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Supreme Court declines to consider medical diagnostic patents

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The U.S. Supreme Court stayed out of the debate over what types of medical diagnostic tests can be patented, leaving in legal limbo companies that discover ways to diagnose and treat diseases based on patients' unique characteristics.

The justices rejected an appeal by Quest Diagnostics's Athena unit that sought to restore its patent for a test to detect the presence of an autoimmune disease. A lower court had ruled in favor of the nonprofit Mayo Clinic that the test wasn't eligible for a patent because it merely covered a natural law—the correlation between the presence of an antibody and the disease.

Justices also rejected appeals to clarify the rules regarding software patents. The Supreme Court's action leaves it to Congress to resolve an issue that's created a legal gray area for such discoveries.

The Athena case is one of five the court was asked to consider regarding eligibility for patents. The justices also rejected an appeal over a patent owned by Vanda Pharmaceuticals for a method of using its Fanapt schizophrenia drug, as well as three patent cases related to software.

Congress held a series of hearings in 2019 but is unlikely to pass any legislation in this election year. Lawyers and experts had seen the case as the best shot at getting the high court to take up the issue after what Athena lawyer Seth P. Waxman called an "unprecedented cry for help" from the appeals court that handles all patent disputes.

The U.S. Court of Appeals for the Federal Circuit in July split 7-5 on whether any medical diagnostic could be patented. The judges issued eight opinions over 80 pages lamenting the confusion over patenting diagnostic tests and its impact on patient care.

The request for the justices to take up the issue united those who say more patents should be granted, and those who say too many are being issued and could lead to higher medical costs. The Trump administration, in court filings, said the high court had "fostered uncertainty" about what is eligible for a patent, and suggested the Athena dispute would be a good vehicle to revisit the subject.

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

Among the patents tossed by Federal Circuit since 2012 are ones on a blood test that replaced the sometimes dangerous amniocentesis used to detect fetal abnormalities, for early diagnosis of cardiovascular disease and for a way to detect tuberculosis.

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 led to the invalidation of thousands of software patents and made it harder to get legal protection for inventions related to artificial intelligence and the use of data to detect new medical correlations.

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

"It's important, not just to us nerdy patent practitioners, but to patients and to the medical industry," Lisa Pensabene, a patent lawyer with O'Melveny & Myers in New York who specializes in life sciences patents, said before the court acted. "Diagnostics are critical in identifying and characterizing the type of disease. We're treating patients now in a much more nuanced way than in years past. Think of a scalpel rather than a sledgehammer."

Athena's patent comes from a discovery, made 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 percent of patients suffering from the disorder couldn't be diagnosed. Among those with the disease are Philippines President Rodrigo Duterte, though it's unknown if he was diagnosed using the Athena test.

Athena, which has the license to the patent, sued the Mayo Clinic for royalties and lost. It was a repeat of the 2012 case, in which Mayo had 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.

The cases are Athena Diagnostics Inc. v. Mayo Collaborative Services, 19-430; Hikma Pharmaceuticals USA v. Vanda Pharmaceuticals, 18-817; HP Inc. v. Berkheimer, 18-415; Power Analytics Corp. v. Operation Technology Inc. 19-43; Garmin USA v. Cellspin Soft, 19-400.