

IP LAW ADVISORY

December 16, 2010

**Federal Circuit Holds that Iterative Method of Medical Treatment
is Patentable Subject Matter**

By Danni Tang, Esq. and Craig Smith, Esq.

The Federal Circuit issued its decision in *Prometheus v. Mayo*, No. 2008-1403 (Fed. Cir. 2010), holding (once again) that the two Prometheus patents for an iterative method of medical treatment satisfy the §101 requirement for patentable subject matter. Applying the machine-or-transformation test in light of the Supreme Court's ruling in *Bilski*, the Federal Circuit concluded that the claims do not pre-empt a law of nature because the specific treatment steps are an application of natural correlations, and are transformative. The practical implication of this decision is that medical treatment method claims can be patentable subject matter provided they primarily recite specific action steps that cause transformations in a patient or tissue, for example.

The two Prometheus patents at issue were directed to a method for treating autoimmune gastrointestinal disorders using known compositions to maximize efficacy and minimize toxicity. The treatment steps included (1) administering a drug providing specific metabolites (6-TG and/or 6-MMP) and (2) determining the level of the metabolites in the patient and whether the level meets an upper or a lower threshold, whereby exceeding the upper threshold signals a need to decrease the concentration of the medication, and exceeding the lower threshold signals a need to increase the concentration of the medication.

Previously, the United States District Court for the Southern District of California had found the Prometheus patents invalid for unpatentable subject

matter because the patents recite and claim the correlation between concentrations of metabolites and efficacy and toxicity, which are natural phenomena. On appeal to the Federal Circuit, the Court reversed, finding that the claims were transformative under the machine-or-transformation test, and therefore patentable. Mayo sought certiorari to the Supreme Court. In June, the Supreme Court decided *Bilski*, holding that while the machine-or-transformation test was informative of patentable subject matter, it was not determinative. In light of its decision in *Bilski*, the Supreme Court granted Mayo's petition for certiorari, vacated, and asked the Federal Circuit to reconsider the patentability of the Prometheus patents.

On this second look, the Federal Circuit again reached the same conclusion of patentability. The Court, applying the machine-or-transformative test as guidance, more broadly analyzed whether the disputed claims, as a whole, impermissibly claimed or pre-empted a law of nature, or permissibly claimed an application of a law of nature.

In light of the Supreme Court's decision in *Bilski*, patent eligibility in this case turns on whether Prometheus's asserted claims are drawn to a natural phenomenon, the patenting of which would entirely preempt its use ..., or whether the claims are drawn only to a particular application of that phenomenon ...

The Court found that the Prometheus “claims recite specific treatment steps, not just the correlations themselves.”

[T]he steps involve a particular application of the natural correlations: the treatment of a specific disease by administering specific drugs and measuring specific metabolites. As such ..., the claims do not preempt all uses of the natural correlations; they utilize them in a series of specific steps.

The Court also found that the claims are transformative because both the steps of administering and determining are transformative. The administering step transformed the patient, and the measuring step transformed the measured tissue matter.

When administering a drug such as AZA or 6-MP, the human body necessarily undergoes a transformation. The drugs do not pass through the body untouched without affecting it. In fact, the transformation that occurs, viz., the effect on the body after metabolize the artificially administered drugs, is the entire purpose of administering these drugs...The fact that the change of the administered drug into its metabolites relies on

natural processes does not disqualify the administering step from the realm of patentability.

...
Determining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation. Some form of manipulation, such as the high pressure liquid chromatography method specified in several of the asserted dependent claims or some other modification of the substances measure, is necessary to extract the concentration.

Finally, although the Court agreed that the step of comparing the results of the determination with the threshold values was a mental step that was not patent eligible per se, the claims had to be evaluated as a whole. Citing *Bilski*, the Court noted that “it is inappropriate to determine the patent eligibility of a claim as a whole based on whether selected limitations constitute patent-eligible subject matter.” Analyzing the Prometheus claims as a whole, the claims were not only mental steps and “a subsequent mental step does not, by itself, negate the transformative nature of prior steps... does not detract from the patentability of Prometheus’s claimed methods as a whole.”

DISCLAIMER: This case summary provides general information only. This is not a legal opinion or legal advice and does not establish any form of attorney-client relationship with Lando & Anastasi. Lando & Anastasi disclaims any liability for any errors or omissions in this summary. You should consult your own lawyer concerning any issues, questions or actions relating to the information contained in this summary.