

## **PATENT-ELIGIBILITY AFTER *BILSKI*: REVISITING THE SUPREME COURT'S *PROMETHEUS* DECISION**

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### **ABSTRACT**

The Supreme Court decided *Mayo v. Prometheus* on March 20, 2102, addressing the patent-eligibility of the claimed processes under 35 U.S.C. § 101. This Article otherwise provides an alternative perspective of the justification other than the *Prometheus* Court's reasoning but likewise conclude the unpatentability of the method claims is dispute.

In addition to the Court's comparison of certain controlling precedents with *Prometheus*'s claimed processes, this Article analyzes some other prior case law and argues that the structure of the claimed processes here is nearly identical to the claims in *Labcorp* and *Grams*. In spite of the concurring opinion this Article shares with the Court's analysis in transformation prong of the machine-or-transformation test, this Article attempts to point out one of the questions left open in *Bilski* and remained unanswered post-*Prometheus*, namely the priority in applying the machine-or-transformation test and other rules in determining patent-eligibility under § 101. Finally, to further reinforce the reasons to negate the patent-eligibility of the claimed processes, this Article reads the *Bilski* decision more closely and proposes a rule to determine the patent-eligibility under § 101, in light of *Bilski*, that the machine-or-transformation test merely viewed as a "clue" must be governed by the preemption analysis to determine *Prometheus*'s claimed process methods.

Keywords: Machine-or-transformation test, preemption analysis, *Bilski*, diagnostic methods, patent-eligibility

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## I. Introduction

On June 20, 2011, the Supreme Court granted Mayo Collaborative Services and Mayo Clinic Rochester (Mayo)'s petition for writ of *certiorari* of Appeals for the Federal Circuit in *Prometheus Lab. Inc. v. Mayo Collaborative Serv.*, and then decided on March 20, 2012. Mayo centralizes its question in petition is whether the Prometheus Laboratories, Inc. (Prometheus)'s claimed processes describing the correlation between the concentration of certain thiopurine metabolites in the blood and the ineffectiveness and harm that the drug dosage may cause are patent-eligible that apply natural laws.

This Article proceeds in three parts. Part I summarizes the Supreme Court's findings of Prometheus's claimed processes have not add enough to the correlations to transform these unpatentable natural laws into patentable applications of those laws. Comparing with the Supreme Court's reasoning in *Mayo Collaborative Serv. v. Prometheus Lab. Inc.*, Part II and III both read the Supreme Court's opinion in *Bilski v. Kappos* from other perspectives than the Court in *Prometheus* perceived in two aspects. First, Prometheus's claimed methods are merely natural phenomena analogous to *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, and insignificant extra-solution with *In re Grams*. Second, in light of the Court's *Bilski* opinion, the machine-or-transformation test merely viewed as a "clue" must be governed by the preemption analysis to determine Prometheus's claimed process methods. Part IV further comments on the policy concerns behind the *Prometheus* decision. However, any arguments in this Article supporting either the legal justification or policy concerns do not lead to a different conclusion other than the Supreme Court's decision in *Prometheus*.

## II. Summary of the *Prometheus* Decision

Prometheus Laboratories, Inc. (Prometheus) is the sole and exclusive licensee of U.S. Patents 6,355,623 ("the '623 patent") and 6,680,302 ("the '302 patent"), which claim methods for determining the optimal dosage of thiopurine drugs used to treat gastrointestinal and non-gastrointestinal autoimmune diseases. These drugs include 6-mercaptopurine (6-MP) and azathiopurine (AZA), a pro-drug that upon administration to a patient converts to 6-MP, both of which are used to treat inflammatory bowel diseases (IBD).<sup>2</sup> Prometheus marketed a PROMETHEUS Thiopurine

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<sup>2</sup> Although drugs such as 6-MP and AZA have been used for years to treat autoimmune diseases, non-responsiveness and drug toxicity may complicate treatment in some patients. Accordingly, the patents claim methods that seek to optimize therapeutic efficacy while minimizing toxic side effects. As written, the claimed methods typically include two separately lettered steps: (a) "administering" a drug that provides 6-TG to a subject, and (b) "determining" the levels of the drug's metabolites, 6-TG and/or 6-MMP, in the subject. *See*,



Metabolites test that used the technology covered by the patents in suit. Mayo Collaborative Services and Mayo Clinic Rochester (Mayo) formerly purchased and used Prometheus's test, but in 2004, Mayo announced that it intended to begin using internally at its clinics and selling to other hospitals its own test.<sup>3</sup> Mayo's test measured the same metabolites as Prometheus's test, but Mayo's test used different levels to determine toxicity of 6-thioguanine and its nucleotides (6-TG) and 6-methyl-mercaptopurine (6-MMP).<sup>4</sup> Prometheus then sued Mayo for patent infringement.

