



Supreme Court *Prometheus* Decision On Patent-Eligible Subject Matter

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On March 20, 2012, the Supreme Court of the United States in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* held Prometheus' patent claims covering processes that help doctors determine whether a given dosage level of thiopurine drugs is too low or too high are not patentable and are invalid under 35 U.S.C. § 101, for "effectively claim[ing] the underlying laws of nature themselves." This decision reverses the Federal Circuit's December 17, 2010 decision.

The Supreme Court considered claim 1 of U.S. Patent No. 6,355,623 representative of the claims in dispute:

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 8×10^8 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 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

The Court rejected analyzing the claims under §§ 102, 103 and 112, explaining that "§§ 102 and 103 say nothing about treating laws of nature as if they were part of the prior art when applying those sections" and § 112 "does not focus on the possibility that a law of nature (or its equivalent) that meets these [written description and enablement] conditions will nonetheless create the kind of risk that underlies the law of nature exception, namely the risk that a patent on the law would significantly impede future innovation." The Court found the relevant precedential cases (*Bilski*, *Diehr*, *Flook* and *Benson*) "rest their holdings upon section 101."

Judge Breyer, writing for a unanimous Court, framed the issue: "[D]o the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?" The Court answered this question in the negative, finding "the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field."

In its § 101 analysis, the Court reasoned that the "machine-or-transformation test" does not "trump[] the 'law of nature' exclusion." Breaking down claim 1 into an "administering" step, a "determining" step and "wherein" clauses, the Court found "[t]hese additional steps are not themselves natural laws but neither are they sufficient to transform the nature of the claim." The "administering" step "simply helps to pick out the group of individuals who are likely interested in applying the law of nature." The "determining" step uses "highly general language covering all processes that

make use of the correlations after measuring metabolites, including later discovered processes that measure metabolite levels in new ways.” The “wherein” clauses “simply tell a doctor about the relevant natural laws, at most suggesting that he should take those laws into account when treating his patient.”

The Court summarized its analysis: “the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons, we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.”

The *Prometheus* decision should have impact, not only in the pharmaceutical industry, but in other industries, in particular, electronics and finance, prompting accused infringers to consider a § 101 defense where the patented steps arguably “add nothing of significance to the natural laws themselves.”

To discuss any questions you may have regarding the opinion discussed in this Alert, or how it may apply to your particular circumstance, please contact Marilyn Neiman at mneiman@cozen.com or 212.883.4985.