

CLIENT ALERT: PROMETHEUS LABORATORIES V. MAYO COLLABORATIVE SERVICES

The Court of Appeals for the Federal Circuit (the Court that hears all patent appeals) issued a favorable decision for medical diagnostic companies and others yesterday in the case of Prometheus Laboratories v. Mayo Collaborative Services (--- F.3d ----, 2009 WL 2950232 (C.A.Fed., 2009)).

Prometheus obtained two patents on methods for calibrating the dose of certain drugs for treating gastrointestinal disorders. The patented methods involve administering the drug and then measuring levels of a metabolite in order to optimize therapeutic efficacy. The Mayo Clinic challenged the patents, asserting that the claimed methods were not patentable subject matter. The lower court agreed with Mayo and invalidated the patents.

On appeal, the Federal Circuit, applying the “machine or transformation test” set forth in *In re Bilski*, determined that the Prometheus claims were indeed patentable subject matter. In the prior *Bilski* case, the Court stated that a method claim that requires transforming “an article into a different state or thing” is patent-eligible. According to the Federal Circuit, the steps of administering a drug and determining the level of its metabolite is a “transformation” due to chemical changes that occur in the patient upon administration of the drug.

The Prometheus decision is the latest example that *Bilski* applies to more than just software, business methods, and computer-related inventions. Moreover, the decision in Prometheus reduces ambiguity surrounding the patentability of diagnostic methods and provides positive guidance for companies in the diagnostics and personalized medicine space.



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