The District Court concluded that Mayo's test infringed Prometheus' patents, finding that "the processes claimed by the patents effectively claim natural laws or natural phenomena—namely the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drug dosages,"<sup>5</sup> and thus not patent eligible. On appeal, the Federal Circuit reversed, explaining that the processes are patentable under the Circuit's "machine or transformation test." In its reasoning, the steps claiming "administering a thiopurine drug' to a patient" and "determining the resulting metabolite level" both transform the human body or blood taken from the human body.<sup>6</sup> Then this case returns to the Federal Circuit on remand from the Supreme Court for further consideration in light of the Court's decision in *Bilski v. Kappos*.<sup>7</sup> On remand, the Federal Circuit once again held that Prometheus's asserted method claims satisfy the preemption test as well as the transformation prong of the machine-or-transformation test. It reversed the judgment of the District Court and remand to the Federal Circuit with instructions to deny Mayo's motion for summary judgment that the asserted claims are invalid under 35 U.S.C. § 101.<sup>8</sup> Then, the Supreme Court again granted Mayo's petition for *certiorari*, and found that Prometheus' process is not patent eligible because Prometheus' claims fail to "apply natural laws,"<sup>9</sup> but only "simply describe [the] natural relations."<sup>10</sup>

In the Court's ruling, it first reasoned that "the three additional steps in the claimed processes are not themselves natural laws but neither are they

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*e.g.*, '623 patent claim 1. The measured metabolite levels are then compared to pre-determined metabolite levels, "wherein" the measured metabolite levels "indicate a need" to increase or decrease the level of drug to be administered so as to minimize toxicity and maximize treatment efficacy. *See, e.g., Id.*

<sup>3</sup> *See Mayo Collaborative Serv. v. Prometheus Lab. Inc.*, 132 S. Ct. 1289, 1291 (2012).

<sup>4</sup> *See Id.* at 1296.

<sup>5</sup> *Id.*

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

<sup>7</sup> *See Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

<sup>8</sup> 35 U.S.C. § 101(2010).

<sup>9</sup> *Mayo Collaborative Serv.*, 132 S. Ct. at 1297.

<sup>10</sup> *Id.*



sufficient to transform the nature of the claims. The process here recites three steps, an “administering” step (referring to the doctors treating patients with thiopruine drugs), a “determining” step (telling the doctors to decide the level of the metabolites in the blood), and a “wherein” step (explaining the doctors about the relation between the metabolites and the dosage),” to instruct a doctor or a laboratory about the correlations between the efficacy of harm of a thiopurine drug dosage and the level of the relevant metabolites in the blood.<sup>11</sup> These additional steps here are merely “well understood, routine, conventional activity engaged in by the scientific community,”<sup>12</sup> but add nothing significant beyond the laws of nature. The Court thus found that the claimed steps “are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.”<sup>13</sup> The second reason to further support the Court’s holding is to view “the high level of generality” of the conventional steps known by the persons in the relevant field.<sup>14</sup> The Court found that the claims here are overly broad comparable to the claim in *Benson*<sup>15</sup> that made “no substantial practical application except in connection with a digital computer.”<sup>16</sup> The Court further pointed out that the “determining” step very likely “cover[s] all processes that make use of the correlations after measuring metabolites, including later discovered process that measure metabolite levels in new ways.”<sup>17</sup> The Court addressed its last concern that “even a narrow law of nature can inhibit future research”<sup>18</sup> that simply reinforces the Court’s conclusions that the claimed processes are not patentable.

