligibility as an independent doctrine of patentability, creating exceptions to the broad statutory language permitting patents on new and useful products and processes. In the interest of clarity, this Essay will sometimes refer to these exceptions as “fundamental principles,” although through the years the Court has used a variety of terms to define the exceptions, such as abstract ideas or natural phenomena. These early patent eligibility cases form the foundation for the principle that although a specific application of a fundamental principle can be patented, a patent claim that preempts a fundamental principle is patent ineligible.

Some would disagree with my assertion that *Benson* was the first Supreme Court decision that explicitly addressed the doctrine we now refer to as patent eligibility. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*<sup>27</sup> was decided in 1948 and is often cited as patent eligibility precedent, even at times by the Supreme Court. But it is important to recognize that *Funk Brothers* was decided prior to the 1952 patent statute, and thus prior to Congress’s creation of a statutory nonobviousness requirement.<sup>28</sup> When placed in the proper historical context, the better interpretation of *Funk Brothers* is that the Court was really addressing the issue of inventiveness, i.e., obviousness, rather than what we think of today as patent eligibility.<sup>29</sup>

The second Supreme Court intervention occurred in the early 1980s in *Diamond v. Chakrabarty*<sup>30</sup> and *Diamond v. Diehr*,<sup>31</sup> and it

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<sup>25</sup> See Brief for Software Assocs., Inc. as Amicus Curiae, *Parker v. Flook*, 437 U.S. 584 (1978) (No. 77-642), 1978 WL 206641; Brief for the Ass’n of Data Processing Serv. Orgs., Software Prods. & Serv. Section as Amicus Curiae, *Gottschalk v. Benson*, 409 U.S. 63 (1972) (No. 71-485), 1972 WL 137530.

<sup>26</sup> See *Flook*, 437 U.S. at 595; *Benson*, 409 U.S. at 71; see also 35 U.S.C. § 101 (2012).

<sup>27</sup> *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

<sup>28</sup> See *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1295–97 (Fed. Cir. 2013) (Rader, C.J., concurring in part and dissenting in part).

<sup>29</sup> See Brief for Alnylam Pharms., Inc. as Amicus Curiae Supporting Defendants-Appellants at 8, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406 (Fed. Cir. Oct. 28, 2010) (on file with author).

<sup>30</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

resulted in an important recalibration of the doctrine. In these decisions, the Supreme Court did not overrule *Benson* and *Flook*, but it did set the patent eligibility bar at a relatively nonstringent level, such that patent protection would generally be available for practical technological innovations, particularly in computer programming and biotechnology.<sup>32</sup> This second intervention can be rationalized as the result of the Court's recognition that new modalities of technological innovation, such as computer programming and biotechnology, warrant patent protection, and that indeed patents could play a critical role in incentivizing advances in these new technologies. These decisions laid the groundwork for a subsequent dramatic expansion in the recognized scope of patent-eligible subject matter, based on the holding in *Chakrabarty* that any product of human intervention—even living organisms—is patent eligible,<sup>33</sup> and *Diehr*'s holding that a computer program is patent eligible so long as it provides a sufficiently tangible practical outcome.<sup>34</sup>

*Chakrabarty* and *Diehr* were split decisions, and the dissenting Justices in *Chakrabarty* protested that such a substantial expansion in the scope of patentable subject matter was a matter to be decided by Congress, not the judiciary.<sup>35</sup> In spite of these misgivings, Congress has acquiesced by never overruling the decisions, although Congress has at times enacted legislation to address concerns associated with certain narrow categories of patentable subject matter—such as methods of medical treatment and tax strategies.<sup>36</sup> In fact, in retrospect it seems clear that Congress indirectly but effectively expanded patentable subject matter when it created the Court of Appeals for the Federal Circuit in 1982,<sup>37</sup> immediately in the wake of *Chakrabarty* and *Diehr*. By establishing a specialized appellate court to manage and harmonize the development of patent law, Congress in effect created a powerful advocate for the patent system.

The post-*Diehr* expansion of patent-eligible subject matter under the watch of the Federal Circuit accelerated markedly in the late 1990s—most particularly with respect to computer-implemented

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<sup>31</sup> *Diamond v. Diehr*, 450 U.S. 175 (1981).

<sup>32</sup> See *Diehr*, 450 U.S. at 186–87; *Chakrabarty*, 447 U.S. at 315.

<sup>33</sup> See *Chakrabarty*, 447 U.S. at 310.

<sup>34</sup> See *Diehr*, 450 U.S. at 192–93.

<sup>35</sup> See *Chakrabarty*, 447 U.S. at 322 (Brennan, J., dissenting).

<sup>36</sup> See *In re Alappat*, 33 F.3d 1526, 1542–44 (Fed. Cir. 1994); see also 35 U.S.C. § 287(c) (2012) (medical procedures); Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 14, 125 Stat. 284, 327 (2011) (tax strategies).

<sup>37</sup> See generally Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25.

methods, financial methods, and methods of conducting business, but eventually spilling over into other technologies such as biotechnology and the life sciences. A significant event in this regard was the Federal Circuit's adoption of a "useful, concrete, and tangible result" test for patent eligibility, a development that traces its origin back to the 1994 decision of *In re Alappat*.<sup>38</sup> The claims at issue in *Alappat* essentially recited a computer that had been programmed to perform the mathematical calculations necessary to convert waveform data into pixel illumination, a process referred to as "rasterization."<sup>39</sup> The Board of Patent Appeals and Interferences affirmed a patent examiner's rejection of the claims under Section 101, finding that the claimed "rasterizer" did nothing more than implement the abstract idea of a "mathematical algorithm for computing pixel information."<sup>40</sup> On appeal, the Federal Circuit reversed, characterizing the rasterizer as a specific machine that produces a useful, concrete, and tangible result, as opposed to "a disembodied mathematical concept which may be characterized as an 'abstract idea.'"<sup>41</sup>

*Alappat*'s "useful, concrete, and tangible result" test really began to make its impact felt after the Federal Circuit applied it in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*,<sup>42</sup> a landmark decision wherein the court essentially held that a mathematical algorithm is patent eligible to the extent it is applied in a manner that is practically useful.<sup>43</sup> The useful, concrete, and tangible result test, as applied in *State Street Bank*, arguably obviated patent eligibility as a meaningful limitation on the patenting of abstract ideas. After all, the long-established utility doctrine already requires that a claimed invention have a "specific" and "substantial" utility in order to be patentable.<sup>44</sup> It is difficult to imagine a claimed invention that has a practical, specific, and credible utility (thus satisfying the utility requirement), but that is patent ineligible nonetheless for failure to provide a "useful, concrete, and tangible result."

As a practical matter, the "useful, concrete, and tangible result" test opened the floodgates of patentability, resulting in the issuance of a large number of patents on "inventions" that would have previously

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<sup>38</sup> See *In re Alappat*, 33 F.3d 1526, 1544–45 (Fed. Cir. 1994).

<sup>39</sup> *Id.* at 1538–39.

<sup>40</sup> *Id.* at 1541, 1539–40 (internal quotation marks omitted).

<sup>41</sup> *Id.* at 1544.

<sup>42</sup> See *State St. Bank & Trust Co. v. Signature Fin. Grp., Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998); see also *AT&T Corp. v. Excel Commc'ns, Inc.*, 172 F.3d 1352, 1357 (Fed. Cir. 1999).

<sup>43</sup> See *State Street Bank & Trust Co.*, 149 F.3d at 1373.

<sup>44</sup> See *In re Fisher*, 421 F.3d 1365, 1367 (Fed. Cir. 2005).

been considered patent ineligible, including what many would characterize as “business method patents.” As the existence of these patents became publicized, and particularly as they came to be enforced against firms and individuals unaccustomed to being sued for patent infringement, these patents generated a great deal of negative backlash, particularly outside the patent community.<sup>45</sup> Many came to believe that the scope of patentable subject matter had expanded beyond the bounds of sound policy.<sup>46</sup> Eventually the Supreme Court took notice, which has resulted in the Court’s third and ongoing intervention into the patent eligibility doctrine.

Justice Breyer has explicitly called out the “useful, concrete, and tangible result” test as the source of much of the problem he sees in the Federal Circuit’s expansive view of the scope of patentable subject matter.<sup>47</sup> His dissent from the Court’s decision to dismiss certiorari in *LabCorp* characterizes the test as inconsistent with Supreme Court precedent, pointing out that the software inventions found to be patent ineligible in *Gottschalk* and *Flook* seemed to provide useful, concrete, and tangible results.<sup>48</sup> In Justice Breyer’s concurrence in *Bilski v. Kappos*,<sup>49</sup> he suggests a causal relationship between the Federal Circuit’s adoption of the test and the issuance of patents which have “ranged from the somewhat ridiculous to the truly absurd.”<sup>50</sup> In the face of mounting criticism of the “useful, concrete, and tangible result” test, which is reflected in the statements of Justice Breyer, the en banc Federal Circuit explicitly jettisoned the test in *In re Bilski*.<sup>51</sup> The Supreme Court appears to have left that aspect of the Federal Circuit’s decision intact.<sup>52</sup>

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<sup>45</sup> See Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263, 276 (2000).

<sup>46</sup> See *id.*

<sup>47</sup> See *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 136–37 (2006) (Breyer, J., dissenting).

<sup>48</sup> See *id.*; see also *Parker v. Flook*, 437 U.S. 584 (1978) (system for triggering alarm limits in connection with catalytic conversion); *Gottschalk v. Benson*, 409 U.S. 63 (1972) (process that transforms decimal figures into binary figures within the computer’s wiring system for computer programming purposes).

