

4-1-2013

## ***Prometheus v. Mayo*: Limited Implications for § 101 Jurisprudence**

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### **Recommended Citation**

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*PROMETHEUS V. MAYO*: LIMITED IMPLICATIONS FOR  
§ 101 JURISPRUDENCE

*Jessica Belle*\*

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Cite as: 8 WASH. J.L. TECH. & ARTS 555 (2013)  
<http://digital.law.washington.edu/dspace-law/handle/1773.1/1241>

ABSTRACT

*The United States Supreme Court recently confirmed the importance of the patent eligible subject matter inquiry under 35 U.S.C. § 101 when assessing whether a claimed invention (“claim”) is patentable in Mayo Collaborative Services v. Prometheus Laboratories, Inc. The Court also stressed that patents will not be issued to a claim that simply recites a law of nature unless there are additional steps that ensure the claim is sufficiently tailored to not preempt further use of the natural law. The Court’s decision shocked the patent law community. However, decisions by lower courts since have demonstrated that Prometheus has not dramatically altered the landscape of patent eligibility analysis, though it has deeply impacted cases involving diagnostic medical therapeutic techniques. While the Court of Appeals for the Federal Circuit remains split as to how narrowly it will read Prometheus, its forthcoming en banc opinion in CLS Bank Int’l v. Alice Corp. Pty. Ltd. will likely unify its interpretation of the case. In the meantime, following the lower court cases is the best approach to understanding how the patent law landscape has changed since the landmark case.*

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## INTRODUCTION

The United States’ patent system incentivizes investment in discoveries that will benefit our society by ensuring that rightful inventors possess “the exclusive Right to their respective . . . Discoveries” for a certain period of time.<sup>1</sup> However, patent laws are also crafted to prevent patents from being granted when such patents would stifle scientific and technological progress. For that reason, a claimed invention must consist of patentable subject matter<sup>2</sup> and be novel,<sup>3</sup> nonobvious,<sup>4</sup> and fully and particularly described.<sup>5</sup>

Under 35 U.S.C. § 101, a patentable innovation is “any new and useful process, machine, manufacture, or composition of

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<sup>1</sup> U.S. CONST., art. I, § 8, cl. 8.

<sup>2</sup> 35 U.S.C. § 101 (2012).

<sup>3</sup> 35 U.S.C. § 102.

<sup>4</sup> 35 U.S.C. § 103.

<sup>5</sup> 35 U.S.C. § 112.

matter, or any new and useful improvement thereof.”<sup>6</sup> The United States Supreme Court has held that the use of “any” to modify such broad terms in § 101 demonstrated that Congress had “contemplated that patent laws would be given [a] wide scope.”<sup>7</sup> Arguably the United States Patent and Trademark Office has previously considered § 101 to be a mere formality<sup>8</sup> and this provision has seldom been the basis for rejecting a patent application, unless one of the judicially created exceptions applied.<sup>9</sup> Indeed, the judicially created exceptions to § 101—for claims that seek to patent “laws of nature, natural phenomena, and abstract ideas”<sup>10</sup>—have historically been the sole basis for rejecting a claim under § 101. Granting a patent to a claim falling within any of these three categories would “impede innovation more than it would tend to promote it” by preventing the free use of basic scientific and technological tools.<sup>11</sup>

In March 2012, however, the Supreme Court held in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* that a § 101 patentability analysis is the threshold inquiry in any determination of whether a patent is valid, and that a claim must contain a patent eligible concept to pass this threshold inquiry. Despite initial apprehension among commentators and practitioners that *Prometheus* would radically alter patent law, opinions by lower courts indicate that the case is being read narrowly so as to simply reiterate prior Supreme Court jurisprudence. The question remains open whether the United States Court of Appeals for the Federal Circuit will embrace or cabin the *Prometheus* holding. Section I of this Article summarizes

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<sup>6</sup> 35 U.S.C. § 101.

<sup>7</sup> *Bilski v. Kappos*, 561 U.S. \_\_\_, 130 S. Ct. 3218, 3225 (2010) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)).

<sup>8</sup> *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. \_\_\_, 132 S. Ct. 1289, 1304 (2012) (explaining that the government believes other patent law provisions besides 35 U.S.C. § 101 can perform the screening function of that provision).

<sup>9</sup> See Denise DeFranco, *Mayo: A Force to Be Reckoned With*, 4 LANDSLIDE 24, 28 (2012).

