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## Prometheus Laboratories v. Mayo Clinic's Gift to the Biotech Industry: A Study of Patent-Eligibility of Medical Treatment and Diagnostic Methods after *Bilski*

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*Prometheus Laboratories v. Mayo Clinic's*  
**Gift to the Biotech Industry:**  
**A Study of Patent-Eligibility of Medical Treatment and**  
**Diagnostic Methods after *Bilski***

*Dan Hoang*



# ***Prometheus Laboratories v. Mayo Clinic's Gift to the Biotech Industry: A Study of Patent-Eligibility of Medical Treatment and Diagnostic Methods after *Bilski****

By Dan Hoang\*

## I. INTRODUCTION

¶1 In *In re Bilski*, the Federal Circuit, sitting en banc, attempted to create a definitive test to determine whether a claimed process was patentable subject matter.<sup>1</sup> The Federal Circuit declared, “A claimed process is surely patent-eligible under § 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>2</sup> When the Supreme Court granted certiorari,<sup>3</sup> the collective patent community entered a period of uncertainty, as it was unclear whether the new “machine-or-transformation” test would pass muster with the Supreme Court and how the stricter standard for patent-eligibility would impact many of the different industries that depend on process patents to protect their innovations.<sup>4</sup>

¶2 For all of the fanfare awaiting the Supreme Court’s decision, it was ultimately unsatisfying, as the Court chose to draft a narrow opinion on the patent-eligibility of the particular technology at issue in the case, and the Court refused to establish any definitive standard or multi-factor test for patent-eligibility across all technologies.<sup>5</sup> Furthermore, while the Court accepted the machine-or-transformation test as a useful tool in determining patentability, the Court refused to accept it as the sole test.<sup>6</sup> Rather, the

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\* Northwestern University School of Law, J.D. Candidate 2011. I dedicate this article to my parents, Phuong and Huong-Nga, for their unwavering support and for being the source of my drive and inspiration. I also thank my sister, Trang, for her enduring encouragement and willingness to always share a laugh.

<sup>1</sup> *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008).

<sup>2</sup> *Id.* (citing 35 U.S.C. § 101 (1952); *Diamond v. Diehr*, 450 U.S. 175, 192 (1981); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972)).

<sup>3</sup> *Bilski v. Doll*, 129 S. Ct. 2735, 2735 (2009).

<sup>4</sup> See Lauren Katzenellenbogen et al., *Alternative Software Protection in View of In re Bilski*, 7 NW. J. TECH. & INTELL. PROP. 332 (2009) (discussing alternate means of intellectual property protection for the software industry, because it is unclear whether processes encoded in software for general purpose computers are sufficiently tied to a particular machine to qualify for protection under *In re Bilski*); Elizabeth Ruzich, *In re Bilski and the Future of Business Method and Software Patents*, 50 IDEA 103 (2009) (critically reviewing the key decisions from the Board of Patent Appeals and Interferences concerning business method and software patents that were decided shortly after *In re Bilski* was released).

<sup>5</sup> *Bilski v. Kappos*, 130 S. Ct. 3218, 3229–30 (2010) (“Rather than adopting categorical rules that might have wide-ranging and unforeseen impacts, the Court resolves this case narrowly on the basis of this Court’s decisions in *Benson*, *Flook*, and *Diehr*, which show that petitioners’ claims are not patentable processes because they are attempts to patent abstract ideas.”).

<sup>6</sup> *Id.* at 3227 (“[T]he machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101. The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible ‘process.’”).

Court warned that the machine-or-transformation test was developed from technologies of the Industrial Age, and it may be insufficient for the new technological fields that have blossomed with the Information Age<sup>7</sup>—such as “software, *advanced diagnostic medicine techniques*, and inventions based on linear programming, data compression, and the manipulation of digital signals.”<sup>8</sup>

¶3 The Supreme Court’s warning raised significant concerns among the biotechnology industry about whether it could continue to use process patents to protect proprietary diagnostic techniques.<sup>9</sup> However, the biotechnology industry can seek comfort in the Federal Circuit’s recent opinion in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*.<sup>10</sup> The patent at issue claimed a method for administering dosages of a class of drugs into the human body to optimize efficacy and minimize adverse effects.<sup>11</sup> The Federal Circuit was presented with the question of whether the patent permissibly claimed a specific and practical application of a natural correlation, or whether the patent impermissibly claimed exclusive rights over all uses of the natural correlation.<sup>12</sup> Despite the Supreme Court’s recent ruling in *Bilski v. Kappos*, the Federal Circuit found that the machine-or-transformation test was still the appropriate standard for patent-eligibility.<sup>13</sup> Upon applying the machine-or-transformation test, the Federal Circuit found that this treatment method was patent-eligible, because the treatment method necessarily transformed the biochemical composition of the human body and the drug as they reacted.<sup>14</sup> As this Note will explain, the machine-or-transformation test is over-inclusive when applied to the biotechnology industry, as the *Prometheus Laboratories* decision leaves the door open to granting process patents for even broader claims, such as medical treatments, surgical procedures, diagnostic methods, and other medical procedures.

¶4 This Note will provide a critical analysis of the methods the Federal Circuit employed in *Prometheus Laboratories* to find that the claimed medical treatments were not patentable subject matter. Furthermore, this Note will emphasize the disconnect between the manner in which the Federal Circuit applied the machine-or-transformation test in *Prometheus Laboratories* and the directive from the Supreme Court in *Bilski* to consider alternate standards for patent-eligibility. Section II traces the history of the machine-or-transformation test as originally developed and characterized by the Supreme Court. This section will explain how the machine-or-transformation test developed as one of the means to determine whether a patent that makes use of a natural phenomenon

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<sup>7</sup> *Id.* (“The machine-or-transformation test may well provide a sufficient basis for evaluating processes similar to those in the Industrial Age . . . . But there are reasons to doubt whether the test should be the sole criterion for determining the patentability of inventions in the Information Age.”).

<sup>8</sup> *Id.* (emphasis added).

<sup>9</sup> Brief for Biotechnology Industry Organization et al. as Amici Curiae in Support of Neither Party, *Bilski v. Kappos*, 130 S. Ct. 3218 (2010) (No. 08-964), 2009 WL 2418478, at \*5–6. See also Brian P. Murphy & Daniel P. Murphy, *Bilski’s “Machine-or-Transformation” Test: Uncertain Prognosis for Diagnostic Methods and Personalized Medicine Patents*, 20 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 755 (2010); Margaret Kubick, Comment, *An Uncertain Future: The Impact of Medical Process and Diagnostic Method Patents on Healthcare in the United States*, 9 NW. J. TECH. & INTELL. PROP. 280 (2010); Matthew D. Show, Note, *A Dreadful Prognosis: Patentability of Diagnostic and Personalized Medical Procedures in the Wake of In re Bilski*, 2 HASTINGS SCI. & TECH. L.J. 301 (2010).

<sup>10</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347 (Fed. Cir. 2010).

<sup>11</sup> *Id.* at 1349–50.

<sup>12</sup> *Id.* at 1354.

<sup>13</sup> *Id.* at 1355.

