Federal Circuit Decides Myriad: Holds Isolated Genomic DNA Patentable

By Jonathan Loeb on July 29, 2011

On July 29th, the Federal Circuit handed down its decision in the much-discussed *Association for Molecular Pathology v. U.S. Patent and Trademark Office* (commonly known as the "Myriad Genetics" case). The Federal Circuit split the baby — finding Myriad's isolated BRCA DNA claims patentable, but its method claims for analyzing patients for mutations in these genes unpatentable.

Myriad Genetics ("Myriad") owns various patents related to human BRCA1 and BRCA2 genes (Breast Cancer Susceptibility Genes 1 and 2). Some of the claims at issue were directed to the isolated DNA for these genes, while others claimed methods for analyzing these sequences for mutations associated with propensity for breast cancer. As a result of aggressive enforcement of the seven patents-in-suit, Myriad has been essentially the sole U.S. provider of diagnostic tests for these mutations.

A number of Medical Associations and individual doctors — assisted by the American Civil Liberties Union and the Public Patent Foundation — sued Myriad for a declaration that the patents were invalid because they were directed to unpatentable subject matter under § 101 of the Patent Code (and incidentally, that the Myriad patents violate the First Amendment to the Constitution because they restrict the communication of information).

In a surprising and highly controversial ruling, Judge Sweet of the Southern District of New York District Court ruled for the plaintiffs on their § 101 claims, finding that isolated DNAs corresponding to genomic DNA sequences are unpatentable products of nature, and that Myriad's method claims were unpatentable because the method did not effect any meaningful transformation.

On appeal, Judge Lourie, writing the lengthy 55-page majority opinion for a divided panel of the Federal Circuit, reversed Judge Sweet's decision on the patentability of isolated genomic DNA: the isolated DNA molecules are patent eligible because "*BRCA1* and *BRCA2* in their isolated state are not the same molecules as DNA as it exists in the body; human intervention in cleaving or synthesizing a portion of a native chromosomal DNA imparts on that isolated DNA a distinctive chemical identity from that possessed by native DNA." Slip Op. at 42.

But Judge Lourie did affirm Judge Sweet's decision regarding the method claims, holding that "Myriad's claims to 'comparing' or 'analyzing' two gene sequences fall outside the scope of § 101 because they claim only abstract mental processes." Slip. Op. at 49. In coming to this decision, the Court had to navigate the Supreme Court's recent *Bilski* decision concerning the patentability of method claims, and its own decision in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services* finding patentable diagnostic methods which involved the calibration of

drug dosage in the context of a treatment regime, based on the assessment of certain metabolite concentrations obtained from *in vivo* samples. *Prometheus* is now being reviewed by the Supreme Court.

As to the isolated DNA holding, the *Myriad* decision upholds the status quo, and confirms the settled expectations of the many holders of patents to isolated gene sequences. Judge Lourie markedly closed the door to further challenges to patents to molecules isolated from the body by suggesting any changes in this law have to come from Congress, not the courts. Slip Op. at 48. One wonders about the forward-looking impact of this holding, however, since the human genome has been completely sequenced (including many many individuals and not to mention many other species) and the opportunities for patenting novel non-obvious isolated DNA sequences are thereby steadily decreasing.

But on the other hand, the identification of genetic variants that can be the basis of diagnostic tests is an increasingly important area of clinical and pharmaceutical development and is the foundation for personalized medicine. There is significant interest among regulators and industry in using such genetic tests for making decisions concerning dosing, patient selection for efficacy, and patient exclusion for safety. Thus, the question becomes what is the best way of drafting meaningful patent-eligible diagnostic testing claims?

Clearly any method claims will require a "transformative step." The *Myriad* decision has a least one helpful suggestion by distinguishing the claims from those in *Prometheus*, noting that "Myriad's claims, in contrast, do not include the step of 'determining' the sequence of *BRCA* genes by, *e.g.*, isolating the genes from a blood sample and sequencing them, or any other necessarily transformative step." Slip Op. at 52. So specifying a particular, chemical means for determining patients' genotype should be enough to make a claim patent-eligible. The difficulty for patent prosecutors comes from the very advanced state of genetic technology. There are now so many ways to detect and compare individuals' gene sequences, how can one draft a claim to a method — including a specific transformative step — that captures all these techniques, and those to come in the future? For example, today's Wired magazine page has an article discussing the newly discovered importance of chromosomal structure, not DNA mutations, in determining major heritable traits. And, would any such claims embody the true innovation of these important new tests — the correlation between certain gene sequences and the best choice of treatment for a patient?

Perhaps the most certain route to patentability for diagnostic tests can be found in *Prometheus*, where the Federal Circuit found that "administering" a drug was a transformative step and supported patent eligibility. In other words, a method claim that combines the determination of a patient's genotype with actual positive treatment steps depending on the outcome of the genetic determination, such as administering a certain drug in a certain amount, should meet the § 101 requirement for patentability. Depending, of course, on whether the Supreme Court upholds the Federal Circuit's decision in *Prometheus!*