<sup>10</sup> *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

<sup>11</sup> *Prometheus*, 566 U.S. \_\_\_, 132 S. Ct. at 1293 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

the case history and the Supreme Court's reasoning in *Prometheus*. Section II discusses how lower courts' interpretations of *Prometheus* have affected the patent eligibility landscape.

I. *MAYO COLLABORATIVE SERVICES V. PROMETHEUS LABORATORIES, INC.*

In *Prometheus*, the Supreme Court considered whether a method for optimizing the dosage of a drug constituted patentable subject matter and found that in this particular case it was not. After reaching this conclusion, the Court reaffirmed that the "machine or transformation test" previously espoused by the Federal Circuit was not solely determinative of patent eligibility, and rejected attempts by the patent law community and the U.S. government to render § 101 a mere formality in assessing a claim.<sup>12</sup> As will be discussed below, it is debatable whether this analysis was pertinent to the holding or merely dictum.

A. *History of the Case*

At issue in the case were Prometheus's patent claims directed to a method of optimizing the dosage of thiopurine drugs, which are used to treat Crohn's disease.<sup>13</sup> The claims first directed a medical professional to administer the thiopurine drug to the patient.<sup>14</sup> Then, they suggested that the medical professional measure the level of thioguanine metabolites in the patient's blood.<sup>15</sup> Finally, in light of the level of the thioguanine metabolites found in the patient's blood, the claims directed that the dosage of thiopurine be adjusted according to Prometheus's guidelines to achieve an optimal dosage.<sup>16</sup> Mayo Clinic Rochester and Mayo Collaborative Services used Prometheus's patented test until 2004 when it announced its intention to sell its own, slightly different

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<sup>12</sup> *Id.* at 1304.

<sup>13</sup> U.S. Patent No. 6,355,623, col.20, 11.10 20, 2 App. 16.

<sup>14</sup> *Prometheus*, 566 U.S. \_\_\_, 132 S. Ct. at 1295.

<sup>15</sup> *Id.*

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

version of the test.<sup>17</sup> Prometheus subsequently sued for patent infringement.<sup>18</sup>

The district court agreed with Mayo that Prometheus's patent was ineligible because it sought to patent laws of nature, specifically the correlation between metabolite and the efficacy and dangers of thiopurine dosages.<sup>19</sup>

The Federal Circuit reversed, finding that the claim satisfied the "machine or transformation" test and was sufficiently narrow in scope.<sup>20</sup> Courts have traditionally applied the "machine or transformation test" to determine if a claim was patent eligible. Under this test, a claimed process satisfies § 101 "if (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."<sup>21</sup> In this case, Prometheus's claim "involve[d] the transformation of the human body or of blood taken from the body."<sup>22</sup>

The Supreme Court granted certiorari and then remanded the case to the Federal Circuit for consideration of the Court's recent holding in *Bilski v. Kappos*.<sup>23</sup> In that case, the Supreme Court held that the "machine or transformation" test is merely an important consideration in the § 101 inquiry that is to be used as a secondary tool only after assessing the claim in light of prior precedent.<sup>24</sup> Even in light of *Bilski*, the Federal Circuit again found Prometheus's claim to be patent eligible because it did "not encompass laws of nature or preempt natural correlations."<sup>25</sup> The Supreme Court then granted certiorari once more in *Prometheus*.<sup>26</sup>

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<sup>17</sup> *Id.* at 1295–96.

<sup>18</sup> *Id.* at 1296.

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *Bilski v. Kappos*, 561 U.S. \_\_\_, 130 S. Ct. 3218, 3224 (2010) (citations omitted).

<sup>22</sup> *Prometheus*, 566 U.S. \_\_\_, 132 S. Ct. at 1296 (quoting *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336, 1339 (Fed. Cir. 2009), *cert. granted, judgment vacated*, 130 S. Ct. 3543 (2010)).

<sup>23</sup> *Id.* at 1296.

<sup>24</sup> *Bilski*, 561 U.S. \_\_\_, 130 S. Ct. at 3226.

<sup>25</sup> *Prometheus*, at 1355.

<sup>26</sup> *Id.* at 1296.

*B. The Supreme Court Finds Prometheus's Claim Patent Ineligible under § 101*

The Supreme Court began its opinion with two premises that underlie the patent system. First, judicially created exceptions for laws of nature, physical phenomena, and abstract ideas are implicit in 35 U.S.C. § 101.<sup>27</sup> Claims that fall under these categories are “free to all men and reserved exclusively to none”<sup>28</sup> since a patent over laws of nature would “impede innovation more than . . . promote it.”<sup>29</sup> Second, reading any patent claim too broadly would prevent any patent from being issued. After all, most innovations “at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomenon, or abstract ideas.”<sup>30</sup> These principles underscore the tension of patent eligibility and the patent law system as a whole.

