

# CLIENT ALERT

## Federal Circuit Confirms Diagnostic and Therapeutic Methods Can Be Patentable Subject Matter

September 24, 2009

### Executive Summary

On September 16, 2009, in the case of *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, the Court of Appeals for the Federal Circuit (Federal Circuit) issued a decision that has important implications for the biotechnology and pharmaceutical industries. The decision confirms that medical diagnostic and related treatment methods can be patentable subject matter.

The patent-eligibility of such claims was in doubt in the wake of the Federal Circuit's October 30, 2008 *In re Bilski* decision. (To read our client alert on this case, please click [here](#).) In *Prometheus*, the Federal Circuit held that clinical diagnostic methods that include analysis of a sample are patent-eligible subject matter. Likewise, treatment methods that include analyzing the effect of a drug on a human also are patent-eligible.

### Background

The Federal Circuit's *In re Bilski* decision set forth a mandatory "machine-or-transformation" (MOT) test for determining patent-eligibility of methods. In that test, a method claim must either be tied to a particular machine or include a transformation of a particular article into a different state or thing. In addition, the involvement of the machine or transformation must impose meaningful limits on claim scope and must not be merely insignificant "extra-solution" activity. The court in *Bilski* found that a step that consisted only of gathering data is not sufficient to satisfy the transformation prong of the MOT test.

Although the subject matter of the patent at issue in *Bilski* was business methods, that decision applies to all methods. Accordingly, there was substantial uncertainty as to whether claims to medical diagnostic methods that include correlations of biomarkers to disease states were still patentable subject matter. This uncertainty was also fostered by comments made in a dissent from the Supreme Court's 2006 decision not to grant certiorari in the case of *Laboratory Corp. of America v. Metabolite Laboratories*, in which the patent-eligibility of medical diagnostic tests was discussed. (To read our client alert on this case, please click [here](#).) Then, in December 2008, in the non-precedential case *Classen Immunotherapies v. Biogen IDEC*, the Federal Circuit summarily ruled ineligible (as failing the MOT test) method claims for determining whether an

immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals.

The patent claims at issue in *Prometheus* recite optimizing therapeutic efficacy of a particular drug. Some of the claims include steps of administering the drug to a patient and determining the level of the drug or its metabolites in the patient. Other claims at issue include a step of determining the level of the drug administered to the patient or its metabolites, but do not include an administration step. The level of drug or its metabolites that is determined in the methods indicates a need to increase the amount of the drug administered (if below a set level,) or indicates a need to decrease the amount of the drug administered (if above a set level.)

## Federal Circuit's Decision

The Federal Circuit held that the claimed methods are directed to patent-eligible subject matter because both the “administering” step and the “determining” step satisfy the transformation prong of the MOT test, and because the recited transformation is central to the purpose of the claimed methods.

With respect to the “administering” step, the court held that, after administration of a drug, “the human body necessarily undergoes a transformation” and that a method of treatment is “always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition.” This holding resoundingly supports patent-eligibility of medical treatment method claims, in sharp distinction to the *Classen* ruling.

With respect to the “determining” step, the court held that determining the levels of a drug or its metabolites “necessarily involves a transformation, for those levels cannot be determined by mere inspection.” A transformation was evident because analyzing a sample requires some form of manipulation to extract the drug or its metabolites and determine their concentration in the sample. In other words, a transformation was inherent. This holding supports patent-eligibility of medical diagnostic method claims that include a similar “determining” step.

The court also reiterated that the presence of a mental step in a claim does not exclude the claim from patent-eligibility. Here, the recitation of “indicating a need” to adjust the amount of drug administered in the claims was found to be a mental step that, standing alone, would not be patent-eligible subject matter. However, the court stated that “[a] subsequent mental step does not, by itself, negate the transformative nature of prior steps.” Instead, the claims must be viewed as a whole to determine if patent-eligible subject matter exists.

## Effect on Current Practice

The Federal Circuit's decision clearly supports patent-eligibility of claims to medical diagnostic methods and related treatment methods. The next major development is not likely to come from the Federal Circuit, though. The U.S. Supreme Court will be hearing an appeal of *In re Bilski* on November 9, 2009, and that court's decision may alter or negate the effect of this decision by the Federal Circuit.

Based on the *Prometheus* decision, patent applicants should review pending medical diagnostic method claims and related treatment method claims and, if necessary, amend the language of the

claims to clearly state a transformation. The decision by the Federal Circuit serves as a guide to the use of language in medical diagnostic method claims and related treatment method claims that meets the standard for patentable subject matter.

For example, the *Prometheus* court held that “determining” a level of a drug “necessarily involves a transformation, for those levels cannot be determined by mere inspection.” However, in some patent applications, a “determining” step could be construed more broadly to be a mental step. Therefore, in view of the *Prometheus* decision, it is probably still important to include terminology in which a transformation is explicit or inherent—such as “performing an assay to determine”—in at least some of the diagnostic method claims and related treatment method claims.

### **For Further Information**

To read the full *Prometheus* decision by the Federal Circuit, please click [here](#).