$1.50 VOL. 34 NO. 28 www.ocbj.com JULY 11-17, 2011

ORANGE COUNTY BUSINESS JOURNAL

Are Methods for Medical Treatments Patentable?

Yes, for now, if they are transformative, but that may change as the Supreme Court takes action

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Many patent holders in the medical community are nervously watching the U.S. Supreme Court, and many speculate that its actions could cause patents covering methods for medical treatment to be challenged and litigated.

Background

After the United States Supreme Court's decision in the *Bilski v. Kappos* case last summer, it became unclear whether patents purporting to protect methods for medical treatment would remain valid. Following its *Bilski* decision, the Supreme Court remanded to the Federal Circuit the case of *Prometheus v. Mayo,* to decide this issue, and the Federal Circuit determined that these methods remain patentable as long as they are transformative.

For further clarification, on June 20, the Supreme Court granted certiorari on the question of whether patent law under 35 USC Section 101 is satisfied by a 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 blood chemistry."

Machine-or-Transformation Test

The *Bilski* decision determined whether certain method claims (in that case a method of hedging risk) constituted patentable subject matter. The *Bilski* decision did not draw any bright lines other than to re-confirm that abstract ideas, laws of nature and physical phenomena could not be patented. The Supreme Court also held that the Federal Circuit's machine-or-transformation ("MOT") test was not the sole basis for determining patentability, although it noted that the machine-or-transformation test remained a useful and important tool for determining patentable subject matter.

The Federal Circuit applied this test to methods for medical treatments in the *Prometheus* case. Prometheus is the exclusive licensee of two patents, which claim methods for determining the optimal dosage of thiopurine, a drug that is commonly used to treat gastrointestinal and non-gastrointestinal autoimmune diseases. The patents claim methods that seek to optimize therapeutic efficacy while minimizing toxic side effects. The method consists of administering the drug and then determining the levels of the drug's metabolites in the blood. The measured metabolites are then compared to pre-determined metabolite levels to determine whether the metabolite levels measured are associated with either toxic or beneficial effects, so as to determine whether to increase or decrease the dosage level of the drug to minimize toxicity and maximize treatment efficacy.

Focusing on whether Prometheus' claims were "drawn to a natural phenomenon," the Federal Circuit found that they were not because the claims in the patents recited specific treatment steps and not just correlations that naturally occurred. The specific treatment steps cited by the Federal Circuit were the administration of a drug and the measurement of specific metabolites. The Federal Circuit then concluded that the claims passed the machine-or-transformation test.

In analyzing Prometheus' claims the Federal Circuit found that the claims passed the transformation prong of the test because method of treatment claims "are always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition." Thus, the step of administering the drug was transformative because a drug transforms the body and the determining step is also transformative because it involves some modification of the substances to be measured. The Court noted: "The transformation is of the human body and of its components following the administration of a specific class of drugs and the various chemical and physical changes of the drugs' metabolites that enable their concentrations to be determined." In so holding, the Federal Circuit rejected the argument that the change of the administered drug into its metabolites relies on natural processes and does not take the method outside the realm of patentability because every transformation operates by natural principles. It is the administration of the drug to a subject to treat the subject which is transformative.

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Patents Covering Methods for Medical Treatment may be Questioned

This holding is now in question with the recent certification of the *Prometheus* decision. Indeed, it is likely that the Supreme Court will put some restriction on the Federal Circuit's use of the transformative prong at least in application to methods for treatment and could have broader implications for the medical community as a whole.

With the current state of the law in this area in flux, we are certain to see more cases involving challenges to patents covering methods for medical treatment. Method claims that merely describe collecting data and using known mathematical algorithms for analyzing that data, such as those in *In re Grams,* (which involved the performance of a generic method of testing a complex system to determine whether the system condition was normal and to determine the cause of the abnormality), are likely to fall and be declared invalid under the machine-or-transformation test, even after *Bilski.* Indeed, even those methods that involve a medical treatment that includes a transformation of some aspect of the human body may not be patentable, depending on how the Supreme Court defines what constitutes a patentable transformation under Section 101. The medical community is closely watching to see how the Supreme Court handles *Prometheus;* some are preparing legal strategies to protect their patents.

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