THE
NATIONAL LAW REVIEW

Ariosa v. Sequenom: In Search of Yes After a Decade of No

Friday, December 4, 2015

The ***Federal Circuit*** this Wednesday declined to reconsider its June decision in ***Ariosa v. Sequenom***, a closely watched medical diagnostics case involving patents on cell-free fetal DNA testing. Biotech companies, investors, and patent lawyers alike should expect a prompt petition for certiorari, and should hope that the Supreme Court grants it. (Disclosure: I was one of twenty-three law professors who submitted an amicus brief urging the Federal Circuit to grant *en banc* rehearing.)

In the last decade, the Supreme Court has suggested in case after case that the inventions they were considering were not merely unworthy of patent protection because they were, say, not inventive enough or useful enough or disclosed in enough detail. Rather, the Court in these cases gave us information about the very boundaries of the patent system—by placing the disputed inventions outside those boundaries altogether. But they have not yet told us what is *just inside* those boundaries.

Article By
Saurabh Vishnubhakat
Texas A&M University School of Law

Biotech, Food, Drug
Intellectual Property
Litigation / Trial Practice
Federal Circuit / U.S. Court of Spec. Jurisdiction

This legal uncertainty has a significant chilling effect on investment in innovation, one that we are increasingly able to quantify. As USPTO Chief Economist Alan Marco and I explained in a 2013 paper in the Yale Journal of Law and Technology, when a court issues a decision resolving the legal uncertainty over whether a patent was valid, that newfound certainty actually moves the market as much as the initial patent grant does. In other words, the unpredictability of courts forces the market to discount—by as much as half—how much trust to put in the legal rights that the Patent Office issues.

Patent holder Sequenom certainly experienced the downside of that uncertainty, as Wednesday's rehearing denial sent its stock price tumbling over 14% in just two days. Others have taken a hit as well, such as the large-cap DNA analysis firm Illumina, which has pursued Ariosa in a separate patent litigation and whose stock price fell 7% across the same two-day period.

The reason for this uncertainty is that we are effectively back in the late 1970s, when the Court was prominently rejecting inventions as patent-ineligible subject matter—*Gottschalk v. Benson* in 1972 and *Parker v. Flook* in 1978—without saying anything concrete about what was eligible. Relief would come only after *Diamond v. Chakrabarty* in 1980 and *Diamond v. Diehr* in 1981, when the Court finally produced binding precedents going the other way.

The result is that today's patentees can only try to run away from the settlement risk mitigation patent in *Alice Corp. v. CLS Bank* (2014), the breast cancer genetic diagnostic patent in *AMP v. Myriad* (2013), the thiopurine dosage monitoring patent in *Mayo v. Prometheus* (2012), the energy futures risk hedging patent application in *Bilski v. Kappos* (2010), and, although they were never definitively adjudicated, the vitamin deficiency diagnostic patents in *LabCorp v. Metabolite* (2006). There is no case yet to run toward.

Ariosa v. Sequenom could have been that case and still can be, if the Court grants certiorari. Certainly the Federal Circuit order has framed the issue well. The per curiam order denying *en banc* rehearing was

accompanied by three opinions that addressed in different combinations both the reach and the wisdom of the Supreme Court's recent precedents.

Judge Dyk's concurrence concluded that the precedents, particularly *Mayo* and *Alice*, do apply to the present facts and that those precedents are generally sound. He invited "further illumination" from the Supreme Court only on whether the all-important inventive concept must come at the second step of the two-step *Mayo* test (*application* of the natural law or abstract idea) or may also come at the first step (*discovery* of the natural law). Meanwhile, Judge Newman's dissent concluded that the precedents, particularly *Mayo* and *Myriad*, do not apply here, for the facts "diverge significantly." She found the Sequenom patent's subject matter to be eligible and would have proceeded to more specific patentability analysis under §§ 102, 103, 112, etc.

Their midpoint and the best argument for certiorari was Judge Lourie's concurrence, which agreed that *Mayo* controls, with "no principled basis to distinguish this case from *Mayo*"—but which also urged that *Mayo* and the Supreme Court's other precedents from *Bilski* onward are an increasingly unsound basis for differentiating between natural laws and abstract ideas on the one hand, and applications of those laws and ideas on the other hand. Echoing a previously expressed position of the Patent Office, he favored the "finer filter of § 112" for issues of indefiniteness or undue breadth (rather than what the agency's post-*Bilski* Subject Matter Eligibility Guidelines called the "coarse filter" of § 101).

He also pushed back directly against an argument that the Supreme Court frequently invokes to express its preference for flexible standards that foster accuracy over predictable rules that can be manipulated: the draftsman's art. Decisions from *Flook* and *Diehr* to *Mayo* and *Alice* have rested in part on the suspicion that patent lawyers may at any time evade substantive doctrinal limitations through clever claim drafting. To this Judge Lourie's opinion aptly responded that "a process, composition of matter, article of manufacture, and machine are different implementations of ideas, and differentiating among them in claim drafting is a laudable professional skill, not necessarily a devious device for avoiding prohibitions."

In these regards, Judge Lourie's approach may well represent the "center" of the Federal Circuit on subject-matter eligibility. He was in the *en banc* majority in *Bilski* and authored the panel opinion in *Mayo*. He authored both panel majority opinions in *Myriad* (before and after the Supreme Court's GVR order). And he authored the five-judge *en banc* plurality opinion in *Alice*, whose analysis was ultimately consolidated and endorsed in the Supreme Court's opinion in that case.

With the issues so well framed and the recent subject-matter eligibility precedents so well synthesized, then, there is reason to be optimistic that a decade of hearing "no" from the Supreme Court may finally give way to a "yes" and better orient us on the true boundaries of our patent system.

Source URL: https://www.natlawreview.com/article/ariosa-v-sequenom-search-yes-after-decade-no