### **III. Legal Justification #1: Prometheus’s Claimed Structure Are Analogous to *Labcorp* and *Grams***

Even though I agree with the Federal Circuit’s plain reading of *Bilski*’s holding that “the Court did not disavow the machine-or-transformation test,”<sup>19</sup> its application of machine-or-transformation test in Prometheus’s claims is inapposite with what I conceive. The Circuit again held, as in pre-*Bilski* decision that Prometheus’s asserted method claims in this case not only “recite transformative ‘administering’ and ‘determining’ steps, but also that Prometheus’s claims are drawn not to a law of nature, to a particular

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<sup>11</sup> *See Id.*

<sup>12</sup> *Mayo Collaborative Serv.*, 132 S. Ct. at 1298.

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

<sup>14</sup> *Id.* at 1300.

<sup>15</sup> *Gottschalk v. Benson*, 409 U.S. 63 (1972).

<sup>16</sup> *Mayo Collaborative Serv.*, 132 S. Ct. at 1301.

<sup>17</sup> *Id.* at 1302.

<sup>18</sup> *Id.* at 1303.

<sup>19</sup> *Prometheus Lab. Inc. v. Mayo Collaborative Serv.*, 628 F.3d 1347, 1355 (2010).



application of naturally occurring correlations, and accordingly do not preempt all uses of the recited correlations between metabolite levels and drug efficacy or toxicity.”<sup>20</sup>

In terms of machine-or-transformation test analysis of Prometheus’s asserted method claims, the Federal Circuit reasoned that “the asserted claims are in effect claims to methods of treatment, which 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>21</sup> This categorical rule does not survive *Bilski*, where the Court recognized that “adopting categorical rules that might have wide-ranging and unforeseen impacts.”<sup>22</sup> In light of *Bilski*’s caution, categorical inclusion for “treatment/therapeutic methods” as the present claim phrased in this case should not be allowed, just like categorical exclusion of business methods patented in *Bilski*. Therefore, the Circuit’s categorical inclusion as patentable subject matter under § 101 for all claims reciting “treatment/therapeutic methods” is contrary to *Bilski*.

The Federal Circuit in *Prometheus* further reaffirms the “transformation” in the methods claimed in Prometheus’s patents here, as “the result of the physical administration of a drug to a subject to transform –i.e., treat-the subject, which is itself not a natural process.”<sup>23</sup> The *Prometheus* Circuit cited pre-*Bilski* decision in this Circuit to reaffirm its reasoning that “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>24</sup> In fact, such premise of transformation analysis is incorrect. As *Mayo* argued, nothing is transformed by the administering and determining steps in Prometheus’s claimed methods, outside of the body’s natural biologic response to a previously-invented drug that was well known to physicians decades before Prometheus claimed.

The Supreme Court in *Prometheus* found that the three steps (the ‘administering’ step, the ‘wherein’ clause and the ‘determining’ step) “add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field.”<sup>25</sup> In addition to the Court’s finding, there is one more approach to argue the unpatentability viewing some other controlling precedents in analyzing the claimed processes. The structure of Prometheus’s claims is nearly identical

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

<sup>21</sup> *Id.* at 1356.

<sup>22</sup> *Bilski*, 130 S. Ct. at 3229.

<sup>23</sup> *Prometheus Lab. Inc.*, 628 F.3d at 1356.

<sup>24</sup> *In re Bilski*, 545 F.3d 943, 962 (Fed. Cir. 2008).

<sup>25</sup> *Mayo Collaborative Serv.*, 132 S. Ct. at 1292.



to claim of *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*,<sup>26</sup> which recites assaying step (comparable to the “administering” step providing thiopurine drugs for the purpose of treating disease that Prometheus claimed), and correlating step (comparable to the “determining” step measuring the drugs’ metabolite levels for the purpose of assessing the drugs’ dosage during the course of treatment in Prometheus’s claims). The *Labcorp* Court rejected the machine-or-transformation argument because the claim “is not a process for transformation blood or any other matter,” but rather “instructs the user to (1) obtain test results and (2) think about them.”<sup>27</sup> Similarly, Prometheus claimed methods are not a process for transformation, either in blood samples or individual patient. Indeed, these claims recite simply the metabolite levels be measured and then doctors to relate the correlations between those levels and patient’s health condition. The Court in *Labcorp* relied on the principles underlying §101 that *Labcorp* claims are not patent-eligible because “to use virtually any natural phenomenon for virtually any useful purpose may well involve the use of empirical information obtained through an unpatented means that might have involved transforming matter.”<sup>28</sup> Likewise, the Prometheus’s claims recite a natural phenomenon disguised as some transforming steps involved, contrary to this Circuit’s observation in *Prometheus* that “determining metabolite levels in the clinical samples taken from patients is transformative.” Indeed, the subsequent determining step in Prometheus’s claimed methods is merely a necessary data-gathering step for use of the correlations as Mayo argued. To more extent, even given the integral involvement of the administering and determining steps in Prometheus’s claimed method as “central to the purpose of the claimed process” to determine the transformation prong in machine-or-transformation test,<sup>29</sup> the claims that are not truly reciting any transformation, but rather combination of data-gathering step of empirical information and a subsequent mental processing step, just like *Labcorp* claimed, cannot sufficiently circumvent the prohibition against patentability on natural phenomena. Thus, the two steps that Prometheus claims, as a whole, negate the transformative nature, inapposite with this Circuit’s reaffirmed findings of “transformation.”

