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# *Federal Circuit Upholds Invalidity of Cleveland Clinic's Claims Directed to Methods for Detecting an Elevated MPO Concentration*

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In *Cleveland Clinic Foundation, Cleveland Heartlab, Inc. v. True Health Diagnostics LLC, (Cleveland Clinic II)* [1], a unanimous panel of the Federal Circuit provided yet another guidepost illustrating what is not patent-eligible subject matter in the diagnostic industry, as well as a blow to the United States Patent and Trademark Office's (USPTO's) subject matter eligibility guidance. The Court upheld a judgment of invalidity under 35 U.S.C. § 101 against Cleveland Clinic's patent claims directed to methods of identifying and detecting an elevated myeloperoxidase ("MPO") concentration/mass in a plasma sample. The court reasoned "that the claims are directed to the natural law that blood MPO levels correlate with atherosclerotic CVD." According to the Federal Circuit, "the claims contain no additional inventive concept," and the argument "that using a known technique in a standard way to observe a natural law can confer an inventive concept—has been consistently rejected by [the] court . . . ." Similar to the recent *Athena Diagnostics, Inc. v. Mayo Collaborative Services* decision[2], the Court discussed that "the specification and prosecution history plainly concede that each of the process steps was well-known in the art." Indeed Cleveland Clinic's complaint echoed the same admissions.

Of note, the Federal Circuit specifically addressed Example 29 of the Subject Matter Eligibility Guidance ("Guidance") published by the USPTO on May 4, 2016.[3] Cleveland Clinic argued that the district court erred by not giving deference to the Examiner's decision that the claims at issue were patent-eligible in light of Example 29, claim 1 of the Guidance. The Court explicitly stated that it was "not bound" by the Guidance of the USPTO, taking head on an argument that was somewhat side-stepped in the lower court's decision.[4] The Court remarked that claim 1 of Example 29 of the Guidance was "remarkably" similar to claim 1 in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* [5], which was held invalid under section 101. The Federal Circuit stated that *Ariosa* was controlling and declined to follow the USPTO's Guidance.

The *Cleveland Clinic II* decision adds yet another pointed example in the diagnostic industry of claims that passed USPTO muster but failed to pass the patent eligibility bar in court. Since the primary benchmark in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[6] the Federal Circuit has consistently rejected claims reciting naturally occurring correlations "with no additional inventive concept," as not patent eligible. *See Ariosa Diagnostics, Inc. v. Sequenom, Inc.,*[7] *Cleveland Clinic Found. v. True Health Diagnostics LLC (Cleveland Clinic I)*,[8] *Athena Diagnostics, Inc. v. Mayo Collaborative Services*,[9] and now *Cleveland Clinic II*. The types of claims that have survived the Court's scrutiny include "new and improved" laboratory techniques, as in *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.,*[10] or a "novel method of treating a disease," as in *Vanda Pharm. Inc. v. West-Ward Pharm. International Ltd.*,[11] (*see also Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.,*[12]). The USPTO's recent guidance on subject matter eligibility of abstract ideas identifies these positive decisions as useful to a patent applicant's traversal or avoidance of a section 101 rejection during examination.[13] However, the Court's direct rejection of the Guidance in Example 29 will require the USPTO to redraft and issue new guidance for diagnostic inventions.

Because the Federal Circuit declined to follow the USPTO's Guidance, at least where it directly conflicts with existing case law, patent applicants should carefully parse the USPTO's subject matter eligibility guidance when relying on it during examination. *Cleveland Clinic II* makes clear that strict adherence to the USPTO's subject matter eligibility guidance, or the examples provide by the USPTO, is not a guarantee of valid patent claims.

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[1] 2018-1219 (Fed. Cir. Apr. 1, 2019) (non-precedential).
[2] 915 F.3d 743 (Fed. Cir. 2019).
[3] Subject Matter Eligibility: Life Science Examples 28-33, USPTO (May 4, 2016).
[4] *Cleveland Clinic Found. v. True Health Diagnostics LLC,* 2017 WL 3381976 at n.8 (E.D. Va. 2017); *see also* "How Courts Treat USPTO Subject Matter Eligibility Guidelines" Law360 (August 2017).
[5] 788 F.3d 1371 (Fed. Cir. 2015).
[6] 566 U.S. 66 (2012).
[7] 788 F.3d 1371 (Fed. Cir. 2015).
[8] 859 F.3d 1352 (Fed. Cir. 2017).
[9] 915 F.3d 743 (Fed. Cir. 2019).
[10] 827 F.3d 1042 (Fed. Cir. 2016).
[11] 887 F.3d 1117 (Fed. Cir. 2018).
[12] 2017-1240, 2019 WL 1387988 (Fed. Cir. Mar. 28, 2019).
[13] 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 53 (Jan. 7, 2019).

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