Ex-Fed. Circ. Chief Backs Another Patent Eligibility Case - Law360

Ex-Fed. Circ. Chief Judge Backs Another Patent ‘101 Eligibility Case

By Andrew Karpan · Listen to article

Law360 (May 31, 2023, 6:47 PM EDT) -- A retired top Federal Circuit judge is backing a legal effort to get the U.S. Supreme Court to hear a dispute over the eligibility of a patent covering a method for testing transplanted kidneys, telling Law360 on Friday that current patent eligibility legal precedent "has practically destroyed the diagnostics industry."

Paul Michel, chief judge of the Federal Circuit from 2004 to his retirement in 2010, endorsed yet another amicus brief on Thursday over a patent that was ruled ineligible by the courts in the wake of former Justice Stephen Breyer's unanimous opinion in Mayo Collaborative Services v. Prometheus Laboratories in 2012.

The Mayo decision created a new legal standard to review patent claims, which Michel says in Friday's interview "ignores some of the elements in the patent under review in order to say that all that's left is a natural phenomena," considered outside the protection of patent law.

"The Mayo decision essentially made diagnostic inventions no longer eligible for patenting, even if they met all the conditions for a patent," Michel said. "The Supreme Court has practically destroyed the diagnostics industry."

Michel last jumped into the fraught debate over patent eligibility law, covered by Section 101 of the Patent Act, when he endorsed a brief urging the justices to take the American Axle case. The justices rejected that effort last year.

"They don't seem to find my views attractive or useful," Michel admitted. But he was undeterred. The decade since the Mayo decision has seen "60 or so" appeals to the justices over the issue, by his count. Nevertheless, he persisted.

"Many small biotech companies doing innovative diagnostic work have gone bankrupt and

run out of business because they can't attract capital, because they don't have valid patents," Michel said. "The Supreme Court's impact on diagnostic medicine has been very harmful, and this case was a very strong candidate, partially because it was dealing with such a meritorious diagnostic invention."

The case he is advocating for involved patents issued to researchers at Stanford University that were the subject of a 2019 lawsuit from the school and CareDx, the company the school licenses those patents through, against Natera Inc. and diagnostics laboratory Eurofins Viracor Inc.

In late 2021, a Delaware federal judge ruled that the method of correlating DNA information with organ rejection that the patents covered was merely a way or organizing "natural phenomena." The ruling was upheld by a unanimous Federal Circuit panel last year.

Backers of the appeal say that this case is meaningfully stronger than some of the other patent appeals that have landed in front of the justices lately. Last week, the court turned down two cases that explicitly sought more guidance on the legal issues, despite the endorsement of U.S. Solicitor General Elizabeth Prelogar.

"The luggage case, if you looked at the patent, it was just a really bad patent," said University of Virginia School of Law professor John Duffy, who has also endorsed the brief supporting the CareDx case, in an interview with Law360 on Friday. The patent in that case involved a new way of letting the Transportation Security Administration workers unlock and screen luggage.

"It was a terrible patent. It should have been invalidated, one way or another," Duffy said. Unlike that patent, the one in the CareDx case was a good one, he said.

"By contrast, the CareDx patent seems like a really important invention, the kind of thing that would score well in all the other doctrines of patent law and that would really help people," he said.

CareDx's counsel Edward Reines of Weil Gotshal & Manges LLP told Law360 Friday that his client appreciated the support, and he agreed that his case was special.

"The patented organ transplant rejections inventions at issue here are much more

compelling than many of the patented inventions before the Supreme Court in past Section 101 cases," Reines said to Law360 in an email.

"The support from prominent thought leaders ... speaks volumes as to the power of this petition," Reines added.

Representatives for Natera and Eurofins Viracor, which have both declined the opportunity to respond to CareDx's petition at the high court, did not return a request for comment Friday.

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

Michel and Duffy are represented by Matthew Dowd and Robert Scheffel of Dowd Scheffel PLLC.

CareDx and Stanford are represented by Zachary D. Tripp, Edward R. Reines and Shai Berman of Weil Gotshal & Manges LLP.

Natera is represented by Gabriel K. Bell of Latham & Watkins LLP.

Eurofins Viracor is represented by William Jay of Goodwin Procter LLP.

The case is CareDx Inc. et al. v. Natera Inc. et al., case number 22A754, before the Supreme Court of the United States.

--Additional reporting by Adam Lidgett, Dani Kass and Ryan Davis. Editing by Adam LoBelia.