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Ex-Fed. Circ. Chief Tells Supreme Court To Undo Ax Of Tech Patent

By Jasmin Jackson · Listen to article

Law360 (October 3, 2022, 6:11 PM EDT) -- A former Federal Circuit chief judge has urged that appellate court to overturn a panel's decision agreeing that three of Stanford University's diagnostic patents are ineligible for protection since they're directed toward a natural phenomenon, arguing that the ruling unnecessarily forecloses patent protection for novel and nonobvious diagnostic techniques.

Former Chief Judge Paul Michel, who retired from the Federal Circuit in 2010, said in an amicus brief Friday that the appellate court should grant Stanford and licensee CareDx Inc.'s bid for a rehearing en banc after a panel upheld the invalidation of the university's kidney transplant diagnostic technology. According to Michel, the panel wrongly found that the invention was partly ineligible for patenting because "[t]his is not a case involving a method of preparation or a new measurement technique."

"That conclusion, if upheld, will unnecessarily foreclose patent protection for diagnostic techniques that use a novel and nonobvious combination of techniques that yield a novel and nonobvious result," Michel said.

The former chief judge argued that the suit also provides the appellate court with an "ideal opportunity" to clarify Section 101 of U.S. Code Title 35, which establishes statutory requirements for patentable inventions, since "there is wide consensus that patent-eligibility law remains confused and internally inconsistent."

According to the brief, the Federal Circuit could "fix the current situation with [Section] 101" by accurately assessing the legal underpinnings of the Mayo-Alice patent eligibility test. That test stems from both the Supreme Court's 2014 decision in Alice v. CLS Bank and its 2012 ruling in Mayo v. Prometheus, which respectively set ground rules for the

invalidation of patents involving technology and natural phenomena.

"Amicus respectfully suggests that the current case can be used to revisit the overly broad application of Mayo and Alice — an application that, in this case, led to the erroneous conclusion that an entirely new method of diagnosing potential organ-donor failure is not eligible for patent protection," Michel said.

Matthew J. Dowd of Dowd Scheffel PLLC, counsel for Michel, told Law360 Monday that the former chief judge "is pleased to file an amicus brief in this case, where it seems we have yet another life-saving patent struck down."

"Section 101 case law needs improvement, and this is an important case," Dowd said. "Medical diagnostic inventions are the very type that the U.S. patent system should be incentivizing."

A three-judge Federal Circuit panel affirmed a lower court's invalidation of the university's patents in a July opinion. According to the filing, the diagnostic methods related to kidney transplants were ineligible for patenting since they were directed toward a natural phenomenon.

Stanford and CareDx — the exclusive licensee of the axed patents — petitioned for a rehearing en banc last month. According to the petition, incorrectly invalidated technology that purportedly improves upon the natural phenomenon of measuring when a transplant recipient begins undergoing organ rejection.

"The Stanford Patents establish that the claimed advance is new, different, and better ways to measure a natural correlation that had eluded the prior art for a decade," the university said. "Improved measurement methods are eligible for patent protection because they are human-made and [Section] 101 expressly protects 'improvement[s].'"

Michel said in the Friday amicus brief supporting the rehearing bid that "the problem with the panel's conclusion … is that it impermissibly parses the claimed invention into its separate limitations, rather than assessing the claim as a whole."

"It also conflates patent eligibility with nonobviousness and other aspects of patentability," Michel said.

Edward R. Reines of Weil Gotshal & Manges LLP, counsel for the university and CareDx, told Law360 on Monday that Michel's brief "explains eloquently why this case is a superb vehicle to improve patent eligibility law."

"Former Chief Judge Michel is a wise thought-leader — and his amicus brief trumpets his wisdom on Section 101 loud and clear," Reines said.

Natera and its counsel did not immediately respond to requests for comment Monday.

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

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.

Michel is represented by Matthew J. Dowd and Robert J. Scheffel of Dowd Scheffel PLLC.

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

—Additional reporting by Adam Lidgett. Editing by Andrew Cohen.