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Federal Circuit Affirms District Court Ruling of Patent Invalidity Under 35 U.S.C. § 101 Where Claims are Directed to a Natural Law

The Federal Circuit recently affirmed the ruling of the United States District Court for the Eastern District of Virginia, in *Cleveland Clinic Foundation*, *Cleveland Heartlab, Inc., v. True Health Diagnostics LLC*, dismissing Cleveland Clinic's infringement claims under U.S. Patent No. 9,575,065 ("the '065 patent") and U.S. Patent No. 9,581,597 ("the '597 patent") on the grounds that the asserted claims were invalid, under 35 U.S.C. § 101, as directed to an ineligible natural law.

By way of background, the '065 patent and '597 patent are directed to diagnostic tests which can be used to determine whether an individual is at a lower risk or higher risk of developing or having cardiovascular disease. These diagnostic tests are based on the discovery that patients with coronary artery disease ("CAD") have significantly greater levels of leukocyte and blood myeloperoxidase ("MPO") levels. MPO is a naturally-occurring heme protein associated with some types of white blood cells. The patents disclose several methods of measuring a patient's blood MPO level. The Federal Circuit had previously addressed the subject matter eligibility of a parent patent, U.S. Patent 7,223,552 ("the '552 patent"), in *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, 859 F.3d 1352 (Fed. Cir. 2017), cert. denied, 138 S. Ct. 2621, (2018) ("Cleveland Clinic I").

In *Cleveland Clinic* I, the Federal Circuit held the claimed methods of the '552 patent invalid under Section 101 as directed to the ineligible natural law that blood MPO levels correlate with atherosclerotic CVD, holding that the claimed method "starts and ends" with observation of "naturally occurring phenomena," based upon *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015). The Federal Circuit further held that, because Clevland did not assert the '552 patent to claim any of the biological techniques used to detect MPO or the statistical methods used to compare a patient's MPO levels to the control group, the claims recited no further inventive concept sufficient to transform the nature of the claims into a patent-eligible application of the natural law, based upon *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 78 (2012).

On appeal, Cleveland Clinic argued that the claims were not directed to a natural law, but to the technique of using an immunoassay to measure the blood MPO levels of patients with atherosclerotic CVD. Cleveland Clinic further asserted that, in any case, the correlation between blood MPO levels and atherosclerotic CVD is not a natural law because it can only be detected using certain techniques. Cleveland Clinic further argued that, while performing an immunoassay on blood samples was known, using the immunoassay to detect the correlation between blood MPO levels and atherosclerotic CVD supplies an inventive concept sufficient to transform the claims into patent-eligible subject matter.

True Health responded that the correlation between atherosclerotic CVD and blood

MPO levels is a natural law because the correlation exists in nature apart from human intervention, regardless of the technique used to observe it. True Health further argued that using known techniques in a standard way to observe a natural law, neither renders the claims directed to something other than this natural law nor supplies an additional inventive concept.

The Federal Circuit agreed with True Health and held, as in Cleveland Clinic I, that the claims were directed to the natural law that blood MPO levels correlate with atherosclerotic CVD, and not new techniques for performing an immunoassay to detect a patient's blood MPO levels. That is, the claims only recite applying known methods to detect MPO levels in plasma, comparing the levels to standard MPO levels, and reaching a conclusion: that the patient's blood MPO levels are elevated in comparison to a control group. The Federal Circuit concluded that this was simply another articulation of the natural law that blood MPO levels correlate with atherosclerotic CVD, and held that the claims were directed to the patent-ineligible natural law that blood MPO levels correlate with risk of atherosclerotic CVD. The Federal Circuit noted that: (i) rephrasing the claims does not make them less directed to a natural law, nor is the fact that blood MPO levels correlate with atherosclerotic CVD any less a natural law because it can only be observed by use of certain techniques; and (ii) Cleveland Clinic's argument that using a known technique in a standard way to observe a natural law can confer an inventive concept has been consistently rejected in circumstances nearly identical to this case.
Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743, 753-54 (Fed. Cir. 2019) (holding that there is no inventive concept in "applying standard techniques in a standard way to observe a natural law"); see also
Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1377 (Fed. Cir. 2015) ("For process claims that encompass natural phenomenon, the process steps are the additional features that must be new and useful.").

Cleveland Clinic also argued that the District Court failed to give the appropriate deference to the subject matter eligibility guidance published by the PTO in 2016 as required by *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), which "requires courts to give some deference to informal agency interpretations of ambiguous statutory dictates, with the degree of deference depending on the circumstances."

The Federal Circuit agreed with True Health that the District Court did not err in finding the instant claims ineligible stating that "[w]hile we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance. And, especially regarding the issue of patent eligibility and the efforts of the courts to determine the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws, we are mindful of the need for consistent application of our case law."

Hulu Patent Bid Opens Doors for New Prior Art Precedent

The Presidential Opinion Panel ("POP"), which was created last year, has announced that it will review and reconsider the previous decision by the Patent Trial and Appeal Board ("PTAB") denying Hulu's request for administrative review of a Sound View Innovations, LLC patent involving data processing. Hulu had argued that Sound View Innovation's patented method was obvious due to information in a textbook and therefore unpatentable. The PTAB had tossed Hulu's challenge after finding that the textbook's copyright date was insufficient to qualify it as prior art.

Hulu, in asking the POP to reconsider the denial, argued that the PTAB's finding "conflicts with numerous other Board decisions," and that the PTAB "misapprehended or overlooked prior decisions" finding copyrights sufficient to establish a date of publication for prior art purposes. The decision by the POP could set new precedent for when printed publications constitute prior art, as copyright dates, internet information and a document's accessibility can complicate determining whether content existed prior to a patent application filing. The decision could also affect proceedings where patents are challenged based upon prior art.

Documents in *Inter Partes* Review(s) ("IPR(s)") must qualify as prior art. Some

documents, such as earlier patents and published applications, clearly show dates for comparisons. But dates for other documents, such as those obtained from the internet or a conference presentation, can be harder to establish. Petitioners often submit non-patent literature in IPR proceedings because patent examiners have typically already reviewed previous patents when considering a patent application.

As noted below, the Federal Circuit issued several rulings last year dealing with qualifying printed materials as prior art. In *GoPro, Inc. v. Contour IP Holding LLC*, the Federal Circuit vacated a PTAB finding that a brochure distributed at a widely-attended trade show did not qualify as prior art. In *Acceleration Bay, LLC v. Activision Blizzard Inc.*, the Federal Circuit agreed with the PTAB that a reference uploaded to a technical reports website did not qualify as prior art because the reference was not easily accessible. In *Jazz Pharm., Inc. v. Amneal Pharm., LLC*, the Federal Circuit affirmed the PTAB's invalidating patent claims based upon information published in the Federal Register.

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