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Supreme Court Looks At Medical Patents

Patent eligibility of personalized medicine is at stake in closely watched case

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MEDICAL PROCEDURES

The Supreme Court is considering whether the correlation between blood test results and patient health is patent-eligible subject matter.

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The **U.S. Supreme Court** heard **arguments** last month in a highly complex patent dispute between two medical testing laboratories that could affect the future of molecular diagnostics and the emerging field of personalized medicine, which involves monitoring an individual's response to a drug to tailor treatment.

The decision, which is expected this spring, will likely have important implications for the biotechnology and pharmaceutical industries because the high court is being asked to determine whether certain types of medical treatment methods are eligible for patent protection.

"Some fundamental issues around patent eligibility in the life sciences area are front and center before the court," says Paul M. Rivard, a patent attorney in the Washington, D.C., office of **Banner & Witcoff**, an intellectual property (IP) law firm.

"The court is expected to lay down some basic principles in the area, such as whether processes involving administering a synthetic drug are always patent-eligible, and whether the lack of novelty of individual method steps should be taken into account when determining patent eligibility," he remarks.

The ruling will impact players in the pharma and life sciences fields because there are thousands of issued patents relating to diagnostic methods and tests, says Kendrew H. Colton, a partner at Chicago-based IP law firm **Fitch, Even, Tabin & Flannery**.

"The Supreme Court's decision will likely refine precedent generally for what is patent-eligible subject matter," Colton says. "While not limited to life sciences, the decision will affect life sciences and the still nascent field of personalized medicine."

In the case before the high court, Mayo Collaborative Services, part of the Rochester, Minn.-based **Mayo Clinic**, is appealing a judgment that it infringed patents held by **Prometheus Laboratories**. The patents involve a blood test that helps doctors determine optimal drug dosages for patients with gastrointestinal disorders such as Crohn's disease and other autoimmune ailments.

The test measures metabolite levels and the efficacy and toxicity of thiopurine drugs, the use of which is often accompanied by serious side effects. Because patients metabolize the compounds differently, it had been difficult for doctors to calibrate the proper dosage, and some doctors were reluctant to prescribe the drugs at all, fearing harmful side effects.

The Mayo Clinic used the Prometheus test until 2004, when its doctors announced that they had created a cheaper and faster test to determine a patient's optimal dosage. At that point, San Diego-based Prometheus—a unit of Switzerland's Nestlé Health Science—sued for patent infringement, setting off the legal fight now before the nation's highest court.

Mayo contends that Prometheus is seeking to protect an abstract idea based on natural phenomena: the observed correlations between blood test results and patient health. By law, natural phenomena may not be patented. But Prometheus asserts that its patents describe a specific method for improving the treatment of certain diseases through a series of concrete and transformative steps, and should be allowed.

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In March 2008, the U.S. District Court for the Southern District of California, San Diego, agreed with Mayo's position and invalidated the patents, finding that Prometheus' invention was no more than "a natural body process ... preexisting in the patient population."

But in September 2009, the U.S. Court of Appeals for the Federal Circuit, in Washington, D.C., reversed the lower court ruling, saying the claims are patent-eligible because they involve a physical transformation and thus are not merely an abstract idea or law of nature.

Trade associations representing biotech and research-based drug companies, as well as the Association of University Technology Managers, are siding with Prometheus and have filed briefs urging the Supreme Court to uphold the appellate ruling.

In its filing, the Biotechnology Industry Organization, which represents more than 1,100 biotech companies, warns that excluding biomarker-assisted therapeutic methods from patent eligibility would be "devastating to personalized medicine" because it would discourage investment in the field.

Also called targeted therapy, personalized medicine entails the use of a patient's genetic information to select medicines and treatments that precisely match the needs of the individual.

Mayo's view is backed by a coalition of physicians and health care groups, including the American Medical Association. In a joint brief, the medical establishment argues that "health care will be undermined if conventional medical applications of naturally occurring bodily processes can be patented."

During arguments before the Supreme Court on Dec. 7, 2011, Mayo Clinic attorney Stephen M. Shapiro said that barring Mayo and others from using tests similar to Prometheus' would be detrimental to patients' health.

"The problem with the Prometheus patent is its broad preemption of a physical phenomenon, which prevents others like Mayo Clinic from offering a better metabolite test with more accurate numbers. This is a huge practical problem for patients," Shapiro said.

Several justices also raised questions about Prometheus' diagnostic patent claims. "This is not a treatment protocol; it's not a treatment regimen," Justice Elena Kagan told Prometheus' attorney, Richard P. Bress. "All you have done is pointed out a set of facts that exist in the world and are claiming protection for something that anybody can try to make use of in any way, and you are saying 'you have to pay us,' " she remarked.

Bress acknowledged that the lab's patents build on a known process. "People knew that you could administer thiopurines for these particular diseases" and measure the resulting metabolites, he said. There have been efforts to "come up with what [Prometheus] came up with—a new treatment method, a new way of calibrating the right dose for each individual patient based on their metabolism."

But, Bress explained, the mere fact that others had previously combined administration of thiopurines with measurement of the metabolites in laboratory experiments does not, under the court's precedents, negate the novelty of Prometheus' use of the same steps as integral parts of a successful working treatment method.

Rivard says it is not clear exactly where the court will draw the line between processes involving mere abstract ideas and those meriting patent protection. But the justices, he observes, "seem to be well aware of the need to tread carefully, since any significant limitation on patent eligibility in this area could have a chilling effect on research."

Justice Stephen G. Breyer, for example, expressed skepticism over the patent eligibility of diagnostic method claims, but he also took note of the significant investments that companies have made. "Discovering natural laws is often a very expensive process," he said. "There's lots of investment to be protected."

If the Supreme Court concludes that the Prometheus patents are invalid, some industry players may encounter challenges in the short term on their patents relating to diagnostic methods and tests, says Colton, a past chair and current executive committee member of the American Chemical Society's Division of Chemistry & the Law.

Over the long term, he adds, different approaches to drafting patent claims to protect investments in diagnostic methods and tests will emerge.

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