After discussing the history of the case, the Court began its analysis of Prometheus's claims by stating that neither a law of nature nor a process of simply applying a law of nature is patentable “unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.”<sup>31</sup> To be patent eligible under § 101, a claim based on a law of nature must contain additional steps that either individually or collectively contain a patent-eligible concept.<sup>32</sup>

The Court examined each of the three steps of Prometheus's patent claim individually as well as collectively to determine if the claim simply applied a law of nature or contained a sufficiently innovative application of this law of nature.<sup>33</sup> The correlation between the proper dosage of thiopurine and the level of thioguanine metabolites in a patient's blood stream was held to be

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<sup>27</sup> *Id.* at 1293.

<sup>28</sup> *Id.* (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)).

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* at 1297.

<sup>32</sup> *Id.* at 1293, 1297.

<sup>33</sup> *Id.* at 1297–98.

a natural law.<sup>34</sup> The administration of the drug was a step targeted to physicians; however, the Court had previously held that simply “limit[ing] the use of the formula to a particular technology environment” is insufficient to patent an abstract idea.<sup>35</sup> The Court also held that the next step in the claim—reminding the physicians of the pertinent correlation—merely stated a law of nature.<sup>36</sup> The final claimed step—using any method to determine the relevant metabolite levels in the patient’s bloodstream and adjust the dosage of thioguanine given to the patient—required physicians to use “well-understood, routine, conventional activity previously engaged in by researchers in the field.”<sup>37</sup> Finally, considering all the steps together added nothing to the law of nature, and thus the claim simply recited a law of nature and was patent ineligible.<sup>38</sup>

*C. Dictum: Refusing to Change § 101 Jurisprudence*

Having determined that Prometheus’s claim was not patent eligible under §101, the remainder of the opinion is arguably dictum.<sup>39</sup> In the first portion of the dictum, the Court situated *Prometheus* within the context of its prior holdings.<sup>40</sup> In *Diamond v. Diehr*,<sup>41</sup> the Court held that a process for molding raw rubber into a cured, molded rubber product was patentable where a mathematical equation was integrated into the process by additional steps, which did not “pre-empt the use of [the] equation.”<sup>42</sup> In *Parker v. Flook*,<sup>43</sup> a claim for establishing the

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<sup>34</sup> *Id.* at 1297.

<sup>35</sup> *Id.* (quoting *Bilski v. Kappos*, 561 U.S. \_\_\_, 130 S. Ct. 3218, 3230 (2010)).

<sup>36</sup> *Id.* at 1297–98.

<sup>37</sup> *Id.* at 1294.

<sup>38</sup> *Id.* at 1298.

<sup>39</sup> *Id.* (beginning at section II(B), the Court wrote “a more detailed consideration of the controlling precedents reinforces our conclusion;” II(A) evaluated the steps of the claim individually and collectively to determine the claim was not patent eligible).

<sup>40</sup> *Id.* at 1298–1300.

<sup>41</sup> 450 U.S. 175 (1981).

<sup>42</sup> *Id.* at 187.

<sup>43</sup> 437 U.S. 584 (1978).



alarm limits of catalytic converters of hydrocarbons was held to not be patent eligible because the mathematical formula governing the process was not integrated holistically and did not limit the use of process in a meaningful manner. Like *Flook*, Prometheus's claim was not patent eligible because its post-solution activity was obvious or conventional, and therefore did not "transform an unpatentable principle into a patentable process."<sup>44</sup> Thus, the *Prometheus* claim was found to be "weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook*."<sup>45</sup>

The Court devoted the final section of its opinion to refuting arguments presented by both Prometheus and the government in its amicus brief.<sup>46</sup> First, the Court briefly discussed its *Bilski* holding that the "machine or transformation" test is an "important and useful clue," but not the exclusive test, of whether a claim recites patentable subject matter.<sup>47</sup> Despite the Federal Circuit's opinion to the contrary, the Supreme Court concluded that Prometheus's claim did not satisfy the test.<sup>48</sup> This may suggest that courts should narrowly construe the machine-or-transformation test.

