

# Client Alert.

December 17, 2010

## Clinical Method Claims Dodge a Bullet: *Prometheus v. Mayo*

By Yan Leychkis, James J. Mullen, III, and Matthew Kreeger

On December 17, 2010, the U.S. Court of Appeals for the Federal Circuit confirmed that claims to clinical and diagnostic methods can constitute patent-eligible subject matter in its *Prometheus II*,<sup>1</sup> decision. This was one of the first Federal Circuit opinions applying the recent United States Supreme Court *Bilski* case, which interpreted the statutory requirements for patent eligibility under 35 U.S.C. § 101.<sup>2</sup> In *Prometheus II*, the Federal Circuit essentially reaffirmed its earlier decision in *Prometheus I*,<sup>3</sup> holding that the claims recite a patent-eligible application of naturally occurring correlations and do not wholly preempt all uses of such correlations. *Prometheus II* clarifies that after *Bilski*, clinical and diagnostic methods can still be patented.

### LEGAL BACKGROUND

The scope of patentable subject matter is broadly outlined in Section 101 of the Patent Act, which states that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”<sup>4</sup> However, the Supreme Court has specified three categorical exceptions to the broad principles of Section 101: “laws of nature, physical phenomena, and abstract ideas.”<sup>5</sup> The Federal Circuit attempted to construct a bright-line rule, commonly referred to as the “machine-or-transformation” test. Under this test, a process claim satisfies Section 101 by showing that the “claim is tied to a particular machine,” or the “claim transforms an article into a different state or thing.”<sup>6</sup> Although the Supreme Court regarded it as an “important clue or investigative tool” for establishing patentability, it rejected this test as the exclusive test for determining a patent-eligible subject matter because such interpretation unduly limits the statute.<sup>7</sup>

### PROMETHEUS I

Prometheus sued Mayo for infringement of U.S. Patents 6,355,623 and 6,680,302. The claims at issue are directed to methods of optimizing therapeutic efficacy for treatment of immune-mediated gastrointestinal disorders by a process of administering a drug to a patient, measuring the level of a metabolite of the drug in the patient following administration of the drug, and comparing the level of the metabolite to recited threshold values to determine whether the drug’s dosage needs to be adjusted.

The district court held the claims unpatentable under Section 101.<sup>8</sup> The Federal Circuit reversed, holding that the claims-

<sup>1</sup> *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, No. 2008-1403, slip op. (Fed. Cir. 2010) (“*Prometheus II*”).

<sup>2</sup> *Bilski v. Kappos*, 561 U.S. \_\_\_, 130 S. Ct. 3218 (2010) (“*Bilski*”).

<sup>3</sup> *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009) (“*Prometheus I*”).

<sup>4</sup> 35 U.S.C. § 101.

<sup>5</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

<sup>6</sup> *In re Bilski*, 545 F.3d 943, 961 (Fed. Cir. 2008) (*en banc*) (“*Bilski II*”).

<sup>7</sup> *Bilski*, 130 S. Ct. at 3226-27.

<sup>8</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 04-CV-1200, 2008 WL 878910, at \*6 (S.D. Cal. Mar. 28, 2008).

# Client Alert.

in-suit pass the machine-or-transformation test.<sup>9</sup> Mayo filed a petition for a writ certiorari, arguing that the Federal Circuit's reliance on the machine-or-transformation test as the "single determinant" of patentability conflicts with the Supreme Court's preemption standard and reiterating its argument that Prometheus's claims effectively preempt any use of correlations between metabolite levels and efficacy or toxicity.<sup>10</sup> The Supreme Court granted certiorari, vacated the *Prometheus I* decision and remanded the case to the Federal Circuit for reconsideration in light of *Bilski*.<sup>11</sup>

## PROMETHEUS II

On remand, the Federal Circuit reviewed the district court's grant of summary judgment de novo and again sided with Prometheus. In light of the Supreme Court's decision in *Bilski*, the Federal Circuit framed the issue as "whether Prometheus's asserted claims are drawn to a natural phenomenon, the patenting of which would entirely preempt its use as in *Benson* and *Flook*, or whether the claims are drawn only to a particular application of that phenomenon as in *Diehr*."<sup>12</sup> The Federal Circuit concluded that they are drawn to the latter.<sup>13</sup>

The Federal Circuit rejected Mayo's position that the Supreme Court's decision to grant review, vacate the *Prometheus I* decision, and remand in view of *Bilski* ("GVR Order") indicates that preemption should be used as the controlling standard for Section 101 instead of the machine-or-transformation test. The court stated that "[n]either the Supreme Court's GVR Order [n]or the Court's *Bilski* decision dictates a wholly different analysis or a different result on remand."<sup>14</sup> The Federal Circuit further noted that "[t]he Supreme Court's decision in *Bilski* did not undermine our preemption analysis of Prometheus's claims and it rejected the machine-or-transformation test only as a definitive test."<sup>15</sup>

