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Medical testing sector awaits Supreme Court clarity on patents

Susan Decker, Bloomberg
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The U.S. Supreme Court building at sunrise in Washington D.C. on Nov. 30, 2019.

- **by Taboolaby Taboola**

Medical companies that develop tests to diagnose neurological disorders, heart disease risk and fetal abnormalities have been in legal limbo since a 2012 Supreme Court ruling

that limited the patenting of such tests, finding they occurred in nature and were not invented.

The high court may signal as soon as Friday whether it will revisit the subject as such tests become critical to the burgeoning field of personalized medicine, in which doctors determine whether a patient is genetically susceptible to a particular disease or would respond to certain treatments.

The court may decide to hear a petition by Quest Diagnostics Inc.'s Athena unit to restore its patent for a test to detect the presence of an autoimmune disease. The nonprofit Mayo Clinic won an appeals court ruling that the test merely covered a natural law -- the correlation between the presence of an antibody and the disease -- and so wasn't eligible for a patent.

"There's been so much confusion about this area of the law," said Hans Sauer, deputy general counsel for BIO, the biotechnology industry's trade group.

The Athena case, and another involving Vanda Pharmaceuticals Inc.'s patent for a way to set drug dosage based on the level of certain enzymes, could go a long way in clarifying what types of medical diagnostics are eligible for patent protection.

They are among five appeals seeking Supreme Court review on a debate on patent-eligibility that's raged in the U.S. Patent and Trademark Office, Congress and the courts for more than seven years. The other three petitions relate to software patents. The justices will consider whether to take any of the cases at a private conference Friday.

In 2012, as part of a series of rulings on eligibility, the Supreme Court threw out a patent for a test that looked at the link between metabolites in the body and the amount of drug needed for a stomach medicine. The test, owned by Nestle's Prometheus unit, covered a "law of nature" that can't be patented, the court said.

The U.S. Court of Appeals for the Federal Circuit, which handles all patent appeals, in July split 7-5 over whether the Prometheus ruling blocks patents on any medical diagnostics absent additional steps, such as a new method of treatment. The majority said it had no choice but to declare that Athena and its partners didn't have the right to a patent.

Diabetes prediction, detection of heart disease and tests for transplant recipients and donors are a small portion of the $69 billion market for diagnostics but are key growth areas, according to Arlington, Virginia-based research firm Kalorama Information.

The patents give their developers the right to demand royalties or limit who can conduct the tests. Supporters of diagnostic patents say that helps cover the cost of research and conducting clinical trials to determine whether the tests work.

"A lot of new tests are being offered on the market, but often these new tests are not very well validated," Sauer said. "They may show up in a catalog, but it's not clear what it means clinically or whether it would be reimbursed. It costs a lot of money to prove what a test means."

Funding costs aren't enough to justify the need for patents on the tests, said Joshua Sarnoff, a law professor at DePaul University in Chicago who submitted legal arguments urging the Supreme Court to take the Vanda case and rule that Vanda isn't entitled to a patent either.

"There are many ways to fund innovation and discovery. Historically, we haven't done it by granting patents on natural discoveries," Sarnoff said. "One can hope that the court will take one of these cases to clarify what is an inventive concept."

Athena's patent comes from a discovery by Oxford University and Germany's Max Planck Society for the Advancement of Science of a link between antibodies to a specific protein and an autoimmune disease called myasthenia gravis that causes muscle weakness. Until the discovery of the diagnostic method, 20% of patients suffering from the disorder couldn't be diagnosed.

Athena, which has the license to the patent, sued Mayo for royalties and lost. It was a repeat of the 2012 case, in which Mayo persuaded the Supreme Court to invalidate the Prometheus patent. The Athena patent, Mayo contends, covers "observing a natural law using known techniques." Any policy concerns are up to Congress, not the courts, Mayo told the court.

Vanda said its drug, Fanapt, never would have been allowed on the market without its patented test. The patent is for a way to adjust the dosing of a schizophrenia treatment depending on the level of a specific enzyme in a patient.

The Federal Circuit, in upholding that patent, said it was directed to a "novel method of treating a disease," and not just the relationship between the enzyme levels and the drug's effectiveness. Hikma Pharmaceuticals Plc, which seeks to make a generic version of Fanapt, is asking the high court to overturn that ruling.

In the drug field, critics say companies already obtain too many patents so they can block competition and charge higher prices. Patents like Vanda's just add to the number, and concerns that no patents can be issued are overblown, according to Association for Accessible Medicines, the trade group for generic-drug makers.

"We're in a situation where brand companies have larger and larger patent portfolios," said Karin Hessler, assistant general counsel for the group.

In addition to laws of nature, patents can't be issued for natural phenomena or abstract ideas. A year after the Prometheus decision, the high court ruled that isolated DNA fell under the natural phenomenon exception to patent law. The following year it waded into the never-defined area of "abstract" ideas in a case that's led to the invalidation of thousands of software patents and made it hard to get legal protection for inventions related to artificial intelligence and the use of data to detect new medical correlations.

Patent owners say the rulings have thrown out too many good patents, while critics of the patent system -- and companies sued for infringement -- have argued that they helped weed out ones that never should have been issued.

"It's made it more difficult for patent owners to achieve their goals using the patent system and to encourage people to invent and invest and research," said Kirk Hartung, a patent lawyer with McKee, Voorhees & Sease in Des Moines, Iowa. He argued in a Supreme Court filing that other parts of the law are the better option to determine if something qualifies for a patent.

The Trump administration, in court filings for two of the cases, said the high court had "fostered uncertainty" as to what is eligible for a patent. It recommended that the high court decline to hear the Vanda case and one of the software disputes, where the Federal Circuit had ruled in favor of the patent owner. Instead, Solicitor General Noel Francisco suggested that the Athena dispute may be the better case for the high court to consider.

"We can't figure it out, the Federal Circuit can't figure it out, and the inventors can't figure it out, either," Sauer said. The question for the Supreme Court, he said, is "Do we need to go back in and, if we do, do we know better what to do than we did last time?"

The cases are Athena Diagnostics Inc. v. Mayo Collaborative Services, 19-430, and Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc., 19-817.