

E-ALERT | Life Sciences

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SUPREME COURT DELIVERS IMPORTANT DECISION ON PATENT ELIGIBILITY

The United States Supreme Court has delivered an important, though potentially limited, opinion on the scope of patentable subject matter. The decision may have significant ramifications for life science and medical device companies that—to protect innovation—rely upon method of use patents directed to methods of treatment or diagnosis. The Court decided unanimously in *Mayo Collaborative Services, dba Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc.*, Docket No. 10-1150 (March 20, 2012), that Prometheus' claimed process for improving a category of drug therapy is not eligible for a patent. The Court's Opinion focused on the "laws of nature" exception to Section 101 patent eligibility, and posed the question as "whether the claims do significantly more than simply describe these natural relations." (Slip op. at 8.) The Court's answer was "no."

Prometheus' patents (U.S. Patent Nos. 6,355,623 and 6,680,302) are directed to a method of optimizing the therapeutic efficacy of a drug by targeting certain levels of a particular metabolite in the patient's blood. The representative claim examined by the Court, which is directed to a "method for optimizing therapeutic efficacy" for treating an immune-mediated gastrointestinal disorder, has three elements:

1. an "administering" step of giving a drug providing a particular metabolite (6-thioguanine) to a patient with the gastrointestinal disorder;
2. a "determining" step in which the level of the metabolite is measured in the blood; and
3. a "wherein" clause in which the level of the metabolite below a certain value "indicates a need" to increase the dose of the drug and a level above a certain (higher) value "indicates a need" to reduce the dose.

Both before and after the Supreme Court's 2010 decision on patentable subject matter in *Bilski v. Kappos*, 561 U.S. ___ (2010), the Federal Circuit decided that the Prometheus claims were patent-eligible because they involved a transformation of matter, stating that the claims "are in effect claims 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." (*Prometheus Laboratories, Inc. v. Mayo Collaborative Services (dba Mayo Medical Laboratories), et al.*, 628 F.3d 1347, 1356 (Fed. Cir. 2010).)

The Supreme Court determined at the outset that "Prometheus' patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." (Slip op. at 8) The Court then framed the issue before it as whether the patent claims in Prometheus' patents added "enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?" (*Id.*).

The Court stated that a patent “could not simply recite a law of nature and then add the instruction ‘apply the law.’” (Slip op. at 9.) Because more is required, the Court parsed the claim element-by-element. The Court observed that the “administering step” only “refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs.” (*Id.*) The Court found that this step did not impart patentability and characterized the step as merely “attempting to limit the use of the formula to a particular technological environment.” (*Id.*, quoting *Diamond v. Diehr*, 450 U.S. 175, 191-192 (1981).)

The “determining step” “tells doctors to engage in well-understood, routine, conventional activity,” which the Court stated would normally not be enough to “transform an unpatentable law of nature into a patent-eligible application of such a law.” (*Id.* at 10, quoting *Parker v. Flook*, 437 U.S. 584, 590, see also *Bilski*, 561 U.S. at __ (slip op., at 14).) The Court pointed to the wherein clause in the claim as “simply tell[ing] a doctor about the relevant natural laws.” (Slip op. at 9.) The Court emphasized that the claim did not require the doctor to adjust the dosing based on the measurement of metabolite levels but rather was directed simply to “consider” the correlation between metabolite levels and therapy. (Slip op. at 18.) As a result, in the Court’s view, the claims “tie up the doctor’s subsequent treatment decision whether that treatment does, or does not, change in light of the inference he has drawn using the correlations.” (Slip op. at 18.) The Court summarized its conclusion as follows (Slip op. at 11):

To put the matter more succinctly, 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.

The Court emphasized that it was not deciding “whether were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them.” (Slip op. at 18.) In addition, the Court distinguished the claims at issue from what it viewed as a typical drug use patent: “Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of [the natural laws at issue].” (*Id.*) This distinction may prove important in prosecuting and defending method of treatment or diagnosis claims going forward.

At the end of its decision, the Court signaled that Congress ultimately will determine whether, “from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable.” (Slip op. at 24.) *Prometheus* shows the critical importance of patenting and claims-drafting strategies both in the life sciences industry and elsewhere. An increase of lower court decisions addressing the scope of Section 101 can be anticipated as litigants advance that provision as a defense in patent litigation.

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