

Supreme Court Rejects Medical Testing Patent

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The United States Supreme Court recently issued a key intellectual property decision. In [*Mayo Collaborative Services v. Prometheus Laboratories, Inc.*](#), the Supreme Court ruled that a medical process of making correlations between blood test results and patient health could not be patented because it incorporated laws of nature.

The Facts of the Case

The [patent litigation](#) involved tests for the effectiveness of thiopurines, drugs that are routinely used to treat a variety of gastrointestinal disorders. Their effect depends on how they are metabolized. The patents cover the process for determining whether a given dose produces concentrations of metabolites within a recommended range and allows doctors to adjust it accordingly.

Prometheus sells a test based on its patents to hospitals and clinics. In 2004, Mayo developed a competing test, featuring different recommended levels of metabolites. Citing patent infringement, Prometheus sued.

The Supreme Court's Decision

In finding the diagnostic testing was not patentable, the Court did not create any new standards for evaluating this new type of medical patent. Rather, the court relied on one of the oldest principles of U.S. patent law—you cannot patent laws of nature.

While Prometheus argued that it added steps to the diagnostic process, the Court was not persuaded. As noted by the Court, “The upshot is that the three steps simply tell doctors to gather data from which they may draw in inference in light of the correlations. 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 by the scientific community.”

The Implications

While the Court limited its ruling to the specific patents at issue, the decision will likely impact the future of personalized medicine. Going forward, research firms and drug makers will have to do more to show that medical processes and/or diagnostic testing go beyond the laws of nature and use them in a novel way.

Of course, it is also likely that the full impact of the Court's decision will not be apparent until the lower courts begin to apply it. Therefore, please stay tuned for updates.

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