SCOTUS Requests Response in CareDx Eligibility Petition Following Michel/ Duffy Brief (ipwatchdog.com)

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May 31, 2023

"[The] split [on patent eligibility law] produces intolerable uncertainty for businesses, with the Executive Branch issuing meritorious patents like the three patents at issue here, only to have the courts invalidate them." – Michel/Duffy brief

Last week, retired U.S. Court of Appeals for the Federal Circuit (CAFC) Chief Judge Paul Michel and law professor John F. Duffy filed an amicus brief with the U.S. Supreme Court in support of CareDx, Inc. and the Board of Trustees of the Leland Stanford Junior University. The company and university are asking the Supreme Court to review a 2022 decision invalidating claims of its patents directed to detection levels of donor cell-free DNA (cfDNA) in the blood of an organ transplant patient.

In the amicus brief, Michel and Duffy wrote, "this case concerns [us] because it represents a continuing trend of uncertainty and inconsistency in patent-eligibility jurisprudence…The outcome undermines the innovation promoting goals of U.S. patent law."

Five days after the amicus brief was filed, the Supreme Court requested a response to the brief from Natera with a submission deadline of June 29, 2023.

CareDx, the exclusive licensee of the three Stanford patents in question, began the litigation by suing Natera and Eurofins Viracor, alleging the firm's organ transplant rejection tests infringed upon its patents. However, the CAFC determined in 2022 that CareDx's patent claims used conventional techniques of immunology and molecular biology.

CareDX and Stanford filed a petition for certiorari with the U.S. Supreme Court on May 1 asking the Court to review the CAFC's decision.

Amicus Brief Argument

Michel and Duffy argued the Court's decision conflicts with the Patent Statute and 35 U.S. Code § 100(b), which states a "process includes a new use of a known process." They continued that Congress added this language to "overrule 19th-century judge-made law forbidding patents on new uses for known technologies."

The main gripe with the CAFC is when something should be considered conventional. The brief authors argued the conventionality case is harmed by the fact that the processes that Stanford and CareDx are building on do not occur in nature and did not exist within living memory.

The pair went further by writing that the issue of conventionality is irrelevant to this case because "the process is directed to statutorily defined patent-eligible subject matter." According to Michel and Duffy, the patent eligibility of the claims in the three patents is established by 100(b) because "the patents disclose and claim new and innovative uses of existing processes."

The brief authors also argued that the case presents the Supreme Court with a chance to clarify 35 U.S. Code § 101. They cited multiple

institutions and stakeholders who have sought clarification on patent eligibility law, including Federal Circuit judges, appeals court judges, the United States Patent and Trademark Office (USPTO), and the business, legal, and academic communities.

Michel and Duffy wrote, "that split [in the understanding of patent-eligibility law] produces intolerable uncertainty for businesses, with the Executive Branch issuing meritorious patents like the three patents at issue here, only to have the courts invalidate them."

Continued Confusion

The amicus brief supporting CareDx and Stanford University echoes the complaints made by the institutions before the CAFC.

Previously, a magistrate judge recommended that motions to dismiss the case based on ineligibility should be denied at *Alice* step one. The district court subsequently agreed, and also dismissed later motions for summary judgment on Section 101 grounds. However, the district court later reconsidered its decision *sua sponte* and granted Natera and Eurofins summary judgment.

The district court's comments on the case seemed to bolster CareDx and Stanford's complaint that legal interpretations of Section 101 are inconsistent and potentially confusing. In its ruling, the district court remarked, "the state of § 101 law' is 'fraught, incoherent, unclear, inconsistent, and confusing, and indeterminate and often leading to arbitrary results."

Despite this confusion and the subsequent potential for arbitrary results, both the district court and the CAFC ruled that the patents failed both parts of the *Alice/Mayo* test, and said that, at step two, the three patents lacked an inventive concept.

The 2022 decision was viewed as a blow to the medical diagnostic testing industry, and Michel and Duffy discussed the ruling's implications for this industry. The authors presented concern that under the CAFC's interpretation, "almost any claim to a diagnostic invention could be rewritten at a level of abstraction that renders it ineligible for patent consideration."

The brief's authors asked the Supreme Court to consider the implications of such a standard, which they argued would allow for a judge-made interpretation of "conventionality" to be held more important than the "the traditional, statutory roles of novelty and nonobviousness."

The Supreme Court and supporters of Stanford and CareDx will be waiting on Natera and Eurofins's response.

Matthew Dowd of Dowd Scheffel, who filed the brief for Michel and Duffy, said the Court's latest move is a potentially good sign for those seeking eligibility clarification:

"While we can't be certain that our amicus brief triggered the Court's request for a response, the brief does emphasize the importance of § 100(b) that was not presented in the recent denials of the *Interactive Wearables, Tropp and Avery Dennison* petitions. It seems that the Justices – or at least some of them – are still looking for the right Section 101 case."