<sup>14</sup> *Id.* at 1355–56.

is so broad that it would preempt the entire use of the natural phenomenon. Section III evaluates the manner that the Federal Circuit actually applied the machine-or-transformation test in *Prometheus Laboratories*. This part will suggest that the Federal Circuit applied the machine-or-transformation test rigidly and without full consideration of the purpose behind the test as articulated by the Supreme Court in *Bilski*. Section IV will apply the machine-or-transformation test using the method described in *Bilski* to the facts presented in *Prometheus Laboratories*. This Note concludes that the claims to medical treatment methods in *Prometheus Laboratories* are so broad that they preempt all applications of the natural phenomenon. Especially for patents incorporating a natural phenomenon that is inherently transformative, a rigid application of the machine-or-transformation test is inadequate, because the mere presence of a transformation is not sufficient to limit the scope of the patent claims to particular applications of the natural phenomenon. Finally, Section V will challenge the Federal Circuit's continued use of the machine-or-transformation test as a standard for patent-eligibility for process patents in the biotechnology industry. This section will propose a refined framework that aligns the test for patentable subject matter with the purpose of having a patent-eligibility requirement.

## II. DEVELOPMENT OF THE MACHINE-OR-TRANSFORMATION TEST

### A. *Process Patents as Patentable Subject Matter*

¶15 Section 101 of Title 35 of the United States Code establishes the statutory categories for patent-eligible subject matter. A patent may be granted to “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”<sup>15</sup> Processes have been explicitly listed as patent-eligible subject matter since they were added in the 1952 Amendments to the Patent Act.<sup>16</sup> The Patent Act explicitly defines the term process to mean a “process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”<sup>17</sup> The self-referential definition of the term process proved to be an insufficient definition for the courts to apply. The Supreme Court found that the ordinary sense of the word “process,” as required in a literal reading of the statutory definition, proved to be overly inclusive.<sup>18</sup>

¶16 Instead of relying entirely on the statutory definition, the Supreme Court adopted general principles to determine whether a claimed procedure involving a series of steps falls within the Patent Act's scope of the term process. The Court recognized that the

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<sup>15</sup> 35 U.S.C. § 101 (2006).

<sup>16</sup> See Patent Act of 1952, Pub. L. No. 82-593, § 101, 66 Stat. 792 (1952). Among the categories of patentable subject matter, the term process was added in the 1952 Patent Act in order to replace the term art. S. REP. NO. 82-1979, at 5 (1952). Congress was concerned that the meaning of the term art as used in the Patent Act would be confused with the use of the term useful art in the Constitution and the term art in other statutes. *Id.* However, Congress clarified that the terms art and process as used in the Patent Act were intended to mean process or method. *Id.*

<sup>17</sup> 35 U.S.C. § 100 (1952).

<sup>18</sup> *Parker v. Flook*, 437 U.S. 584, 588–89 & n.9 (1978) (explaining that a purely literal reading of the statutory definition of the term process opened the door for previously ineligible methods that simply claimed laws of nature).

term process should be interpreted broadly,<sup>19</sup> because Congress intended the statutory categories for patent-eligibility to “include anything under the sun that is made by man.”<sup>20</sup> However, “laws of nature, natural phenomena, and abstract ideas” cannot receive patent protection.<sup>21</sup> As a matter of policy, the Court has refused to recognize any patent laying claim to a natural phenomenon, because such phenomena exist outside of human intervention and are free to all people.<sup>22</sup>

### B. Process Patents Incorporating Natural Phenomenon

¶7 The controversy over process patents arose from those inventions that were made by man but also incorporated the laws of nature, natural phenomena, or abstract ideas. The question became how much incorporation of the natural phenomenon was acceptable. The Supreme Court drew a distinction between permissible patents that lay claim to a specific application of a natural phenomenon and impermissible patents that lay claim to the natural phenomenon itself.<sup>23</sup> Patents that would wholly preempt all of the practical uses of a natural phenomenon were rejected as overly broad.<sup>24</sup>

¶8 In response to this distinction, the Supreme Court foresaw attempts by patent prosecutors to draft artificial limitations upon a patent’s claims for the purpose of masking the fact that the patent actually laid claim to the natural phenomenon itself.<sup>25</sup> In *Diamond v. Diehr*, the Supreme Court renounced the practice of adding artificial limitations—such as restricting the patent to a particular field of use—to circumvent the restriction on claiming the natural phenomenon itself.<sup>26</sup> Otherwise, for example, a patent claiming a method to measure far distances by solving the Pythagorean Theorem could contain a final clause limiting the field of use to only land surveying techniques.<sup>27</sup> The Supreme Court explained that merely limiting the use of a natural phenomenon to a particular technological environment did not cure the defect that the patent was laying claim to the natural phenomenon itself.<sup>28</sup>

¶9 Similarly, the Supreme Court renounced the practice of adding artificial limitations upon a patent’s claims by drafting superfluous steps into the claimed process. In *Parker v. Flook*, the patentee claimed a method for updating variable alarm limits during a catalytic conversion process.<sup>29</sup> During the conversion process, data on changes in the

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

<sup>20</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting from S. REP. NO. 82-1979).

<sup>21</sup> *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

<sup>22</sup> *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130–31 (1948).

<sup>23</sup> *Id.* at 130.

<sup>24</sup> *E.g.*, *Gottschalk v. Benson*, 409 U.S. 63, 71–72 (1972) (finding a patent that used an algorithm to convert binary-coded decimal numerals into pure binary numerals would wholly preempt the algorithm, because there were no substantial practical applications of the algorithm outside of the claimed scope of the patent).

<sup>25</sup> *Diehr*, 450 U.S. at 191–92.

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

<sup>27</sup> *In re Bilski*, 545 F.3d 943, 957 n.13 (Fed. Cir. 2008) (citing *Parker v. Flook*, 437 U.S. 584, 590 (1978)).

<sup>28</sup> *Diehr*, 450 U.S. at 191 (explaining “[a] mathematical formula as such is not accorded the protection of our patent laws, and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment”) (citation omitted).

<sup>29</sup> *Parker*, 437 U.S. at 585.

conditions—such as temperature, pressure, and flow rates—were constantly monitored.<sup>30</sup> An algorithm would interpret these measurements and periodically adjust the alarm limits to more accurately reflect the potential for abnormal circumstances.<sup>31</sup> Even though the claimed process included additional steps beyond the claims to the algorithm—such as recalculating the values for the alarm limits—the Supreme Court found these additional steps to be insignificant “post-solution activity.”<sup>32</sup> Insignificant post-solution activities cannot turn an otherwise ineligible claim into patentable subject matter.<sup>33</sup> Since *Parker v. Flook*, the Federal Circuit has carefully examined any data-gathering steps to determine whether they are merely just insignificant post-solution activities.<sup>34</sup> For a process patent that depends upon utilizing a natural phenomenon, the patent must have claims that limit the scope of the patent to a particular application of the natural phenomena, rather than simply adding field-of-use limitations or insignificant post-solution activities.

### C. The Pattern of Patent-Eligible Machines or Transformations

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The machine-or-transformation test began as one of the methods to determine whether a patent’s claims were sufficiently limited to a particular application of a natural phenomenon to be patent-eligible under § 101.<sup>35</sup> Analyzing a few key patents that were deemed to claim only a particular application of a natural phenomenon rather than the natural phenomenon itself, the Supreme Court in *Gottschalk v. Benson* recognized a pattern.<sup>36</sup> The Supreme Court remarked that the “[t]ransformation and reduction of an article ‘to a different state or thing’ is the clue to the patentability of a process claim that does not include particular machines.”<sup>37</sup> At the time, the Supreme Court was not prepared to establish this clue as the definitive standard for determining process patent-eligibility.<sup>38</sup> However, the Supreme Court grew more sympathetic to finding processes that were tied to a particular machine or transformation as patent-eligible. For example, in *Parker v. Flook*, the Supreme Court acknowledged that “[a]n argument can be made, however, that this Court has only recognized a process as within the statutory definition

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

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

<sup>32</sup> *Id.* at 590.

