Federal Circuit Reluctantly Affirms Ariosa v. Sequenom and Denies En Banc Rehearing

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Ariosa v. Sequenom (Fed. Cir. 2015) (**en banc petition denied**)

The Federal Circuit has denied Sequenom's petition for *en banc* rehearing – reconfirming the panel holding that the claimed "*method of detecting paternally inherited nucleic acid*" is unpatentable as a *law of nature*. Patent No. 6,258,540. Following this case, the USPTO may finally begin applying the law-of-nature exception in a major way. The decision also sets up a petition for *writ of certiorari* to the Supreme Court with several members of the Federal Circuit expressly calling for review.

As **I previously wrote**, the invention at issue here solves a very practical problem accessing fetal DNA without creating a major health risk for the unborn child. The big idea was the hypothesis that fetal DNA might be floating around in the mother's blood and that the fetal DNA could be selectively amplified by focusing on the paternally inherited portion of its DNA (rather than the maternally inherited).

The claim itself has two simple steps: (1) amplifying paternally inherited DNA from a plasma sample taken from a pregnant female and then (2) detecting the presence of the DNA. As I mentioned, the big idea was understanding where the baby-DNA could be found (in the mother's blood plama) and that it could be separated from the mother's DNA by linking it to the father's sequence. The technology for amplifying and detecting was already well known at the time of the invention here. Further, these two steps – amplifying and detecting – are the ones always almost used to detect particular DNA sequences.

The district court found the patent invalid under Section 101. That decision was affirmed by a Federal Circuit panel in an opinion written by Judge Reyna and a concurrence by Judge Linn. Now, in the 11-1 en banc denial, we add three more opinions – Judge Lourie (joined by Judge Moore) and Judge Dyk, both concurring in the denial as well as Judge Newman dissenting.

The basic controlling precedent in this case is *Mayo v. Prometheus*. In that case, the Supreme Court held that the discovered therapeutic efficacy and toxicity of a particular administered drug to be an *unpatentable natural law* and that the patented testing and dosage methods were also unpatentable as effectively claiming the same law of nature. In particular, the court noted that the claimed steps were not "genuine applications of those laws[, but] rather … drafting efforts designed to monopolize the [unpatentable] correlations." As in Ariosa, the testing and determination steps were well known in the art and relied upon well-understood, routine, and conventional activity known to those in the field. As such, those additional steps

were insufficient to transform the unpatentable law of nature into a patent eligible application of the natural law.

In *Ariosa*, the Federal Circuit stands almost unanimously in the conclusion that Sequenom's invention is not patent-eligible under the *Mayo* precedent (only Judge Newman disagrees). There is, however, substantial disagreement about whether the Supreme Court was correct in its Mayo analysis.

Judge Dyk: I share the concerns of some of my colleagues that a too restrictive test for patent eligibility under 35 U.S.C. § 101 with respect to laws of nature (reflected in some of the language in *Mayo*) may discourage development and disclosure of new diagnostic and therapeutic methods in the life sciences, which are often driven by discovery of new natural laws and phenomena. This leads me to think that some further illumination as to the scope of Mayo would be beneficial in one limited aspect. At the same time I think that we are bound by the language of Mayo, and any further guidance must come from the Supreme Court, not this court.

Judge Lourie: [I]t is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts. But I agree that the panel did not err in its conclusion that under Supreme Court precedent it had no option other than to affirm the district court.

Judge Linn: In my view, the breadth of the second part of the test was unnecessary to the decision reached in *Mayo*. This case represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain. (Note, Judge Linn participated in the original panel decision but **could not dissent here because of his Senior Status**).

It will be interesting to see how this proceeds, but my view is that the case has a low-chance for certiorari. In *Mayo*, the Supreme Court indicated its understanding that the case would halt patenting of many diagnostics, but expressly called on Congress to "craft[] more finely tailored rules where necessary." In the 3 1/2 years since the Mayo decision, the diagnostic industry has not been able to get a bill even proposed in Congress that would so-tailor these rules (at least that I know of).