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<sup>26</sup> *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006). The claims at issue in *Labcorp* covered a method for detecting a vitamin deficiency with two steps: (1) “assaying a body fluid for an elevated level of total homocysteine” and (2) “correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.”

<sup>27</sup> *Id.* at 136.

<sup>28</sup> *Id.*

<sup>29</sup> *Bilski*, 545 F.3d at 962.



To further reaffirm that the administering and determining steps here are not transformative, but merely insignificant extra-solution activity, I found the claims rejected in *In re Grams*<sup>30</sup> are hardly distinguishable from Prometheus's claims in dispute in this case, again contrary to this court's opinions. In *Grams*, the applicant claimed a process that involved (1) performing a clinical test on individuals, and (2) based on the data from that test, determining if an abnormality existed and determining possible causes of any abnormality by using an algorithm. The Circuit distinguished *Grams*' claimed process from Prometheus's claimed methods in two aspects: first, it found that the essence of *Grams* process was "the mathematical algorithm, rather than any transformation of the tested individuals";<sup>31</sup> second, it noted that "the *Grams* process was unpatentable because 'it was merely an algorithm combined with a data-gathering step.'"<sup>32</sup> These observations, however, are not convincing. Like clinical tests performed on individuals as a data-gathering step combined with a mental processing step in *Grams* process, Prometheus's claims simply recite natural correlations between measured levels and a patient's bodily condition and further recite a mental step of "being warned" that requires no action as far as treatment is concerned. As such, the claimed methods in both *Grams* and *Prometheus* recite merely data-gathering steps along with some other steps amounting to only insignificant extra-solution activities, thus, do not satisfy the transformation prong of machine-or-transformation test.

#### **IV. Legal Justification #2: The Machine-or-Transformation Test as Clue Must be Governed by the Preemption Analysis**

The Supreme Court in *Bilski* repeatedly emphasized that the machine-or-transformation test is merely a "useful and important *clue*, an investigative tool for determining whether *some* claimed inventions are processes under § 101."<sup>33</sup> The Court further explained that "[a]dopting the machine-or-transformation test as the sole test for what constitutes a 'process' (as opposed to just a useful and important clue) violations ... statutory interpretation principles."<sup>34</sup> The passage, however, merely makes plain that the machine-or-transformation test is not by itself determinative of a claim's patentability under § 101, but remains some questions unanswered such as what does the Court mean by the machine-or-transformation analysis is merely a tool or clue, how and when does the machine-or-transformation test apply in deciding patent-eligibility under § 101, its interrelation with other

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<sup>30</sup> *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989).

<sup>31</sup> *Prometheus Lab. Inc.*, 628 F.3d at 1358.

<sup>32</sup> *Id.* (citing *Bilski*, 545 F.3d at 963).

<sup>33</sup> *Bilski*, 130 S. Ct. at 3227.

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





tests or rules in determining patentable subject matter, or how could courts deal with situations in which a claim could meet the machine-or-transformation yet still fail to pass muster under § 101. Despite all the ambiguity behind *Bilski*'s decision, the same implications I conceived as the Federal Circuit in *Prometheus*<sup>35</sup> that the machine-or-transformation test is a part of the analysis as to whether a claim meets § 101, not by itself outcome determinative.

