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Supreme Court Holds Prometheus' Diagnostic Method Claim Unpatentable

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Advisory

On March 20, 2012, the United States Supreme Court unanimously reversed the Federal Circuit in a long-awaited decision that may have broad-reaching effects on diagnostic method patents, as well as personalized medicine patents. At issue in *Mayo Collaborative Services v. Prometheus Laboratories, Inc*., 566 U.S. ___ (2012) was whether the correlation between blood levels and optimal dosages of a drug was a patentable process or an unpatentable law of nature. The Court held that Prometheus' claim, which had been twice upheld by the Federal Circuit, was an unpatentable law of nature.

The method claim at issue recited three elements: (1) administering a drug, (2) determining the level of the drug metabolite, and (3) a "wherein" clause that generally notes a metabolite level for dose adjustment. Justice Breyer wrote that despite these steps, "the patent claims [did not] add *enough* to their statements of the [natural] correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws[.]" Since all of the steps "must be taken in order to apply the laws in question," the Court found that the claims did not confine their reach to particular applications of those laws, and indicated that a patent on such a method would "tie up" too much of the future use of these laws of nature. Notably, the Court did not decide whether including steps that were "less conventional" would make similar claims patentable, but the discussion of the *Diehr* and *Flook* precedents emphasized the importance of specificity.

Applied broadly, the Court's decision may affect many pending and issued diagnostic method and personalized medicine patent claims and patenting strategies. As an initial step, patent applicants, owners, and licensees should review and evaluate their patents and applications to see how the Court's decision might affect their claims. As the specificity of each claim will undoubtedly vary, all claims may not be affected in the same way, so evaluation should be done on a *claim by claim basis* with the assistance of counsel. The owners of issued patents with questionable claims may want to consider narrowing reissues.

Going forward, diagnostic method claims will need to be written with closer attention paid to the specificity and the transformative nature of the steps in light of this decision. In terms of an offensive strategy, companies may also want to review and evaluate competitor diagnostic patent claims and revisit prior freedom to operate analyses in view of this decision.

The *Mayo* decision is expected to have long-term ramifications in the pharmaceutical and biotechnology industries. The full text of the decision can be found here. Any potentially affected or interested parties should continue to follow the developments in this area.

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