<sup>33</sup> *See id.*

<sup>34</sup> *E.g., In re Grams*, 888 F.2d 835, 840 (Fed. Cir. 1989) (reasoning that a “step in the claim to derive data for the algorithm will not render the claim statutory”).

<sup>35</sup> *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008) (recognizing that the Supreme Court developed the machine-or-transformation test “to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself”).

<sup>36</sup> *Gottschalk v. Benson*, 409 U.S. 63, 70–71 (1972). For example, the Supreme Court considered *O’Reilly v. Morse*, 56 U.S. (15 How.) 62 (1853), where Morse claimed a process for transmitting signals across distances using electromagnetism. The Supreme Court rejected Morse’s final claim, because the final claim did not disclose specific machinery that Morse could use to harness the electromagnetic forces. The Supreme Court wanted to preserve the possibility for the future invention of another means to use electromagnetism to transmit signals.

<sup>37</sup> *Gottschalk*, 409 U.S. at 70.

<sup>38</sup> *Id.* at 71 (“It is argued that a process patent must either be tied to a particular machine or apparatus or must operate to change articles or materials to a ‘different state or thing.’ We do not hold that no process patent could ever qualify if it did not meet the requirements of our prior precedents.”).

when it either was tied to a particular apparatus or operated to change materials to a ‘different state or thing.’”<sup>39</sup>

¶11 The Supreme Court had the opportunity in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.* to clarify the test for patentable subject matter.<sup>40</sup> The patent in *Laboratory Corp.* dealt with a process for diagnosing vitamin deficiency based on a patient’s homocysteine levels.<sup>41</sup> The process at issue was essentially comprised of a first step to determine the concentration of a metabolite in a sample of body fluid and a second step to compare the determined concentration against pre-defined levels for diagnosis.<sup>42</sup> The Supreme Court initially granted certiorari to determine “whether the patent claim is invalid on the ground that it improperly seeks to ‘claim a monopoly over a basic scientific relationship.’”<sup>43</sup> Ultimately, however, the Supreme Court decided to revoke the grant of certiorari as improvidently granted.<sup>44</sup>

¶12 In a dissenting opinion, Justice Breyer, joined by Justice Stevens and Justice Souter, suggested that the patent at issue was invalid, because it claimed a natural phenomenon.<sup>45</sup> Characterizing the patent claim as “no more than an instruction to read some numbers in light of medical knowledge,” Justice Breyer argued that the patent used abstract patent language to claim the correlation between homocysteine and vitamin deficiency, which is an unpatentable natural phenomenon.<sup>46</sup> Unfortunately, Justice Breyer did not cite any standard for determining whether the patent was claiming a natural phenomenon, so no standard for determining patentable subject matter for process patents can be gleaned from Justice Breyer’s dissenting opinion.<sup>47</sup>

¶13 The Supreme Court most recently opined on the issue of patentable subject matter in response to the Federal Circuit’s adoption of the machine-or-transformation test in the *Bilski* case.<sup>48</sup> Under the Federal Circuit’s machine-or-transformation test, a claimed

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<sup>39</sup> *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978).

<sup>40</sup> *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006).

<sup>41</sup> *Id.* at 129 (Breyer, J., dissenting).

<sup>42</sup> The patent at issue claimed:

A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:

Assaying a body fluid for an elevated level of total homocysteine; and  
correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

U.S. Patent No. 4,940,658 col.41 (filed Nov. 20, 1986).

<sup>43</sup> *Lab. Corp.*, 548 U.S. at 125 (Breyer, J., dissenting).

<sup>44</sup> *Id.* at 125–26.

<sup>45</sup> *Id.* at 137–38.

<sup>46</sup> *Id.*

<sup>47</sup> Justice Breyer recognized that determining the scope of a phenomenon of nature is not easy to define. *Id.* at 134. Deciding that the facts presented by *Laboratory Corp.* clearly claimed a natural phenomenon, Justice Breyer explained that this case “does not require us to consider the precise scope of the ‘natural phenomenon’ doctrine or any other difficult issue.” *Id.* at 135.

<sup>48</sup> *Bilski v. Kappos*, 130 S. Ct. 3218 (2010); *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008). In addition to the machine-or-transformation test, the Federal Circuit and its predecessors have suggested other standards for determining patentable subject matter under § 101. The Freeman-Walter-Abele Test emphasized that the claimed process must manipulate physical things. *In re Abele*, 684 F.2d 902, 905 (C.C.P.A. 1982). Under the Freeman-Walter-Abele Test, a court must conduct a two-part analysis. *Id.* A court must first determine whether the claim directly or indirectly addressed a natural phenomenon. *Id.* If the patent relates to a natural phenomenon, the court must secondly determine whether the natural phenomenon is “applied in any manner to physical elements or process steps.” *Id.* at 907 (quoting *In re Walter*, 618 F.2d

process must be tied to a particular machine, or it must transform an article into a different state or thing.<sup>49</sup> After identifying the machine or transformation that limits the process to a particular application of the natural phenomenon, the process must satisfy two additional conditions. First, the specific machine or transformed article “must impose meaningful limits on the claim’s scope to impart patent-eligibility.”<sup>50</sup> Second, the involvement of the specific machine or transformed article must be more than insignificant extra-solution activities.<sup>51</sup> These two conditions ensure that the claimed machine or transformation actually places a practical limitation upon the scope of the process so that the patent only lays claim to a specific application of the natural phenomenon.

¶14 The Supreme Court held that the machine-or-transformation test is not the sole test for determining whether a claimed process is patentable under § 101.<sup>52</sup> Indeed, nothing in the Patent Act dictates that a claimed process must be tied to a particular machine or must transform a particular article.<sup>53</sup> Furthermore, while dicta from Supreme Court cases have referenced the machine-or-transformation test, the Supreme Court has never endorsed it as the exclusive test for patentability.<sup>54</sup> Instead of relying on any bright-line rules, the Supreme Court looked to *Benson*, *Flook*, and *Diehr* to determine that the *Bilski* claim fell outside the bounds of § 101.<sup>55</sup> Although the Supreme Court did not apply the machine-or-transformation test, the Court did not reject the machine-or-transformation test outright. Instead, the Supreme Court declared that “the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101.”<sup>56</sup>

### III. *PROMETHEUS LABORATORIES, INC. v. MAYO COLLABORATIVE SERVICES*

#### A. *Procedural History*

¶15 *Prometheus Laboratories* is an important case that has followed *Bilski*’s path through the courts and has served as an indicator of how the Federal Circuit intends to apply the *Bilski* precedent. The Federal Circuit’s first decision in *Prometheus Laboratories* was among the earliest opinions to apply the machine-or-transformation test after the Federal Circuit announced it.<sup>57</sup> The Federal Circuit found that the claimed method was patent-eligible, because it was tied to a particular transformation.<sup>58</sup> After the

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758, 769 (C.C.P.A. 1980). Alternatively, the “useful, concrete, and tangible result” test emphasized the outcome of the claimed process. Claiming a patentable subject matter depended on identifying a useful, concrete, and tangible result from the use of the natural phenomenon. *State St. Bank & Trust Co. v. Signature Fin. Grp., Inc.* 149 F.3d 1368, 1373 (Fed. Cir. 1998). Leading into the Federal Circuit’s decision in *In re Bilski*, it was uncertain which one among these tests was the prevailing standard for patentable subject matter.