Next, the Court rejected Prometheus's argument that its claim involved a very "narrow and specific" law of nature, and that granting a patent would therefore not substantially interfere with innovation.<sup>49</sup> Prior cases have not turned on whether a claim seeks to patent a narrow or broad law of nature because judges are ill suited "to distinguish among different laws of nature."<sup>50</sup> Instead, the Court has embraced a bright-line rule: a claim that simply directs a natural law or formula to be applied is not patent eligible because it would preempt the use of the natural law or abstract idea and preclude further discovery.<sup>51</sup> Although the law of nature at issue in *Prometheus* was very narrow in scope, the claim

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<sup>44</sup> *Id.* at 590.

<sup>45</sup> *Prometheus*, 566 U.S. \_\_\_, 132 S.Ct. at 1299.

<sup>46</sup> *Id.* at 1300–05.

<sup>47</sup> *Id.* at 1303.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> *Id.* at 1301 (discussing *Bilski*, which held that no patent may be issued for either the abstract idea of "hedging" or a formula).

potentially foreclosed future innovation in this specific area and was therefore patent ineligible.<sup>52</sup> This is an example of the preemption premise identified as the beginning of the opinion.

The Court rejected attempts to diminish the importance of a § 101 analysis in assessing patent claims.<sup>53</sup> The government argued that any step beyond stating a law of nature should satisfy the patent eligibility standard of § 101.<sup>54</sup> Effectively, the government wanted patent eligibility to be evaluated by novelty,<sup>55</sup> non-obviousness,<sup>56</sup> and full-and-particular-description<sup>57</sup> inquiries alone.<sup>58</sup> The Court rejected this argument, because such a shift “would make the ‘law of nature’ exception to §101 patentability a dead letter.”<sup>59</sup>

The Court concluded by noting that the balancing between incentivization of scientific discovery by granting patents and inhibition of scientific discoveries by the misuse of patents may differ from field to field.<sup>60</sup> However, only Congress, not the Court, may create specifically tailored patent rules that provide “increased protection for discoveries of diagnostic laws of nature” if it is deemed to be in society’s best interest.<sup>61</sup>

Despite addressing various important questions about § 101, the Court’s holding appeared to be limited to Prometheus’s claim. The remainder of the opinion reiterates Supreme Court jurisprudence in this area and declines to adopt the new positions put forth by the parties and the government.

## II. REVOLUTIONIZING PATENT LAW OR CONFIRMING EXISTING CASES?

The patent law community was generally shocked by the

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<sup>52</sup> *Id.* at 1302–03.

<sup>53</sup> *Id.* at 1303.

<sup>54</sup> *Id.*

<sup>55</sup> 35 U.S.C. § 102 (2012).

<sup>56</sup> 35 U.S.C. § 103.

<sup>57</sup> 35 U.S.C. § 112.

<sup>58</sup> *Prometheus*, 566 U.S. \_\_\_, 132 S. Ct. at 1303-04.

<sup>59</sup> *Id.* at 1303.

<sup>60</sup> *Id.* at 1305.

<sup>61</sup> *Id.*

Court's decision in *Prometheus* and numerous law review articles have been written on the decision in just over a year.<sup>62</sup> Many people were concerned that *Prometheus* would radically change the landscape of patent law.<sup>63</sup> However, lower courts' uses of *Prometheus* have generally indicated the contrary. This section first discusses how lower courts have interpreted *Prometheus* to merely reaffirm prior precedents and then discusses new changes brought about by *Prometheus*.

