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

September 17, 2009

Author(s): Charles R. Macedo, Michael J. Kasdan

(September 17, 2009) On September 16, 2009, the U.S. Court of Appeals for the Federal Circuit issued another decision addressing the scope of patent-eligible subject matter under 35 U.S.C. § 101. In *Prometheus Labs., Inc. v. Mayo Collaborative Servs.,* No. 2008-1403 (Fed. Cir. 2009), a unanimous panel reversed the lower court's finding that the claims at issue were drawn to non-statutory subject matter and thus invalid under Section 101, finding instead that the claims at issue constituted patent eligible subject matter.

Claim 1 of U.S. Patent No. 6,355,623 is representative of the independent claims at issue and is drawn to:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immunemediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8x108 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per 8x108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

The District Court granted Defendant Mayo Clinic's motion for summary judgment of invalidity, finding that the patents impermissibly claim natural phenomena, i.e., the correlations between drug metabolite levels and efficacy or toxicity. The District Court held that the fact that the claims were framed as treatment methods did not render the claims patentable, stating that the "'administering' and 'determining' steps are merely necessary data-gathering steps for any use of the correlations"

and that "as construed, the final step - the 'warning' step (i.e., the wherein clause) - is only a mental step." *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 04-CV-1200, 2008 WL 8789109, at *6 (S.D. Cal. Mar. 28, 2008). With respect to the 'warning' step, the District Court found that "it is the metabolite levels themselves that 'warn' the doctor that an adjustment in dosage may be required." Id. In conclusion, the District Court found that the claims were not patentable, because they cover correlations between drug metabolite levels and efficacy or toxicity that are natural phenomena.

The Federal Circuit reversed. In so doing, the Federal Circuit considered and applied the so-called "machine-or-transformation" test, which it set forth in *In re Bilski*, 545 F.3d 943, 952, 956 (Fed. Cir. 2008) (en banc), *cert. granted*, 129 S.Ct. 2735 (2009), and which is presently being considered on certiorari by the U.S. Supreme Court. Under this test, a patent-eligible process must either be tied to a particular machine or apparatus or must transform a particular article into a different state or thing. In addition, in order impart patent eligibility, "the use of a specific machine or transformation of an article must impose meaningful limits on the claims scope" and "the involvement of the machine or transformation must not merely by insignificant extra-solution activity." *Id*. at 961-62.

Applying the transformation prong of this test, the Federal Circuit found that the claimed method met the Bilski "machineor-transformation" test. The Court disagreed with the District Court and did "not view the disputed claims as merely claiming natural correlations and data-gathering steps." slip. op. at 15. The Federal Circuit went on to state that "[t]he asserted claims are in effect claims to methods of treatment, which are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition." *Id*. As to the "determining" and "administering" steps in particular, the Federal Circuit held that these were not "merely" data-gathering steps or "insignificant extra-solution activity," but that they recite transformations that are central to the purpose of the claims, since they are significant parts of the claimed method of treatment. *Id*. at 17, 19. The Federal Circuit also disagreed with the District Court's conclusion that "the claims cover the correlations themselves." Prometheus Labs., Inc., 2008 WL 8789109, at *11. Rather, the Court held that "the claims are to transformative methods of treatment; not correlations." slip. op. at 21. The Court concluded that although the "claims cover a particular application of natural processes to treat various diseases, [] transformative steps utilizing natural processes are not unpatentable subject matter." *Id*. at 21.

Please feel free to contact us to learn more about this case and its impact on U.S. patent law.

---

* Charles R. Macedo is a Partner, and Michael J. Kasdan was an Associate at Amster, Rothstein & Ebenstein LLP. Their practice specializes in intellectual property issues including litigating patent, trademark and other intellectual property disputes, prosecuting patents before the U.S. Patent and Trademark Office, and other patent offices throughout the world, registering trademarks and service marks with U.S. Patent and Trademark Office, and other trademark offices throughout the world, and drafting and negotiating intellectual property agreements. Charles may be reached at cmacedo@arelaw.com.

Mr. Macedo was principal attorney, along with Amster Rothstein & Ebenstein partner Anthony Lo Cicero and associate Jung S. Hahm on an amicus curiae submission to the Federal Circuit in *In re Bilski* and was principal attorney, along with Amster Rothstein & Ebenstein LLP partner Anthony Lo Cicero and associate Norajean McCaffrey on an amicus curiae submission to the U.S. Supreme Court in *Bilski v. Kappos*.

Mr. Macedo is also the author of *The Corporate Insider's Guide to U.S. Patent Practice*, which will be published by Oxford University Press in October 2009.