As in *Prometheus I*, the Federal Circuit in *Prometheus II* noted 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>16</sup> The court explained that "[t]he steps recite specific treatment steps, not just the correlations themselves," and "involve a particular application of the natural correlations: the treatment of a specific disease by administering specific drugs and measuring specific metabolites."<sup>17</sup>

The Federal Circuit also reaffirmed that "the treatment methods claimed in Prometheus's patents in suit satisfy the transformation prong of the machine-or-transformation test, as they 'transform an article into a different state or thing,' and the transformation is 'central to the purpose of the claimed process.'"<sup>18</sup> The court noted that the asserted treatment methods are always transformative when a drug is administered to ameliorate an undesired condition.<sup>19</sup> While the court recognized that the transformation of the drug upon administration occurs according to natural processes, it emphasized that the act of drug administration itself is not a natural process.<sup>20</sup> Consequently, the administration step is not merely data gathering but rather a transformative element of the claimed methods.<sup>21</sup>

<sup>9</sup> *Prometheus I*, 581 F.3d at 1342.

<sup>10</sup> *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, U.S. No. 09-490, Petition for a Writ of Certiorari (Oct. 22, 2009).

<sup>11</sup> *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 130 S. Ct. 3543 (2010).

<sup>12</sup> *Prometheus II*, slip op. at 12-13.

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

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

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

<sup>16</sup> *Id.* at 15.

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

<sup>18</sup> *Id.* at 16, quoting *Bilski*, 545 F.3d at 962.

<sup>19</sup> See *id.* at 17.

<sup>20</sup> See *id.* at 18.

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

# Client Alert.

Additionally, the Federal Circuit held that the determining step, present in each of the asserted claims, is transformative and central to the claimed methods. This step necessarily entails some form of manipulation to extract the metabolites from a bodily sample and determine their concentration.<sup>22</sup> The court noted that “[w]hile it is true that the administering and determining steps gather useful data, it is also clear that the presence of those two steps in the claimed processes is not ‘merely’ for the purpose of gathering data.”<sup>23</sup> Because both steps are integral to the treatment protocol, they are transformative and central to the claimed methods.<sup>24</sup>

Last, the Federal Circuit reiterated that the inclusion of a mental step does not destroy the patentability of an otherwise patentable process claim. While agreeing with the district court that the final “wherein” clauses in Prometheus’s asserted claims are mental steps, the Federal Circuit stressed that “[a] subsequent mental step does not, by itself, negate the transformative nature of prior steps.”<sup>25</sup> Because the administering and determining steps fall squarely within the realm of patentable subject matter, the mental steps that follow fail to remove the asserted claims as a whole from that realm.<sup>26</sup> The Federal Circuit thus concluded that Prometheus’s asserted methods satisfy the preemption test as well as the transformation prong of the machine-or-transformation test.<sup>27</sup>

## CONCLUSION

The *Prometheus II* decision confirms that inventions that satisfy the machine-or-transformation test will continue to fare well in the post-*Bilski* world. Moreover, *Prometheus II* indicates that the purpose of a claimed method is central to patentability analysis, suggesting that claims directed, at least in part, to methods of therapeutic treatment may have an easier time passing muster under Section 101 than claims directed to purely diagnostic techniques.

## Contact:

**James Mullen, III**  
(858) 720-7940  
[jmullen@mofo.com](mailto:jmullen@mofo.com)

**Matthew I. Kreeger**  
(415) 268-6467  
[mkreeger@mofo.com](mailto:mkreeger@mofo.com)

**Yan Leychkis**  
(858) 314-7702  
[yleychkis@mofo.com](mailto:yleychkis@mofo.com)

## About Morrison & Foerster:

We are Morrison & Foerster—a global firm of exceptional credentials in many areas. Our clients include some of the largest financial institutions, investment banks, Fortune 100, technology and life science companies. We’ve been included on *The American Lawyer’s* A-List for seven straight years, and *Fortune* named us one of the “100 Best Companies to Work For.” Our lawyers are committed to achieving innovative and business-minded results for our clients, while preserving the differences that make us stronger. This is MoFo. Visit us at [www.mofo.com](http://www.mofo.com).

<sup>22</sup> *Id.*

<sup>23</sup> *Id.* at 19.

<sup>24</sup> *See id.* at 20.

<sup>25</sup> *Id.* at 21.

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

<sup>27</sup> *Id.* at 23.

# Client Alert.

---

*Because of the generality of this update, the information provided herein may not be applicable in all situations and should not be acted upon without specific legal advice based on particular situations.*