<sup>49</sup> *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

<sup>50</sup> See *id.* at 3259 (Breyer, J., concurring) (citing as examples of “absurd” patented inventions a “method of training janitors to dust and vacuum using video displays,” a “system for toilet reservations,” and a “method of using color-coded bracelets to designate dating status in order to limit ‘the embarrassment of rejection’” (quoting *In re Bilski*, 545 F.3d 943, 1004 (Fed. Cir. 2008) (Mayer, J., dissenting) (internal quotation marks omitted))).

<sup>51</sup> See *In re Bilski*, 545 F.3d 943, 959–60 (Fed. Cir. 2008) (en banc), *aff’d sub nom. Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

<sup>52</sup> See *Bilski*, 130 S. Ct. at 3259 (Breyer, J., concurring in the judgment) (“[A]lthough the

This third intervention began in 2006 with the grant of certiorari in *LabCorp*, and it continues to this day with the Court's recent decision in *Alice Corp. Pty. Ltd. v. CLS Bank International*.<sup>53</sup> Although the Court dismissed certiorari in *LabCorp* as improvidently granted, the mere fact that the Court had granted certiorari—coupled with Justice Breyer's dissent expressing the eagerness of some Justices to invalidate the diagnostic claims at issue in the case for lack of patent eligibility—encouraged the PTO to raise the bar, and encouraged attorneys to bring a subsequent round of patent eligibility cases before the Court, which within a few short years resulted in the *Bilski-Mayo-Myriad* trilogy of decisions.<sup>54</sup>

The current intervention is in my view a direct response to the dramatic expansion of patent-eligible subject matter that occurred under the watch of the Federal Circuit during the twenty-five years subsequent to *Chakrabarty* and *Diehr*. Today's Justices are clearly concerned with what they see as an ill-advised expansion of patent-eligible subject matter. Without overruling precedent established during the second intervention, and indeed cognizant of the important role of the patent system in incentivizing future technological innovation, the current Supreme Court seems intent upon imposing a much more restrictive reading of *Chakrabarty* and *Diehr* upon the lower courts and the PTO. In doing so, the Court has reinvigorated the doctrine of patent eligibility, transforming it into a pragmatic, potentially potent wildcard for reining in the scope of patentable subject matter and invalidating patent claims that, in the Court's view, should never have been allowed in the first place.

## II. THE SUPREME COURT HAS REPUDIATED CORE PRECEPTS OF THE FEDERAL CIRCUIT'S PATENT JURISPRUDENCE

Part of what has been so jarring about the Supreme Court's most recent engagement with the patent eligibility doctrine is the Court's implicit repudiation of some of the core precepts of recent Federal Circuit jurisprudence. For example, the Federal Circuit, and in particular former Chief Judge Rader, has downplayed the role of patent eligibility as the gatekeeper to patentability, preferring to rely on the statutory requirements of patentability, such as novelty, nonobvious-

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machine-or-transformation test is not the only test for patentability, this by no means indicates that anything which produces a 'useful, concrete, and tangible result' . . . is patentable.'").

<sup>53</sup> See *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014).

<sup>54</sup> See *infra* Part II.

ness, and enablement.<sup>55</sup> The Federal Circuit has also adopted a rigorous approach to claim interpretation, emphasizing the literal language of the claim as a whole, rather than looking beyond the words of the claim in an attempt to discern the “heart” or “gist” of an invention.<sup>56</sup> As explained in this section, the Supreme Court has taken a very different tack in assessing the patent eligibility of the patent claims that have been brought before it.

For example, in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,<sup>57</sup> Justice Breyer opined that the “[Section] 101 patent-eligibility inquiry” does work for which other doctrines of patentability, particularly the Section 102 novelty inquiry, are not equipped.<sup>58</sup> He went on to complain:

Section 112 requires only a “written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same.” It does not focus on the possibility that a law of nature (or its equivalent) that meets these conditions will nonetheless create the kind of risk that underlies the law of nature exception, namely the risk that a patent on the law would significantly impede future innovation.<sup>59</sup>

There are other examples of judge-made patent doctrines created by the Supreme Court in an effort to address a perceived deficiency in the statutory requirements of patentability. Prior to 1952, the statutory requirements of patentability specified explicitly that a claimed invention must be new, useful, and adequately disclosed, but there was no explicit requirement of inventiveness or nonobviousness.<sup>60</sup> In the nineteenth and early twentieth century, the Supreme Court created and developed a nonstatutory “inventiveness” requirement to preclude the patenting of novel but noninventive subject matter, which the Court saw as violating a constitutional requirement of “invention.”<sup>61</sup> *Hotchkiss v. Greenwood*<sup>62</sup> is widely cited as the original source of the judge-made requirement of “inventiveness,” and a sub-

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<sup>55</sup> See, e.g., *Ultramercial, LLC v. Hulu, LLC*, 657 F.3d 1323, 1326 (Fed. Cir. 2011), *vacated sub nom. WildTangent, Inc. v. Ultramercial, LLC*, 132 S. Ct. 2431 (2012) (mem.).

<sup>56</sup> See *infra* notes 68–69.

<sup>57</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).

<sup>58</sup> See *id.* at 1304.

<sup>59</sup> *Id.* (omissions in original).

<sup>60</sup> See *CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1295–97 (Fed. Cir. 2013), *aff'd*, 134 S. Ct. 2347 (2014).

<sup>61</sup> See *id.*

<sup>62</sup> *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1850).

sequent line of cases clearly established that mere novelty is not enough for patentability.<sup>63</sup> The requirement of inventiveness was not jettisoned, but in an attempt to provide some structure and predictability to the analysis, it was codified in 1952 and expressed in terms of “nonobviousness” rather than “invention.”<sup>64</sup>

The Supreme Court’s approach to claim interpretation in its recent patent eligibility jurisprudence also diverges significantly from that endorsed by the Federal Circuit. Prior to *Bilski*, it seemed well established that any inquiry into claim validity must focus on the literal language of the claim.<sup>65</sup> As succinctly stated by Judge Giles Rich: “[T]he name of the game is the claim.”<sup>66</sup> The paramount importance of the literal language of the claim as a whole is manifest throughout Federal Circuit jurisprudence, and can be seen in the court’s emphasis on formalized claim construction as a prerequisite to determination of infringement—and in most cases as a prerequisite to an assessment of validity.<sup>67</sup>

Federal Circuit jurisprudence has stressed the importance of formal interpretation and literal application of claim language, rather than analysis that would seek to discern the “heart” or “gist” of a patented invention.<sup>68</sup> It has also emphasized analysis of the claim as a whole, rather than piecemeal analysis that might tend to obscure the presence of a patentable invention.<sup>69</sup> Historically, the Supreme Court has appeared to endorse this approach. For example, the *Diehr* majority emphasized that “[i]n determining the eligibility of [a] claimed process for patent protection under § 101, [the] claims must be considered as a whole,” rather than “dissect[ing] the claims into old and new

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<sup>63</sup> See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 4 (1966).

<sup>64</sup> See *id.* at 3–4; see also 35 U.S.C. § 103 (2012).

<sup>65</sup> See, e.g., *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (“[W]e look to the words of the claims themselves . . . to define the scope of the patented invention.”).

<sup>66</sup> Giles S. Rich, *Extent of Protection and Interpretation of Claims—American Perspectives*, 21 INT’L REV. INDUS. PROP. & COPYRIGHT L. 497, 499, 501 (1990). Judge Rich was a founding member of the Federal Circuit whose influence on modern patent law cannot be overstated.

<sup>67</sup> See, e.g., *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (2005) (noting that it is a “bedrock principle” of patent law to look to the words of a claim in determining its patent eligibility).

<sup>68</sup> See *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1315 (Fed. Cir. 2013) (Moore, J., dissenting in part) (“Federal Circuit precedent [has] abolished the ‘heart of the invention’ analysis for patentability.”); see also *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 345 (1961) (“[T]here is no legally recognizable or protected ‘essential’ element, ‘gist’ or ‘heart’ of the invention . . .”).

<sup>69</sup> See *CLS Bank Int’l*, 717 F.3d at 1298 (Rader, C.J., concurring in part and dissenting in part).

elements and then [ignoring] the presence of the old elements in the analysis.”<sup>70</sup>

Although the Supreme Court continues to pay lip service to *Diehr*’s admonition that the patent eligibility inquiry must consider the language of the claim as a whole,<sup>71</sup> the actual approach taken by the Court in the recent *Bilski-Mayo-Myriad* trilogy of cases reflects a much less rigorous “shoot from the hip” mentality that deemphasizes the literal language of the claims. The Court’s patent eligibility analysis tends to focus more on what the Court perceives to be the subject matter “embodied” by the claim rather than that which is literally recited by the claim.<sup>72</sup> Rather than considering the scope of claimed subject matter as defined by the language of the claim as a whole, the Court tends to focus on what it perceives to be a particularly abstract element of the claimed invention and limit its analysis to that particular element. The Supreme Court’s propensity to deemphasize the language of the claim has not gone unnoticed by the Federal Circuit. In *Ultramercial, LLC v. Hulu, LLC*,<sup>73</sup> for example, Judge Rader observed that in *Bilski* the Supreme Court had “f[ound] subject matter ineligible for patent protection without claim construction.”<sup>74</sup>

In *Bilski*, the closest the Court came to construing the language of the claims was in statements such as “[the independent claims at issue] explain the basic concept of hedging . . . [while the narrower dependent claims] are broad examples of how hedging can be used in commodities and energy markets.”<sup>75</sup> The Court’s characterization of the claims by reference to what they “explain” and exemplify, rather than the subject matter explicitly defined by the claims, suggests that the Court was conflating the role of the patent claims with that of the patent specification.<sup>76</sup> Section 112 of the patent statute requires that the specification “explain” the patented invention (by describing and enabling it), and inventors often satisfy the requirement by the use of

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<sup>70</sup> *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

<sup>71</sup> See *Bilski v. Kappos*, 130 S. Ct. 3218, 3230 (2010) (citing *Diehr*, 450 U.S. at 188).

