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Supreme Court Finds Medical Diagnostic Method Unpatentable

In an important decision that most directly impacts the medical diagnostics industry but will also have wider reverberations, the U.S. Supreme Court not only reconfirmed that abstract ideas and laws of nature are not eligible for patent protection, but unanimously approached the problem of determining patent eligibility in a way that once again requires companies to reassess their patent portfolios and those of their competitors. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. __ (March 20, 2012), the Supreme Court gave short shrift to the machine-or-transformation test that has been favored by the Federal Circuit, relying instead on what amounts to a sliding-scale analysis in relation to its own precedents.

Background

In both 2009 and 2010, before and after the Supreme Court rendered its *Bilski* decision, the Federal Circuit held patentable Prometheus' process claims directed to "administering" a drug to a patient; "determining" whether a given dosage level is too low or too high; and, depending on that result, "indicating a need" to modify the administered level. The point of modifying the dosage is to avoid having an ineffective (too low) or harmful (too high) dosage of metabolites in the blood. The Federal Circuit found that such a claimed process provides for the "transformation of the body" or blood, satisfying the much embraced machine-or-transformation test.

The Sliding Scale of Patent Eligibility: *Benson*, *Flook* and *Diehr*

The Supreme Court, however, paid little attention to the machine-or-transformation test, only visiting it to explain why the Federal Circuit had gotten the patentability issue wrong. The "transformation of the body" analysis, applied so famously by the Federal Circuit in both of its *Prometheus* decisions, was deemed "irrelevant" to the specific claim limitations at issue. In short, the test, though "important and useful," does not "trump the law of nature exclusion."

Instead, the Supreme Court analyzed the claims at issue on what effectively is a sliding scale, using its own precedents in *Benson*, *Flook*, and *Diehr*, as benchmarks. In *Benson*, the court had found claims directed to a mathematical algorithm unpatentable because the claims did little more than apply the algorithm. Similarly, in *Flook*, the inclusion of conventional or obvious post-solution activity could not save claims directed to a novel mathematical algorithm. In *Diehr*, in contrast, because the claimed steps directed to curing rubber went beyond mere application of natural law to materially cabin the scope of the claims, the court had found the claims patent-eligible. In *Prometheus*, the Supreme Court concluded the claims were "weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook*." Prometheus' three-step claims required measuring drug levels, applying a formula and reconsidering the drug dosage and so, like those in *Benson*, essentially recited nothing more than a method to "apply the algorithm." "[T]here is a danger," the Supreme Court noted, that granting certain patents "will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to 'apply the natural law,' or otherwise forecloses more future invention than the underlying discovery could reasonably justify."

What This Means to You

As laid out in *Prometheus*, method claims -- whether drug-related or related to other fields such as software -- must be directed to something more than natural responses or abstract ideas in order to be patent-eligible. The door remains open for those seeking to patent claims directed to medical diagnostics and the application of pharmaceuticals. The Supreme Court noted that "[w]e need not, and do not, now decide whether were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them. For here, as we have said, the steps add nothing of significance to the natural laws themselves. 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 those laws." Thus, those seeking in the future to patent method claims related to abstract ideas and laws of nature should take care to include nonconventional claim elements sufficient to demonstrate the concrete nature of the invention.

The implications of this decision go well beyond pending and future patent claims. Patent portfolio owners should consider which of their method claims may no longer be enforceable, particularly in the life sciences and software industries. Licensees should consider whether they are paying royalties on potentially invalid patent claims. Similarly, manufacturers should revisit the possibility of operating in technology areas they may have avoided because of patent claims that may no longer have validity. If you are faced with such considerations, we can assist you in determining whether and how to proceed.