Thompson Coburn LLP |One US Bank Plaza | St. Louis, MO 63101

Supreme Court Comments on Patentable Subject Matter in *Mayo Collaborative Services v. Prometheus Lab's, Inc.*

In an opinion handed down on March 20, 2012, the Supreme Court determined that patents covering thiopurine dosing tests covered unpatentable subject matter. The Court held that while the application of a law of nature to a known structure or purpose may deserve patent protection, to transform an unpatentable law of nature into patent eligible technology takes more than stating the law of nature and asking that the law be applied.

The Prometheus patent claims are directed to test kits associated with the treatment of autoimmune diseases with thiopurine drugs.[1] It had been well known that when ingested, thiopurine is broken down by the body to produce certain chemicals (or metabolites) in the bloodstream. It had also been known that there were correlations between the metabolite levels in the bloodstream and the toxicity and efficacy of thiopurine drugs. The Prometheus claims were directed to the use of those correlations of bloodstream metabolites to inform treating physicians about the level of thiopurine in their patients and how those levels needed to be adjusted for maximum benefit.

The Mayo Clinic was a former customer of Prometheus who decided to produce their own test kit that checked for the level of thiopurine metabolites in the blood. Prometheus sued Mayo for patent infringement. While the District Court concluded that Mayo's tests infringed the Prometheus patent claims, it ultimately granted Mayo summary judgment reasoning that the claims of the Prometheus patents effectively claimed natural laws or natural phenomena.

On appeal, the Court of Appeals for the Federal Circuit held that the claimed steps of "administering a [thiopurine] drug" and "determining the [resulting metabolite] level" acted to transform the human body or blood taken from the body and thus was patentable under the Federal Circuit's "machine or transformation test". Mayo petitioned the Supreme Court for certiorari. In the first appeal to the Supreme Court, the Court vacated the Federal Circuit judgment and remanded the case in consideration of the Supreme Court's *Bilski* decision (which clarified that the "machine or transformation" test is not a definitive test of patent eligibility—only an important and useful clue). On remand, the Federal Circuit, applying the post-*Bilski* machine or transformation test, reaffirmed its earlier decision holding that the test led to the "clear and compelling conclusion…that the…claims…do not encompass laws of nature or preempt natural correlations." 628 F.3d 1347, 1355 (2010).

Back before the Supreme Court on Mayo's second petition for certiorari, the Supreme Court acknowledged that Prometheus' work had led to identifying specific relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug would prove ineffective or cause harm. But it held that this relationship between the metabolites and the effectiveness or harmfulness of the drug was an entirely natural process and that a patent that simply describes that relation "sets forth a natural law."

The Court then looked to whether the additional steps in Prometheus' claims transformed that natural law into patentable subject matter. The Court found that there were three additional steps in Prometheus' claims: (1) the "administering" step, (2) the "determining" step, and (3) the "wherein" steps. With respect to the "administering" step, the Court found that this simply referred to the relevant audience (doctors who treat patients with thiopurine drugs). Because the prohibition on patenting abstract ideas cannot be circumvented by limiting the use of the idea to a particular technological environment, the Court dismissed this step as transformative. With respect to the "determining" step, the Court held that this step was well known in the prior art. The Court noted that the use of this prior art technology did not transform the natural phenomena into patentable subject matter. With respect to the "wherein" steps, the Court held that this was the communication of the natural law to the treating physician. Put differently, the Court held that these clauses told the relevant audiences about the natural phenomena while trusting them to use those phenomena appropriately where relevant to their decisionmaking. And finally, with respect to the combination of each of these three steps, the Court found that the combination amounted to nothing more than an instruction to doctors to apply the applicable natural laws when treating their patients.

Prometheus and several amici argued that finding these patents invalid would significantly interfere with the ability of medical researchers to make valuable discoveries in the area of diagnostic research. That possibility seems unlikely to materialize. The claims of Prometheus' patents broadly covered technology known in the prior art. The only novel aspect of its claims was the inclusion of metabolite ranges that identified effective doses and doses associated with possible harmful effects. That novelty, was not developed, but was discovered. Prometheus did not develop a way to alter metabolism to increase the effectiveness of thiopurine drugs and it did not develop a system which removed the physician from the equation to allow automatic reading of thiopurine metabolite levels and dosing. Instead, Prometheus' claims were directed to the use of the naturally occurring correlation (within the treating physician's mind) to inform a physician's thiopurine treatment dosing. Protecting such naturally occurring phenomena would, as the Supreme Court saw things, stifle innovation and prevent better uses of that phenomena.

[1] Claim 1 of Prometheus' U.S. Patent No. 6,355,623 is typical and reads: "A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising: (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject."

If you have questions regarding this or any Intellectual Property topic you may contact your Thompson Coburn attorney or one of the Intellectual Property attorneys listed below.

Jason M. Schwent	314-552-6291	jschwent@thompsoncoburn.com
Benjamin L. Volk	314-552-6352	bvolk@thompsoncoburn.com

Thompson Coburn LLP

Chicago | St. Louis | Southern Illinois | Washington, D.C.

www.thompsoncoburn.com
