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The latest ruling involving patent eligibility of medical diagnostics comes from Chief Judge Connolly of the United States District Court for the District of Delaware in a consolidated case brought by CareDx, Inc. and the Board of Trustees of the Leland Stanford Junior University against Natera, Inc. (Civil Action No. 19-0567-CFC-CJB) and Eurofins Viracor, Inc. (Civil Action No. 19-1804-CFC-CJB). After initially denying the Defendants' motions for summary judgment of invalidity of the asserted patents under 35 U.S.C. §101 in December 2020, the Court then later denied certification motions for interlocutory appeal and instead ruled *sua sponte* to reconsider its own denial of summary judgment. Following an evidentiary hearing during which expert testimony was heard, the Court reversed its previous ruling to find all claims of the asserted patents invalid as a matter of law under §101.

Supreme Court Makes Eligibility Waves

The wake created by the Supreme Court in *Mayo Collaborative Services v. Prometheus Laboratories*, 566 U.S. 66 (2012) continues to rock the boat for the world of medical diagnostics. In *Mayo*, the Court held invalid patent claims directed to methods of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder. The claims included the steps of administering

a drug to a subject and determining the level of metabolites of that drug in the subject, wherein levels below and above certain thresholds indicate a need to respectively increase and decrease the amount of drug for subsequent administration. The Court found these method steps to represent a law of nature without reciting significantly more ("simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable"). The Supreme Court relied on *Mayo* for its landmark ruling in *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014), a software case that addressed the patent eligibility of an electronic escrow service for facilitating financial transactions. *Alice* created a two-part eligibility test under Section 101: (i) are the claims in question directed to a patent-ineligible concept (*i.e.*, law of nature, natural phenomenon or abstract idea), and if so, (ii) do they set forth an inventive concept (*i.e.*, an element or combination of elements sufficient to ensure that the claims in practice amount to significantly more than a patent of the ineligible concept itself)?

Lower courts have wrestled with *Mayo*/*Alice* Supreme Court precedent. In the case of *Athena Diagnostics v. Mayo Collaborative Services* in 2019, the Federal Circuit denied *en banc* a rehearing after holding invalid Athena's medical diagnostic patent claims as patent ineligible under Section 101. The denial is notable in that there were four concurring and four dissenting opinions, illustrating the unsettled nature of the patent eligibility issue as it pertains to medical diagnostics. The claims in *Athena* recited a method for diagnosing certain neurological disorders by detecting autoantibodies that bind to certain epitopes. The Court found the claims to be directed to a natural law: the correlation between the presence of the naturally-occurring autoantibodies and the recited neurological disorders. The Court further found the claimed process steps to be based upon routine laboratory experiments, highlighted by Athena's admission that its innovation was limited to the discovery of the link between the autoantibodies and the disorders. The claims were therefore found to not represent an inventive application beyond the discovery of a natural law itself. The Supreme Court denied *certiorari* in January 2020.

Delaware Court Applies *Alice* and Athena

In the CareDx case, the patents-in-suit describe and claim methods for determining organ transplant rejection through the detection of donor-specific, cell-free DNA (cfDNA) in the bodies of donor recipients. Although the link between the amount of donor cfDNA and the likelihood of organ rejection was acknowledged to be well-known in the prior art, CareDx characterized attempts to detect necessary concentrations of cfDNA as deficient and described the use of innovative, highly precise assays to cure this deficiency. The methods recited in the claims at issue, however, were condensed by the court to have the following four steps for detecting a donor's cfDNA in a transplant recipient:

1. obtaining or providing a sample from the recipient that contains cfNDA;
2. genotyping the transplant donor and/or recipient to develop polymorphism or SNP profiles;
3. sequencing the cfDNA from the sample using multiplex or high-throughput sequencing, or performing digital PCR; and
4. determining or quantifying the amount of donor cfDNA.

The court noted that the CareDx patent specifications include statements that the techniques used in each of these steps are described to be conventional.

The CareDx court looked to *Athena* and related Federal Circuit precedent to boil the *Alice* two-part test down into a single inquiry for medical diagnostic claims: "where a patent claims a method for detecting a natural phenomenon, the dispositive inquiry under both steps of the *Alice* inquiry is whether the asserted method uses more than standard or conventional techniques of detection." In so doing, the court appears to propose a simplified analysis by establishing medical diagnostic method claims as recitations of natural laws that are ineligible for patent protection unless they include an inventive concept in the form of detection techniques that are not standard or routine. And in this case, the detection techniques were found to be conventional. Particularly damning for CareDx were statements throughout the patent specifications regarding the conventional nature of the techniques described therein. CareDx argued that such admissions in

its specifications are common in biotech patents and should not be construed as a confession that there is no inventive concept. The court rejected this argument, noting that patentees are bound by the words used in their patents, upon which the USPTO relies in examination and competitors rely in seeking to design around infringement. The court also noted the friction that can exist for inventors seeking to satisfy the requirements of 35 U.S.C. §112 by describing techniques as conventional, while at the same time arguing that such techniques are part of an inventive methodology. According to the court, inventors can't have it both ways, nor can they look to extrinsic evidence contradicting specification statements regarding the conventional nature of described techniques. Further, the court found that to the extent the CareDx patents related to less conventional methodologies, such methodologies were not described in detail, nor were they claimed.

Surviving the Uncertainty

The takeaways from *CareDx* are clear enough, although the law will undoubtedly continue to evolve regarding patent eligibility of medical diagnostics. During this evolutionary period, inventors and practitioners are well-advised to include in their patent specifications robust descriptions of any preparation, detection, or analytical techniques that are novel, non-standard, or non-routine in any way. Such unconventional techniques should be expressly recited in the claims. Statements regarding the conventional nature of other techniques should be avoided to the extent possible. Where a particular order of conventional steps is itself unconventional, that order should be specifically recited in the claims. And until the line establishing patent eligibility becomes more pronounced, it should prove helpful to file claims of varying scope with different combinations of preparation, detection, and analytical techniques to improve the likelihood of claims that stand the test of time.