<sup>72</sup> The Supreme Court’s tendency to downplay formal claim construction is evident in patent cases outside the context of patent eligibility. This can be seen, for example, in *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008), where Justice Thomas’s opinion focused on subject matter purportedly “embodied” by the patent claims rather than subject matter explicitly delineated by the language of the claims. *Id.* at 628.

<sup>73</sup> *Ultramercial, LLC v. Hulu, LLC*, 657 F.3d 1323 (Fed. Cir. 2011), *vacated sub nom. WildTangent, Inc. v. Ultramercial, LLC*, 132 S. Ct. 2431 (2012) (mem.).

<sup>74</sup> *Id.* at 1325.

<sup>75</sup> *Bilski*, 130 S. Ct. at 3231.

<sup>76</sup> See *id.*

“examples.”<sup>77</sup> In contrast, under the statute it is not the function of the claims to explain or exemplify the invention, but rather to clearly and concisely define the subject matter of the patent grant.<sup>78</sup> The *Bilski* Court also appeared to ignore specific claim limitations in its preemption analysis, particularly with respect to the relatively narrow dependent claims.<sup>79</sup>

The claims at issue in *Mayo* were also subject to a textual claim construction, although in this instance perhaps the Court should not be faulted, because the patent owner argued for such a construction. Some of the patent claims at issue in the case essentially recited diagnostic methods comprising of (1) an “administering” step, in which a drug is administered to a patient, (2) a “determining” step, in which the level of drug metabolite in the patient is determined, and (3) a “wherein” clause that identifies specific drug metabolite levels that would indicate that the dosage of the drug subsequently administered to the patient should be increased or decreased.<sup>80</sup> The “administering” and “determining” steps were apparently known in the prior art, presumably rendering the “wherein” clause critical to the nonobviousness (and hence patentability) of the claimed method.<sup>81</sup> But note that the “wherein” clause does not recite any positive action, not even a mental action, and so under normal rules of claim construction would not be treated as a meaningful limitation to the scope of the claim. Nonetheless, the district court interpreted the wherein clause as re-

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<sup>77</sup> 35 U.S.C. § 112 (2012); see *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988).

<sup>78</sup> 35 U.S.C. § 112; see *Biosig Instruments, Inc. v. Nautilus, Inc.*, 715 F.3d 891, 897–98 (Fed. Cir. 2013).

<sup>79</sup> See *Bilski*, 130 S. Ct. at 3231.

<sup>80</sup> Claim 1 of U.S. Patent No. 6,680,302, for example, recites:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

- (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
- (b) determining a level of 6-thioguanine or 6-methylmercaptapurine in said subject having said immune-mediated gastrointestinal disorder,

wherein a level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein a level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells or a level of 6-methylmercaptapurine greater than about 7000 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

U.S. Patent No. 6,680,302 col. 20 I. 24–43 (filed Dec. 27, 2001).

<sup>81</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 04cv1200 JAH (RBB), 2008 WL 878910, at \*5 (S.D. Cal. Mar. 28, 2008).

quiring an active step of “be[ing] warned that an adjustment in dosage may be required.”<sup>82</sup>

The district court’s atextual interpretation of a passive “wherein clause” as a positive “being warned” step was critical in teeing up the issue of patent eligibility for review by the Supreme Court. After all, claims reciting nothing more than the administration of a drug to a patient are quite common, and up until now have not been seen as raising patent eligibility issues. Justice Breyer particularly noted that the Court’s decision in *Mayo* should not be interpreted as calling into question the patent eligibility of drug method-of-treatment claims.<sup>83</sup> If the district court had not interpreted the wherein clause as reciting a positive “being warned” step, analysis of claim validity would have focused on the novelty and nonobviousness of the administering and determining steps, and if it is true that these steps were not novel, the claims could have been readily invalidated under Sections 102 or 103.<sup>84</sup>

In attempting to articulate an explanation as to why the claims at issue in *Mayo* were patent ineligible, Justice Breyer essentially ignored the literal language of the claims, instead repeatedly referring to the nebulous concept of what the claims “embodied.”<sup>85</sup> In fact, although he used the term “embody” twelve times in the decision, he never defined it. What is clear is that the subject matter he considered to be “embodied” by the claims is not subject matter that is literally covered by the claims. For example, he repeatedly asserted that the claims “embodied” the inventor’s discovery of a correlation between drug metabolite level and optimal dosage.<sup>86</sup> The discovery of a correlation, however, is not a process, and hence literally cannot be claimed under 35 U.S.C. § 101.

At other points in *Mayo*, Justice Breyer asserted that the patent “simply describe[d]” the correlation.<sup>87</sup> This also seems to misconstrue the role of the patent claim, because the question in assessing patent eligibility is not what the patent describes, but rather what the claims encompass. At another point Justice Breyer stated that “the ‘administering’ step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs.”<sup>88</sup>

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<sup>82</sup> *Id.* at \*6.

<sup>83</sup> See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1302 (2012).

<sup>84</sup> See *id.* at 1303.

<sup>85</sup> See *id.* at 1295, 1302.

<sup>86</sup> See *id.*

<sup>87</sup> See *id.* at 1297.

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

Once again, the function of the patent claim has nothing to do with referring to one audience or another, but rather to describe the steps of the claimed process. The “administering” step literally imposes a limitation on the claim, i.e., infringement of the claim requires the administration of a drug to a patient, it does not “refer” to an audience.

The Supreme Court’s tendency to ignore the literal language of a claim is also apparent in *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*<sup>89</sup> The plaintiffs in *Myriad* purportedly brought the lawsuit based on an apprehension that DNA sequencing and genetic testing methodologies would infringe the claims at issue in the case.<sup>90</sup> The district court engaged in some limited claim construction, but it never held a *Markman* hearing<sup>91</sup> to formally address the meaning of important technical terms used in the claims.<sup>92</sup> In particular, the court failed to address what would seem to be a highly pertinent question: would the challenged isolated DNA claims be infringed by any form of genetic testing in which any of the plaintiffs might wish to engage? Bear in mind that the plaintiffs’ avowed purpose in bringing the lawsuit was to improve access to genetic testing, and the plaintiffs’ standing was based entirely on representations that the patents were preventing certain parties from engaging in diagnostic testing.<sup>93</sup>

In fact, during oral arguments before the Federal Circuit, Judge Bryson specifically asked the attorneys representing both sides whether the isolated DNA claims would be infringed by whole genome sequencing, and he received inconsistent answers.<sup>94</sup> Defendant *Myriad*’s attorney asserted that the claims would not be infringed by whole genome sequencing, while the plaintiffs’ attorney answered in the affirmative.<sup>95</sup> In all likelihood, neither attorney could intelligently

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<sup>89</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

<sup>90</sup> See *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 380–81 (S.D.N.Y. 2009).

<sup>91</sup> See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

<sup>92</sup> See *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 214–17 (S.D.N.Y. 2010); see also Brief for CropLife Int’l as Amicus Curiae Supporting Respondents at 20, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (No. 12-398), 2013 WL 1098260.

<sup>93</sup> See *Ass’n for Molecular Pathology*, 669 F. Supp. 2d at 370–71, 381; see also *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1344–45 (Fed. Cir. 2011).

<sup>94</sup> See Recording of Oral Argument at 11:02, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406 (Fed. Cir. Apr. 4, 2011) [hereinafter Oral Argument], available at <http://www.ca9.uscourts.gov/oral-argument-recordings/search/audio.html> (search appeal number “2010-1406” and argument date “2011-04-04”).

<sup>95</sup> *Id.* at 12:20 (Defense saying “as long as the . . . DNA is isolated, I can’t imagine why that [would] . . . be . . . covered . . . because it wouldn’t be isolated . . . . If it’s isolated, then arguably

answer the question, because the claims had not been construed with sufficient specificity to answer what would seem to be an extremely relevant question based on the plaintiffs' professed motive in bringing a lawsuit, i.e., to provide freedom to operate in genetic testing. Nonetheless, as was the case in *Mayo*, neither the Supreme Court nor the Federal Circuit deemed a thorough construction of the claim language to be a prerequisite to a determination of patent ineligibility.

