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Covid-19 Spotlights Ruling's Chilling Effect on Diagnostic Tests

The new coronavirus outbreak highlights how a 2012 U.S. Supreme Court decision has discouraged drugmakers from developing new diagnostic tests for diseases like Covid-19—a problem that should be addressed, intellectual property lawyers said.

The decision, *Mayo v. Prometheus*, has undermined the ability of companies to protect intellectual property related to diagnostic testing, the attorneys said. It's made some companies—especially smaller biotech companies—wary of pursuing new diagnostics for fear of not being able to patent any discoveries.

While at least two companies are producing tests for the Covid-19 infection for the U.S., some may have been more enthusiastic about pursuing diagnostics if patent protections were stronger.

Mayo ''disincentivized a lot of diagnostic companies from developing these tests in general,'' Maria Zacharakis, a member of McCarter & English's IP practice and managing partner of the Boston office, said.

The court in *Mayo*, a case concerning an infringement suit over diagnostic tests, ruled that claims merely covering a natural law—for example, the correlation between an antibody's presence and a disease—aren't eligible for patenting.

The court didn't provide guidance, though, for determining if a patent directed toward a law of nature or a natural phenomenon, such as a DNA sequence or the chemical compounds in the body, is ineligible for protection.

''These tests are very expensive to develop and patent protection is necessary,'' Zacharakis said. ''The same costs are associated with developing Covid-19 tests, and the same disincentivization will be there. Though there may be more incentive because of the pandemic and the government involvement.''

The spread of the new coronavirus could also pressure the courts and Congress to act on the inability to patent diagnostic testing, she said.

''If there is a silver lining from a patent law perspective to this coronavirus pandemic, in my mind it is that it will bring renewed focus on the need for patentability of diagnostic testing,'' Zacharakis said.

Changes Under Mayo The Supreme Court's decision in *Mayo* has ''resulted in a single, one-size-fits-all [legal] test,'' said Jeffrey Morton, a partner in the San Diego and Phoenix offices of Snell & Wilmer.

The test now requires ''something more'' than a claimed diagnostic invention, with lawyers finding creative ways to work around the law. For example, some incorporate treatment methods in their claims for diagnostic inventions, said MaryAnne Armstrong, a partner with Birch Stewart Kolasch & Birch in Virginia.

''Companies have learned how to approach things in other ways, how to draft their claims so they're not the *Mayo* type of claim,'' she said.

In addition, Covid-19 likely requires a unique diagnostic tool because it's a new disease. That could make patent protection easier for drugmakers pursuing those tests, Armstrong said.

However, some companies—particularly smaller biotech companies—remain gun-shy about investing in a product that could have its patents invalidated.

''The lack of meaningful patent protection can severely impact a company developing such methods when they have no recourse to recoup their substantial investment,'' said Morton, a member of the firm's Coronavirus Response Team.

Following *Mayo*, the Supreme Court in *Alice Corp. v. CLS Bank International* established a two-part test for determining if an invention has an inventive concept that takes it beyond unpatentable laws of nature, natural phenomenon, or abstract ideas to be eligible for patenting.

Drugmakers often look to treatment-related language in claims to provide that all-important, extra inventive step. Still, a lack of clarity in the *Alice* language, coupled with Mayo's uncertainty, has meant IP attorneys representing pharmaceutical clients continue to be frustrated over what, exactly, can be patented.

Offsetting Mayo Some coronavirus-related incentives out there could offset the effects of *Mayo*. For example, The Trump administration has awarded $1.3 million to two companies for developing rapid Covid-19 tests.

The Department of Health and Human Services designated $679,000 for California-based DiaSorin Molecular, and $598,000 for Maryland-based Qiagen, to speed development of new tests.

Trump also weighed invoking the 70-year-old Defense Production Act, which gives the government more authority to control private production in an effort to address shortages of medical supplies. That could extend to diagnostic testing.

Illumina v. Ariosa Drugmakers may also be afforded new avenues for patent protection, post-*Mayo*, in wake of the U.S. Court of Appeals for the Federal Circuit's March 18 revival of Illumina Inc.'s fetal DNA test patents.

The court held in *Illumina v. Ariosa Diagnostics* that Illumina's patents for a way to detect fetal DNA in the mother's bloodstream aren't invalid—even though they

involve a natural phenomenon. The court also held the patents are valid because they are related to a method for utilizing, not just detecting, fetal DNA.

Although another Federal Circuit panel, in a different case, held that a patent that amplified and detected fetal DNA was invalid, the *Illumina* panel said the act of physically separating out the DNA was enough to patent the inventions.

The *Illumina* decision was a big deal in the world of diagnostics, even though it's still subject to a potential appeal and rehearing, Stephen Maebius, a partner with Foley & Lardner LLP, said.

''This isn't the last word, but it's a snapshot into the evolution that's taking place,'' he said.

Congressional Relief In Congress, draft legislation by Sens. Thom Tillis (R-N.C.) and Chris Coons (D-Del.) would make major changes to sections 101 and 112(f) of the Patent Act that would eliminate Mayo- and Alice-related issues by adding language that ties patent eligibility to the invention as a whole.

That would help the courts avoid questions of whether a patent is directed simply toward a law of nature or natural phenomenon and, instead, focus on a simpler, fundamental question: is this a useful innovation?

Neither Tillis' or Coons' offices responded to a request for comment on the legislation, which appears stalled. But Thomas Hedemann, an intellectual property lawyer with Axinn, Veltrop & Harkrider LLP, said the legislation could conceivably be revived due to the pandemic.

The draft provides ''a powerful argument for the pharma side of the debate that Congress really should step in,'' he said.

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