Here, the *Prometheus* Court simply stated that “simply appending conventional steps, specified at a high level of generality to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable,”<sup>36</sup> but avoidably specified the priority in applying the machine-or-transformation test and other rules in determining patent-eligibility under § 101, the question remained unanswered in *Bilski*. As the *Bilski* Court addressed that the presence of a machine or transformation can only be applied in patentability as a “clue,” some other principles must remain focus in reviewing any supposed machine-or-transformation test in *Prometheus*'s claims. The Supreme Court in *Bilski* reiterated that “no one can patent ‘laws of nature, natural phenomena, and abstract ideas,’” which are “basic tools of scientific and technological work.”<sup>37</sup> In analyzing the claims in *Bilski*, the *Bilski* Court relied on the preemption standard noting that any claim “wholly-preempt[s] subject matter that falls into one of these categories is unpatentable.”<sup>38</sup> More specifically, to determine whether claims recite patentable subject matter under § 101, the preemption analysis has always been the fundamental guide. In applying the preemption standard in this case, firstly, it is notable to observe whether *Prometheus*'s claims impermissibly preempt a natural phenomenon, abstract idea, or mental process are not patent-eligible under § 101.<sup>39</sup> Secondly, if the transformation involved in *Prometheus*'s claims is merely insignificant extra-solution activity, then it cannot “transform an unpatentable principle into a patentable process.”<sup>40</sup> Additional steps that are merely for gathering data are one example of insignificant extra-solution activities and therefore do not impart patentability to an otherwise unpatentable principle.<sup>41</sup> In sum, machine-or-transformation test must be closely tied to the governing preemption standard, despite its supplemental benefit of construing the standard as a “clue.”

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<sup>35</sup> *Prometheus Lab. Inc.*, 628 F.3d at 1355.

<sup>36</sup> *Mayo Collaborative Serv.*, 132 S. Ct. at 1292.

<sup>37</sup> *Bilski*, 130 S. Ct. at 3253(Stevens, J., concurring).

<sup>38</sup> *Id.* at 3230.

<sup>39</sup> See *Gottschalk v. Benson*, 409 U.S. 63 (1972).

<sup>40</sup> See *Diamond v. Diehr*, 450 U.S. 175, 184 (1981).

<sup>41</sup> See *Bilski*, 130 S. Ct. at 3230; see also *Parker v. Flook*, 437 U.S. 584, 589-90 (1970).





Under the governing preemption standard, restated in *Bilski*, Prometheus's claimed method is not patent-eligible under § 101, on the basis that Prometheus claims the mental recognition of naturally-occurring correlations between metabolite levels and efficacy or toxicity, which preempts all uses of the correlations that have long exist as natural phenomena. But, the Federal Circuit again erred in ruling that "Prometheus's asserted method claims recite a patent-eligible application of naturally occurring correlations between metabolite levels and efficacy or toxicity, and thus do not wholly preempt all uses of the recited correlations."<sup>42</sup> To support such finding, in its reasoning it explained that "other drugs might be administered to optimize the therapeutic efficacy of the claimed treatment."<sup>43</sup>

The correlations in the Prometheus's claimed methods, undoubtedly, are a natural phenomenon. As the inventors' testimony in *Labcorp* that the "correlating" step simply required "a physician's recognizing that a test that shows an elevated homocysteine level" shows "the patient likely has a cobalmin or folate deficiency."<sup>44</sup> Likewise, Prometheus' own expert acknowledged that "the key therapeutic aspect of such thiopurine drugs is that they are converted naturally by enzymes within the patient's body to form an agent that is therapeutically active." More specifically, Prometheus's claims recite a "process" which is "no more than an instruction to read some numbers in light of medical knowledge."<sup>45</sup> As the Court in *Labcorp* observed, that any process can be reduced to a series of steps, but, "aside from the unpatented test, [the steps] embody only the correlation between [drug level] and [bodily condition] that the researchers uncovered" applies equally to the *Labcorp* and Prometheus's claims.<sup>46</sup> As a result, both sets of claims in *Labcorp* and *Prometheus* preempt all practical use of these correlations that occur naturally within the human body, and thus do not pass the preemption standard.

