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On December 17, the Court of Appeals for the Federal Circuit (CAFC) confirmed the patent eligibility of certain medical treatment claims in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services et al.* The CAFC answered its own question "What did the applicant invent?" and identified transformative steps that optimize efficacy and reduce toxicity of a treatment for particular diseases using particular drugs. So stated, it deemed the treatment to be patent eligible.

The Prometheus patents claim methods for determining optimal dosage of drugs used to treat certain autoimmune diseases. Patent claims recite (a) "administering" a drug that provides a metabolite to a subject and (b) "determining" the level of the drug's metabolites in the subject. Once measured, a comparison of metabolite levels indicates a need to increase or decrease the level of drug subsequently administered to the subject.

At trial, Mayo contended that the claims impermissibly preempt use of natural phenomena; namely, correlations between drug metabolite levels and efficacy and toxicity. The District Court for the Southern District of California agreed and granted Mayo's motion for summary judgment of invalidity of the patents under 35 U.S.C. § 101. In its first review of the district court decision in 2009 (*Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009)), the CAFC held that the district court erred as a matter of law under its machine-or-transformation test, which deemed a claimed process patent eligible only if it (1) is tied to a particular machine or apparatus or (2) transforms a particular article into a different state or thing. This case was later returned to the CAFC for further consideration after the *Bilski* decision, in which the Supreme Court held that the machine-or-transformation test was not the sole test for determining the patent eligibility of process claims.

In its second consideration of this case, the CAFC commented on the *Bilski* decision, pointing out that the Supreme Court (1) declined to adopt categorical rules beyond the well-established exceptions from patent eligibility for laws of nature, physical phenomena, and abstract ideas; (2) did not reject the machine-or-transformation test, but rather characterized it as "a useful and important clue" for determining patent eligibility; and (3) established that "an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." Turning to Prometheus's patents, the CAFC framed the issue this way: "patent eligibility in this case turns on whether [the] claims are drawn to a natural phenomenon, the patenting of which would entirely preempt its use ..., or whether the claims are drawn only to a particular application of that phenomenon"

The CAFC ultimately held that Prometheus's method claims do not wholly preempt all uses of the recited correlations; instead, they recite a patent-eligible application of naturally occurring correlations between metabolite levels and efficacy or toxicity. In reaching this holding, the CAFC focused on several primary conclusions. First, it concluded that the claims recite specific treatment steps and involve a particular application of natural correlations - the treatment of a specific disease by administering specific drugs and measuring specific metabolites - without preempting all uses of those natural correlations.

Second, the CAFC concluded that the treatment steps satisfy the "transformation" prong of the machine-or-transformation test because they transform the human body following the administration of a specific class of drugs and because of the various chemical and physical changes of the drugs' metabolites that enable their concentrations to be determined. The CAFC explained that methods of treatment are "always" transformative "when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition." The administering step was thus deemed a significant transformative element of the treatment methods, and the determining step was also deemed transformative in view of the manipulation needed to extract metabolites from a bodily sample and determine their concentration.

Despite concluding that Prometheus's claims are patent eligible, the CAFC commented on the claimed step that involved comparing measured metabolite levels to indicate a need to increase or decrease the level of drug to be administered. Here, the CAFC agreed with the district court that these are mental steps and are thus not patent-eligible *per se*. Nevertheless, such mental steps do not negate the transformative nature of the prior administering and determining steps.

In *Prometheus*, the CAFC has provided a post-*Bilski* glimpse at how it will analyze patent eligibility of medical treatment claims. It also confirmed that the machine-or-transformation test will continue to play a central role in determining patent eligibility of medical treatment inventions.