<sup>49</sup> *In re Bilski*, 545 F.3d at 961.

<sup>50</sup> *Id.* at 961–62.

<sup>51</sup> *Id.* at 962.

<sup>52</sup> *Bilski*, 130 S. Ct. at 3226–27.

<sup>53</sup> *Id.* at 3226.

<sup>54</sup> *Id.* at 3226–27.

<sup>55</sup> *Id.* at 3229–30.

<sup>56</sup> *Id.* at 3227.

<sup>57</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009).

<sup>58</sup> *Id.* at 1346.

Supreme Court granted certiorari to the *Bilski* case,<sup>59</sup> the Court also chose to grant certiorari to *Prometheus Laboratories* for the same issue of patentable subject matter.<sup>60</sup> While *Bilski* concluded with the judgment from the Supreme Court, *Prometheus Laboratories* was remanded back to the Federal Circuit for further consideration in light of the new *Bilski* decision.<sup>61</sup> The Federal Circuit has recently released its second decision in *Prometheus Laboratories*,<sup>62</sup> which is among the earliest opinions by the Federal Circuit on the issue of patent-eligibility after the Supreme Court decision in *Bilski*.

¶16 Applying a similar analysis as in its first decision, the Federal Circuit reaffirmed that the claimed method in *Prometheus Laboratories* was patentable subject matter.<sup>63</sup> Comparing the Federal Circuit's reasoning in its first and second opinion provides insight into the Federal Circuit's perception of how the Supreme Court's decision in *Bilski* changed the doctrine of patent-eligibility. In particular, the fact that the Federal Circuit applied the same reasoning in both of its opinions in *Prometheus Laboratories*, despite the Supreme Court's invitation to adopt alternative standards for this type of technological field,<sup>64</sup> suggests that the Federal Circuit does not view the *Bilski* case as a major game-changer to its prior decisions on patent-eligibility.

### B. Factual Background

¶17 Prometheus Laboratories is the exclusive licensee of two patents that claim methods for treating immune-mediated gastrointestinal disorders.<sup>65</sup> These disorders irritate and inflame the gastrointestinal tract, causing diarrhea, abdominal pain, and fever.<sup>66</sup> In more severe cases, these disorders may require surgery to repair, and they place patients at an increased risk for developing intestinal cancer.<sup>67</sup> These disorders can be treated with certain types of drugs that deliver 6-mercaptopurine and 6-thioguanine to the patient, which help to alleviate the symptoms of the disorder.<sup>68</sup> However, these drugs can be prone to complications, such as non-responsiveness and drug toxicity, which exacerbate the condition.<sup>69</sup>

¶18 Prometheus Laboratories' two patents seek to optimize the delivery of these drugs to improve efficacy and prevent any complications. The first patent ('623 Patent) claims a "method of treating IBD/Crohn's Disease and related conditions wherein drug

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<sup>59</sup> *Bilski v. Doll*, 129 S. Ct. 2735 (2009).

<sup>60</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 130 S. Ct. 3543 (2010).

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

<sup>62</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347 (Fed. Cir. 2010).

<sup>63</sup> *Id.* at 1355 ("We do not think that either the Supreme Court's *GVR Order* or the Court's *Bilski* decision dictates a wholly different analysis or a different result on remand. . . . [T]he Court did not disavow the machine-or-transformation test. And, as applied to the present claims, the 'useful and important clue, an investigative tool,' leads to a clear and compelling conclusion . . .").

<sup>64</sup> *Bilski v. Kappos*, 130 S. Ct. 3218, 3227 (2010) ("[T]here are reasons to doubt whether the [machine-or-transformation] test should be the sole criterion for determining the patentability of inventions in the Information Age. . . . [T]he machine-or-transformation test would create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals.").

<sup>65</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1339 (Fed. Cir. 2009).

<sup>66</sup> U.S. Patent No. 6,355,623 col.1 (filed Apr. 8, 1999).

<sup>67</sup> *Id.*

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

<sup>69</sup> *Id.*

metabolite levels in host blood cells determine subsequent dosage.”<sup>70</sup> The second patent (’302 Patent) claims “methods of optimizing drug therapeutic efficacy for treatment of immune-mediated gastrointestinal disorders.”<sup>71</sup> The first claim in the ’623 Patent is representative of the claims at issue in both patents.<sup>72</sup> The first claim in the ’623 Patent states:

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
  - (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
  - (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

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

wherein the level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.<sup>73</sup>

The district court found that both patents recited a natural phenomenon in a manner that wholly preempted the use of that natural phenomenon.<sup>74</sup> The district court first determined that the correlations recited in the wherein clauses are natural phenomena, because metabolizing 6-thioguanine naturally produces the desired therapeutic and toxic effects.<sup>75</sup> Furthermore, the district court found that because the steps of administering and determining the levels of 6-thioguanine are merely data-gathering steps, the claims cover the correlations themselves.<sup>76</sup> By claiming the correlations, the patent claimed all substantial practical applications of the correlations, which preempted the use of the natural phenomenon.<sup>77</sup> However, based on its application of the machine-or-transformation test, the Federal Circuit reversed the district court’s findings.<sup>78</sup> The Federal Circuit found that both patents were sufficiently tied to the transformations of various articles to be patent-eligible.<sup>79</sup>

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<sup>70</sup> *Id.* at [54].

<sup>71</sup> U.S. Patent No. 6,680,302, at [54] (filed Dec. 27, 2001).

<sup>72</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1340 (Fed. Cir. 2009).

<sup>73</sup> ’623 Patent col.20.

<sup>74</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 04cv1200, 2008 WL 878910, at \*5, \*10–13 (S.D. Cal. Mar. 28, 2008).

<sup>75</sup> *Id.* at \*9.

<sup>76</sup> *Id.* at \*11.

<sup>77</sup> *Id.*

<sup>78</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1349–50 (Fed. Cir. 2009).

<sup>79</sup> *Id.* at 1345–46.

C. *Federal Circuit's First Opinion in Prometheus Laboratories Prior to the Supreme Court's Opinion in Bilski*

¶19 The Federal Circuit broke up the patents' claimed process into three general steps. The first step (the administering step) claimed a process of administering the drug into the patient's body.<sup>80</sup> The second step (the determining step) claimed a process of determining the concentration of particular metabolites in the patient's body.<sup>81</sup> The third step (the mental step) claimed a mental process of comparing the determined concentrations against pre-established limits.<sup>82</sup>

¶20 The Federal Circuit determined that the administering step inherently laid claim to the transformation of the body and the drug.<sup>83</sup> As the drug is introduced into the body, the drug is metabolized in a series of biological and chemical reactions.<sup>84</sup> The metabolizing of the drug and the resulting biochemical changes to the body provide the treatment that mitigates the symptoms of these immune-mediated gastrointestinal disorders.<sup>85</sup> Since the purpose of the entire process is to optimize the treatment method for these immune-mediated gastrointestinal disorders, the Federal Circuit determined that the administering step was central to the claimed purpose.<sup>86</sup>

¶21 The Federal Circuit was not deterred by the fact that the drug, once introduced into the body, metabolizes according to the natural biological and chemical processes. Agreeing with the position advocated by Prometheus Laboratories, the Federal Circuit explained that "quite literally every transformation of physical matter can be described as occurring according to natural processes and natural law."<sup>87</sup> Consequently, the Federal Circuit was not concerned that the claimed transaction operated by natural principles; rather, the Court emphasized that the process of administering the drug into the body is not itself a result of a natural process.<sup>88</sup> In other words, so long as the claimed process sets up the conditions needed for the natural process to proceed, the Federal Circuit is satisfied that a patent for the process of setting up the conditions involves a transformation.