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<sup>62</sup> See, e.g., Veronica Lambillotte, Comment, *An Overview of Patentable Subject Matter and the Effect of Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 63 CASE W. RES. L. REVIEW 635 (2012); Eric Rogers, Note, *Patenting Medical Diagnostic Methods: The Mort Strikes Back*, 17 J. TECH. L. & POL'Y 111 (2012); Nathan Reed, Comment, *A New Metric to Determine Patent Eligible Subject Matter for Medical Methods*, 16 MICH. ST. U. J. MED. & L. 321 (2012); Scott Frederick Peachman, *The Patent Eligibility of Diagnostic Methods After Prometheus: A Redefined Test for Transformation*, 22 HEALTH MATRIX 589 (2013); Harvard Law Review Ass'n, *Diagnostic Method Patents and Harms to Follow-On Innovation*, 126 Harv. L. Rev. 1370 (2013); Bernard Chao, Colloquy Essay, *Moderating Mayo*, 107 NW. U. L. REV. 423 (2012); Stephen McJohn, *Top Tens in 2012: Patent, Trademark, Copyright and Trade Secret Cases*, 11 NW. J. TECH. & INTELL. PROP. 173 (2013); Michael Malecek & Kenneth Maikish, *The Prometheus Effect on Software Patents*, 24 No. 6 INTELL. PROP. & TECH. L.J. 3 (2012); Brian McNamara, *Patent Protection of Computer Hardware and Software*, 2 WAKE FOREST J. BUS. & INTELL. PROP. L. 137 (2012); Anna Laakmann, *An Explicit Policy Lever For Patent Scope*, 19 MICH. TELECOMM. & TECH. L. REV. 43 (2012); Max Stul Oppenheimer, *Patents 101: Patentable Subject Matter and Separation of Powers*, 15 VAND. J. ENT. & TECH. L. 1 (2012); Guyan Liang, *Molecules of Carriers of Biological Information: A Chemist's Perspectives on the Patentability of Isolated Genes*, 22 ALB. L.J. SCI. & TECH. 133 (2012); Tiana Leia Russell, *Unlocking the Genome: The Legal Case Against Genetic Diagnostic Patents*, 16 MARQ. INTELL. PROP. L. REV. 81 (2012); Johanna Jacob, *Should Our Genes Be Part of the Patent Bargain? Maximizing Access to Medical Diagnostic Advances While Ensuring Research Remains Profitable*, 28 SANTA CLARA COMPUTER & HIGH TECH. L.J. 403 (2012); Shannon Murphy, *Who Is Swimming in Your Gene Pool? Harmonizing The International Pattern of Gene Patentability to Benefit Patient Care and the Biotechnology Industry*, 89 U. DET. MERCY L. REV. 397 (2012).

<sup>63</sup> See, e.g., Robert R. Sachs, *Punishing Prometheus: The Supreme Court's Blunders in Mayo v. Prometheus*, PATENTLY-O (Mar. 26, 2012), <http://www.patentlyo.com/patent/2012/03/punishing-prometheus-the-supreme-courts-blunders-in-mayo-v-prometheus.html> (last visited July 10, 2012).

A. “Machine or Transformation” Test and Additional Analysis  
Reaffirming Prior Precedent

As noted above, the Supreme Court initially remanded *Prometheus* to the Federal Circuit for consideration of the claim in light of its holding in *Bilski*. The Federal Circuit found that Prometheus’s claim was still patent eligible under the machine or transformation test, even though under *Bilski* this was no longer a dispositive test. The Supreme Court rejected the Federal Circuit’s conclusion and found that Prometheus’s claim failed both prongs of the test. Following the Supreme Court’s ultimate decision in *Prometheus*, members of the patent law community have wondered whether the “machine or transformation test” is still relevant, or if it has become an afterthought that the Supreme Court only addressed among its exhaustive rejections of all of Prometheus’s claims.

Lower courts—including the Federal Circuit—have consistently,<sup>64</sup> with one exception,<sup>65</sup> assessed a claim in light of both the “machine or transformation” analysis and additional elements laid out in *Prometheus* or prior Supreme Court or circuit court jurisprudence. The first case to cite *Prometheus* did not assess the claim under the “machine or transformation test,” but this now appears to have been an anomaly.<sup>66</sup> The remaining lower court cases have applied both the “machine or transformation” analysis and an additional analysis established under *Prometheus* or prior Supreme Court precedence when evaluating whether a claim has a patentable subject matter.<sup>67</sup> In all cases, both analyses

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<sup>64</sup> *Smartgene, Inc. v. Advanced Biological Labs.*, SA, 852 F. Supp. 2d 42 (D.D.C. 2012); *Advanced Software Design Corp. v. Fiserv, Inc.*, 625 F. Supp. 2d 815 (E.D. Mo. 2012); *Bancorp Services LLC v. Sun Life Assurance Co. of Can.*, 687 F.3d 1266 (Fed. Cir. 2012); *Aria Diagnostics, Inc. v. Sequenom Inc.*, 2012 WL 25999340 (N.D. Cal. 2012).

<sup>65</sup> *Nazomi Commc’n Inc. v. Samsung Telecomm.*, 2012 WL 967968, \*4 (N.D. Cal. 2012).

<sup>66</sup> *Id.* This may be due to the district court’s finding that the claim was patent eligible because it contained specific steps that rendered the claim to be “a specific, useful application.”

<sup>67</sup> *Smartgene*, 852 F. Supp. 2d 42; *Fiserv*, 2012 WL 1684495; *Bancorp Services*, 687 P.3d 1266; *Aria Diagnostics*, 2012 WL 25999340.

reached the same conclusion regarding whether a claim was patent eligible. Thus, the “machine or transformation test” remains an independent and important, but not solely dispositive, means for courts to assess patent eligibility.

