Merely Applying Law of Nature does not Constitute Patentable Subject Matter

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In *Mayo Collaborative Services dba Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc.*, No. 10-1150 (March 20, 2012), the Supreme Court addressed the issue of patentable subject matter. The Court evaluated whether the claimed processes transformed otherwise-unpatentable natural laws into patent-eligible applications of those laws. It ruled that the claimed processes had not done so and thus were not patentable. The patent claims covered processes that help doctors to determine the appropriate dosage when administering thiopurine drugs to their patients. The Court interpreted the claims as covering the practical application of natural laws governing the relationship between concentrations in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side effects.

The case involved two patents covering the use of thiopurine drugs to treat autoimmune disease. Respondent Prometheus Laboratories, Inc. ("Prometheus") was the exclusive licensee of the two patents at issue—U.S. Patent Nos. 6,355,623 and 6,680,302. The patent claimed processes embodying researchers' findings, indentifying correlations between metabolite levels and likely harm or ineffectiveness. Each claim recited (1) an "administering" step—instructing a doctor to administer the drug to his patient; (2) a "determining" step—telling the doctor to measure the resulting metabolite levels in the patient's blood; and (3) a "wherein" step—describing the metabolite concentrations, above which there is a likelihood of harmful side-effects and below which it is likely that the drug dosage is ineffective. For many years, Petitioners Mayo Collaborative Services and Mayo Clinic Rochester (collectively, "Mayo") used Prometheus' diagnostic tests based on these patents. But in 2004, Mayo announced that it intended to sell and market its own diagnostic test. Prometheus then sued Mayo, contending that Mayo's diagnostic test infringed its patents.

The District Court granted summary judgment for Mayo. It reasoned that, although Mayo's test would have infringed Prometheus' patent claims were they valid, Prometheus' patents were not valid because they effectively claimed natural laws—namely, the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drugs—which are ineligible subject matter. The Federal Circuit reversed, finding that the processes were patent eligible under the machine-or-transformation test. The Supreme Court granted certiorari and remanded the case for reconsideration in light of *Bilski*. On remand, the Federal Circuit reaffirmed that the processes were patent eligible; the Federal Circuit reasoned that the claims did more than claim laws of nature under the machine-or-transformation test because they contemplated transforming the condition of the patient to whom the drug was administered. The Supreme Court, again, granted certiorari.

The Supreme Court unanimously reversed in an opinion authored by Justice Breyer. The Court held that Prometheus' processes were not patent eligible and that the claims were invalid. The Court concluded that the patent claims effectively appropriated the underlying laws of nature themselves, and that the claims were therefore not patentable.

In reaching this conclusion, the Court explained that the three steps in the claimed processes added nothing to the laws of nature such that they would be considered a patentable application of those laws. The "administering" step simply identified a group of people who would be interested in the correlations—doctors. The "determining" step merely told a doctor to measure patients'

metabolite levels, through whatever process the doctor wished to use; this step instructed doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists in the field. The "wherein" step simply told a doctor about the relevant natural laws, adding, at most, a suggestion that they consider the test results when making their treatment decisions. Finally, the Court held that the combination of these three steps added nothing that is not already present when the steps are considered separately in light of the disclosed natural law. Thus, the claimed processes effectively appropriated the relevant laws of nature, and did not constitute a patentable application of those laws of nature.

A review of controlling precedent reinforced the Court's decision that the claims were not patentable. The claims in this case were deemed weaker than the patent-eligible claim in *Diehr*, and no stronger than the unpatentable claim in *Flook*: the process at-issue adds nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field. Such claims were not patent eligible.

If you have any questions regarding any matters discussed in this briefing, please contact any of the Winston & Strawn attorneys listed below or your usual Winston & Strawn contact.

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