¶22 Similarly, the Federal Circuit found that the determining step was tied to a particular transformation.<sup>89</sup> The Federal Circuit recognized that determining the concentration of metabolite levels required the testing of a bodily sample from the patient.<sup>90</sup> As the metabolites are extracted from the blood, the sample is transformed into a substance that is no longer human blood or human tissue.<sup>91</sup> The Federal Circuit found that the determining step was central to the purpose of the overall process, because optimizing the efficacy and minimizing the toxicity of the drug during a course of

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<sup>80</sup> *Id.* at 1346.

<sup>81</sup> *Id.* at 1347.

<sup>82</sup> *Id.* at 1348.

<sup>83</sup> *Id.* at 1346.

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

<sup>85</sup> *Id.*

<sup>86</sup> *Id.* at 1345.

<sup>87</sup> *Id.* at 1346.

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

<sup>89</sup> *Id.* at 1347.

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

treatment required getting accurate measurements of the concentration of these metabolites in the body.<sup>92</sup>

¶23 The Federal Circuit was not concerned that some claims of the process did not describe a particular method for determining the concentration of the metabolites. In particular, Claim 1 of the '623 Patent, which the Court found representative of the independent claims at issue, is not tied to a particular procedure for determining the level of the metabolite.<sup>93</sup> However, the Federal Circuit was satisfied that the determining step necessarily involved a transformation, because some of the dependent claims to the patent specify a method of manipulation for determining the concentration, such as high pressure liquid chromatography.<sup>94</sup>

¶24 The Federal Circuit also found that the mental step did not detract from the patent-eligibility of the entire process, despite recognizing that the mental step was entirely a mental process that did not transform any physical articles.<sup>95</sup> The Federal Circuit declared that the presence of the mental step did not affect the patent-eligibility of the entire process, as long as the remaining steps, namely the administering and determining step, did lay claim to a transformation.<sup>96</sup>

¶25 Finally, the Federal Circuit evaluated whether the entire three-step process wholly preempted the natural phenomenon—the correlations between metabolite levels and the efficacy or toxicity of the metabolites.<sup>97</sup> The Federal Circuit's preemption analysis simply provided a series of assertions that were based on its earlier conclusion that the administering and determining steps were tied to a transformation. The extent of the Federal Circuit's analysis is the assertions that "[t]he claims cover a particular application of natural processes to treat various diseases" and that "the claims do not preempt natural processes; they utilize them in a series of specific steps."<sup>98</sup> Illustrative of the Federal Circuit's interpretation of the relationship between the machine-or-transformation test and the doctrine against the preemption of a natural phenomenon, the Federal Circuit explained that "because the claims meet the machine-or-transformation test, they do not preempt a fundamental principle."<sup>99</sup> Finding that the claims at issue were tied to a particular transformation, the Federal Circuit determined that the claimed process was patentable subject matter.<sup>100</sup>

#### D. Federal Circuit's Second Opinion in *Prometheus Laboratories After the Supreme Court's Opinion in Bilski*

¶26 On remand from the Supreme Court, the Federal Circuit was directed to reconsider *Prometheus Laboratories* in light of the Supreme Court's decision in *Bilski*.<sup>101</sup> One of the biggest lessons illuminated by the Supreme Court's decision was the importance of

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

<sup>93</sup> *See id.* at 1340.

<sup>94</sup> *Id.* at 1347.

<sup>95</sup> *Id.* at 1348–49.

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

<sup>97</sup> *Id.* at 1349.

<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

<sup>100</sup> *Id.* at 1345–46.

<sup>101</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1348 (Fed. Cir. 2010).

choosing the appropriate standard for determining patentable subject matter. While the Supreme Court considered the machine-or-transformation test to be a useful tool in determining patentable subject matter, the Court also cautioned that the machine-or-transformation test was less useful for newly developed technologies, such as “advanced diagnostic medicine techniques.”<sup>102</sup> Considering that the Supreme Court granted certiorari for *Prometheus Laboratories* prior to releasing its decision in *Bilski*, it stands to reason that explicitly listing “advanced diagnostic medicine techniques” served as an invitation for the Federal Circuit to consider alternative standards for patentable subject matter. In fact, the Supreme Court explicitly stated, “[W]e by no means foreclose the Federal Circuit’s development of other limiting criteria [for patentable subject matter] that further the purposes of the Patent Act and are not inconsistent with its text.”<sup>103</sup> Nevertheless, the Federal Circuit did not engage in a thorough analysis of potential alternative factors for patent-eligibility. Rather, the Federal Circuit interpreted the Supreme Court’s decision as approval to use the machine-or-transformation as the primary basis, although not the exclusive basis, for its analysis of patentable subject matter.<sup>104</sup>

¶27 Having accepted the machine-or-transformation test as an appropriate standard in this case, the Federal Circuit reaffirmed that the claimed process was patentable subject matter under § 101 for many of the same reasons previously expressed in the first Federal Circuit opinion.<sup>105</sup> The claimed process passed the transformation prong, because “methods of treatment . . . are always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition.”<sup>106</sup> The claimed process does not preempt all uses of the correlation, because the administering and determining steps limit the scope of the claim to a particular application of the correlation.<sup>107</sup> Even though the administering and determining steps gather useful data, the purpose of these steps is not merely for gathering data but also to serve integral functions in treating the patients.<sup>108</sup> Consequently, the Federal Circuit held that the claimed process was patentable subject matter under § 101.<sup>109</sup>

#### IV. APPLYING THE MACHINE-OR-TRANSFORMATION TEST TO *PROMETHEUS LABORATORIES*

¶28 In deciding whether the claims at issue in *Prometheus Laboratories* were patentable subject matter, the Federal Circuit, in both of its opinions, applied the machine-or-transformation test rigidly without consideration of the broader role that the machine-or-transformation test played. The machine-or-transformation test originated as a means “to determine whether a process claim is tailored narrowly enough to encompass

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<sup>102</sup> *Bilski v. Kappos*, 130 S. Ct. 3218, 3227 (2010).

<sup>103</sup> *Id.* at 3231.

<sup>104</sup> *Prometheus Labs.*, 628 F.3d at 1355 (“The [Supreme] Court did not disavow the machine-or-transformation test. And, as applied to the present claims, the ‘useful and important clue, an investigative tool,’ leads to a clear and compelling conclusion, *viz.*, that the present claims pass muster under § 101.”).

<sup>105</sup> *Id.* at 1355–56.

<sup>106</sup> *Id.* at 1356.

<sup>107</sup> *Id.* at 1356–57.

<sup>108</sup> *Id.* at 1358.