### *B. How to Assess Patent Eligibility under § 101*

Lower federal courts have interpreted *Prometheus* in three ways that reaffirm prior patent eligibility precedent that lower courts were not always following. First, the district courts in the District of Columbia and Northern California have cited *Prometheus* for the proposition that courts should assess patent eligibility of claims by carefully analyzing them in light of prior precedent.<sup>68</sup> This approach was adopted in *Bilski* by only four justices,<sup>69</sup> so the unanimous affirmation of this approach in *Prometheus*,<sup>70</sup> even if only in dictum, was perhaps necessary to establish this analysis as the proper approach to such cases.

Second, lower courts have cited *Prometheus* for how to assess whether a claim is patent eligible under § 101.<sup>71</sup> In *Diehr*, the Supreme Court specifically noted that while steps individually may not be patent eligible, a new combination of these steps might be.<sup>72</sup> Yet, the *Prometheus* Court was very explicit in its approach of assessing each step of a claim individually and then considering all the steps collectively to determine if—after ignoring any aspects of a claim that simply restated a law of nature—the claim stated a

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<sup>68</sup> *OIP Techs., Inc. v. Amazon.com, Inc.*, 2012 WL 3985118, \*4 (N.D. Cal. 2012); *Smartgene*, 852 F. Supp. 2d at 52.

<sup>69</sup> *Bilski v. Kappos*, 561 U.S. \_\_\_, 130, S. Ct. 3218, 3229–31 (2010). The remaining justices concurred in the result only and not with respect to this portion of the opinion.

<sup>70</sup> *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. \_\_\_, 132 S. Ct. 1289, 1300–05 (2012).

<sup>71</sup> *Smartgene*, 852 F. Supp. 2d at 56–57 (D.D.C. 2012); *Bancorp Services*, 687 F.3d at 1279–80; *Cyberfone Sys., LLC v. Cellco P’ship*, 885 F. Supp. 2d 710, 716 (D.Del. 2012); *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1335 (Fed. Cir. 2012); *OIP Technologies*, 2012 WL 3985118 at \*17–18; *Classen Immunotherapies, Inc. v. Biogen IDEC*, 2012 WL 3264941, \*4–5 (D. Md. 2012).

<sup>72</sup> *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

patent eligible concept. This approach was implicitly followed in prior cases, but lower courts appear to cite *Prometheus* for this process because it was so explicitly stated.<sup>73</sup>

Although the Federal Circuit has followed the *Prometheus* approach in two cases,<sup>74</sup> Federal Circuit Judge Prost argued in his dissent to *CLS Bank* that the majority—written by Circuit Judge Linn and joined by Circuit Judge O’Malley—“does not even attempt to inquire whether the claims disclose anything inventive.”<sup>75</sup> The majority in *CLS Bank* claims to have followed this *Prometheus* approach by “examining the language of the claims”<sup>76</sup> and determining that the claim was not “manifestly abstract” after considering it in light of prior Supreme Court and Federal Circuit jurisprudence.<sup>77</sup> This case is now being heard en banc by the Federal Circuit, which may address this strong disagreement between the majority and dissent regarding whether the *Prometheus* approach was followed or simply ignored. The en banc decision on this issue could either reaffirm this *Prometheus* approach to the § 101 analysis or cabin the approach as one of several possible approaches that a court may take.<sup>78</sup>

Finally, although one district court held that *Prometheus* established § 101 as the threshold inquiry in any case determining if a patent was properly issued, the Federal Circuit remains split as to the holding of the case. Barely a week after the opinion in *Prometheus* was issued, the district court for the District of Columbia held that *Prometheus* reconfirms that § 101 is the

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<sup>73</sup> *Smartgene*, 852 F. Supp. 2d at 56–55; *Cyberfone Systems*, 2012 WL 3528115, at \*8; *OIP Technologies*, 2012 WL 3985118, at \*17–18; *Classen Immunotherapies*, 2012 WL 3264941, at \*4–5.

<sup>74</sup> *Bancorp Services*, 687 P.3d at 1279 (Lourie, J., joined by Prost and Wallach, J.) (noting that after setting aside unpatentable aspects of a claim, the court must determine under § 101 “what additional features remain in the claim” and referencing *Prometheus*, 132 S. Ct. at 1297). *Ass’n for Molecular Pathology*, 689 F.3d at 1335 (Lourie, J.; Moore, J., concurring; and Bryson, J., concurring in part and dissenting in part).

