Client Alert.

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The Threshold Patentability Question: The Supreme Court Entertains Oral Arguments in *Mayo v. Prometheus*

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Oral arguments were presented yesterday to the U.S. Supreme Court in *Mayo v. Prometheus*. The parties and the United States, appearing as amicus curiae, addressed the question of whether the Prometheus claims directed to methods of determining suitable dosage ranges for thiopurine drugs constitute patent-eligible subject matter under 35 U.S.C. § 101. The Supreme Court's ruling in this case is expected to provide additional guidance to medical treatment and diagnostics businesses about the standards for patent-eligible subject matter under Section 101 of the Patent Act.

CASE BACKGROUND

The scope of patent-eligible 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."[1] Interest in the *Prometheus* case is running high because its outcome will help flesh out the Supreme Court's previous guidance regarding patent-eligible subject matter.[2]

The Prometheus claims at issue are directed to methods of determining the levels of certain drug metabolites in patients with auto-immune 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] 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*.[4]

On remand, the Federal Circuit again sided with Prometheus. The Federal Circuit noted "[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."[5] 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."[6] The appellate court explained that "[t]he steps recite specific

[1] 35 U.S.C. § 101.

[2] *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 130 S. Ct. 3543 (2010).

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

[4] *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

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

[6] *Id.*

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."[7] For more information on this decision, see our previous Client Alert (Clinical Method Claims Dodge a Bullet: *Prometheus v. Mayo*). Mayo filed a Petition for Certiorari, which was granted by the Supreme Court last June. (Back in the High Court Again: *Prometheus v. Mayo*)

THE ARGUMENTS PRESENTED TO THE SUPREME COURT[8]

In its briefs and during oral proceedings, Mayo argued the issued claims run afoul of the preemption standard because they "monopolize the field of blood testing for thiopurine metabolites, covering *anything* a physician might do with knowledge of the natural correlation between metabolite levels and health." (Brief for Petitioner, No. 10-1150, at 18.) In addition, Mayo offered that the drug administration and metabolite determination steps the Federal Circuit found to be transformative were merely token additions of well-established procedures to a purely mental step of observation and correlation. According to Mayo, these preliminary steps fail to limit the preemptive scope of the claims in any meaningful way because any use of the correlation requires performing the active steps. Mayo argued the "sweeping patent claims" at issue here chill medical research and increase health care costs. During oral argument, Mayo focused on the wide range of metabolite levels described in the claims as evidence of this broad preemptive effect.

Both Prometheus and the Solicitor General stressed that the claims cover a method that uses the correlations not in the abstract, but in conjunction with a series of physical steps involving specific drug administration and testing protocols that generate useful dosing and toxicity information. (*Brief for the United States as Amicus Curiae*, No. 10-1150 at 18 (Solicitor General was invited by the Supreme Court to express the views of the United States). Prometheus and the Solicitor General both emphasized that removing these active steps from the section 101 analysis on the basis that they were well-known improperly imports the requirements of sections 102 and 103 into the calculus. With regard to preemption, Prometheus noted that the correct analysis is whether the claims preclude use of physical phenomena or laws of nature when viewed at a high level of abstraction. For example, while natural metabolic processes would not themselves be patent-eligible subject matter, the process of administering specific drugs, measuring a patient's metabolic response, and characterizing those results would satisfy section 101. Finally, Prometheus criticized Mayo's position that the determination of patent eligibility should take into account the extent to which the monopoly enjoyed by the claims would hinder or promote medical research, as such an analysis would create unpredictable case-by-case results.

With Justice Breyer, the dissenter in the Court's previous decision to deny certiorari in *LabCorp*,[9] handling the bulk of the questioning, the Supreme Court attempted to tease out how much must be added to the application of a law of nature for a patent claim to satisfy section 101. The Justices also focused on the relationship, if any, of sections 102 and 103 to the patent-eligibility analysis, and the risks and benefits of having a low threshold for patentability under section 101.

IMPACT OF THE CASE

A decision in this case is expected by the end of the term in June 2012. The outcome here, in combination with the upcoming Federal Circuit decisions in the Myriad Genetics case and *Classen v. Biogen*, has the potential to clarify the

[7] *Id*.

[8] Briefs submitted to the Supreme Court on behalf of the parties and amicus curiae may be found at the following website: http://www.americanbar.org/publications/preview_home/10-1150.html.

[9] *Laboratory Corp. of Am. Holdings v. Metabolite Labs Inc.*, 548 U.S. 124 (2006).

appropriate standards for patent-eligible subject matter. Clients operating in the biotechnology space generally, as well as the personalized medicine and diagnostics fields, will want to keep a close watch on the future judicial developments and are encouraged to contact their patent counsel to assess the potential impact of the evolving patent landscape on their businesses.

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