<sup>109</sup> *Id.* at 1359.

only a particular application of a fundamental principle rather than to pre-empt the principle itself.”<sup>110</sup> Rather than whether the claimed process simply passes the machine-or-transformation test, the standard for patent-eligibility of process claims that make use of natural phenomena should be whether the claimed process preempts the use of the principle. The machine-or-transformation test can be used as a means to determine preemption, but passing the machine-or-transformation test should not be the end of the analysis. This section will apply the machine-or-transformation test with an eye towards determining whether the claimed process is tailored narrowly enough to claim only particular applications of the natural phenomenon.

¶29 While the Federal Circuit is focused on whether there was a transformation of a physical article into a different state or thing, this section concedes that the overall claimed process does involve the transformation of physical objects. The biochemical composition of the human body changes as the drug is metabolized, so the human body is transformed by administration of drugs. As the Federal Circuit correctly quoted from *In re Bilski*, “It is virtually self-evident that a process for a chemical or physical transformation of *physical objects or substances* is patent-eligible subject matter.”<sup>111</sup> Although the claims of the patent do relate to the physical transformation of various articles, the claimed process should still fail the machine-or-transformation test, because, as the Supreme Court has emphasized in *Benson*, *Flook*, and *Diehr*, there are additional conditions to ensure that the process is tailored narrowly to a particular application of the natural phenomenon. The steps of the claim need to add meaningful limits to the scope of the claim.<sup>112</sup> In addition, the steps of the claim need to be more than post-solution activities, so that the claims do not wholly preempt the use of the natural phenomenon.<sup>113</sup>

¶30 In *Prometheus Laboratories*, the claims in the patent are not narrowly tailored to a particular application of the natural phenomenon. Rather, the claims recite the necessary extra-solution steps that establish the conditions needed to use the natural phenomenon. The most telling evidence that Prometheus Laboratories’ patent claims should not be patentable subject matter is that there is no way to use the natural phenomenon within the claimed field-of-use without implicating Prometheus Laboratories’ patent.<sup>114</sup> In other words, if a physician were to use the natural phenomenon—the correlation between

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<sup>110</sup> *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008).

<sup>111</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1346 (Fed. Cir. 2009) (quoting *In re Bilski*, 545 F.3d at 962).

<sup>112</sup> *In re Bilski*, 545 F.3d at 961–62.

<sup>113</sup> *Id.*

<sup>114</sup> The district court was presented with arguments from Prometheus Laboratories concerning alternate uses of the natural phenomenon that were not implicated by the patent claim. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 04cv1200, 2008 WL 878910, at \*11 (S.D. Cal. Mar. 28, 2008), *rev’d*, 581 F.3d 1336 (Fed. Cir. 2009). Prometheus Laboratories presented six possible uses of the natural phenomenon. *Id.* at \*12. However, the district court determined that none of these uses had any practical application. Prometheus Laboratories suggested that the correlations could be used to treat other disease besides autoimmune or gastrointestinal disorder, but the district court found that there were no known practical uses for this correlation outside of those claimed disorders. *Id.* Similarly, Prometheus Laboratories suggested that physicians would not violate the patent by determining the metabolite levels so long as they did not use the results for the purpose of adjusting the dosage of the drugs that provided the metabolite levels. *Id.* The district court reasoned that the physician would have no reason to determine the metabolite levels, if the physicians were not able to use the results to adjust the metabolite levels in their patients. *Id.* Therefore, the district court found that the correlations had “‘no substantial practical application’ outside of the context of the claims.” *Id.* at \*11.

metabolite levels and the efficacy or toxicity of the metabolites—to treat a patient, the physician would necessarily have to administer a drug that delivers the metabolite to a patient and determine the concentration of the metabolite once it is within the patient, which would infringe Prometheus’s patent.

*A. The Natural Phenomenon at Issue Is Unique*

¶31 The ultimate question in dispute is whether the patent claims are narrowly tailored to a particular application of a natural phenomenon or whether the patent claims are drafted in a manner that wholly preempts the use of the natural phenomenon. In *Prometheus Laboratories*, the natural phenomenon at issue is the correlation between the concentration of certain metabolites in the body and the performance of the metabolites in treating various gastrointestinal disorders.<sup>115</sup> This correlation is incorporated in the “wherein” clauses of the claim.<sup>116</sup> If the concentration of 6-thioguanine is below 230 pmol per  $8 \times 10^8$  red blood cells, the metabolite is ineffective in mediating the symptoms from the disorder, and the drug dosage needs to be increased.<sup>117</sup> However, if the concentration of the metabolite in the body is above 400 pmol per  $8 \times 10^8$  red blood cells, the presence of such a high concentration can be toxic, and the amount of the drug administered needs to be reduced.<sup>118</sup> The effect that varying levels of concentrations of the metabolites has on the body is entirely dictated by this natural phenomenon.

¶32 Compared to prior cases involving process patents, the natural phenomenon at issue is unique because any and all uses of the natural phenomenon necessarily involve a transformation in the human body. The natural phenomenon is rooted in the reaction of the human body in response to the presence of certain chemical and biological conditions. Consequently, even a patent that clearly preempts the entire use of the natural phenomenon would pass a rigid application of the machine-or-transformation test, as applied in *Prometheus Laboratories*, because the natural phenomenon necessarily initiates biochemical transformations. For natural phenomena that are inherently transformative, it is especially important for the court to analyze carefully whether the steps of the process add meaningful limits and are more than insignificant extra-solution activities in order to avoid entirely preempting the use of the natural phenomena.

*B. The Administering Step Adds No Meaningful Limits on the Natural Phenomenon*

¶33 Claim 1 of the ’623 Patent comprises a step of “administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder.”<sup>119</sup>

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<sup>115</sup> See *Prometheus Labs.*, 581 F.3d at 1349.

<sup>116</sup> The “wherein” clauses of the claim establish:

[W]herein the level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject; and

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

<sup>117</sup> ’623 Patent col.20.

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

<sup>119</sup> ’623 Patent col.20.

Although the words of the administering step only lay claim to the human act of delivering the metabolite into the human body, the practical effect of the administering step is to claim the biochemical reactions between the metabolite and the human body.

¶34 In its application of the machine-or-transformation test, the Federal Circuit expanded the scope of the administering step to encompass the biochemical reactions resulting from the introduction of the metabolite into the human body. The administering step passed the Federal Circuit’s application of the machine-or-transformation test, because the Federal Circuit imputed the transformative effect of the natural phenomenon onto the human act of delivering the drug into the human body.<sup>120</sup> The Federal Circuit emphasized that the transformation in the administering step is “the effect on the body after metabolizing the artificially administered drugs.”<sup>121</sup> So, even though, in form, the administering step is claiming the human action of administering the metabolite, in practice, the administering step also recites the biochemical reactions that result from administering the metabolite.

¶35 The administering step is so broad that it entirely preempts any use of the natural phenomenon. In order to use the claimed natural phenomenon—the correlations between the active metabolite and its efficacy and toxicity in the body—the active metabolite would need to be administered into the body. A step calling for the administration of the metabolite does not limit the scope of the claim to fit a narrowly tailored application of the natural phenomenon. Rather, the act of administering the drug is a necessary step that establishes the conditions needed to use the natural phenomenon. Although the administering step is worded in such a way to make it seem as if it is an independent step of the process, the administering step does not limit the use of the natural phenomenon to a particular application, because administering the drug that provides the metabolite is an antecedent step that is common to all applications of the correlation associated with the metabolite levels. Since any use of this natural phenomenon requires the administration of the metabolite, the administering step adds no meaningful limits on the claims to using the natural phenomenon.