### III. THE SUPREME COURT HAS BOLSTERED THE USE OF PATENT ELIGIBILITY AS A DOCTRINAL WILDCARD FOR INVALIDATING "UNWORTHY" PATENT CLAIMS

In his dissent to the Federal Circuit's en banc 2010 decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*<sup>96</sup> (wherein the majority affirmed the continuing vitality of what I refer to as the "*Lilly* written description doctrine"<sup>97</sup>), Chief Judge Rader observed that the Federal Circuit's "inadequate description of its written description requirement acts as a wildcard on which the court may rely when it faces a patent that it feels is unworthy of protection."<sup>98</sup> Clearly there are those who see some merit in an amorphous, subjective test of patentability, as evidenced by the active role Eli Lilly's lawyers played in the creation of the *Lilly* written description requirement in *Regents of the University of California v. Eli Lilly & Co.*<sup>99</sup> and its affirmation in *Ariad*,<sup>100</sup> as well as the substantial amicus support the doctrine received when the Federal Circuit heard *Ariad* en banc.<sup>101</sup> The *Lilly* written description can serve as a useful "wildcard" for an accused infringer, a basis for patent invalidation unencumbered by the more rigorous standards of proof associated with more established doctrines of patentability, such as enablement and nonobviousness.

Today the Supreme Court seems intent upon promoting the use of an invigorated patent eligibility doctrine as yet another judicial

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there's infringement."); *id.* at 34:35 (Plaintiff's attorney saying "isolated DNA . . . [is] contained in the whole genome. And so if I sequence the whole genome I own a[n] . . . isolated [sequence of DNA].").

<sup>96</sup> *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010).

<sup>97</sup> See Oral Argument, *supra* note 94, at 13:36; see also Christopher M. Holman, *Is Lilly Written Description a Paper Tiger?: A Comprehensive Assessment of the Impact of Eli Lilly and Its Progeny in the Courts and PTO*, 17 ALB. L.J. SCI. & TECH. 1 (2007).

<sup>98</sup> *Ariad*, 598 F.3d at 1366 (Rader, J., dissenting in part and concurring in part).

<sup>99</sup> *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

<sup>100</sup> See *supra* note 98.

<sup>101</sup> See, e.g., Corrected Brief for Pub. Patent Found. as Amicus Curiae Supporting Defendant-Appellant, *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (No. 2008-1248), 2009 WL 4922508.

wildcard to expedite the invalidation of “unworthy” patent claims. Although questionable claims such as those at issue in *Bilski*, *Mayo*, and *Myriad* appear to have been vulnerable to invalidation under Sections 102, 103, or 112,<sup>102</sup> it can be difficult, as a practical matter, to successfully deploy these doctrines to invalidate a patent without spending a great deal of time and money, along with the attendant uncertainty of prolonged litigation. In contrast, an amorphous test for patent eligibility that deemphasizes a rigorous analysis of the explicit language of the claims can facilitate invalidation of patent claims by summary adjudication. Consistent with this view of the role of patent eligibility as a relatively low-cost tool for disposing of unworthy patent claims, Justice Breyer opined in *Mayo* that patent eligibility “serves as a somewhat more easily administered proxy” for the Court’s underlying concern that patents should not be permitted to restrict access to the fundamental “building-blocks” of research and innovation.<sup>103</sup>

The fact that patent eligibility is treated as a question of law could facilitate its use as a wildcard, because it does not raise issues that must be addressed by a trier of fact—and is thus potentially more amenable to summary adjudication.<sup>104</sup> The parties to patent litigation have the option of a jury trial, in which case an issue of fact generally needs to be decided by the jury, unless the judge determines that no reasonable jury could find for a nonmoving party. The Supreme Court’s characterization of patent eligibility as a “threshold test” for patentability can foster the use of the doctrine for earlier adjudication of patent eligibility, and this characterization hence promotes its use as a wildcard to facilitate streamlined invalidation of patent claims.<sup>105</sup> On the other hand, as a question of law the doctrine is subject to de novo review, and the resulting lack of deference could result in a higher likelihood of reversal on appeal.<sup>106</sup>

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<sup>102</sup> See, e.g., *Ass’n for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107, 2114 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1303 (2012); *Bilski v. Kappos*, 130 S. Ct. 3218, 3229 (2010).

<sup>103</sup> *Mayo Collaborative*, 132 S. Ct. at 1303.

<sup>104</sup> See *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1369 (Fed. Cir. 2011) (“Issues of patent-eligible subject matter are questions of law . . .”); see also *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (noting that the Supreme Court has only recognized “a process as within the statutory definition when it either was tied to a particular apparatus or operated to change materials to a ‘different state or thing’” (quoting *Cochrane v. Deener*, 94 U.S. 780, 788 (1876))).

<sup>105</sup> *Bilski*, 130 S. Ct. at 3225.

<sup>106</sup> *Bancorp Servs., L.L.C. v. Sun Life Assurance Co. of Can. (U.S.)*, 687 F.3d 1266, 1273 (Fed. Cir. 2012) (“We review questions about patent-eligible subject matter under 35 U.S.C.

The Federal Circuit's Judge Mayer has repeatedly voiced his opinion that the Supreme Court's recent reinvigoration of the patent eligibility doctrine has provided the lower courts with a useful tool for expediently invalidating unworthy patent claims. For example, in *Highmark, Inc. v. Allcare Health Management Systems, Inc.*,<sup>107</sup> the Federal Circuit held that the patentee's allegations of infringement of a patent claim directed to method of managing an integrated health care management system were objectively unreasonable and were brought in subjective bad faith, and thus warranted an award of exceptional-case attorney's fees to the alleged infringer.<sup>108</sup> The alleged infringer had prevailed based on a determination of noninfringement. Dissenting in part, Judge Mayer took pains to point out "that the infringement trial in this case occurred prior to the Supreme Court's decisions in *Bilski* . . . and *Mayo*," and that if the trial court had "had the benefit of these decisions, it could have applied 35 USC § 101 to invalidate [the asserted claims] at the summary judgment stage of the proceedings."<sup>109</sup> He went on to opine that in the future courts confronted with unworthy patents such as this, which he characterized as merely describing an abstract idea without disclosing any new technology or inventive concept, should apply the patent eligibility doctrine in a robust manner at the summary judgment stage in order to "save both courts and litigants years of needless litigation."<sup>110</sup>

The Supreme Court and Federal Circuit have further facilitated the use of patent eligibility as a judicial wildcard by encouraging summary adjudication without formal claim construction. For example, in *Cardpool, Inc. v. Plastic Jungle, Inc.*,<sup>111</sup> a district court ruled, on a motion to dismiss, that the patent claims at issue, which recited a "method of exchanging a gift card," were directed towards ineligible subject matter.<sup>112</sup> The court rejected the patentee's contention that a determination of patent ineligibility on a motion to dismiss and prior to any formal claim construction was improper, citing the Federal Circuit's statement in *Bancorp Services, L.L.C. v. Sun Life Assurance Co.*

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§ 101 without deference."); *CyberSource Corp.*, 654 F.3d at 1369 ("Issues of patent-eligible subject matter are questions of law . . .").

<sup>107</sup> *Highmark, Inc. v. Allcare Health Mgmt. Sys., Inc.*, 687 F.3d 1300 (Fed. Cir. 2012), *vacated*, 134 S. Ct. 1744 (2014).

<sup>108</sup> *See id.* at 1313.

<sup>109</sup> *Id.* at 1323–24 (Mayer, J., dissenting in part).

<sup>110</sup> *Id.* at 1324.

<sup>111</sup> *Cardpool, Inc. v. Plastic Jungle, Inc.*, No. C 12–04182 WHA, 2013 WL 245026 (N.D. Cal. Jan. 22, 2013).

<sup>112</sup> *Id.* at \*1.

of Canada (U.S.)<sup>113</sup> that “claim construction is not an inviolable prerequisite to a validity determination under § 101.”<sup>114</sup>

Although the Supreme Court’s patent eligibility jurisprudence tends to encourage its use as a judicial wildcard, the Court has on occasion cautioned the lower courts against deploying the doctrine in an overly liberal fashion that might threaten to deprive worthy inventions of patent protection. For example, in *Bilski* the Court stated that the doctrine of patent eligibility is not intended to give the judiciary carte blanche to impose limitations on patentability that are inconsistent with the patent statute’s text, purpose, and design.<sup>115</sup> The Court went on to emphasize that “Congress plainly contemplated that the patent laws would be given wide scope . . . [in order] to ensure that ingenuity should receive a liberal encouragement.”<sup>116</sup>

The Court has taken particular pains to guard against the potential for a reinvigorated patent eligibility doctrine to have the unintended consequence of precluding the patentability of new drugs and new therapeutic uses of drugs. Drugs are considered by many to be the sort of invention for which patent protection is most critical, due to the extremely high cost of developing and commercializing new pharmaceuticals.<sup>117</sup> In *Mayo*, for example, Justice Breyer explicitly noted that the Court’s expansion of the patent eligibility doctrine should not be interpreted as threatening the validity of “a typical patent on a new drug or a new way of using an existing drug.”<sup>118</sup>

The Supreme Court’s distinction between isolated genomic DNA and cDNA in *Myriad* appears to be another manifestation of the Court’s unwillingness to allow a newly reinvigorated patent eligibility doctrine to unduly interfere with patent protection for drugs. In holding that isolated genomic DNA is patent ineligible, while cDNA is patent eligible, the Supreme Court adopted the views of the United

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<sup>113</sup> *Bancorp Servs., L.L.C. v. Sun Life Assurance Co. of Can.* (U.S.), 687 F.3d 1266 (Fed. Cir. 2012).

<sup>114</sup> *Cardpool, Inc.*, 2013 WL 245026, at \*3 (quoting *Bancorp Services, L.L.C.*, 687 F.3d at 1273).

<sup>115</sup> *Bilski v. Kappos*, 130 S. Ct. 3218, 3226 (2010).

<sup>116</sup> *Id.* at 3225 (internal quotation marks omitted).

