Saul Ewing LLP
CELEBRATING 90 YEARS
LIFE SCIENCES PRACTICE GROUP
FEBRUARY 2011

"What keeps you up at night?"

Saul Ewing
Life Sciences
Practice Group:

Charles M. Lizza
Co-Chair

Deborah L. Spranger
Co-Chair

Mark C. Levy
Vice Chair

Medical diagnostic testing alive and well after *Bilski*

By Gregory S. Bernabeo

SUMMARY

Recent developments in patent law continue to provide ample room for continued innovation in the field of medical diagnostics and treatment.

The diagnostic testing field should be emboldened by a recent decision from the U.S. Court of Appeals for the Federal Circuit (CAFC) in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*. The decision confirmed that Prometheus Labs's medical testing patents are valid, even after the U.S. Supreme Court's recent decision relating to patent-eligible subject matter in *Bilski v. Kappos*, 561 U.S. __, 130 S. Ct. 3218 (2010).

The patents at issue are related to determining the optimal dosage of thiopurine drugs used to treat gastrointestinal and non-gastrointestinal autoimmune diseases. Though these drugs had been known to be useful in treating such diseases, non-responsiveness and drug toxicity complicated treatment in certain patients. The claimed methods sought to optimize therapeutic efficacy while minimizing toxic side effects. Generally, the claimed methods included steps of (a) administering a drug that provides a 6-thioguanine (6-TG) metabolite to a patient, and (b) determining the levels of the drug's metabolites in the patient. The measured metabolite levels are then compared to predetermined metabolite levels, such that the measured metabolite levels indicate a need to increase or decrease the level of administered drug to reduce toxicity or increase efficacy.

The decision in this case was rendered after this case was returned to the CAFC on remand from the Supreme Court for further consideration in light of the Supreme Court's decision in *Bilski v. Kappos*. In its earlier decision, before the Supreme Court issued its ruling in *Bilski* (*Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009)), the CAFC reversed the District Court for the Southern District of California's grant of summary judgment of invalidity of U.S. Patents 6,355,623 ("the '623 patent") and 6,680,302 ("the '302 patent") under 35 U.S.C. § 101, finding that the district court had erred as a matter of law in finding

Prometheus's asserted medical treatment claims to be drawn to non-statutory subject matter. That holding was made under the machine-or-transformation test, which the CAFC had previously determined (in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008)) to be the definitive test for determining the patentability of a process under § 101. Following this first CAFC decision in *Prometheus*, the Supreme Court held that the CAFC's machine-or-transformation test, although "a useful and important clue," was not the sole test for determining the patent eligibility of process claims (*Bilski*, 130 S. Ct. at 3226-27). Based on that decision, the Supreme Court vacated and remanded the CAFC's first *Prometheus* decision. On remand, the CAFC held that Prometheus's asserted method claims were drawn to statutory subject matter even under the new post-Supreme Court *Bilski* regime, and again reversed the district court's grant of summary judgment of invalidity under § 101.

While the language of the patent statute provides that "any new and useful process, machine, manufacture, or composition of matter" may be entitled to a patent, there are limits to what type of subject matter is patentable. As noted by the Supreme Court in *Bilski*, laws of nature, physical phenomena and abstract ideas are not patent eligible. However, patent law provides that an application of a law of nature to a process may be entitled to patent protection. Whether the claimed methods were patent eligible turned on whether they were drawn to a natural phenomenon (and thus unpatentable), or whether they were drawn only to a particular application of that phenomenon (and thus patentable).

On remand, the CAFC reaffirmed its earlier finding that the recited administering and determining steps were transformative, and thus met the machine-or-transformation test. Specifically, the claims were held to involve transformation of the human body and its components into a different state following the administration of specific drugs, and of various chemical and physical changes of the drugs' metabolites that occur during assessment of their concentrations. Further, the CAFC found that the claims were not drawn to a law of nature, but to a particular application of naturally occurring correlations between metabolite levels and drug efficacy and toxicity, and thus did not preempt all uses of the recited correlations. The CAFC stated that the inventive nature of the claimed methods flowed from the application of a natural metabolic phenomenon in a series of steps involving a specific method of treatment. The CAFC specifically rejected Mayo's argument that the claims were patent ineligible as merely involving natural correlations and mere data-gathering steps. The fact that the transformation of the administered drug into its metabolites occurred according to natural processes was found not to disqualify the administering step from patent eligibility. Further, the CAFC found that the determining step required some form of manipulation for measurement, such as high pressure liquid chromatography processing, and that such manipulation caused transformation of human blood or tissue to a different state. Thus, the CAFC held that the claims were patent eligible.

Accordingly, recent developments in patent law continue to provide ample room for continued innovation in the field of medical diagnostics and treatment, which is of paramount importance as medicine continues to place greater emphasis on diagnostic testing as part of a trend toward personalized medicine.

This Alert was written by Gregory S. Bernabeo, a member of the firm's Life Sciences Practice Group. Gregory can be reached at 215.972.7755 or gbernabeo@saul.com.

Baltimore, MD
500 East Pratt St.
Charles O. Monk, II
410.332.8668

Chesterbrook, PA
1200 Liberty Ridge Dr.
Michael S. Burg
610.251.5750

Harrisburg, PA
2 North Second St.
Eric L. Brossman
717.257.7570

Newark, NJ
One Riverfront Plaza
Stephen B. Genzer
973.286.6712

New York, NY
400 Madison Ave.
John J. Jerome
212.980.7212

Philadelphia, PA
1500 Market St.
Bruce D. Armon
215.972.7985

Princeton, NJ
750 College Rd. E
Marc A. Citron
609.452.3105

Washington, DC
2600 Virginia Ave. NW
Mark L. Gruhin
202.342.3444
Edward R. Levin
202.342.3420

Wilmington, DE
222 Delaware Avenue
Wendie C. Stabler
302.421.6865
William E. Manning
302.421.6868