### C. *The Determining Step Is Merely a Data-Gathering Step*

¶36 The Federal Circuit erred in its analysis of the determining step by glossing over the argument that the determining step was merely a data-gathering step. The determining step entails “determining the level of 6-thioguanine in said subject having immune-mediated gastrointestinal disorder.”<sup>122</sup> The transformation prong of the machine-or-transformation test requires the process to transform an article into a different state or thing.<sup>123</sup> “The transformation must be central to the purpose of the claimed process.”<sup>124</sup> Otherwise, a clever patent prosecutor can add insignificant steps to the process that do not tie the claimed process to a particular application of the natural phenomenon.

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<sup>120</sup> *Prometheus Labs.*, 581 F.3d at 1346.

<sup>121</sup> *Id.*

<sup>122</sup> ‘623 Patent col.20.

<sup>123</sup> *In re Bilski*, 545 F.3d 943, 961–62 (Fed. Cir. 2008).

<sup>124</sup> *Id.* at 962.

¶37 The only purpose of the determining step is to gather information about the concentration of the active metabolite in the body, which is needed to make use of the natural correlation between the concentration of the active metabolite and the human body's reaction to the active metabolite. Although determining the concentration of the metabolite in the body would necessarily involve biochemical reactions that transform the original bodily sample, this transformation is not central to the purpose of the claimed process. The utility of the patent comes from its ability to create an effective treatment method, rather than its ability to determine the concentration of the metabolite. Furthermore, the wording of the determining step does not enumerate any of the methods used to calculate the concentration of the metabolite.<sup>125</sup> The lack of enumerated methods for determining the concentration of the metabolite suggests that the claims of the patent are more focused on the natural phenomenon than on the transformations that occur during a particular procedure that determines the concentration of the metabolites.<sup>126</sup> The transformation associated with performing biochemical tests to determine the concentration of the metabolites is not sufficient to make the entire claimed process pass the machine-or-transformation test.

¶38 In prior cases, the Federal Circuit has not recognized performing diagnostic tests as being central to process patents for medical treatments. In *In re Grams*, the Federal Circuit was presented with a proposed patent claiming, "A method of diagnosing an abnormal condition in an individual."<sup>127</sup> The process entailed collecting data from clinical trials and inputting the data into an algorithm.<sup>128</sup> The only step of the process that potentially implicated a physical transformation was a step of "performing said plurality of clinical laboratory tests on the individual [sic] to measure the values of the set of parameters."<sup>129</sup> The Federal Circuit determined that the performance of the clinical laboratory tests merely involved gathering data, which would be used in an algorithm to optimize the diagnosis of an abnormal condition.<sup>130</sup> Recognizing that any use of a particular algorithm would require antecedent steps in order to collect the necessary values to input into the algorithm, the Federal Circuit acknowledged that these data-gathering steps were necessary in any process that claims to use an algorithm.<sup>131</sup> However, regardless of how necessary the data-gathering steps are to the use of the algorithm, these antecedent steps could not make a process claim into patentable subject matter.<sup>132</sup> Otherwise, every patentee attempting to lay claim to an algorithm could craft the claims into a series of steps involving collecting the data, applying the algorithm, and measuring the resulting value.<sup>133</sup> Similarly, the claims in *Prometheus Laboratories* artificially break the process into a series of insignificant steps. The determining step is

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<sup>125</sup> The full extent of the determining step in Claim 1 of the '623 Patent disclosed a step consisting of "determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder." '623 Patent col.20.

<sup>126</sup> See *In re Bilski*, 545 F.3d at 963 ("A requirement simply that data inputs be gathered—without specifying how—is a meaningless limit on a claim to an algorithm because every algorithm inherently requires the gathering of data inputs.")

<sup>127</sup> *In re Grams*, 888 F.2d 835, 836 (Fed. Cir. 1989).

<sup>128</sup> *Id.* at 836–37.

<sup>129</sup> *Id.* at 836.

<sup>130</sup> *Id.* at 839.

<sup>131</sup> *Id.* at 839–40.

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

<sup>133</sup> *Id.*

an antecedent step to making use of the natural phenomenon and does not add any meaningful limits upon the claim to the natural phenomenon.

¶39 The Federal Circuit should have recognized that the determining step was another necessary part of any use of the natural phenomenon. Determining the concentration of the metabolites did not limit the scope of the claims to a particular application of the phenomenon; rather, the broad claim for determining the concentration allowed the patent holder to expand the claims of the patent to any use of the claimed phenomenon.

#### *D. The Mental Step Is Insufficient to Establish Patentable Subject Matter*

¶40 The first mental step in the '623 Patent states that 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."<sup>134</sup> The second mental step in the '623 Patent states that a "level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject."<sup>135</sup> These mental steps describe the natural phenomenon that the patent attempts to monopolize. The mental step does not transform a particular article into a different state or thing, because these steps merely indicate the appropriateness of future treatment options. In fact, fulfilling the mental step does not explicitly require any action. The mental step merely provides a set of rules based on the correlation between the concentration of the metabolite and the efficacy and toxicity of the drug. Since the mental step does not transform an article into a different state or thing, the mental step by itself is insufficient to establish patentable subject matter. The permissibility of claiming the mental step depends upon the existence of additional steps that fulfill the machine-or-transformation test.

#### *E. The Claimed Process Preempts All Uses of the Natural Phenomenon*

¶41 In order to pass the transformation prong of the machine-or-transformation test, the claimed process must contain a transformation that is central to the purpose of the claimed process.<sup>136</sup> For process patents that make use of natural phenomenon, this transformation must impose meaningful limits on the claim's scope to prevent the patent from laying claim to all uses of the natural phenomenon.<sup>137</sup> The purpose of the process in the '623 Patent is to treat gastrointestinal disorders by administering a drug that provides a metabolite that ameliorates the symptoms of the disorder. The transformation that is central to this claimed process is the series of biochemical reactions that occur between the metabolite and the body.

¶42 The '623 Patent involves three types of steps: an administering step, a determining step, and mental steps. While the administering step incorporates the transformation of metabolizing the metabolite in the body, the administering step imposes no meaningful limits that restrict the scope of the claimed process to only a particular application of the natural phenomenon. Since any use of the natural phenomenon requires administering

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<sup>134</sup> '623 Patent col.20.

<sup>135</sup> *Id.*

<sup>136</sup> *In re Bilski*, 545 F.3d 943, 962 (Fed. Cir. 2008).

<sup>137</sup> *Id.* at 961–62.

the metabolite into the body, the administering step is functionally preempting the entire use of the natural phenomenon. Similarly, the determining step is not sufficient to turn an otherwise ineligible process patent into patentable subject matter. While the determining step involves transforming the bodily sample to measure the concentration of the metabolite, this transformation is not central to the purpose of the claimed process. Rather, the determining step is an insignificant extra-solution activity to gather data to make use of the natural phenomenon, which is not sufficient to pass the machine-or-transformation test. Finally, the mental steps can be accomplished without any transformations, so the mental steps cannot pass the machine-or-transformation test. Since none of the individual steps is narrowly tailored to a particular application of the natural phenomenon, the practical effect of the '623 Patent is to preempt all of the uses of natural phenomenon; so, the patent impermissibly lays claim to non-patentable subject matter.