<sup>117</sup> See Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 *MANAGERIAL & DECISION ECON.* 469, 475–76 (2007) (discussing research and development costs of biotech and pharmaceutical firms). For pharmaceuticals generally, see Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is It Really \$802 Million?*, 25 *HEALTH AFFAIRS* 420, 422–24 (2006); Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 *J. HEALTH ECON.* 151, 180–81 (2003).

<sup>118</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1302 (2012).

States government, as reflected in its amicus brief.<sup>119</sup> The Solicitor General attempted to distinguish between the two forms of DNA in terms of their chemical nature, but as I explained in an amicus brief I submitted to the Federal Circuit when it heard *Myriad*, the science really does not support such a distinction.<sup>120</sup> A better rationale for the government's position is that it was driven primarily by policy. Isolated DNA is used for multiple purposes, including research, genetic testing, and drug production.<sup>121</sup> I believe the government equated cDNA with the production of biotech drugs, and genomic DNA with research and genetic testing, and sought to retain patent protection to incentivize drug development while providing freedom to operate for researchers and genetic diagnostic testing firms. In distinguishing between genomic and cDNA, the Supreme Court has essentially sought to maintain patent incentives for the development of biotech drugs while addressing perceived concerns that gene patents are interfering with research and restricting access to genetic testing.

#### IV. THE SUPREME COURT HAS YET TO CLARIFY THE STANDARD TO BE APPLIED IN ASSESSING PATENT ELIGIBILITY

The Supreme Court's recent engagement of the patent eligibility doctrine has sent a clear signal to the lower courts and the PTO that the doctrine is to be applied in an expanded and more robust fashion. But the Court has provided little guidance with respect to what standard to apply when analyzing a claim for patent eligibility. To give one example, the Court repeatedly refers back to decisions from the 1970s and early 1980s for the proposition that certain implicit exceptions apply to Section 101's otherwise expansive definition of patent-eligible subject matter, i.e., "any new and useful process, machine, manufacture, or composition of matter."<sup>122</sup> Unfortunately, however, the Court has yet to provide any coherent definition of these judge-made exceptions.

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<sup>119</sup> See Brief for United States as Amicus Curiae Supporting Neither Party at 12, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (No. 12-398), 2013 WL 390999.

<sup>120</sup> See Brief for Christopher M. Holman as Amicus Curiae Supporting Neither Party at 8, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2012 WL 2884112.

<sup>121</sup> See Christopher M. Holman, *Learning from Litigation: What Can Lawsuits Teach Us About the Role of Human Gene Patents in Research and Innovation?*, 18 KAN. J.L. & PUB. POL'Y 215, 221 (2009).

<sup>122</sup> 35 U.S.C. § 101 (2012).

For example, in *Bilski*, the Court asserted that its “precedents provide three specific exceptions to § 101’s broad patent-eligibility principles: ‘laws of nature, physical phenomena, and abstract ideas.’”<sup>123</sup> The Court acknowledged that the exceptions “are not required by the statutory text,” but stated that they “have defined the reach of the statute as a matter of statutory *stare decisis* going back 150 years.”<sup>124</sup> I recently participated in an interdisciplinary roundtable in which law professors and patent attorneys sat down with scientists, linguists, and philosophers and attempted to make some sense of the current state of the patent eligibility doctrine. I found it interesting that some of the participants seemed to believe that insight into the nature of patent eligibility could be gleaned by rigorously parsing the language used by the Court in defining the “three exceptions.” Implicit in this earnest inquiry was an assumption that the Supreme Court had carefully considered the language it had used to define the three exceptions, and that each of the three exceptions had independent meaning and corresponded to some discrete category of patent-ineligible subject matter. But I think that if one traces the origins of the purported three exceptions to patent eligibility it will become apparent that any search for deep and profound meaning in the language used by the Court will prove largely futile.

Although the Court has adopted a practice identifying a triad of specific exceptions to patent eligibility in each of its patent eligibility decisions, the exceptions identified vary from decision to decision. For example, the two patent eligibility decisions decided after *Bilski*—*Mayo* and *Myriad*—both identify the three exceptions as “laws of nature, *natural phenomena*, and abstract ideas.”<sup>125</sup> Although this is not too different from the *Bilski* formulation<sup>126</sup> (the only difference residing in the substitution of *natural* for *physical* phenomena), the precedents which purportedly provide the basis for the exceptions actually set forth a quite different articulation of the exceptions. Moreover, the origin of the language used to define the exceptions is for the most part best characterized as dicta.<sup>127</sup> The fact that the language arose as

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<sup>123</sup> *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)).

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

<sup>125</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012) (alteration omitted) (emphasis added) (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)); see also *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013) (quoting *Mayo Collaborative*, 132 S. Ct. at 1293).

<sup>126</sup> See *Bilski*, 130 S. Ct. at 3221.

<sup>127</sup> Black’s Online Law Dictionary defines dictum as “an observation or remark made by a

dicta is I think significant, since as a consequence it was not applied to the facts of the case and thus does not provide any specific example of how the exceptions are to be applied. When writing in dicta, the Court is less constrained by the facts and outcome of the case, and thus I believe more likely to engage in loose speculation and “shooting from the hip.”

*Benson* established the Court’s practice of identifying three specific exceptions to patent eligibility in each of its patent eligibility decisions.<sup>128</sup> But note that the three exceptions set forth in *Benson* (phenomena of nature, mental processes, and abstract intellectual concepts) are entirely distinct from the three “specific” exceptions identified in *Bilski* (laws of nature, natural phenomena, and abstract ideas).<sup>129</sup> Two of the *Benson* exceptions, phenomena of nature and mental processes, appear in the decision as what I consider to be pure dicta, since the Court provided no definition for the terms and did not apply them to the facts of the case. Indeed, the computer-implemented mathematical algorithms at issue in *Benson* would not appear to be phenomena of nature under any reasonable interpretation of that term. The only rationale the Court provided in support of an exception for phenomena of nature was a citation to a passage from *Funk Brothers* in which the Court used the term in connection with its assessment of the inventiveness of a product claim—an inquiry which post-1952 is treated under the rubric of nonobviousness.<sup>130</sup>

Similarly, the *Benson* Court did not cite any precedent in support of a purported “mental process” exception, and it provided no definition for the term. The Court never asserted that the method claims at issue involved mental processes. To the contrary, the Court explicitly characterized the patent as being directed towards a “method of programming a general-purpose digital computer.”<sup>131</sup>

The only exception identified in *Benson* that might arguably have had some bearing on the resolution of the case at hand was the “abstract intellectual concept” exception. The Court never explicitly came out and said that it believed the claims were directed towards an

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judge in pronouncing an opinion upon a cause, concerning some rule, principle, or application of law, or the solution of a [q]uestion suggested by the case at bar, but not necessarily involved in the case or essential to its determination; any statement of the law enunciated by the court merely by way of illustration, argument, analogy, or suggestion.” *What is Dictum?*, LAW DICTIONARY, <http://thelawdictionary.org/dictum/#ixzz2tVMDdxx1> (last visited Dec. 19, 2014).

<sup>128</sup> *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

<sup>129</sup> *See id.*

<sup>130</sup> *See id.*

<sup>131</sup> *Id.* at 65.

abstract intellectual concept, but at one point the Court stated that the “claim is so abstract and sweeping as to cover both known and unknown uses of the BCD to pure binary conversion.”<sup>132</sup> The Court appears to have been using the word “abstract” in the sense of overly broad, as opposed to suggesting that the claim embodied nothing more than an abstract intellectual concept. Indeed, it would seem hard to justify a characterization of the claim as an abstract intellectual concept, given that the language of the claim was explicitly tied to a computer.

In the next patent eligibility case decided by the Supreme Court, *Flook*, the majority simply quoted *Benson* for its list of exceptions, i.e., phenomena of nature, mental processes, and abstract intellectual concepts.<sup>133</sup> However, as was the case in *Benson*, the exceptions appear in *Flook* as mere dicta, untethered by any application to the claims at issue in the case. Instead, the majority characterized the claims as encompassing an algorithm or mathematical formula and focused its analysis on the patent ineligibility of algorithms and mathematical formulas without reference to the three exceptions.<sup>134</sup> Because the claims were directed towards a computer-implemented process, it is difficult to understand how they could be characterized as mental processes or abstract intellectual concepts, nor do they seem at all analogous to the phenomenon of nature identified in *Funk Brothers*, i.e., the synergistic interaction of naturally occurring microorganisms.<sup>135</sup>

Writing for the dissenting Justices in *Flook*, Justice Stewart provided his own list of three exceptions: laws of nature, physical phenomena, and abstract ideas.<sup>136</sup> He did not provide any precedent that would support his formulation of the list, simply stating that the notion that these three categories of subject matter are patent ineligible is “commonplace.”<sup>137</sup> Like the *Flook* majority, Justice Stewart never attempted to define his exceptions or to explain them, and he never applied them to the claims at issue in the decision. In any event, the *Flook* dissent is the original source of the three specific exceptions identified in *Bilski*.

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<sup>132</sup> *Id.* at 68.

<sup>133</sup> See *Parker v. Flook*, 437 U.S. 584, 589 (1978).

<sup>134</sup> See *id.* at 593.

<sup>135</sup> See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 128–29 (1948).

<sup>136</sup> See *Flook*, 437 U.S. at 598 (Stewart, J., dissenting).

<sup>137</sup> See *id.* at 598–99.

