



## ARE Patent Litigation Alert: Federal Circuit Turns Its Attention to Natural Phenomena Under 35 U.S.C. Â§ 101

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On December 17, 2010, the U.S. Court of Appeals for the Federal Circuit issued an Opinion and Order confirming the patent-eligibility of claims directed to methods used in treating gastrointestinal and non-gastrointestinal autoimmune diseases in [Prometheus Laboratories, Inc. v. Mayo Collaborative Services](#), No. 2008-1403 (Fed. Cir. Dec. 17, 2010).

The district court in *Prometheus* granted summary judgment that Prometheus's asserted claims were invalid for not reciting patent eligible subject matter under 35 U.S.C. § 101. The Federal Circuit reversed the district court's decision, and upheld the validity of the asserted claims. [Prometheus Laboratories, Inc. v. Mayo Collaborative Services](#), 581 F.3d 1336 (Fed. Cir. 2009). Following that decision, the U.S. Supreme Court handed down its decision in *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). Thereafter, the Supreme Court granted Mayo's petition for certiorari, and vacated and remanded the Federal Circuit's *Prometheus* decision for consideration in light of *Bilski*. On remand, the Federal Circuit again found the claims in question to be drawn to patent-eligible subject matter.

After reviewing the general principles governing the broad scope of patent-eligible subject matter, the Federal Circuit concluded that the patent-eligibility of Prometheus's claims depended on whether they were drawn to a natural phenomenon:

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 as in *Benson* or *Flook*, or whether the claims are drawn only to a particular application of that phenomenon as in *Diehr*. *Bilski*, 130 S. Ct. at 3230.

(Slip. op. at 12–13).

In discussing its conclusion that Prometheus's asserted claims were drawn to an application of a naturally occurring phenomenon, and not to the phenomenon itself, the Federal Circuit explained that Prometheus's claims involve a particular application of a naturally occurring correlation: "the treatment of a specific disease by administering specific drugs and measuring specific metabolites." (Slip. op. at 15). Focusing on each claim as a whole, the Federal Circuit stated that they recited steps that involve a transformation:



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.

(Slip op. at 16). Unlike the district court, which viewed the claims as being drawn to natural correlations and data gathering steps, the Federal Circuit viewed the claims as being directed to methods of treatment, "which are always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition." (Slip op. at 16–17).

The fact that some of the steps recited in the claims are mental steps did not dissuade the Federal Circuit:

We agree with the district court that the final "wherein" clauses are mental steps and thus not patentable per se. However, although they alone are not patent-eligible, the claims are not simply to the mental steps. A subsequent mental step does not, by itself, negate the transformative nature of prior steps.

(Slip op. at 21).

In sum, when viewed as a whole, the Federal Circuit concluded that Prometheus's claims did not preempt all uses of a natural phenomenon, but instead recited an application of a naturally occurring correlation in the body:

In other words, when asked the critical question, "What did the applicant invent?," (citations omitted), the answer is a series of transformative steps that optimizes efficacy and reduces toxicity of a method of treatment for particular diseases using particular drugs.

(Slip op. at 23)

For more information on patent-eligible subject matter, please feel free to contact us.

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