ARIOSA DIAGNOSTICS, INC. v. SEQUENOM, INC., Appeal Nos. 2014-1139, -1144 (Fed. Cir. June 12, 2015). Before Reyna, Linn, and Wallach. Appealed from N.D. Cal. (Judge Illston).

Background:

Sequenom owns a patent directed to methods for detecting a paternally inherited nucleic acid of fetal origin (cell-free fetal DNA or cffDNA) in maternal blood that represented a breakthrough in non-invasive prenatal diagnosis. On remand to the district court from the Federal Circuit for an error not related to the subject of this appeal, Ariosa and Sequenom both filed cross motions for summary judgment regarding subject matter eligibility under §101. The district court held the claims of the patent ineligible under §101 and granted Ariosa's motion for summary judgment. Sequenom appealed.

Issue/Holding:

Did the district court err in finding invalidity? No, affirmed.

Discussion:

On appeal, the Federal Circuit applied the Supreme Court's two-step *Mayo* framework for determining eligibility. In the first step, the Federal Circuit analyzed whether the claims are directed to a patent-ineligible concept, namely a law of nature, natural phenomenon, or abstract idea. Regarding the first step, it was undisputed that the existence of cffDNA in maternal blood is a natural phenomenon, and thus the claimed methods are directed to detecting a naturally occurring thing. Therefore, according to the Federal Circuit, the claims are directed to naturally occurring phenomena.

Regarding the second step, the Federal Circuit analyzed the claims to determine whether the claims contained an inventive concept sufficient to establish that the claimed methods are a patent-eligible application of natural phenomena. Sequenom argued that the claimed methods are patent eligible applications of cffDNA because they involve methods like PCR to amplify and detect cffDNA. The Federal Circuit found that these techniques were well-understood, routine and conventional at the time the application for patent was filed, citing corroborating evidence in the specification and from Sequenom's own expert.

Sequenom also argued that its claims were not preemptive by identifying alternative uses of cffDNA not preempted by its claims. However, the Federal Circuit dismissed this argument by finding that, while preemption may signal patent ineligible subject matter, the absence of complete preemption does not necessarily demonstrate patent eligibility. Thus, the Federal Circuit held the claims of the Sequenom patent invalid for lack of subject matter eligibility under §101 and affirmed the district court's grant of summary judgment.

In concurrence, Judge Linn stated his opinion that the Supreme Court's unnecessary discounting of conventional post-solution activity in the second step of the *Mayo* test doomed the Sequenom patent, which otherwise claimed a discovery (cffDNA in maternal blood) that was deserving of patent protection. To conclude, Judge Linn stated that, "[b]ut for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible."

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