The next patent eligibility case to be decided by the Supreme Court, *Chakrabarty*, identified the same three exceptions as Justice Stewart's dissent in *Flook*, i.e., laws of nature, physical phenomena, and abstract ideas.<sup>138</sup> The *Chakrabarty* Court's invocation of Stewart's dissent for its formulation of the exceptions is consistent with the outcome of the case, seeing as that the *Chakrabarty* majority adopted the relatively expansive view of patent eligibility espoused by the dissent in *Flook*. The next patent eligibility case decided by the Court, *Diehr*, marks the first time that the Court identified the three exceptions as laws of nature, natural phenomena, and abstract ideas.<sup>139</sup>

To summarize, although *Bilski* states that there are three exceptions (laws of nature, physical phenomena, and abstract ideas), in reality, over the years the Court has identified seven different exceptions: phenomena of nature, mental processes, abstract intellectual concepts, laws of nature, physical phenomena, natural phenomena, and abstract ideas. The Court appears to have exercised little care with the specific language used to define the exceptions, instead treating the seven terms as largely interchangeable. For example, although the Court's two most recent patent eligibility decisions, *Myriad* and *Mayo*, both identify natural phenomena and laws of nature as two of the exclusions, the Court has a long history of treating these two terms as synonyms. In *Benson*, for example, the only point in the decision where the Court used the terms "phenomenon of nature" and "law of nature" was a direct quote from *Funk Brothers* that treats the terms as synonymous.<sup>140</sup>

*Benson* is not the only Supreme Court decision to treat "law of nature" and "phenomenon of nature" as synonyms. In *Mayo*, the district court and Federal Circuit decisions both characterized the correlation at issue as a "natural phenomenon."<sup>141</sup> On appeal, and without comment, the Supreme Court characterized the correlation as a law of nature, implicitly treating the terms as synonymous.<sup>142</sup> In *Myriad*, the Court did the same thing, first stating that the outcome of the case hinged upon whether or not *Myriad*'s patents "claim naturally occur-

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<sup>138</sup> See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

<sup>139</sup> See *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

<sup>140</sup> See *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) (quoting *Funk Bros. Seed Co.*, 333 U.S. at 130).

<sup>141</sup> See *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 04cv1200 JAH (RBB), 2008 WL 878910, at \*6–7 (S.D. Cal. Mar. 28, 2008); see also *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1354 (Fed. Cir. 2010).

<sup>142</sup> See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1296 (2012).

ring phenomena,”<sup>143</sup> and then going on to decide the case based on its conclusion that Myriad’s patent claims fell “squarely within the law of nature exception.”<sup>144</sup> Similarly, the Court has repeatedly treated the terms “natural phenomena” and “physical phenomena” as synonyms. For example, *Diehr* and *Mayo* cite *Flook* and *Chakrabarty*, respectively, for the proposition that *natural* phenomena constitutes one of the three exceptions, when in fact *Flook* and *Chakrabarty* both refer to a *physical* phenomena exception.<sup>145</sup>

The Court has also provided (again in dicta) specific examples of subject matter purportedly falling within the exceptions, but even these specific examples provide little useful guidance. For example, Justice Stewart’s dissent in *Flook* identifies the law of gravity, the multiplication tables, the phenomenon of magnetism, and the fact that water at sea level boils at 100 degrees centigrade and freezes at zero as subject matter falling within the exceptions.<sup>146</sup> He does not identify which of the exceptions these fundamental principles represent, although presumably he would characterize them as physical phenomena or laws of nature (as opposed to abstract ideas). The fact that he does not distinguish between the two suggests that, once again, the terms are being used interchangeably.

In *Chakrabarty*, the Court pointed to a new mineral discovered in the earth or a new plant found in the wild, Einstein’s law that  $E = mc^2$ , and Newton’s law of gravity as specific examples of patent-ineligible subject matter.<sup>147</sup> *Chakrabarty*’s exhortation that naturally occurring minerals and plants are patent ineligible represents a judicial expansion of the literal language of Section 101.<sup>148</sup> The laws of Newton and Einstein, multiplication tables, the boiling point of water, and the phenomenon of magnetism, on the other hand, all clearly fall outside the statutory definition of patentable subject matter because none of them are processes, machines, manufactures, or compositions of matter.<sup>149</sup> The examples provided in Justice Stewart’s dissenting opinion in *Flook* offer no insight into the actual question decided by the Court,

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<sup>143</sup> See *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013).

<sup>144</sup> See *id.* at 2117.

<sup>145</sup> See *Mayo Collaborative*, 132 S. Ct. at 1293; *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

<sup>146</sup> See *Parker v. Flook*, 437 U.S. 584, 598–99 (1978) (Stewart, J., dissenting).

<sup>147</sup> See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

<sup>148</sup> See 35 U.S.C. § 101 (2012).

<sup>149</sup> *Id.* (“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 . . .”).

i.e., is a claimed process or product patent ineligible for claiming one of the exceptions.<sup>150</sup> Clearly an invention that takes advantage of effects of a magnetic field or the fact that water boils at a certain temperature is not barred from patentability per se, and the Court provides no explanation as to how these examples would be helpful in determining the patentability of a claim directed towards statutory subject matter, i.e., a product or process.<sup>151</sup>

The Supreme Court has emphasized that although the fundamental principles embodied in the “three exceptions” are patent ineligible, practical applications of these fundamental principles can potentially be patented.<sup>152</sup> But the Court has provided little guidance in discerning where the line is to be drawn between a patent-ineligible fundamental principle and the patent-eligible application of the principle. The Court has stated that a claim that “preempts” a fundamental principle is patent ineligible, as is a claim that does not infuse a fundamental principle with sufficient “inventive concept.”<sup>153</sup> Standards based on preemption and inventiveness seem to mirror the statutory requirements of enablement and nonobviousness, but the Supreme Court has yet to explain how these elements of patent eligibility might differ from the statutory requirements, nor what they are meant to accomplish above and beyond what the statute already provides.

Given the lack of clarity in the Court’s patent eligibility decisions, there appears to be a strong consensus that the primary outcome of the Supreme Court’s recent patent eligibility decisions has been increased confusion in the lower courts, the PTO, and the innovator community.<sup>154</sup> In a Federal Circuit decision decided shortly after *Bilski*, Judge Plager referred to patent eligibility jurisprudence as a “swamp of verbiage” and a “murky morass.”<sup>155</sup> Subsequently, the Court issued decisions in *Mayo* and *Myriad* that appear to have only made matters worse, as reflected in the en banc Federal Circuit’s fractured decision in *CLS Bank*.<sup>156</sup> At this Symposium, Professor Mark Lemley was asked whether he thought the Federal Circuit would be able to provide more clarity with respect to the contours of the patent eligibility doctrine in future decisions. He answered yes, explaining

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<sup>150</sup> See *Flook*, 437 U.S. at 588.

<sup>151</sup> See *id.* at 592.

<sup>152</sup> See, e.g., *id.* at 590; *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

<sup>153</sup> See *Flook*, 437 U.S. at 594; *Benson*, 409 U.S. at 72–73.

<sup>154</sup> See, e.g., Risch, *supra* note 5.

<sup>155</sup> See *MySpace, Inc. v. GraphOn Corp.*, 672 F.3d 1250, 1260 (Fed. Cir. 2012).

<sup>156</sup> See *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1272 (2013), *aff’d*, 134 S. Ct. 2347 (2014).

only half-jokingly that since the most recent en banc decision in *CLS Bank* had resulted in absolutely no clarity, he could safely guarantee that any future decisions by the Federal Circuit could not make matters any worse.<sup>157</sup>

After *Mayo* was decided, Judge Newman (one of the longest tenured judges on the Federal Circuit) bemoaned the “ascendancy of section 101 as an independent source of litigation, separate from the merits of patentability, [as] a new uncertainty for inventors.”<sup>158</sup> A district court judge recently complained that the confused and “fractured state” of the Federal Circuit’s patent eligibility jurisprudence, as reflected in the *CLS Bank* opinion, had left him in a quandary as to how to assess the patent eligibility of the patent claims at issue in the case.<sup>159</sup> He pointed out that not only do the judges on the Federal Circuit “disagree about which legal test to use to determine abstractness,” but “those circuit judges who do agree on which test to use cannot agree on the application of that test.”<sup>160</sup> The district court voiced agreement with Judge Newman’s observation in her *CLS Bank* opinion that, as a result of the split en banc decision, “the only assurance” is that, unless the Supreme Court takes up the issue again, the patent eligibility of any invention challenged on abstractness grounds “will depend on the random selection of the [Federal Circuit] panel.”<sup>161</sup>

## V. THE JUDICIARY’S RESPONSE TO *BILSKI-MAYO-MYRIAD*

### A. *Some Judges Continue to Apply Patent Eligibility Narrowly*

Although the *Bilski-Mayo-Myriad* triad encourages the lower courts to put more teeth into the patent eligibility doctrine, some judges continue to insist that the doctrine should be interpreted narrowly and applied sparingly, and have found language in the Supreme Court’s recent decisions that would appear to support their position. For example, in *Classen Immunotherapies, Inc. v. Biogen IDEC*,<sup>162</sup> the

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<sup>157</sup> Mark Lemley, Remarks at The George Washington Law Review Symposium on Cracking the Code: Ongoing § 101 Patentability Concerns in Biotechnology and Computer Software, Software Panel, at 12:00 (Nov. 15, 2013), available at <http://video.law.gwu.edu:8080/ess/echo/presentation/c04aab31-1255-41cb-9286-b3f1be07574b?ec=true>.

