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U.S. Supreme Court Prometheus Ruling May Limit Future Research

Last week's U.S. Supreme Court decision on the patent eligibility of a diagnostic could have ramifications for in vitro diagnostic (IVD) devicemakers, limiting investment in novel tests because of uncertainty about what is and is not patentable, a U.S. patent attorney tells *D&DL*.

The High Court ruled unanimously Tuesday that Prometheus Laboratories' biomarker-measuring diagnostic couldn't be patented because it relied too much on measuring natural phenomena. The 28-page decision doesn't draw a clear line between Prometheus' patent and other drugs or diagnostics, simply stating it applies to patents that rely too heavily on laws of nature.

But while the decision explains why the court found Prometheus' patent invalid, it doesn't give companies any guidance on how to ensure a patent will hold up when challenged, said D'vorah Graeser, founder and CEO of Graeser Associates International, an intellectual property strategy firm.

"I was hoping to see specific guidance" on what makers of molecular diagnostic tests need to include in a patent, Graeser told *D&DL*, adding that companies will have to wait for future court cases to clarify the issue. In the meantime, the U.S. Patent and Trade Office will also have to react to the decision and could develop some guidance for industry, she added.

But Graeser fears companies that make biomarker-measuring tests, especially small concerns and start-ups, are going to have a hard time finding investors to back product development.

Case Centered on Specific Metabolite Range

The High Court case centered on patent eligibility of a diagnostic that measured metabolites from thiopurine drugs to treat autoimmune diseases. Doctors found it difficult to determine if a patient's dose was too high and therefore toxic, so Prometheus' test allowed physicians to adjust dosing levels to fall within a determined range based on the level of metabolites.

Mayo Collaborative Services sought to market its own test, claiming the process wasn't covered by a patent because it measures metabolites the drug produces. Prometheus sued and the case made it to the Supreme Court in December (*D&DL*, Dec. 12, 2011).

In *Mayo v. Prometheus*, Justice Stephen Breyer wrote in the court's opinion that interpreting and acting on a diagnostic's results "are not themselves natural laws but neither are they sufficient to transform the nature of the claims." Laws of nature, natural phenomena and abstract ideas are not patentable.

But narrowing patent eligibility for biomarker-based diagnostics could threaten investment incentives, the Biotechnology Industry Organization (BIO) said.

"We are concerned that it introduces new and confusing concepts into the traditional body of patent law, which patent examiners and lower courts will struggle to consistently and rationally implement," BIO said.

For now, makers of diagnostic tests would be wise to revisit the opinion when writing patent claims, said Kwame Mensah, an associate with McDonnell Boehnen Hulbert & Berghoff. It remains to be seen how the ruling affects

existing patents, he added.

Some Predict Little Impact

Some patent experts say the vagueness of the U.S. Supreme Court's decision should preclude a big impact. The ruling should only apply to novel ways of interpreting data from a scientific method, such as interpretations that rely heavily on biomarkers, American University law professor Jonas Anderson told *D&DL*.

"The cases in the future will likely turn on how much a future method 'preempts' all uses of a law of nature or how 'significant' the additional limitations are," he said.

Jason Rantanen, a University of Iowa law professor who specializes in patent law, agrees that while the case pushes patentability away from natural concepts, it doesn't drastically change patent law.

One area that likely won't be affected by the decision is companion diagnostics, Graeser said. Because they work side by side with a drug, if the drug is patented, then "what you have is almost a captive audience for that diagnostic. The two are validated together."

Prometheus said it was disappointed with the court's ruling and echoed concerns it would limit future investment in diagnostics development. "This decision will, in our view, encourage imitation, not innovation," the company said.

View Justice Breyer's decision at www.fdanews.com/ext/files/3-22-12-Prometheus.pdf. — David Pittman, Meg Bryant

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