Federal Circuit Rejects USPTO Patent Eligibility Guidance

USPTO Guidance is Found to be Non-Binding, Exacerbating Uncertainty

By: Chris Eggert & Reid Huefner| April 8, 2019

On April 1, 2019, the Court of Appeals for the Federal Circuit, in a nonprecedential decision *Cleveland Clinic Foundation v. True Health Diagnostics*, affirmed the invalidity of two patents regarding medical diagnostic tests for determining whether a patient was at risk for cardiovascular disease. This follows a previous 2017 decision invalidating similar Cleveland Clinic Foundation patents in a separate dispute between the two parties. In both cases, the challenged patent claims were held invalid under 35 U.S.C. § 101 as being directed to a natural law without reciting an inventive concept beyond the natural law itself. Cleveland Clinic had argued that the claims recited a method of measuring blood levels and correlating values, which was not a natural law as previous prior art techniques were inadequate or invasive. Cleveland Clinic also argued that the trial court had improperly resolved factual disputes at the pleadings stage.

Perhaps of greatest interest, though, Cleveland Clinic also argued that the district court failed to give appropriate deference to subject matter eligibility guidance published by the USPTO in 2016, as allegedly required by *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). By not deferring to the USPTO guidance, Cleveland Clinic argued, the district court erred when it failed to give deference to the examiner's decision to allow the patents to issue. The USPTO guidance at issue specifically provided an exemplar claim that was analogous to the Cleveland Clinic claims at issue and specifically explained that this exemplar claim *would* be patent eligible.

The Federal Circuit, while stating that it had "great respect" for the USPTO's guidance and expertise, stated that the Federal Circuit is "not bound by its guidance" and, therefore, disregarded it. Specifically, the court found that when the Federal Circuit's caselaw conflicts with USPTO guidance, the caselaw is the measure that must be consistently applied. As such, the Federal Circuit found that the claim detailed in Example 29 was similar to a claim at issue in a previous Federal Circuit case, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015). As the *Ariosa* claim was found ineligible under Section 101, the Federal Circuit held that the Cleveland Clinic's claims must also be held ineligible.

In so holding, the Federal Circuit has injected more uncertainty into the post-*Alice/Mayo* standard for patent eligibility, a standard that the USPTO has hoped to standardize through further guidance, including new guidance announced on January 7, 2019, as well as provide more predictability and uniformity in decisions to patentees. With the Federal Circuit's finding that it is not bound by administrative guidance and, instead, affirmatively declining to apply it, the Federal Circuit's guideposts in determining what matter is patent eligible under section 101 are primarily its own contradictory findings on the topic, thereby further complicating patentees attempts to find predictability in what constitutes patent eligible subject matter. For some time, predictability has seemed to largely be out of reach for patentees on the issue of what the standard for patent eligibility is in a post-*Alice/Mayo* world. That does not appear to be likely to change any time soon.