



ARE Patent Litigation Alert: US Supreme Court Grants Cert for the Second Time in *Prometheus v. Mayo* Case on Patent-Eligible Subject Matter

June 21, 2011

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The U.S. Supreme Court has granted certiorari for the second time in *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347 (Fed. Cir. 2010) ("*Prometheus II*"), cert. granted, No. 10-1150, 2011 U.S. LEXIS 4764 (U.S. June 20, 2011) to address the issue of whether and in what circumstances a patent claim should be held invalid for failure to claim patent-eligible subject matter under 35 U.S.C. § 101. The patent claims at issue in *Prometheus* relate to the diagnosis and/or treatment of patients using the drugs AZT or 6-MP. The challenged claims include "administering" and/or "determining" steps, which the Federal Circuit has twice confirmed are "transformative" under the so-called "machine-or-transformation" test.

In its original *Prometheus* decision, issued after the Federal Circuit decided *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc) ("*Bilski II*"), *aff'd sub nom. Bilski v. Kappos*, 130 S. Ct. 3218 (2010) ("*Bilski III*"), the Federal Circuit found the claims at issue to be patent-eligible under the machine-or-transformation test. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009) ("*Prometheus I*"), cert. granted, judgment vacated, and remanded, 130 S. Ct. 3543 (2010) ("*Prometheus II*"); see Charles R. Macedo & Michael J. Kasdan, *ARE Patent Law Alert: Prometheus Labs v. Mayo Clinic: Federal Circuit Applies Transformation Prong of In re Bilski Test and Finds Drug Usage Method Claim to be Patentable Subject Matter Under Section 101* (Sept. 17, 2009).

The day after the Supreme Court issued its 5-4 decision in *Bilski III*, the Supreme Court issued a "grant-vacate-remand" ("GVR") order, in which it granted certiorari, vacated the Federal Circuit's decision in *Prometheus I*, and remanded the case for further proceedings consistent with the Court's decision in *Bilski III*. See *Prometheus II*. At the same time, the Court also issued a separate GVR order in another case in which the Federal Circuit found a similar claim to be patent ineligible for failing to meet the machine or transformation test as described in *Bilski II*. Cf. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 304 Fed. Appx. 866 (Fed. Cir. 2008) ("*Classen I*"), cert. granted, judgment vacated, and remanded, 130 S. Ct. 3541 (2010) ("*Classen II*").

On remand, in *Prometheus III*, as in *Prometheus II*, the Federal Circuit "again h[e]ld that Prometheus's asserted method claims [we]re drawn to statutory subject matter, and []



again reverse[d] the district court's grant of summary judgment of invalidity under § 101." 628 F.3d at 1349; see Charles R. Macedo, *ARE Patent Litigation Alert: Federal Circuit Turns Its Attention to Natural Phenomena Under 35 U.S.C. § 101* (Dec. 17, 2010).

After discussing the Supreme Court's holdings in *Bilski III*, *Prometheus III* characterized the issue on remand as follows:

[W]hether 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*.

628 F.3d at 1353. *Prometheus III* concluded the claims at issue were drawn to the latter, and thus were patent-eligible.

Prometheus III confirmed that, despite the GVR order by the Supreme Court in *Prometheus II*, "the Court did not disavow the machine-or-transformation test." 628 F.3d at 1356. Rather, the fact that the claims met the machine-or-transformation test was a relevant factor upon which the Federal Circuit could again rely to conclude that the claims were indeed patent-eligible subject matter.

The latest petition for certiorari poses the following detailed question concerning patent-eligible subject matter:

Whether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve "transformations" of body chemistry.

Petition for Writ of Certiorari, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, No. 10-1150, 2011 U.S. LEXIS 4764 (U.S. Mar. 17, 2011) (No. 10-1150). We will continue to monitor this case and other patent-eligible subject matter cases.

For more information on these developments, please contact one of our attorneys.

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