

SUPREME COURT REMANDS MEDICAL PROCESS CASES IN VIEW OF BILSKI

On June 29th, the U.S. Supreme Court remanded to the Court of Appeals for the Federal Circuit two medical process cases (*Mayo Collaborative Services v. Prometheus Laboratories and Classen Immunotherapies, Inc. v. Biogen IDEC*) in view of the Supreme Court's decision in *Bilski v. Kappos*. The Supreme Court held in that decision that the "machine-or-transformation" test is not the exclusive test for patent-eligible subject matter. Under the "machine-or-transformation" test, a process claim will be deemed patent eligible subject matter if it is tied to a particular machine or transforms an article into a different state or thing.

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 Federal Circuit applied the "machine-or-transformation" test and determined that the *Prometheus* claims recited patentable subject matter. 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.

In the other remanded case, *Classen* obtained four patents on methods of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disease. The methods involved immunizing a treatment group and comparing the incidence of chronic immune mediated disorders in the treatment group relative to a control group. The Federal Circuit held that the *Classen* claims did not recite patent eligible subject matter because the claims were not "tied to a particular machine or apparatus" and also did not "transform a particular article into a different state or thing".

The Federal Circuit's decisions in both *Classen* and *Prometheus* were based on the presumption that the machine-or-transformation test was the sole test for determining patent-eligible subject matter. However, the Supreme Court held in *Bilski* that the machine-or-transformation test is not the sole test for determining whether a process is patent eligible subject matter.

Since the Federal Circuit found that the *Prometheus* claims constituted statutory subject matter under the machine or transformation test, we presume that the decision in that case will not change based upon the Supreme Court's *Bilski* ruling. However, since claims were found ineligible for patent protection in *Classen*, the Federal Circuit's reconsideration of that case may shed light on how that court interprets statutory subject matter questions that fail the machine-or-transformation test.



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