The Coalition for 21st centurymedicine

C21 Comments on Expected Ariosa Cert Petition

The collective experience of the Members of the Coalition for 21st Century Medicine in trying to obtain much needed patent protection for their novel, life-saving technologies has led to one inescapable conclusion: It is critical to the future of precision medicine that the Supreme Court review the Federal Circuit's decision in Ariosa Diagnsotics, Inc. v. Sequenom, Inc.

When Mayo Collaborative Servs. v. Prometheus Labs, Inc. first came down from the Court, after the initial shock wore off, some in the innovation community were optimistic any problems could be corrected through district court and Federal Circuit cases. While some of the dicta in Mayo was sweeping, the facts of the case and the holding were quite narrow. After all, the claims literally "told" doctors about what the Court deemed a law of nature without incorporating that law into the claimed process. Thus, there was reason to hope that the higher number of "shots on goal" in the lower courts and the patent office would lead to an appropriately measured application of Mayo.

This optimism proved to be correct but very short-lived. In Ass'n for Molecular Pathology v. Myriad Genetics, Inc., the Federal Circuit twice upheld the patent eligibility of a biotech invention even in view of a Supreme Court GVR based on Mayo. And the Supreme Court's decision in Myriad was even narrower than in Mayo, including the Court going out of its way to emphasize its limits ("*We merely hold…*"). But like a high-stakes version of the children's game "telephone," the lower courts and the U.S. Patent and Trademark Office apparently received a very different message from what the Supreme Court transmitted.

Rather than engaging in a careful study of the facts in Mayo and Myriad and a principled, contextual application of these to new facts, former Federal Circuit champions of the narrow application of § 101 started expanding on isolated commentary from these cases. Then Judge Rader, one of the other primary defenders against the evisceration of the patent system by metastasizing application of § 101, stepped down as Chief Judge of the Federal Circuit. The Federal Circuit has now ruled against eligibility in every case where § 101 was at issue except one.

District courts in turn appear to have amplified the Federal Circuit's signal to a troubling extent. They began not only invalidating nearly everything that came before them, but invalidating at the pleadings stage. Thus, in the space of a couple years we went from the Federal Circuit upholding the Mayo claims to a patent statutorily presumed valid being struck down on a 12(b)(6) motion.

Completing the circle of feedback distortion, the USPTO has gone even further by issuing examination guidance that significantly expands on Mayo and its progeny such that obtaining meaningful patent protection in molecular diagnostics has become nearly impossible. Though the USPTO facially retreated from some of the more controversial elements of its first round of guidance, the reality is that examiners steadfastly reject nearly all diagnostic claims and the atmosphere feels to stakeholders like one of "reject first, ask questions later."

In short, optimism that the lower courts and the USPTO could or would correct any problems in Mayo was misplaced. The natural question, then, is what else can be done. The opposite approach now appears to be our best bet—i.e., appeal to the Supreme Court to reiterate the narrow nature of its § 101 jurisprudence and direct lower courts and the USPTO to faithfully interpret such. The primary cause of the devastation of life science patenting over the last few years is the failure of these lower courts and the USPTO to correctly interpret the Supreme Court's decisions. But the Court must be helped to see the role its broad statements of general principles have played in this tragedy. We must move the Court not to abandon its recent decisions, since this is not necessary. We must instead urge the Court to mandate a course correction in the application of those decisions.

Ariosa may offer the best chance to do this for the foreseeable future. First, Ariosa is cleaner and more sympathetic than past cases and other current cases. Sequenom's invention represents a profound innovation in molecular diagnostics that gave rise to a whole new type of diagnostic activity. Of course, so did the discovery of the BRCA genes at issue in the Myriad case. But Sequenom does not have a history that can be twisted by anti-patent folks so as to turn the Ariosa case into a referendum on breast cancer or patenting "the blueprint of life" (Myriad) or on patent trolls (the up and coming Genetic Technologies Limited v. Merial L.L.C. case). Prenatal testing has had its share of controversy, but the controversy is unrelated to the patents or Sequenom.

Second, Ariosa has been served up as best as can be hoped to maximize the odds that the Supreme Court both takes the certiorari petition and dials back Mayo and the devastation it has wrought in diagnostic patents. The panel decision itself in Ariosa begs to be overturned due to its lack of clear or convincing reasoning alone. The chances of the Supreme Court taking notice are further increased by Ariosa's frightening implications and the Federal Circuit commentary surrounding it.

As to implications, Ariosa shows the Supreme Court just how broadly and badly Mayo has been interpreted and expanded. The innovation in Ariosa is not an example of what the courts have accepted as implicitly excluded from the patent system for over a hundred years. It is instead precisely the kind of technical advance the patent system was intended to protect. Ariosa takes the Supreme Court's loose language from Mayo regarding "well understood, routine and conventional" and extends it to convert § 101 eligibility into a bizarre obviousness test that, taken to its logical conclusion, virtually every claim could fail. The Ariosa panel decision thus effectively requires two independent inventions in the life sciences, the discovery of a new biomarker or a new utility for a known biomarker coupled to an independent advance in the technical art of assaying biomarkers that is unrelated to the specific biomarker at issue.

Perhaps more influential in spurring Supreme Court review, however, are the Federal Circuit voices who practically beg the Court to take up Ariosa. At least three and arguably four Federal Circuit judges were quite vocal in expressing their concern over Ariosa as an indicator of just how far afield we have been driven by Mayo and its down-stream interpretation. In the original panel decision, Judge Linn bemoaned the pernicious effects of Mayo and the fact that, in his view, it required him to reject what he felt was clearly patent eligible. En banc, Judge Lourie returned to defend innovation by echoing Judge Linn's sentiment. Even Judge Dyk, who has

done at least as much damage to life science patenting as any other Federal Circuit judge through his opinions in In re BRCA1- & BRCA2-Based Hereditary Cancer Test (improperly extending Mayo and Myriad) and In re Roslin Inst. (improperly extending Myriad), admitted in Ariosa

> *I worry that method claims that apply newly discovered natural laws and phenomena in somewhat conventional ways are screened out by the Mayo test. In this regard I think that Mayo may not be entirely consistent with the Supreme Court's decision in Myriad.*

Many in the life science community have for years suffered with the same worries at which Judge Dyk appears to have finally arrived.

Judge Newman's en banc opinion in Ariosa may have set up the case best for Supreme Court review. While she was critical of Mayo, she astutely and forcefully argued that Sequenom's claims are patent eligible in full view of Mayo and Myriad.

> *I agree with my colleagues that this case is wrongly decided. However, I do not share their view that this incorrect decision is required by Supreme Court precedent. The facts of this case diverge significantly from the facts and rulings in [Mayo] and in [Myriad]. […] Precedent does not require that all discoveries of natural phenomena or their application in new ways or for new uses are ineligible for patenting; the Court has cautioned against such generalizations.* (Emphasis added.)

It is not necessarily Mayo itself, but judicial interpretation of Mayo that has swept away Sequenom's claims and those of dozens of other issued patents. Likewise the USPTO's application of Mayo has categorically excluded thousands of meritorious technological advances from the patent system specifically designed to protect them. Ariosa, with its relatively clean profile, sub-par panel decision, and coalition of dissenting voices at the Federal Circuit, presents what may well be the best chance we will ever have to correct the damage done to life science innovation by errant lower court and USPTO application of Mayo and its progeny.