<sup>158</sup> *CLS Bank Int’l*, 717 F.3d at 1321 (Newman, J., concurring in part and dissenting in part).

<sup>159</sup> See *Planet Bingo, LLC v. VKGS, LLC*, 961 F. Supp. 2d 840, 845 (W.D. Mich. 2013).

<sup>160</sup> *Id.* at 844.

<sup>161</sup> *Id.* at 845 (quoting *CLS Bank Int’l*, 717 F.3d at 1321 (Newman, J., concurring in part and dissenting in part)).

<sup>162</sup> *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011).

Federal Circuit decided the case “in accordance with the guidance of *Bilski v. Kappos* that ‘[r]ather than adopting categorical rules that might have wide-ranging and unforeseen impacts,’ exclusions from patent-eligibility should be applied ‘narrowly.’”<sup>163</sup> The panel went on to point out that *Bilski* “emphasized the expansive terms of § 101 as evidence of the intent that the patent laws would be given wide scope,” and noted that a permissive approach to analyzing the medical research claims at issue in the case “warrant[ed] specific consideration in the context of evolving technologies, for Congress took [a] permissive approach to patent eligibility to ensure that ingenuity should receive a liberal encouragement.”<sup>164</sup>

In *Ultramercial*, the Federal Circuit pointed to language in *Mayo* and *Bilski* that the court felt supported the proposition that the Supreme Court has emphasized that too broad an interpretation of the patent eligibility exclusions “could eviscerate patent law.”<sup>165</sup> The Federal Circuit in *Ultramercial* opined that Congress intended Section 101 to be interpreted as broadly inclusive, and that a restrictive reading would improperly exclude from patentability some of the most beneficial inventions, which are “often unforeseeable” and were thus not anticipated by Congress at the time the patent statute was enacted.<sup>166</sup> The court concluded that a finding of patent ineligibility should be a “rare” occurrence.<sup>167</sup> Otherwise, “as a practical matter,” the intended function of the statute could be “eviscerate[d].”<sup>168</sup> Along similar lines, in *CLS Bank* Judge Rader opined that the patent eligibility exceptions, as “judicially created exceptions” to the patent statute, are to be narrowly construed in order to prevent the courts from improperly narrowing the enactments of Congress.<sup>169</sup>

### *B. The Role of Claim Construction in Assessing Patent Eligibility*

The Federal Circuit has taken the position that

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<sup>163</sup> *Id.* at 1066 (quoting *Bilski v. Kappos*, 130 S. Ct. 3218, 3229 (2010)).

<sup>164</sup> *Id.* at 1067 (internal quotation marks omitted).

<sup>165</sup> *Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335, 1341 (Fed. Cir. 2013) (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012)) (internal quotation marks omitted), *vacated sub nom.* *WildTangent, Inc. v. Ultramercial, LLC*, 134 S. Ct. 2870 (2014).

<sup>166</sup> *See id.* at 1342 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 316 (1980)) (internal quotation marks omitted).

<sup>167</sup> *See id.*

<sup>168</sup> *Id.*

<sup>169</sup> *See CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1303 (Fed. Cir. 2013) (Rader, C.J., concurring in part and dissenting in part).

[although] claim construction is not an inviolable prerequisite to a validity determination under § 101[.] . . . it will ordinarily be desirable—and often necessary—to resolve claim construction disputes prior to a § 101 analysis, for the determination of patent eligibility requires a full understanding of the basic character of the claimed subject matter.<sup>170</sup>

In spite of this admonition, some district courts have exercised their discretion not to engage in claim construction. For example, in *Cardpool*, a district court declared the plaintiff's patent invalid for claiming patent-ineligible subject matter on a motion to dismiss.<sup>171</sup> The plaintiff argued that dismissal was premature because claim construction “is required before patentability can be determined.”<sup>172</sup> The district court rejected this argument, however, citing to the Federal Circuit's statement that claim construction is not an “inviolable prerequisite to a validity determination under § 101.”<sup>173</sup> At least with respect to the claims at issue in *Cardpool*, the district court held that the “basic character of the claimed subject matter is readily ascertainable from the face of the patent,” and thus “[c]laim construction is not necessary.”<sup>174</sup>

*Cardpool* illustrates an important practical ramification of allowing courts to declare patent claims ineligible without engaging in any formal claim construction: it facilitates summary adjudication and early dismissal of patent infringement lawsuits. This enhances the role of patent ineligibility as a doctrinal wildcard for invalidating patents deemed unworthy by the court, consistent with the notion that patent eligibility is being promoted as a tool for dealing with a perceived problem of patent trolls and frivolous patent lawsuits.<sup>175</sup>

Although in its recent decisions the Supreme Court has for the most part ignored *Diehr*'s admonition that the “claims must be considered as a whole” when assessing patent eligibility,<sup>176</sup> some Federal Circuit judges continue to cling to the *Diehr* standard. Chief Judge Rader has been particularly adamant that the *Diehr* “claim as a whole” ap-

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<sup>170</sup> *Bancorp Servs., L.L.C. v. Sun Life Assurance Co. of Can. (U.S.)*, 687 F.3d 1266, 1273–74 (Fed. Cir. 2012); see also *CLS Bank Int'l*, 717 F.3d at 1282 (Lourie, J., concurring) (“Although not required, conducting a claim construction analysis before addressing § 101 may be especially helpful in this regard by facilitating a full understanding of what each claim entails.”).

<sup>171</sup> See *Cardpool, Inc. v. Plastic Jungle, Inc.*, No. C 12–04182 WHA, 2013 WL 245026, at \*4 (N.D. Cal. Jan. 22, 2013).

<sup>172</sup> *Id.* at \*3.

<sup>173</sup> *Id.* (quoting *Bancorp Services, L.L.C.*, 687 F.3d at 1273).

<sup>174</sup> *Id.* at \*4.

<sup>175</sup> *Supra* Part III.

<sup>176</sup> *Diamond v. Diehr*, 450 U.S. 175, 189 (1981).

proach remains good law, and that the literal language of the claim as a whole, read in its entirety, is critical to the patent eligibility inquiry.<sup>177</sup> Judge Rader came out strongly on this point in his recent *CLS Bank* opinion:

The claims are key to this patent eligibility inquiry. A court must consider the asserted claim *as a whole* when assessing eligibility . . . [and] must consider the *actual* language of each claim. . . . Any claim can be stripped down, simplified, generalized, or paraphrased to remove all of its concrete limitations, until at its core, something that could be characterized as an abstract idea is revealed. Such an approach would if carried to its extreme, make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious. A court cannot go hunting for abstractions by ignoring the concrete, palpable, tangible limitations of the invention the patentee actually claims. . . . Different claims will have different limitations; each must be considered as actually written.<sup>178</sup>

Still, some judges on the Federal Circuit and in the district courts appear to be disregarding Chief Judge Rader's exhortation. Judge Moore took note of this in *CLS Bank*, accusing some of her fellow judges on the Federal Circuit of "trampl[ing] upon a mountain of precedent that requires us to evaluate each claim as a whole when analyzing validity."<sup>179</sup> The particular object of Judge Moore's ire was an opinion authored by Judge Lourie that basically conflated the patent eligibility analysis of product claims reciting "data processing systems" and process claims directed towards computer-implemented methods of operation.<sup>180</sup> Judge Moore argued that in doing so Judge Lourie had "stripp[ed] away all known elements from the asserted system claims and analyz[ed] only whether what remains, as opposed to the claim as a whole, is an abstract idea."<sup>181</sup> She characterized Judge Lourie's approach as "inconsistent with the 1952 Patent Act, and years of

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<sup>177</sup> *Ultramercial, Inc. v. Hulu, LLC*, 722 F.3d 1335, 1344 (Fed. Cir. 2013) ("In determining [patent eligibility], the court must focus on the claim as a whole."), *vacated sub nom. WildTangent, Inc. v. Ultramercial, LLC*, 134 S. Ct. 2870 (2014).

<sup>178</sup> *CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1298 (Fed. Cir. 2013) (Rader, C.J., concurring in part and dissenting in part) (internal quotation marks and citations omitted).

<sup>179</sup> *Id.* at 1314 (Moore, J., dissenting in part).

<sup>180</sup> *See id.* at 1315.

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

Supreme Court, CCPA, and Federal Circuit precedent that abolished the ‘heart of the invention’ analysis for patentability.”<sup>182</sup>

Another recent example of a Federal Circuit judge apparently losing focus of the literal language of the claims as a whole appears in *PerkinElmer, Inc. v. Intema Ltd.*,<sup>183</sup> wherein Judge O’Malley’s patent eligibility analysis focuses on the “*concept* which is the focus of the claims,” rather than the actual language of the claims.<sup>184</sup> This harkens back to the approach taken by Justice Breyer in *Mayo*, in which his analysis focused more on what the claims *embody* than what they literally claim.<sup>185</sup> The tendency of judges to lose focus on the actual language of the claims is also apparent at the district court level. For example, in *OIP Technologies, Inc. v. Amazon.com, Inc.*,<sup>186</sup> a district court judge gave lip service to “the Federal Circuit’s admonition that ‘[i]t is fundamentally improper to paraphrase a claim in overly simplistic generalities in assessing whether the claim falls under the limited “abstract ideas” exception to patent eligibility under 35 U.S.C. § 101,’” but then proceeded to focus its patent ineligibility analysis on the “essence” of what the patent teaches “in simple English.”<sup>187</sup>

### C. Preemption Analysis in the Lower Courts

Although the *Bilski-Mayo-Myriad* trilogy points to preemption as a key consideration in assessing the patent eligibility of a claim, there appears to be a substantial divergence of opinion among lower court judges as to what it means to impermissibly “preempt” a fundamental principle.