## V. Policy Concerns behind the *Prometheus* Decision

To further support this conclusion of unpatentability, the *Prometheus* Court has repeated "a concern that patent law not inhibit future discovery by improperly tying up the use of laws of nature and the like," similarly, the policy concerns underlying *Bilski* are strongly against this Federal Circuit's reaffirmed holding of patentability in Prometheus's claimed methods in the present case. The *Bilski* Court cautioned that the great challenge of patent law is to strike a proper "balance between protecting inventors" while not

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<sup>42</sup> *Prometheus Lab. Inc. v. Mayo Collaborative Serv.*, 628 F.3d at 1355.

<sup>43</sup> *Id.*

<sup>44</sup> *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. at 129.

<sup>45</sup> *Id.* at 137.

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



“granting monopolies” that would chill “creative endeavor and dynamic change.”<sup>47</sup> The same strike of balance of claims to either “facilitate” or “impede” “legitimate competition and innovation” should be deliberately considered here, especially when the claimed methods involving medical testing may affect the medical field significantly.<sup>48</sup> As with the business method claimed in *Bilski*, the radically expanded patent protection for natural correlations in Prometheus’ claims would conceivably result in severe consequences that “[therapeutic] decisions, no matter how small, could be potential patent violations.”<sup>49</sup> Such “constant fear of litigation” to physicians and researchers in medical field requires them to “undertake the costs of searching through patents” whenever making therapeutic decisions or conducting researches, which inevitably block off whole areas of scientific development and public interest.<sup>50</sup>

Interestingly, the Federal Circuit repeatedly phrased Prometheus’ claims as “treatment methods” or “therapeutic methods” throughout its opinion. Also, in its analysis of transformation prong in machine-or-transformation test, it emphasized that “the invention’s purpose to treat the human body is made clear in the specification and the preambles of the asserted claims.”<sup>51</sup> Similarly, in terms of preemption analysis, the Federal Circuit suggested that “other drugs might be administered to optimize the therapeutic efficacy of the claimed treatment.”<sup>52</sup> Assuming with the quotes above that this Circuit intended to facilitate innovation or competition by granting monopoly of valuable knowledge so as to minimize toxicity and maximize treatment efficacy in some autoimmune diseases, however, such justification may not tilt for its finding of patent-eligibility of Prometheus’ claimed methods because it overlooked public interests. Instead, as Mayo correctly argues, that “a physician who only evaluates the result of the claimed methods, without carrying out the administering and/or determining steps that are present in all the claims, can[] infringe any claim that requires such steps.”<sup>53</sup> Additionally, as one of the basic elements in medical research, drawing blood and testing its properties occur thousands of times a day in the labs. In sum, it is practically impossible to prevent a physician or researcher from thinking about the lab results. Accordingly, by “allowing [Prometheus] to patent these fundamental principles would ‘wholly preempt’ the public’s access to the

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<sup>47</sup> *Bilski*, 130 S. Ct. at 3229.

<sup>48</sup> *Id.* at 3255 (Stevens, J., concurring).

<sup>49</sup> *Id.* at 3256.

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

<sup>51</sup> *Prometheus Lab. Inc.*, 628 F.3d at 1355.

<sup>52</sup> *Id.*

<sup>53</sup> *Id.* at 1358.



‘basic tools of scientific and technological work,’”<sup>54</sup> it would conceivably lead to “chill on creative endeavor and dynamic change” which was not the intent of Congress.<sup>55</sup>

## VI. Conclusion

In conclusion, the *Prometheus* Court did not make a new wave of change in the law of § 101 after *Bilski*. Rather, in determining whether a claimed method is patent-eligible, the Court in *Prometheus* simply adopted the machine-or-transformation test and preemption analysis in case law but failed to clarify the interrelation between the machine-or-transformation test and other rules in deciding the patent-eligibility under § 101, the question left open in *Bilski*. Although the *Prometheus* Court considered the controlling precedents to further reinforce its conclusion and therefore noted that the conventional steps in the claimed processes here are not sufficient to transform the nature of the claims into a patent-eligible application of such a law, the Court did not specify how specified of a claim required to satisfy the transformation prong of the machine-or-transformation test. Still, there has been no bright line separating the patent-eligibility and non-patent-eligibility in determining whether the transformation prong has been met. So, we will have to wait and see what lower courts do with the unanswered questions after the Court’s *Prometheus* decision.

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<sup>54</sup> *Bilski*, 130 S. Ct. at 3253.

<sup>55</sup> *Id.* at 3228-29.

