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Federal Circuit Upholds Invalidation Of Kidney Test Patents

By **Adam Lidgett**

Law360 (July 18, 2022, 6:20 PM EDT) -- The Federal Circuit on Monday refused to undo a lower court's finding that three Stanford University patents licensed to a developer of commercial tests for kidney transplant rejections were invalid, saying they are directed toward natural phenomena.

A three-judge panel on Monday affirmed a Delaware federal judge's September ruling that said the claims in the patents — for methods to detect an organ donor's cell-free DNA, or cfDNA, in a transplant recipient — weren't eligible for patent protection.

The panel cited U.S. Supreme Court decisions like Alice Corp. v. CLS Bank and Mayo v. Prometheus, which held that certain types of inventions can't be patented. The circuit court panel said the Stanford patent claims are directed at nothing more than a natural phenomenon.

"The claims boil down to collecting a bodily sample, analyzing the cfDNA using conventional techniques, including [polymerase chain reaction]; identifying naturally occurring DNA from the donor organ; and then using the natural correlation between heightened cfDNA levels and transplant health to identify a potential rejection, none of which was inventive," the panel wrote.

The panel added that nothing was inventive enough in the patented claims that would save them from invalidation.

U.S. Patent Nos. 8,703,652; 9,845,497; and 10,329,607 were all issued to Stanford's Stephen R. Quake, Thomas M. Snyder and Dr. Hannah Valantine. They are licensed exclusively to CareDx, a transplant company, and figure in its AlloSure product for analyzing genetic material from donated organs, allowing the detection of weakened or dying transplants.

The patents are at the center of an infringement suit CareDx and Stanford filed against Natera Inc. and Eurofins Viracor Inc. in March 2019 claiming that Natera's kidney transplant rejection test, described as an "organ transplant rejection assay" and "allograft rejection" test, infringed the three patents.

"Eurofins Viracor is very pleased that the court has agreed with its arguments and affirmed the judgment in Eurofins Viracor's favor in this challenge to Eurofins' critically important diagnostic tools to manage organ rejection risk," William M. Jay, an attorney for Eurofins Viracor, said in a statement to Law360 on Monday.

Also in a statement, Edward R. Reines, an attorney for CareDx and Stanford, called the panel decision an

"outlier" and highly restrictive, adding that it will "suffocate innovation in the lifesaving arts."

Reines said that even though the availability of CareDx's products are not affected by the ruling, "this is a broadly anti-innovation decision."

"This decision further calls into question Natera's own patents in this same area," he said.

"The panel's opinion distressingly ignores — totally — 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 — all of which was documented in the Stanford patents themselves," he said. "If it were so conventional to measure the long-known correlation in the patented fashion, how come so many workers over so many years tried and failed to do so, concluding it was 'impractical'?"

Natera's chief legal officer, Daniel Rabinowitz, said the company was "pleased that multiple courts have rejected CareDx's baseless claims against Natera's proprietary technology."

The patents-in-suit are U.S. Patent Nos. 8,703,652; 9,845,497; and 10,329,607.

Circuit Judges Alan Lourie, William C. Bryson and Todd M. Hughes sat on the panel for the Federal Circuit.

CareDx and Stanford are represented by Edward R. Reines and Derek Walter of Weil Gotshal & Manges LLP.

Natera is represented by Gabriel K. Bell and Ashley M. Fry of Latham & Watkins LLP.

Eurofins Viracor is represented by Darryl M. Woo, William M. Jay, Kevin J. DeJong and Jordan Bock of Goodwin Procter LLP.

The case is CareDx Inc. et al. v. Natera Inc., case number 22-1027, at the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Dani Kass. Editing by Karin Roberts.