Former Chief Judge Rader seemed to advocate a relatively permissive preemption standard that, in most cases, would uphold the patent eligibility of claims that recite practical and tangible applications of the fundamental principle. In his *CLS Bank* opinion he stated that a “claim may be premised on an abstract idea,” and “the question for patent eligibility is whether the claim contains limitations that meaningfully tie that idea to a concrete reality or actual application of

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

<sup>183</sup> *PerkinElmer, Inc. v. Intema Ltd.*, 496 F. App’x 65 (Fed. Cir. 2012).

<sup>184</sup> *Id.* at 73 (emphasis added).

<sup>185</sup> See *supra* note 85 and accompanying text.

<sup>186</sup> *OIP Techs., Inc. v. Amazon.com, Inc.*, No. C-12-1233 EMC, 2012 WL 3985118 (N.D. Cal. Sept. 11, 2012).

<sup>187</sup> *Id.* at \*16 n.13 (quoting *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, 685 F.3d 1341, 1351 (Fed. Cir.), *vacated*, 484 F. App’x 559 (Fed. Cir. 2012)).

that idea.”<sup>188</sup> In invoking a standard of “concrete reality or actual application,” Judge Rader seemed to be suggesting a standard akin to the Federal Circuit’s discredited “useful, concrete, and tangible” test. He acknowledged that under Supreme Court precedent any claim that covers all “practical applications” of a fundamental principle is patent ineligible, but he emphasized that the standard is whether “the claim covers every practical application of [the fundamental principle].”<sup>189</sup> Judge Rader seemed to suggest that a claim that leaves any practical application of a fundamental principle uncovered would be patent eligible.

Judge Lourie on the other hand appears to be advocating a more stringent standard of preemption that would put more teeth into patent eligibility. Judge Lourie states that the ultimate question to be decided is whether a patent claim “contains additional substantive limitations that narrow, confine, or otherwise tie down the claim so that, in practical terms, it does not cover the full abstract idea itself.”<sup>190</sup> Lourie’s criterion that the claim must not cover the fundamental principle “in practical terms,” on its face, seems close to Judge Rader’s criterion that a claim must not cover “all practical applications” of the fundamental principle. But reading further into Lourie’s opinion it becomes apparent that he would impose a stricter standard for preemption than Rader. A district court judge recently pointed out the split between Judges Rader and Lourie in their approaches to assessing “abstractness under 101,” which he referred to as Lourie’s “Integrated Approach” and Rader’s “Meaningful Limitations Approach.”<sup>191</sup>

In elaborating what it means for a claim to have “substantive claim limitations beyond the mere recitation of a disembodied fundamental concept,” Judge Lourie invoked a requirement of an “inventive concept,” which must represent a “genuine human contribution” and must be “a product of human ingenuity.”<sup>192</sup> He went on to insist that the “human contribution must represent more than a trivial appendix to the underlying abstract idea,” explaining that “[l]imitations that represent a human contribution but are merely tangential, routine, well-understood, or conventional, or in practice fail to narrow the

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<sup>188</sup> *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1299–1302 (Fed. Cir. 2013) (Rader, C.J., concurring in part and dissenting in part).

<sup>189</sup> *Id.* at 1300.

<sup>190</sup> *Id.* at 1282 (Lourie, J., concurring).

<sup>191</sup> See *Planet Bingo, LLC v. VKGS, LLC*, 961 F. Supp. 2d 840, 844–45 (W.D. Mich. 2013).

<sup>192</sup> *CLS Bank Int’l*, 717 F.3d at 1282–83.

claim relative to the fundamental principle therein, cannot confer patent eligibility.”<sup>193</sup>

In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,<sup>194</sup> a district court judge recently applied the preemption standard in a quite stringent fashion that, if adopted by other courts, would render patent eligibility a potent wildcard for invalidating patent claims directed towards inventions that are based on biological or medical discoveries, particularly molecular diagnostic tests. The claims at issue in *Ariosa Diagnostics* were directed towards prenatal detection methods performed on a maternal serum or plasma sample from a pregnant female, which methods comprise detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.<sup>195</sup> The claimed invention was based on the discovery that cell-free fetal DNA (sometimes referred to as “cffDNA”) is detectable in maternal serum or plasma samples.<sup>196</sup> The “invention enables non-invasive prenatal diagnosis, including for example sex determination, blood typing and other genotyping, and detection of pre-eclampsia in the mother.”<sup>197</sup> The court treated “the presence of cffDNA in maternal plasma or serum” as the relevant natural phenomenon for the purpose of its patent eligibility analysis of the claims.<sup>198</sup>

In its preemption analysis, instead of assessing whether the claims would preempt all “practical” applications of the natural phenomenon, i.e., the standard set forth by Judge Rader, the district court found the claims patent ineligible for preempting all “commercially viable” means of testing for paternal cffDNA.<sup>199</sup> The patent owner argued that alternate methods are available for detecting cffDNA which would not be infringing, but the district court essentially found that a competitor would be at a disadvantage if it used those techniques, and as a consequence the proposed alternatives would not be “commercially viable.”<sup>200</sup> Under this standard, it seems likely that an alternative that would be considered “practical” under Judge Rader’s approach might very well be found lacking in commercial viability, and hence insufficient to render a claim patent eligible. With regard to the timing of when the commercially viable alternative first be-

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<sup>193</sup> *Id.* at 1283.

<sup>194</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 19 F. Supp. 3d 938 (N.D. Cal. 2013).

<sup>195</sup> *See id.* at 940–42.

<sup>196</sup> *See id.*

<sup>197</sup> *See id.* at 941 (internal quotation marks omitted).

<sup>198</sup> *See id.* at 948.

<sup>199</sup> *See id.* at 953–54.

<sup>200</sup> *See id.*

comes available, the district court suggested that a method claim is patent ineligible unless, “at the time of the invention or at the time of issuance of the patent,” there are available commercially viable alternative applications of the claimed natural phenomenon.<sup>201</sup>

The *Ariosa Diagnostics* court also looked at whether the claims introduced sufficient “inventive concept” to the natural phenomenon of cffDNA to render the claims patent eligible. It held that “use of a newly discovered natural phenomenon . . . will not render a claim patentable if the use of that natural phenomenon . . . is the only innovation contained in the patent.”<sup>202</sup> The court found that the only inventive aspect of the claimed method was the discovery of the presence of cffDNA in maternal plasma, and that the detection of cffDNA using conventional techniques for DNA detection was not sufficiently inventive to render the claim patent eligible.<sup>203</sup> In effect, the district court in *Ariosa Diagnostics* appears to have applied an obviousness-type analysis to the claims under the guise of patent eligibility, an approach that seems inconsistent with Judge Rader’s statement in *CLS Bank* that the Supreme Court’s recent patent eligibility decisions have not injected an “inventiveness” criterion in the test for patent eligibility.<sup>204</sup>

## CONCLUSION

At this Symposium, Professor Mark Lemley characterized the re-invigorated patent eligibility doctrine as an “inelegant” solution to a very real problem of “an unbelievable mountain of crappy . . . patents” and abusive litigation tactics, particularly in the area of software.<sup>205</sup> I think there is some merit in this observation, but I also believe that the uncertainty created by the Supreme Court’s recent patent eligibility decisions has imposed a substantial cost on society in a number of ways, not the least of which is the extreme difficulty it has created for innovators and investors trying to discern the validity of their existing patents and the availability of meaningful protection for future innovations.

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<sup>201</sup> *Id.* at 954.

<sup>202</sup> *Id.* at 951.

<sup>203</sup> *Id.*

<sup>204</sup> See *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1302 (Fed. Cir. 2013), *aff’d*, 134 S. Ct. 2347 (2014).

<sup>205</sup> See Mark Lemley, Remarks at The George Washington Law Review Symposium on Cracking the Code: Ongoing § 101 Patentability Concerns in Biotechnology and Computer Software, Software Panel, at 9:50 (Nov. 15, 2013), *available at* <http://video.law.gwu.edu:8080/ess/echo/presentation/c04aab31-1255-41cb-9286-b3f1be07574b?ec=true>.

I had hoped that the Supreme Court would recognize the problems it has created and attempt to address them by deciding *Alice Corp.* in a manner that deemphasizes the role of patent eligibility as a gatekeeper to patentability, thereby encouraging the lower courts and Congress to develop more “elegant” solutions to the admittedly real deficiencies in the patent system. Unfortunately, this did not happen.<sup>206</sup> As Chief Judge Rader and others have noted, established statutory requirements of patentability, such as nonobviousness and enablement, are the more appropriate—and in my view adequate—doctrinal tools for addressing the bulk of the policy concerns associated with the inventions claimed in *Bilski*, *Mayo*, and *Myriad*. If necessary, lingering concerns such as the fear that doctors might be sued for communicating with their patients, or for merely thinking about a medically significant correlation, would be better addressed at the point of enforcement, perhaps through a statutory exemption from remedies along the lines of the Section 287(c) exemption already available to health care providers who feel threatened by medical procedure patents.<sup>207</sup>

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<sup>206</sup> See *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014).

<sup>207</sup> See 35 U.S.C. § 287(c) (2012).