Kavanaugh Signals Openness to Revisiting Patent Eligibility Framework as Supreme Court Declines CareDx Petition

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The Supreme Court declined to hear an important patent eligibility case on October 2nd, denying certiorari in *CareDx v. Natera*. This leaves in place a Federal Circuit ruling that invalidated CareDx's patents on its method for detecting organ transplant rejection.

The patents at issue covers breakthrough diagnostic technique using cell-free DNA to non-invasively detect organ transplant rejection. For over a decade, scientists had tried unsuccessfully to use cell-free DNA for this purpose. The key innovation was applying high-throughput DNA sequencing and identifying SNP thresholds to make the technique clinically useful. However, the lower courts ruled the

patents invalid under the judicial exception to patent eligibility for natural phenomena.

The Supreme Court's denial means this important legal issue remains unsettled. The Court's *Mayo*/*Alice* framework for patent eligibility has been heavily criticized for over-invalidating diagnostic patents based on natural phenomena. But the Federal Circuit felt bound to apply it to CareDx's patents. Justice Kavanaugh dissented from the cert denial, signaling his view that the Court should refine or reconsider its eligibility framework as applied to diagnostic patents.

For the medical diagnostics industry, the outcome is disappointing. These types of pioneering diagnostic techniques often require massive investment to develop clinically. Without reliable patent protection, investors may turn away from funding this research and scientists may avoid commercializing it. As a result, patients may never benefit from potentially life-saving tests.

Looking ahead, the eligibility framework will likely need to be addressed by the Supreme Court or Congress. Justice Kavanaugh's dissent signals openness of at least one Justice, with four typically required to grant certiorari. Congress is also considering steps to revamp section 101 of the Patent Act, but action is unlikely prior to the 2024 election.

One eligibility petition is still pending in the case of *ChromaDex, Inc. v. Elysium Health, Inc.*, No. 23-245. ChromaDex is asking the court to rationalize its natural phenomenon jurisprudence from *Myriad* with its abstract idea and law of nature jurisprudence from *Alice*/*Mayo* respectively. Does the same two part test apply to products of nature?