

In *Prometheus Labs, Inc. v. Mayo Collaborative Services*, decided September 16, 2009, the U.S. Court of Appeals for the Federal Circuit reversed a grant of summary judgment from the Southern District of California which held claims to methods for calibrating the proper dose of drugs based on the measurement of metabolites of the drugs invalid as unpatentable subject matter under 35 U.S.C. § 101.

The field of personalized medicine, a relatively new branch of the biotechnology and pharmaceuticals industries, aims to optimize disease diagnosis and treatment efficacy through use of genetic and molecular analyses, generally by comparing conditions in a particular patient against standards. Typically, patents and patent applications claiming methods of diagnosis involving personalized medicine technology include the basic steps of gathering data from a patient sample, comparing the data with a standard, and generating information about or diagnosing the patient based on the comparison.

Increasingly, such method claims are being scrutinized in the courts and before the U.S. Patent and Trademark Office as encompassing patent-ineligible subject matter under 35 U.S.C. § 101. Challengers contend that diagnostic method claims including only these basic steps merely capture a correlation, and therefore pre-empt a law of nature or the use of a natural phenomenon. The challengers had been emboldened by a dissent of Justice Breyer from a Supreme Court decision revoking *certiorari* in *Laboratory Corp. of America Holding v. Metabolite Labs., Inc.* Justice Breyer, with two other justices, questioned whether the claims in that case, covering a diagnostic test procedure in which certain variables were measured and correlated, covered an unpatentable natural phenomenon. More recently, challengers have questioned whether such claims satisfy the requirement, set forth in the Federal Circuit's *In re Bilski* opinion, that patent claims include a "machine or transformation" element to be considered patent eligible subject matter under Section 101.

In *Prometheus*, the patentees claimed a method for optimizing treatment efficacy by administering a drug to a patient, measuring the level of the drug's metabolite in the patient, and comparing the measured value with a reference value, wherein a concentration of metabolite lower than a certain threshold indicates a need to increase the amount of drug subsequently administered to the patient and a concentration of metabolite higher than a certain threshold indicates a need to decrease the amount of drug subsequently administered. Relying on the Breyer dissent, the accused infringer asserted that the patents were invalid for claiming correlations that pre-empt the use of natural phenomena. The District Court agreed with the accused infringer, and granted summary judgment for invalidity on the grounds the claims recited correlations that result from natural metabolism in the body, and the claims wholly pre-empt this correlation.

The Federal Circuit found the claims were drawn to patent eligible subject matter. According to the Court, the claimed methods satisfy the "transformation" branch of *Bilski*. In this regard, the Court suggested the transformation occurs through the effect the "artificially administered" drug has on the body. The Federal Circuit explained that although natural processes in the body change the administered drug into a metabolite, this fact does not negate patentability, noting that the transformation results from the act of administering the drug to treat (*i.e.*, transform) the patient, which itself is not a natural process. The Federal Circuit disagreed with the District Court's determination that the claims merely recited natural correlations, finding that the claims were methods of treating the human body and indicating that method of treatment claims are always transformative when they relate to administering drugs to the body to ameliorate the effects of a disease. Interestingly, the Court did not appear to regard the metabolite production as the necessary transformation step.

The Court added that the administering and data gathering steps of the claims are part of the claimed treatment protocol and relate to the transformation, and therefore are central to the claims and not trivial extra-solution activities, and also noted that the inclusion of mental steps in a claim will not negate patentability where the claim on the whole falls within the realm of patentable subject matter.

In a footnote, the *Prometheus* panel addressed Justice Breyer's dissent from *Laboratory Corp.*, finding that the dissent is not controlling law and related to different claims from those at issue in this case. It may be interesting to see if the Supreme Court agrees to review this *Prometheus* decision. It could do so in conjunction with its review of *Bilski*. This would enable a review of the law of patent eligible subject matter across a spectrum of technologies.