Akin®

Federal Circuit Decision Provides Opening for Preparation Methods in Diagnostic Space, But Not for Diagnostic Claims

Mar 17, 2020

Reading Time : **2 min**

By: Rachel J. Elsby, Steven D. Maslowski, Matthew A. Pearson

In 1996, two scientists discovered that maternal plasma and serum, which is usually discarded as medical waste, contain some amount of cell-free fetal DNA that can be used for diagnostic purposes. Those scientists obtained a patent for detecting small fractions of paternally inherited cell-free fetal DNA, which the Federal Circuit invalidated under Section 101 in 2015. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (Fed. Cir. 2015). The patents in this case are unrelated to the patent in *Ariosa*, but rely on the same scientific discovery as their foundation. Specifically, the patents acknowledge the discovery, but then identify a technical problem with its application in medicine—namely, that it is very difficult to separate the fetal DNA in maternal plasma and serum from the extracellular DNA derived from the mother.

The inventors of the patents at issue here found a solution to this problem after they realized that fetal DNA and maternal DNA can be distinguished by size. Using that information, the inventors developed methods for preparing samples of fetal DNA through size discrimination, and patented those methods. Illumina, Inc. and Sequenom, Inc. (collectively, "Illumina") later sued Ariosa Diagnostics, Inc. and others (collectively, "Ariosa") for infringing two such method patents. Ariosa moved for summary judgment of invalidity under Section 101, which the district court granted based on step one of the *Alice* test.

On appeal, the Federal Circuit noted that it was undisputed that the inventors discovered a natural phenomenon, but that was not the question before the court. The question was whether the patents *claim that natural phenomenon* or claim subject matter that exploits the discovery. As to that question, the Federal Circuit determined they did not. The claims

here are to a process for preparing and separating DNA samples, i.e., they "achieve[] more than simply observing that fetal DNA is shorter than maternal DNA or detecting the presence of that phenomenon." As such, they meet the standards for eligibility under step one, leaving no need to address step two.

In distinguishing this case from *Ariosa*, the court explained the only operative steps in *Ariosa* involved amplifying DNA and then detecting it. In other words, the inventors in *Ariosa* discovered the existence of cell-free fetal DNA and then claimed the knowledge that it exists and a method to see it exists. Here, the claims cover more—they cover the process of separating DNA fractions to enrich for a particular type of DNA: "The claimed methods utilize the natural phenomenon that the inventors discovered by employing physical process steps to selectively remove larger fragments of cell-free DNA and thus enrich a mixture in cell-free fetal DNA."

Judge Reyna dissented from the court's decision. In his view, the claims at issue here differed little from the claims at issue in *Ariosa*, and should be held invalid for the same reasoning applied in that case.

We'll have to wait and see if this decision survives further review. But if it holds, this case may limit the application of *Ariosa* and provide a much-needed avenue for companies seeking to obtain defensible patent rights in the diagnostics space.

Illumina, Inc. v. Ariosa Diagnostics, Inc., C.A. No. 2019-1419 (Fed. Cir. 2020)

Categories

Federal Circuit | § 101 Analysis under Alice

York limited liability partnership authorized and regulated by the Solicitors Regulation Authority under number 267321. A list of the partners is available for inspection at Eighth Floor, Ten Bishops Square, London E1 6EG. For more information about Akin Gump LLP, Akin Gump Strauss Hauer & Feld LLP and other associated entities under which the Akin Gump network operates worldwide, please see our Legal Notices page.