Modest Impact on Personalized Medicine Expected from Recent SCOTUS Rulings

By Roz Sweeney, Ph.D., Nerac Analyst

The recent Supreme Court decision on the Association for Molecular Pathology v. Myriad Genetics case was the culmination of much litigation on the validity of patent protection for the genomic sequences of BRCA1 and BRCA2. Myriad Genetics’ patents on these two genes gave it the exclusive right to offer genetic testing on the sequences it had identified. On June 13, 2013, the court essentially ruled that composition claims on products of nature (in this case, isolated DNA sequences) are not valid. Because Myriad did not create anything, there is no patentable invention.

The Supreme Court’s decision on this case seems in-line with recent rulings. According to Patrick Fahey, Partner in the business and intellectual property litigation practice at Shipman & Goodwin, “Generally speaking, the Myriad ruling is not that remarkable when read in the context of the Mayo ruling.” In the earlier Mayo v. Prometheus ruling, the Court ruled on claims around a medical process: 1) administering a drug to a patient 2) determining metabolite levels and 3) providing feedback on dose adjustment based on test results. The Court ruled that the first two steps were merely data gathering and that the third step was an unpatentable mental step. The reasoning behind the decision was that naturally-produced metabolites and therapeutic efficacy are part of “nature”; therefore, there is no transformative step. “Through the Mayo and Myriad rulings, SCOTUS essentially closed the door on natural DNA composition of matter claims. The court did not touch methods claims, and synthetic DNA is still eligible. The ruling affirmed that the claims need to have an inventive or transformative process,” said Fahey.

Ruling was largely anticipated
The Myriad ruling disallows composition claims on single genes. Based on checks with attorneys and others close to the diagnostics industry, we believe that companies were largely anticipating this ruling and that most small companies in the space have derisked their business models well ahead of the ruling. In anticipation of the ruling, companies have focused more on the strength of their methods claims and trade secrets. According to David Mack, Partner in the Health Law Practice Group at Shipman & Goodwin, “A single gene patent should not make much competitive difference and I don’t see it as being problematic to diagnostics companies. Most companies had already diversified their patent portfolio in advance of the rulings.”

Using Myriad as an example, the company has built up significant patient-level data, data analytics, and data mining capabilities, which is the true value of its business. Even though Myriad is now expected to face competition from other BRCA tests, these competitors do not have the expertise around data interpretation, nor do they have the breadth of other markers and signals that Myriad has incorporated into their test.
Mack believes that the issues presented by the Myriad and Mayo decisions raise several policy questions relevant to the future of personalized medicine. “Will patent law encourage investment in diagnostic technology and personalized medicine or will patent protection put barriers on basic research and access to medical care? Will patent law encourage innovation by creating financial incentives or threaten the public’s health by stifling competitive research?” These are questions for lawmakers in Congress and other policymakers to answer.

Litigation is now ongoing, but not unexpected
After the SCOTUS decision, several competitors announced their intention to launch BRCA testing products. In response to these announcements, Myriad was placed in a difficult position, which compelled them to defend their market from a business, legal, and shareholder perspective. In response, Myriad has filed a lawsuit against Ambry Genetics and Gene By Gene, the first companies to announce their intention of entering the BRCA testing market. There are several valid possible reasons for why Myriad filed the lawsuit, in the face of the recent SCOTUS ruling. First, it is likely that Myriad brought the lawsuit just to delay the introduction of competitive products into the market. Second, Myriad brought the claims knowing that their patents aren’t that strong, but that the lawsuit could result in a settlement that allows Myriad to get royalties. Finally, Myriad really thinks they can defend the claims, although this is unlikely. Essentially, Myriad brought the lawsuit in order to protect its market and to show investors that it is doing everything to defend its position.

Key unanswered questions
A key unanswered question is the effect the SCOTUS decision will have on patents for other products of nature. The decision seems calls into question whether other naturally occurring products (e.g. stem cells, tissues) are patentable. Mack stated, “Patents on products such as compounds and devices and methods claims around natural products will be more pertinent,” now that single gene composition claims have seemingly been disallowed. He added, “There remains the likelihood that cDNA can still be patented, but the cDNA will need to satisfy other tests of patentability not addressed in Myriad or Mayo, namely novelty, nonobviousness and to be subject to an adequately explicit written description.”
About the Analyst

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Roz Sweeney, Ph.D., advises medical technology clients on new market opportunities, reimbursement, and regulatory issues. Before joining Nerac, Dr. Sweeney was an associate with Mitchell Madison Group, a global management consulting firm focusing on cost reduction for clients in healthcare, high tech manufacturing, and financial services. She also worked in healthcare equities research at Royal Bank of Canada, Capital Markets, covering small and mid-cap biotech companies. Dr. Sweeney has an academic background in cell and molecular biology (Ph.D. University of Texas) and was a postdoctoral fellow at California Institute of Technology, where she conducted research in nanoparticle-based drug delivery systems.

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