Intellectual Property

March 28, 2012

Supreme Court Rejection of Prometheus Lab's Claims Bodes Challenges for Biotech Patents

by Patrick A. Doody and Sheridan K. Snedden

On March 20, the Supreme Court reversed the Federal Circuit in the long-awaited Mayo Collaborative Labs v. Prometheus Laboratories, Inc. *decision, striking down Prometheus' patents on the grounds that the claims too broadly preempt the use of natural correlations between levels of drug metabolite and pharmaceutical effect. While the claims were written to include additional steps, such as an administration step, the Court held these steps were insufficiently integrated into the process as a whole and failed to transform the process into an inventive application of a natural phenomenon. The holding in* Mayo *clarifies the "law of nature" exclusion under a "preemption test" and has broad implications in determining patent-eligible subject matter in the fields of diagnostic testing, personalized medicine, and biotechnology.*

Patent law excludes from patent protection laws of nature, natural phenomena, and abstract ideas. *Diamond v. Diehr*, 450 U. S. 175, 185 (1981). In assessing the "law of nature" exclusion, the Supreme Court articulated a "preemption test" that prohibits patentability of claims under 35 U.S.C. § 101 if they do nothing more than broadly cover the application of a law of nature or natural phenomena and preempt all uses of the natural phenomena. *See e.g.*, *Gottschalk v. Benson*, 409 U. S. 63, 67-68 (1972). The preemption test considers whether or not the patent claim would "wholly preempt" the idea; that is, whether the patent would effectively preempt scientific exploration by occupying a basic concept or exclude use of the idea itself.

Justice Breyer delivered the opinion for a unanimous Court in *Mayo Collaborative Labs v. Prometheus Laboratories, Inc.*, in which the Court applied this preemption test to the process claims of Prometheus' patents U.S. 6,355,623 (the "'623 patent") and U.S. 6,680,302 (the "'302 patent").[1] Claim 1 of the '623 patent recited:

[1] The claims of the '623 patent and '302 patent are directed to similar processes for optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder using similar claim language and method steps. Although the Court discussed the '623 patent in greater detail, the holding is equally applicable to the '302 patent claims.

1) 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 8x108 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 8x108 red blood cells *indicates a need* to decrease the amount of said drug subsequently administered to said subject.

The Court held that the Prometheus process is not patent eligible, finding that the claims apply natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be effective or induce harmful side-effects, but fail to transform these unpatentable natural laws into patent eligible applications of those laws. *Slip. Op.* at 3. The Court found that none of the additional features of the "administration" step, "determining" step, or "wherein" clauses was sufficient to transform the nature of the claims to render the claimed process inventive because the combination of steps amounted "to nothing more than an instruction to doctors to apply the applicable laws when treating their patients." *Slip. Op.* at 10.

The presence of the "administration" step, involving "transformations" of body chemistry, was at least one factor that persuaded the Federal Circuit to find the claims passed the "machine or transformation test." The Supreme Court, however, explained that "[t]he 'administering' step simply identifies a group of people who will be interested in the correlations, namely, doctors who used thiopurine drugs to treat patients suffering from autoimmune disorders." The Court therefore found that this step merely defines a "particular technological environment." A "prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.'" *Slip. Op.* at 4, *citing Bilski v. Kappos*, 561 U.S. _____.

The Court found the "determining" step merely instructs a doctor to measure patients' metabolite levels, through whatever process the doctor wishes to use, a step that could be satisfied without transforming blood "should science develop a [system] that did not involve such a transformation." *Slip. Op.* at 19. The Court, however, suggests that even a recitation of "determining from blood" would not have rendered the claimed process sufficiently transformative. Here, the Court reasoned that because methods for making such determinations were well known in the art, the "determining" step was insignificant because it simply instructs doctors to engage in well understood, routine, conventional activity previously engaged in by scientists in the field—activities not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law. *Slip. Op.* at 10, *citing Parker v. Flook*, 437 U. S. 584, 590 (1978).

Finally, the Court noted that the "wherein" clauses inform a doctor about the relevant natural laws, adding, at most, a suggestion that they should consider the test results when making their treatment decisions. However, "to transform an unpatentable law of nature into a patent eligible application of such a law, a patent must do more than simply state the law of nature while adding the words 'apply it.'" *Slip. Op.* at 10, *citing Gottschalk v. Benson*, 409 U. S. 63, 71–72.

Prometheus had argued that the claims did not totally preempt an abstract idea or natural law, since they involved the use of man-made drugs or, even if they involved a natural process, the claims

related to a particular application of the natural phenomenon ("specific means of treating specific diseases using specific drugs"). To this, the Court explained that even though the laws of nature at issue before them in this case were narrow laws that have limited applications, the claims tie up all uses of the natural law such as a doctor's subsequent treatment decision, whether or not that decision changes in light of the inference he has drawn using the correlations. The Court therefore concluded that "the patent claims do not confine their reach to particular applications of these laws." *Slip. Op.* at 18.

While the Court reaffirmed that the machine or transformation test remains an "important and useful clue" to patentability, the Court noted that "we have neither said nor implied that the test trumps the 'law of nature' exclusion," and that "the test fails here." *Slip. Op.* at 19. The presence of "transformative" steps in the claims were not sufficient to render the claims patent eligible because they merely "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." *Slip. Op.* at 11.

To guide application of the preemption test, the Court reconciled their holdings in *Diehr*, in which claims reciting a mathematical formula were found to be patent eligible, and *Flook*, in which claims reciting a mathematical formula were found to be patent ineligible. The claims at issue in *Diehr* used a formula that was integrated with a tangible result, the production of a rubber mold. The application of a mathematical formula at issue in *Flook*, however, was insufficient to establish an independent invention because "the additional steps of the process did not limit the claim to a particular application." The Court distinguished the result in *Flook* from that in *Diehr* because the claimed processes had numeric rather than physical outputs, and were either less well defined or produced fewer tangible results than the process of the patents in *Diehr*. The Court's analysis of these cases suggests that claim features attempting to be "transformative" are insufficient if they relate to well-known, purely conventional or obvious steps. Such conventional or obvious steps cannot transform an unpatentable principle into a patentable process. See *Slip. Op.* at 13, *citing Flook* at 589, 590.

As a result of *Mayo*, it appears that the machine or transformation test is but one test for determining patent eligibility and is not dispositive as to whether patent claims satisfy the requirements of 35 U.S.C. § 101. Any analysis for determining patent eligibility using the machine or transformation test now requires additional consideration to determine whether potential transformative steps do more than limit the claimed process to a particular technological environment or add insignificant post-solution activity. Patent claims will need to be drafted to ensure that recited transformation steps avoid running afoul of the law of nature exclusion as well.

The holding in *Mayo* clarifies the broad reach of the law of nature exclusion using the preemption test and restricts a liberal application of the machine or transformation test that may have been suggested in prior Federal Circuit cases. The Court's decision has broad implications in determining patent-eligible subject matter in the fields of diagnostic testing, personalized medicine, and biotechnology.

If you have questions, contact the Pillsbury attorney with whom you regularly work or the authors:

Patrick A. Doody (bio)
Northern Virginia
+1.703.770.7755
patrick.doody@pillsburylaw.com

Sheridan K. Snedden (bio)
Washington, DC
+1.202.663.8870
sheridan.snedden@pillsburylaw.com