

# Client Alert.

March 20, 2012

## ***Mayo v. Prometheus*: The Supreme Court Finds Certain Medical Diagnostic Claims Are Not Patent-Eligible**

By Matthew A. Chivvis, Kate McElhone, and James J. Mullen, III

The Supreme Court today delivered a unanimous opinion in *Mayo v. Prometheus*. The central question the Court addressed was whether the diagnostic method claims in patents assigned to Prometheus constituted patent-eligible subject matter under 35 U.S.C. § 101. Those claims were directed to a method for determining suitable dosing ranges of drugs used to treat autoimmune diseases. Reversing a decision by the Federal Circuit, the Court found the diagnostic testing method claims were invalid because they represented conventional applications of laws of nature.

### BACKGROUND

Section 101 of the Patent Act outlines the scope of patent-eligible subject matter: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” However, the Supreme Court has long held that this provision contains an important exception — that “laws of nature, natural phenomena, and abstract ideas” are not patentable.<sup>1</sup> At issue in *Mayo* was how this exception applies to medical diagnostic testing claims.

The claims at issue from Prometheus’s patents involve methods of determining the levels of thiopurine drug metabolites in patients with autoimmune disorders and comparing those levels to threshold values that indicate the drug’s efficacy or toxicity. Mayo purchased and used diagnostic tests based on Prometheus’s patents but in 2004, Mayo decided to try to develop and market its own version of the test. Prometheus sued, and while the district court found the patents were infringed, it granted Mayo’s motion for summary judgment of invalidity under § 101. In a 2009 decision, the Federal Circuit reversed the district court’s grant of summary judgment to Mayo, and found the disputed claims patent-eligible under the “machine-or-transformation” test.<sup>2</sup> The Supreme Court granted Mayo’s request for certiorari, vacated the Federal Circuit decision, and remanded the case for reconsideration in light of the Supreme Court’s intervening decision in *Bilski*.<sup>3</sup>

On remand, the Federal Circuit again sided with Prometheus, concluding 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>4</sup> The Federal Circuit explained that “[t]he steps recite

<sup>1</sup> *Diamond v. Diehr*, 450 U. S. 175, 185 (1981); see also *Bilski v. Kappos*, 561 U. S. \_\_\_, \_\_ (2010) (slip op., at 5); *Diamond v. Chakrabarty*, 447 U. S. 303, 309 (1980); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

<sup>2</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1342 (Fed. Cir. 2009).

<sup>3</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 130 S. Ct. 3543 (2010).

<sup>4</sup> *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1355 (Fed. Cir. 2010).

# Client Alert.

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>5</sup> For more background information, see our previous Client Alerts ([The Threshold Patentability Question: The Supreme Court Entertains Oral Arguments in \*Mayo v. Prometheus\*](#); [Back in the High Court Again: \*Prometheus v. Mayo\*](#); [Clinical Method Claims Dodge a Bullet: \*Prometheus v. Mayo\*](#)).

## THE SUPREME COURT’S DECISION

According to the Supreme Court, the claims at issue in *Mayo v. Prometheus* sat at the intersection between those that encompass non-patentable “laws of nature, natural phenomena, and abstract ideas,” and those that describe a patent-eligible “application of a law of nature or mathematical formula to a known structure or process.”<sup>6</sup> As the Court recognized, “a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.”<sup>7</sup> However, the Court also noted that, “to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words ‘apply it.’”<sup>8</sup>

As discussed above, the claims in *Prometheus*’s patents concern diagnostic methods relating to the use of thiopurine drugs in the treatment of autoimmune diseases. Because thiopurine compounds are metabolized differently by different people, doctors had difficulty determining whether a given dose was too high or too low for a particular patient. Though scientists at the time already understood that certain thiopurine metabolites were correlated with a likelihood that a particular dose was too high (which could cause harmful side effects) or too low (which could cause the treatment to be ineffective), those in the field did not know the precise correlations between metabolite levels and likely harm or ineffectiveness. The discovery described in the patents identified these correlations with more precision than had been known previously.

From the Supreme Court’s point of view, it was clear that the claims at issue applied natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage would be ineffective or would induce harmful side-effects.<sup>9</sup> The Court reasoned that while it takes human action to trigger the occurrence of these relationships, “the relation itself exists in principle apart from any human action.”<sup>10</sup> It found the correlation between the presence of metabolites and either harm on the one hand, or efficacy on the other, simply describes a relationship that “sets forth a natural law.”<sup>11</sup> Thus, the Court had to determine whether the claimed diagnostic methods included additional steps that transformed otherwise unpatentable laws of nature into patent-eligible applications of those laws.

First, the Supreme Court looked at an “administering” step in the claims, but found it simply referred to the relevant audience — doctors treating patients.<sup>12</sup> Second, the Court considered “wherein” clauses that described the likely

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

<sup>6</sup> 566 U. S. \_\_\_, \_\_\_ (2012) (slip op., at 2) (citing *Diehr*, 450 U. S. at 185, 187).

<sup>7</sup> *Id.*

<sup>8</sup> *Id.* at 3 (citing *Benson*, 409 U.S. at 71-72).

<sup>9</sup> *Id.* at 8.

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

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

<sup>12</sup> *Id.* at 9.

## Client Alert.

consequences of certain high or low concentrations of the metabolites.<sup>13</sup> The Court found these limitations were just a suggestion to take the relevant natural laws into account when treating a patient. Third, the Court analyzed a “determining” step that required doctors to determine the level of relevant metabolites in the blood.<sup>14</sup> Because the techniques for doing so were well-known, the Court also found this step insufficient to make the claims patent-eligible. Indeed, the Court noted that purely conventional or obvious pre-solution activity “is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.”<sup>15</sup> Additionally, the Court stated its concern that the claims were so broad that they might prevent too much future use of the relevant natural laws.<sup>16</sup> In reaching its conclusion, the Court also declined the Solicitor General’s invitation to address the breadth of the claims under the novelty or other substantive provisions of the Patent Act, as the Federal Circuit had suggested.

### IMPACT

The Supreme Court’s decision today creates uncertainty for diagnostic method patent claims and for the personalized medicine industry. From the Supreme Court’s analysis of prior precedent, it appears the guiding principle from *Mayo* will be that an observed “correlation” or “relationship” is not itself patentable because it constitutes a “law of nature,” which is excluded from patent protection. While the Court did advise that a claimed process should do more than simply instruct users to apply the natural law, it was vague on what exactly constitutes a patent eligible *application* of a natural law. Clients pursuing intellectual property protection for method claims, particularly in the areas of medical treatment and diagnosis, will want to work closely with their patent counsel to address the impact of this decision on their businesses and patent estates.

### Contact:

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

**Kate McElhone**  
(858) 720-7997  
[kmcelhone@mofo.com](mailto:kmcelhone@mofo.com)

**Matthew A. Chivvis**  
(415) 268-7307  
[mchivvis@mofo.com](mailto:mchivvis@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 eight 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).

*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. Prior results do not guarantee a similar outcome.*

<sup>13</sup> *Id.* at 9-10.

<sup>14</sup> *Id.* at 10.

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

<sup>16</sup> *Id.* at 18.