Bloomberg Law Reports® Intellectual Property

Reading Tea Leaves: An Update on Personalized Medicine: Innovation, Threats, and Opportunities

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Previously we reported on a recent judicial challenge to the patenting of technologies that support personalized medicine.[1] The Association for Medical Pathology and others (represented by the American Civil Liberties Union) successfully challenged several patent claims to forms of two human genes linked to breast or ovarian cancer.[2] The patents are licensed by Myriad Genetics. The U.S. District Court for the Southern District of New York held the challenged claims invalid, finding that the U.S. Patent and Trademark Office should not have granted the patents because information related to genes and their use in a genetic test should not be patentable *per se*. The court reasoned in part that the challenged claims were unconstitutional and invalid because the subject matter was a product of nature and should not be patented. Myriad has appealed this ruling to the U.S. Court of Appeals for the Federal Circuit.

Recent developments at the U.S. Supreme Court and the Federal Circuit suggest that appellate courts may not be, as many feared, placing a *per se* bar on the patenting of genetic tests that utilize isolated nucleic acids and genes for medical diagnosis. Additional clarity on the standards for patenting these technologies is expected from the Federal Circuit when it reconsiders two of its prior decisions that addressed the patent eligibility of such tests and when it reviews the *Myriad* ruling.[3]

Bilski v. Kappos

The U.S. Supreme Court in *Bilski v. Kappos*[4] addressed the issue of the patent eligibility of a method of doing business. The business method explains how commodities buyers and sellers in the energy market can protect or hedge against the risk of price changes. Although not related to biotechnology or medical diagnostic tests, the Supreme Court's ruling was cautiously monitored for its potential impact on the patent eligibility of medical diagnostic tests. Of particular interest was the Supreme Court's evaluation of the "machine or transformation test" created by the Federal Circuit to determine the patent eligibility of business methods that was subsequently applied to medical diagnostic methods. The Federal Circuit's "machine or transformation test" stated that if a business or diagnostic method was either tied

to a particular machine or an apparatus,such as by the use of a computer processor or other analytical tool, or alternatively, the method transforms a particular article into a different state or thing, then the claimed method was patent eligible. The Supreme Court agreed that the Federal Circuit's "machine or transformation test" was one tool to determine patent eligibility under 35 U.S.C. § 101, but cautioned that it is not the sole test. Also, rather than addressing the application of the test to medical methods or whether medical methods in general were patent eligible, the Supreme Court asked the Federal Circuit to re-evaluate two of its prior opinions in light of the *Bilski* decision.[5]

Prometheus Laboratories, Inc. v. Mayo Collaborative Services

The first decision remanded by the Supreme Court to the Federal Circuit is *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*.[6] In this ruling, the Federal Circuit opined that methods for optimizing dosage of a pro-drug for the treatment of an immune-mediated gastrointestinal disorder were patent eligible because, in part, the methods required determining the patient's levels of drug metabolites, which could not be done by mere inspection of a laboratory sample. Some of the claims required the administration of the pro-drug to the patient and the subsequent measurement of the pro-drug's metabolites in a sample from the patient. Other appealed claims did not require administration of the pro-drug, but still required the analysis of a sample taken from the patient. The patent holder -argued, and the Federal Circuit agreed, that the administration of the pro-drug and the testing of the metabolite constituted a "transformation" as required by "machine or transformation test." Thus, the claims were held to be patent eligible under Section 101.

Classen Immunotherapies, Inc. v. Biogen Idec

The second decision remanded by the Supreme Court to the Federal Circuit is *Classen Immunotherapies, Inc. v. Biogen Idec*.[7] The invention at issue in *Classen* is a method of determining whether an immunization schedule affects the incidence or severity of a chronic immune related disorder in a treatment group of animals relative to a control group. The method requires first immunizing the animals with one or more doses of an immunogen and then comparing the incidence, prevalence, frequency, or severity of disease or the level of a marker of the disorder in the treatment group with that of the control group. In contrast to *Prometheus*, the Federal Circuit held that this method did not satisfy the "machine or transformation test" even though the method, similar to some of the claims in *Prometheus*, required the administration of a drug or immunogen which was transformed in the body of the animal or patient. Unfortunately, the Federal Circuit's opinion in *Classen* was only 69 words long and did not provide insight as to what distinctions, if any, can be made between a patent eligible method as claimed in *Prometheus* versus a patent ineligible method as claimed in *Classen*.

Looking Ahead

Companies and inventors seeking to patent diagnostic methods or genetic tests are now looking to the Federal Circuit for guidance on what elements in a medical method or genetic test claim are necessary to satisfy patent eligibility. The Supreme

Court in *Bilski* did not disagree with the Federal Circuit's "machine or transformation test" as a means to determine patent eligibility, but the lack of analysis in the application of the "machine or transformation test" in the *Classen* ruling has led to much guessing regarding how to apply the test with a modicum of certainty. The Federal Circuit, with the remanded *Prometheus* and *Classen* cases and the yet to be considered *Myriad* claims, has ample opportunity to provide clarity and a semblance of predictability. Those seeking to patent medical methods and genetic tests now wait for the tea leaves to settle at the Federal Circuit.

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[1] Konski and Waltz, Personalized Medicine: Innovation, Threats and Opportunities. Bloomberg Law Reports – Intellectual Property, Vol. 4, No. 26 (June 28, 2010).

[2] *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09-CV-04515, 2010 BL 112357 (S.D.N.Y. Mar. 29, 2010), *as amended* (April 5, 2010) ("*Myriad*"). A notice of appeal was filed by one of the defendants indicating that it will appeal the ruling to the Federal Circuit. No. 10-01406 (Fed. Cir. appeal filed June 22, 2010).

[3] In two cases related to methods for medical diagnosis, the U.S. Supreme Court granted certiorari, vacated the Federal Circuit's decision, and remanded for further consideration by the appellate court. *See Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009), *cert. granted, vacated, and remanded*, No. 09-00490, 2010 BL 146724 (June 29, 2010); *Classen Immunotherapies, Inc. v. Biogen Idec.*, 304 Fed. App'x 866 (Fed. Cir. 2008), *cert. granted, vacated, and remanded,* No. 08-01509, 2010 BL 146717 (June 29, 2010).

[4] *Bilski v. Kappos*, 561 U.S. __, 2010 BL 146286 (2010).

[5] *Prometheus*, 581 F.3d 1336; *Classen*, 304 Fed. App'x 866.

[6] *Prometheus*, *581 F.3d 1336*.

[7] *Classen*, *304 Fed. App'x 866*.