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Did the Federal Circuit Just Issue the 'Most Restrictive Patent Eligibility Decision Yet'?

Latham and Goodwin Procter persuaded the Federal Circuit that CareDx patents for detecting organ transplant rejection are invalid because they apply a natural law using conventional techniques. Weil Gotshal argues that the patented techniques are anything but conventional, and that the decision will "suffocate innovation in the life-saving arts."

BY SCOTT GRAHAM

What You Need to Know

- CareDx argues it came up with an innovative diagnostic test that had stumped researchers for years.
- Judge Alan Lourie wrote that the patents are 'replete' with references to conventionality.
- Latham and Goodwin Procter successfully argued there was no difference from other diagnostics decisions.

The Federal Circuit has held patents on a noninvasive test for detecting organ transplant rejection ineligible for patent protection.

CareDx v. Natera is the latest instance of medical diagnostic patents being rejected on eligibility grounds. It will probably result in yet another push for review of the *Alice/Mayo* eligibility test by the U.S. Supreme Court.

The patents were developed at Stanford University and licensed to Brisbane, California-based CareDx Inc.

CareDx attorney Edward Reines of Weil, Gotshal & Manges called the Federal Circuit's Monday decision "the most restrictive patent eligibility decision yet, which will further suffocate innovation in the life-saving arts."

Photo: Diego M. Radzinschi/ALM

Judge Alan Lourie of the U.S. Court of Appeals for the Federal Circuit.

The Supreme Court has ruled that patents directed to a natural phenomenon, including a correlation between markers in the blood and a health condition, are ineligible for patent protection if they involve routine and

conventional techniques for detection. The Federal Circuit has applied that precedent, often grudgingly, in cases such as *Ariosa Diagnostics v. Sequenom,* in which aspects of cell-free DNA were correlated with fetal abnormalities.

Latham & Watkins partner Gabriel Bell, who represented Austin, Texas-based Natera Inc., and Goodwin Procter partner William Jay, who represented Lee's Summit, Missouri-based Eurofins Viracor Inc., had argued to the Federal Circuit that there's no meaningful difference between *Ariosa* and CareDx's case. The patents in each describe amplifying and then measuring cell-free DNA, or cfDNA, in a blood sample and then applying a natural law to determine something useful, they said.

A Federal Circuit panel led by Judge Alan Lourie agreed. "CareDx's patents apply conventional measurement techniques to detect a natural phenomenon—the level of donor cfDNA and the likelihood of organ transplant rejection," Lourie wrote. "The claimed methods are indistinguishable from other diagnostic method claims the Supreme Court found ineligible in *Mayo* and that we found ineligible on multiple occasions."

Judges Todd Hughes and William Bryson concurred. The ruling affirms a decision by U.S. District Judge Colm Connolly, who had originally denied summary judgment of ineligibility to Natera and Eurofins, then granted it after holding an evidentiary hearing.

Reines said in a written statement that the opinion ignores "the ***decade*** of prior art failures that could not effectively measure the natural correlation, as well as the prior art's express statements that it was 'impractical' to try to do so."

That history was documented in the Stanford patents themselves, and demonstrated that the approach was anything but conventional, he said.

Lourie disagreed, saying in his opinion that the patents' written description "is replete with characterizations of the claimed techniques in terms that confirm their conventionality."

Daniel Rabinowitz, Natera's chief legal officer, said in a statement, "We are pleased that multiple courts have rejected CareDx's baseless claims against Natera's proprietary technology."