<sup>75</sup> *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, 685 F.3d 1341, 1357, *reh’g en banc granted, opinion vacated*, 484 F. App’x 559 (Fed. Cir. 2012) (Prost, J., dissenting).

<sup>76</sup> *Id.* at 1352, n.2.

<sup>77</sup> *Id.* at n.3.

<sup>78</sup> *CLS Bank*, 484 F. App’x 559.

threshold inquiry for any patent case.<sup>79</sup> This district court noted the Federal Circuit's resistance to the Supreme Court's previous determination of § 101 as at least a threshold determination. In *Bilski*, the nine justices of the Supreme Court agreed that "§ 101 patent-eligibility inquiry is only a threshold test,"<sup>80</sup> and that a claim must also be novel, nonobvious, and fully and particularly described,<sup>81</sup> but there was no strong indication that § 101 must be addressed first. Following *Bilski*, the Federal Circuit had previously expressed doubt about the absoluteness of § 101 as a threshold inquiry.<sup>82</sup> Indeed, the Federal Circuit has directed courts and litigants to first address patent invalidity with respect to the simpler-to-consider patentability defenses in §§ 102, 103, or 112.<sup>83</sup> By noting that *Prometheus* held—in dictum—that § 101 was a threshold inquiry and then applying § 101 as such, this district court implicitly rejected the Federal Circuit's prior approach and interpreted *Prometheus* to reaffirm *Bilski*'s holding that § 101 is a threshold inquiry.

However, in July 2012, the Federal Circuit effectively cabined the use of the § 101 analysis as a threshold inquiry in *CLS Bank*.<sup>84</sup> Circuit Judge Linn, writing for the majority, noted that *Prometheus* established that §§ 101, 102, 103, and 112 each "serves a different purpose and plays a different role."<sup>85</sup> Because a district court is "master of its own docket," it can choose which provision to apply first in determining whether a patent is valid.<sup>86</sup> Thus, the Federal Circuit did not treat *Prometheus* as requiring that § 101 analysis be the threshold inquiry that *must* be addressed *first*. Perhaps, as this

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<sup>79</sup> *Smartgene, Inc. v. Advanced Biological Labs., SA*, 852 F. Supp. 2d 42, 52-52 (D.D.C. 2012).

<sup>80</sup> *Bilski v. Kappos*, 561 U.S. \_\_\_, 130 S. Ct. 3218, 3225 (2010).

<sup>81</sup> 35 U.S.C. § 101 (2012). The other requirements are that a claim is novel, nonobvious, and fully and particularly described; *Bilski*, 130 S. Ct. at 3225.

<sup>82</sup> *Smartgene*, 852 F. Supp. 2d at 51 (citing *MySpace, Inc. v. GraphOn Corp.*, 672 F.3d 1250, 1260 (internal citations omitted)).

<sup>83</sup> *Id.*

<sup>84</sup> *CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 685 F.3d 1341, 1348, *reh'g en banc granted, opinion vacated*, 484 F. App'x 559 (Fed. Cir. 2012).

<sup>85</sup> *Id.* at 1348 (citing *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. \_\_\_, 132 S. Ct. 1289, 1303-04 (2012)).

<sup>86</sup> *Id.*

article suggests, the Federal Circuit felt that this portion of the Supreme Court's opinion was merely dictum. Circuit Justice Prost in dissent strongly disagreed and faulted his fellow judges for "creat[ing] an entirely new framework that in effect allows courts to avoid evaluating patent eligibility under § 101 whenever they so desire,"<sup>87</sup> even after the Supreme Court "hint[ed] (not so tacitly) that [the Federal Circuit's] subject matter patentability test is not sufficiently exacting."<sup>88</sup> As noted above, the Federal Circuit is currently rehearing this case en banc and may address this issue.<sup>89</sup> For now, however, it remains unclear whether the Federal Circuit will interpret *Prometheus* as limited to the facts of that case or having further-reaching implications for § 101 analysis.

### C. Redefining Patentability for Diagnostic Medical Method Claims

*Prometheus* has been more fully analyzed in two cases regarding biomedical patents. First, in *Smartgene, Inc. v. Advanced Biological Laboratories*, the District Court for the District of Columbia concluded that patents regarding "the system, method, and computer program for guiding the selection of therapeutic treatment regimes for complex disorders" were not patent eligible.<sup>90</sup> The court closely summarized *Benson, Flook, Diehr, Bilski* and *Prometheus*<sup>91</sup> before framing Smartgene's claims as situated identically to those in *Prometheus*, between the *Flook* and *Diehr* claims.<sup>92</sup> That is, Smartgene's claims were not patent eligible because they merely restated abstract ideas regarding how physicians diagnose patients.<sup>93</sup>

Second, in *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, the Federal Circuit examined the

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<sup>87</sup> *Id.* at 1356.

