# Client Alert.

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# Back in the High Court Again: *Prometheus v. Mayo*

**By Kate McElhone and James J. Mullen, III**

Today, the Supreme Court granted Mayo's petition for a writ of certiorari to review the Federal Circuit's holding that Prometheus's patent claims to clinical and diagnostic methods constitute patent-eligible subject matter.[1] With this vote, the Supreme Court has waded again into the waters of patent-eligible subject matter in the wake of its decision in *Bilski*.[2] Moreover, the grant of review signals that the Court is inclined to provide further guidance to the lower courts as they flesh out the implications of the *Bilski* ruling. Importantly, the ruling reopens the question whether method claims that may include a "transformation" tangential to the recited steps qualify as patent-eligible subject matter under Section 101 of the Patent Act. As numerous biotechnology patents claim methods similar to those at issue in *Prometheus*, the outcome of this case will have a broad impact on the validity of patents in the biotechnology sector.

The *Prometheus* claims at issue are directed to methods of determining the levels of certain drug metabolites in patients with autoimmune disorders and comparing those levels to threshold values that indicate the drug's efficacy or toxicity. 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.[3] Immediately after its decision in *Bilski*, the Supreme Court granted Mayo's previous petition for certiorari, vacated the Federal Circuit decision, and remanded the case for reconsideration in light of the Court's *Bilski* decision.

On remand, the Federal Circuit again sided with Prometheus. The Federal Circuit reasoned 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."[4] The Federal Circuit concluded 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."[5] 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."[6] For a detailed review of the Federal Circuit ruling, please refer to our previous Client Alert.

Mayo again petitioned the Supreme Court for review. In briefing the petition granted today, the parties argued three key issues: 1) whether the Federal Circuit properly analyzed the claims under the preemption standard mandated by the Supreme Court in *Bilski*; 2) whether the Federal Circuit gave appropriate weight to the machine-or-transformation test in

[1] *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347 (Fed. Cir. 2010), *petition for cert. granted* (U.S. Jun. 20, 2011) (No. 10-1150); see, http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/10-1150.htm.

[2] *Bilski v. Kappos*, 130 S. Ct. 3218, 561 U.S. __ (2010).

[3] *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1342 (Fed. Cir. 2009).

[4] *Prometheus*, 628 F.3d at 1355.

[5] *Id*.

[6] *Id*.

its evaluation of the claims; and 3) whether this case presented the same concerns that convinced the Supreme Court to grant the petition for certiorari in the *LabCorp* case.[7] That case was ultimately dismissed on procedural grounds, despite the vigorous dissent of three Justices.

With the grant of Mayo's petition today, the Supreme Court has again roiled the waters of personalized medicine method claims. Briefing will occur over the next several months, with a decision likely to come by the end of the Term in June 2012. In addition, attention remains focused on the Myriad Genetics case and *Classen v. Biogen*, each of which is awaiting a decision from the Federal Circuit. Together, these three cases should provide additional guidance to personalized medicine and diagnostic business interests about the standards for patent-eligible subject matter. Of course, depending on how the Supreme Court addresses the issues in *Prometheus*, the calculus in this important area of the law could change once again. Clients operating in the biotechnology space generally, as well as the medical treatment and diagnostics fields, will want to keep a close watch on these judicial developments, and are encouraged to contact their patent counsel to assess the potential impact of this evolving patent landscape on their businesses.

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[7] See *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354 (Fed. Cir. 2004), *cert. granted*, 16 S. Ct. 543 and 126 S. Ct. 601 (2005), *cert. dismissed*, 126 S. Ct. 2921 (2006).