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WHO WILL PROTECT LIFE SCIENCE INNOVATIONS?

Supreme Court decisions may mean that some are simply unpatentable. [BY DAVID PRIDHAM AND BRAD SHEAFE]

IN A MOVE WITH FAR-REACHING IMPLICA-tions for the future of diagnostic medical innovation, on March 21 Sequenom Inc. filed a petition for a writ of certiorari with the U.S. Supreme Court challenging the ruling last year by the U.S. Court of Appeals for the Federal Circuit that the first noninvasive prenatal test for fatal conditions in a baby's DNA was unpatentable.

In that case—*Ariosa Diagnostics v. Sequenom*—and in a subsequent denial of an en banc rehearing, the Federal Circuit reluctantly ruled against Sequenom by citing as precedent the Supreme Court's decision in *Mayo Collaborative Services v. Prometheus Labs*. Many believe that the court's 2012 decision in that case, which held that a diagnostic test for a personalized medicine dosing regimen was unpatentable, was overbroad. If the Supreme Court grants Sequenom's cert petition, which has strong support from industry and academia, it may reconsider its ruling in *Mayo*.

Whether or not the Supreme Court accepts cert—a decision that may have been made by the time this article goes to press—diagnostic medical innovators still have cause for hope. A close reading of the Federal Circuit's reasoning in the case—combined with a more strategic approach to patenting in today's uncertain IP legal and legislative environment—offers such companies (and other businesses with a similar dependence on intellectual property) a possible path to protecting and monetizing their innovations. This will be crucial if they wish to continue making the heavy investments in R&D needed for future breakthroughs in medicine and other technologies critical to our economy and quality of life.

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The invention at issue in the *Sequenom* case involved the 1996 discovery by two doctors that cell-free fetal DNA (cffDNA) circulates in the mother's plasma. They then invented a novel test for detecting fetal genetic conditions in early pregnancy without having to employ the dangerous invasive techniques that had previously been used for testing fetal DNA.

After Sequenon sent letters to Ariosa Diagnostics Inc. and several other competitors in 2011 threatening claims of infringement, they each filed declaratory judgment actions against Sequenom. The district court ruled that the claims of Sequenom's patent were not patent eligible under Section 101, and in June 2015 the Federal Circuit affirmed that decision. In December 2015, the court denied a petition for an en banc rehearing.

In its cert petition, Sequenom states that the overriding question is "whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without pre-empting other uses of the discovery?"

This question has enormous significance for the entire life sciences industry. As Sequenom's petition noted, "[We] invested enormously in developing and validating a recognized 'breakthrough' for clinical use, only to see that investment radically undermined by fast-following competitors trading on an uncertain legal doctrine [i.e., the *Mayo* ruling]." As a result, noted the petition, "no company can trust in the patent system when deciding whether to invest in bringing an invention to market. This issue has become particularly life-threatening to life science innovators."

The threat that the *Sequenom* decision poses to life sciences innovators cannot be overstated. In April the Federal Circuit, again relying on the *Mayo* frame-

work, affirmed another invalidation of a medical diagnostic patent in *Genetic Technologies v. Merial*. As PatentDocs, a biotech and patent law blog, observed: "Without the court's intervention and clarification, the *Ariosa* opinion is sufficiently broad that no diagnostic method claim will be safe from the logic set forth in that case and in this opinion."

Indeed, if this trend continues, America's world-leading life sciences industry—and the future cures that humanity is counting on—may wither on the vine. As Hans Bishop, the CEO of breakthrough cancer treatment company Juno Therapeutics, wrote in Forbes last year: "Let us be clear: Investments in the biotech industry are based entirely on patents. Without strong patents, we cannot raise money to find cures for disease." Nor can companies raise money to invent the tests needed to diagnose those diseases.

In his concurrence with the Federal Circuit decision denying Sequenom's petition for an en banc rehearing, Judge Alan David Lourie recognized this danger. "It is said that the whole category of diagnostic claims is at risk," he wrote. "It is also said that a crisis of patent law and medical innovation may be upon us, and there seems to be some truth in that concern."

Judge Timothy Dyk, a vocal critic of what he calls ambiguous and overbroad claims undeserving of patent protection, agreed: "I share the concerns of some of my colleagues that a too restrictive test for patent eligibility under 35 U.S.C. Section 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."

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NONETHELESS, THERE ARE WAYS FOR diagnostic medical innovators to mitigate *Mayo's* impact on their patents, as even the Federal Circuit judges noted. The problem with *Mayo*, Dyk argued, is that "it did not fully take into account the fact that an inventive concept can come not just from creative, unconventional application of a natural law, but also from the creativity and novelty of the discovery of the law itself. This is especially true in the life sciences, where development of useful new diagnostic and therapeutic methods is driven by investigation of complex biological systems."

Therefore, he suggested, "if the breadth of the claim is sufficiently limited to a specific application of the new law of nature discovered by the patent applicant and reduced to practice, I think that the novelty of the discovery should be enough to supply the necessary inventive concept."

In other words, even in the eyes of patent skeptics, there is a path for successfully claiming life science innovations through patents. So long as the patents are properly crafted to capture inventions through well-constructed claims representative of innovation that has been demonstrably reduced to practice, they are likely to survive scrutiny even under *Mayo* (as well as another infamous Supreme Court case affecting the patentability of claims arguably directed to abstract ideas and natural laws that is based on *Mayo*: *Alice v. CLS Bank*).

But more careful claim drafting is only one piece of the larger puzzle in protecting medical diagnostic innovations in the age of *Mayo*, *Alice* and *Ariosa*. The ultimate solution is to address the entire patenting and commercial- ▶

ization process in a much more strategic manner.

In the first place, diagnostic medical companies must consider *Mayo*, *Alice* and other patenting challenges early on in the R&D process, contemplating how best to protect nascent inventions before heavy investments are made in product features that may prove difficult to patent or defend in court. Ultimately, they need a more rigorous approach to holistic innovation management that includes a drafting and prosecution process that accounts for the unfortunate, but very real, constraints of current case law, and that embraces both parallel and sequential patenting efforts.

Second, in today's hostile legal environment for diagnostic patents, companies must take a strategic approach to licensing. Gone are the days when a hardball approach was a cost-effective way to recoup R&D expenditures through patent licensing. Given the number of tools now available to infringing competitors to render patents that protect commercially viable innovations unenforceable—e.g., judicial motions and Patent Trial and Appeal Board "patent trials"—being able to make a sound business case to prospective licensees as part of a comprehensive patent strategy is critical to success. Such a licensing approach can also help to move your innovation toward becoming an industry standard.

In the final analysis, reaping the benefits of a successful medical diagnostic R&D program through patenting is still possible, but only if a strategy is diligently developed and faithfully followed from the earliest days of development. The secret is to recognize that today's patent landscape is the reality to which today's innovators must adapt, and that adapting successfully requires unusually deep and broad experience in the development of patent and commercialization strategies. Otherwise, as Sequenom discovered, the costs of failing to survive the inevitable patent challenges will be enormous.

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