<sup>88</sup> *Id.* (citing *Prometheus*, 566 U.S. \_\_\_, 132 S. Ct. 1289 and *Bilski v. Kappos*, 561 U.S. \_\_\_, 130 S. Ct. 3218 (2010)).

<sup>89</sup> *CLS Bank*, 484 F. App'x 559 (Fed. Cir. 2012) (rehearing en banc).

<sup>90</sup> *Smartgene, Inc. v. Advanced Biological Labs., SA*, 852 F. Supp. 2d 42, 45 (D.D.C. 2012).

<sup>91</sup> *Id.* at 52–55.

<sup>92</sup> *Id.* at 55.

<sup>93</sup> *Id.*



patentability of several claims, the most relevant being diagnostic “method claims for comparing or analyzing isolated DNA sequences associated with predisposition of breast and ovarian cancers.”<sup>94</sup> The Federal Circuit closely compared the situation to that in *Prometheus* when assessing the patent eligibility of this method patent claim.<sup>95</sup> The court held that the claims’ steps comparing breast cancer DNA sequences from patients with control DNA sequences was similar to the administering and determining steps in *Prometheus*.<sup>96</sup> This portion of the claim was held to be patent ineligible.<sup>97</sup>

Collectively, the latter two cases indicate that any method claims that personalize medical treatment through comparison of a patient’s symptoms or naturally occurring DNA sequences to a standard treatment mechanism or standard DNA sequence will not be patent eligible. It is instructive that in *Association for Molecular Pathology*, the Federal Circuit expressly held that *Prometheus* does not govern portions of the claims relating to transformed DNA sequences and transformed host cells.<sup>98</sup> Both claims were found to be novel compositions of matter by the majority.<sup>99</sup> Based on these cases, it seems that companies seeking to patent claims regarding personalized medicine will do best if they have a physically transformed product derived from the patient to guide treatment.

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<sup>94</sup> Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1305 (Fed. Cir. 2012).

<sup>95</sup> *Id.* at 1335.

<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> *Id.* at 1331–37.

<sup>99</sup> *Id.* at 1303 (holding that *Prometheus* does not impact the court’s analysis regarding whether isolated DNA sequences were patent ineligible as natural components; however, Circuit Judge Bryson dissented and argued that “mere incidental changes to a naturally occurring product,” like mere incidental changes to an abstract idea, do not result in a patent eligible claim). This analysis may change, as the Supreme Court has granted certiorari in this case. Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 694 (2012) (granting certiorari).

### CONCLUSION

Despite concern within the patent community, *Prometheus* has not radically changed the landscape of § 101 jurisprudence, and instead has been read as generally reaffirming prior cases. *Prometheus* may have established that § 101 is *the* threshold analysis in that case, but it is unclear how broadly lower courts will apply that portion of the case, which is arguably dictum. The Federal Circuit's *en banc* holding in *CLS Bank* will be instructive in how it, and perhaps district courts, will read *Prometheus*. Nonetheless, critics do appear to be correct that *Prometheus* has had a strong impact on courts' view of method claims regarding personalized medical techniques and will likely continue to pose a great challenge to patentability of these types of claims.

### PRACTICE POINTERS

- Evaluate a claim under both the preemption analysis and “machine or transformation” analysis.
- Address first whether a patent claim contains an innovative concept in claims elements that does not relate to a law of nature or natural phenomena and thus passes the § 101 threshold inquiry before turning to other statutory requirements. Emphasize the significance of these elements in the specification. However, be prepared to address the statutory requirements during patent prosecution and in any order during oral arguments.
- Include claims of varying scope, ranging from those that clearly meet the above patent eligibility test to those that may not meet it. The case law has not established the threshold test for patent eligibility. Be prepared for the threshold analysis to change as the case law develops. If claims are rejected, file a continuation application for allowed claims and appeal with respect to rejected claims in case the threshold test is changed during the prosecution.
- Consider using reexamination as a means to amend a patent claim to include an additional step(s) that contain an innovative concept that will render it patent eligible.

- Note that other countries may have more generous approach for patent eligibility. For example, the European Patent Office allowed Prometheus's claims without any eligibility question.