#### V. REFINING THE FRAMEWORK TO DETERMINE PATENTABLE SUBJECT MATTER FOR PROCESS PATENTS

¶43 The challenge with the machine-or-transformation test is that the Federal Circuit has attempted to synthesize a definitive test from a patchwork of Supreme Court cases that have redefined the rules as technology has evolved.<sup>138</sup> The test for determining whether a claimed process passes the § 101 threshold should return to its original purpose, which was to delineate between those processes that claimed a natural principle itself and those processes that claimed a particular application of the natural principle. Instead of adopting a definitive test, this Note proposes a four-step framework to analyze patentability based on the principles established by the Supreme Court and the Federal Circuit.

¶44 The first step to analyzing a claimed process is to determine whether the claim incorporates a natural principle.<sup>139</sup> Since Congress intended patentability to be a low threshold that should include “anything under the sun that is made by man,” most claimed processes will not raise concerns over incorporating these types of natural principles.<sup>140</sup> However, there are certain key features to a claimed process that trigger concerns over patentability. For example, claims that mention a law of nature as the driving force of the process, recite correlations or algorithms, or manipulate abstract relationships should raise concerns over patentability.<sup>141</sup>

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<sup>138</sup> The Supreme Court has been hesitant to make passing the machine-or-transformation test a necessary condition for patentability. The Supreme Court has described the machine-or-transformation test as the clue to patentability and has acknowledged that only processes that have passed the machine-or-transformation test have been found patentable. *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978). However, the Supreme Court has never made the machine-or-transformation test the definitive standard for patentability.

<sup>139</sup> Use of the term natural principle is intended to serve as a shorthand for the category of laws of nature, natural phenomena, and natural ideas.

<sup>140</sup> S. REP. NO. 82-1979, at 5 (1952).

<sup>141</sup> *See, e.g., O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 86 (1853) (recognizing that a claim to using electromagnetism for communication at distances raises concerns that the patentee was laying claim to a law of nature); *Parker*, 437 U.S. at 585–86 (recognizing that a claim that recited an algorithm raises concerns that the patentee was claiming a natural phenomenon); *State St. Bank & Trust Co. v. Signature Fin. Grp.*, 149 F.3d 1368, 1371 (Fed. Cir. 1998) (recognizing that a claim to a method of manipulating

¶45 Once it is determined that a claim incorporates a natural principle, the second step is to define the scope of these natural principles. This task is a difficult but essential step in delineating between claims over the natural principle itself and claims over a particular application of the natural principle. Defining the scope of the natural principle entails a critical analysis of the relationships that the natural principle describes. The court must evaluate the practical applications of the natural principle. A law of nature that dictates the relationship of all of the objects of the universe should have a broad scope. Conversely, claims to correlations and algorithms that describe the relationship between specific objects should have a narrow scope that is limited to the field in which all of the specific objects are present. The scope of the natural principle is the set of all of the practical applications of the natural principle.

¶46 The third step removes all of the artificial limitations that patent drafters add to break a claim into a series of insignificant steps. If every practical use of the natural principle would entail performing the claimed step, it is an artificial limitation. In other words, artificial limitations include the data-gathering steps or insignificant extra-solution activities, which do not add any meaningful limitations to claimed process. The purpose of this step is to remove any superfluous language and to focus on the heart of the claim.

¶47 The final step analyzes whether the claim preempts all practical uses of the natural principle. One means to perform a preemption analysis is the machine-or-transformation test. In performing this test, the court should focus on the claim's relationship to a particular machine or particular article. Whether a claim is defined narrowly enough to focus only on a particular machine or particular article, and thereby only claim a particular application of the natural principle, should depend on the scope of the natural principle. If all of the practical applications of the natural principle necessarily use the type of machine or article claimed in the patent, then the claim would preempt all uses of the natural principle. Alternatively, a more concrete method of determining preemption is having the patentee describe other practical applications of the natural principle that the claim does not cover. Alternate practical uses of the natural principle that are not covered by the patent are the ultimate proof that a patent only claims a particular application of a natural principle as opposed to the natural principle itself.

¶48 This framework for a patentability analysis only slightly refines the method for performing the machine-or-transformation test. One of the important modifications for this framework is the emphasis on defining the scope of the natural principle. While courts may have identified the natural principle in the past, courts have not focused their analysis on the various applications of the natural principle.<sup>142</sup> Determining the potential applications of the natural principle is essential to identifying the presence of artificial limitations on the claim that merely break the use of the natural principle into insignificant steps. Similarly, determining the potential applications of the natural principle is essential to analyzing whether the patent preempts all practical uses of that principle.

¶49 Another important modification is the rearranged order of analysis. Instead of having the machine-or-transformation test headline the analysis, the antecedent steps

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mutual funds raises concerns of patenting an abstract idea).

<sup>142</sup> See, e.g., *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009) (failing to give sufficient weight to the district court's factual finding that the natural phenomenon had no practical applications outside of the claimed invention).

narrow the factual issues to allow the court to focus on the key issue of whether the patent claims the natural principle itself or merely an application of the natural principle. This framework for determining patent-eligibility highlights the important issues that the Supreme Court has analyzed in *Benson*, *Flook*, *Diehr*, and *Bilski*. By streamlining this analysis, it is more likely that the courts will provide reasoned analysis for each issue, as opposed to merely asserting general conclusions.

## VI. CONCLUSION

¶50 In adopting the machine-or-transformation test, the Federal Circuit wanted to determine whether a patent's claims involving a natural phenomenon were tailored narrowly enough to encompass a particular application of the natural phenomenon rather than the natural phenomenon itself. In addition to determining whether the claims were tied to a particular machine or whether the claims transformed a particular article, the Federal Circuit wanted courts to evaluate the substance of the claims to ensure that they fulfilled the Federal Circuit's policy objectives. Consequently, the Federal Circuit required that the claimed steps to the process impose meaningful limitations upon the scope of the process and be more than insignificant extra-solution activities.

¶51 When the Federal Circuit was first presented with the patent in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, the Federal Circuit's analysis centered on identifying the qualifying transformations and proving that the transformations were central to the purpose of the overall process. However, the existence of the qualifying transformation was never at issue for Mayo Clinic. Rather, Mayo Clinic's argument and the district court's opinion emphasized that the steps involved in the process did not limit the scope of the claimed process. When the Federal Circuit was again presented with Prometheus Laboratories' patents on remand from the Supreme Court, the Federal Circuit ignored the Supreme Court's invitation to experiment with alternative standards for patentable subject matter that would be more attuned to modern technologies.

¶52 Under this Note's proposed framework for patent-eligibility, the claimed process in *Prometheus Laboratories* would not have passed the threshold § 101 requirement. The administering and determining steps are necessary steps for any use of the natural phenomenon—namely, the correlation between the concentration of the metabolite and the efficacy and toxicity of the drug. Since any use of the natural phenomenon would require the administration of the drug and determination of the concentration of the metabolite, the patent preempted the entire use of the natural phenomenon. Even the Federal Circuit's decision does not suggest a manner of using the natural phenomenon without implicating Prometheus Laboratories' claims. If the Federal Circuit had focused on the broader implications of Prometheus Laboratories' patents, the Federal Circuit would have come to the conclusion that the patents impermissibly preempt the use of a natural phenomenon, so they should not have been eligible for patenting.