Myriad Decision Offers Mixed Bag for Biotech: Biopharmaceutical Claims Likely to Survive, but Outcome for Diagnostic Methods and Methods-of-Screening Claims Is Less Certain

On March 29, the United States District Court for the Southern District of New York issued its long-awaited decision in *Association for Molecular Pathology v. United States Patent and Trademark Office (Myriad)*. The decision on summary judgment, if affirmed on appeal by the Federal Circuit, could significantly impact the patentability of certain types of patent claims in biotechnology.

The Myriad case pitted various not-for-profit clinical medicine and breast cancer organizations, academics, and patients diagnosed with breast cancer against the United States Patent and Trademark Office, Myriad Genetics, and the University of Utah Research Foundation. At issue were 15 claims in 7 Utah patents that are exclusively licensed to Myriad and under which Myriad provides breast and ovarian cancer screening tests.

There were three classes of claims. The first were composition claims: isolated DNAs (breast cancer susceptibility genes (BRCA)). The others were method claims: methods of analyzing a BRCA gene from a human sample, often by comparing that gene with Myriad's wild-type BRCA gene, and cell-based methods of screening compounds to identify those potentially useful in treating cancers related to mutations in the BRCA genes. Judge Sweet held all three classes of claims invalid for the same reason. They were, in his view, directed to non-patentable subject matter.

Isolated DNA

In contrast to the Federal Circuit's emphasis in *Amgen* (1991) that a gene is a chemical compound, albeit a complex one, the Court focused on a gene's principal function as a carrier of biological information and dismissed the specific chemical arrangement of the gene as being merely determined by nature. The information-carrying function of DNA, in the Court's view, was not changed by the gene's purification from human tissue or its isolation from the other DNAs of the chromosome. In its analysis, the Court was also not swayed by the fact that the isolated DNA had many uses for which the DNA in its native environment was not useful. As a consequence of its information-based starting point and pointing to Supreme Court precedent that, absent a change that results in the creation of a fundamentally new product, a product of nature is not patent-eligible subject matter, the Court held the Myriad claims invalid as "unpatentable subject matter under 35 U.S.C. § 101."

In reaching its decision, the Court distinguished cases like *Chakrabarty* (1980), where the patentee had modified the claimed biological material so that it had markedly different characteristics in comparison to naturally-occurring bacteria, and *Merck* (1958), where the purification of Vitamin B12 was held to be more than a "mere advance in the degree of purity of a known product." The Court also distinguished cases, like *Bergstrom* (1970) (purified prostaglandins) and *Kratz* (1979) (purified strawberry flavor), as being directed to the statutory novelty requirement for patentability, not to the separate common-law patentable subject matter requirement for patentability of Section 101. Finally, the Court opined that it was not bound by the Patent Office's longstanding practice of granting patent claims to "isolated DNA."

This part of the Court's decision is unlikely to have broad impact on the biotech industry. Most biopharmaceuticals are different from products of nature. Indeed, in its EPO patents, Amgen pointed to glycosylation differences to try to distinguish its recombinant EPO from that already purified from native sources. Likewise, the expression vectors and cells used to produce biopharmaceuticals are not products of nature. Finally, even in the context of DNA claims, careful claim drafting may avoid the Court's "product of nature" concerns. It remains to be seen, however, just how far—if at all—the Court's information-based view of DNA will reach outside of the DNA claims at issue in *Myriad*.

Diagnostic Methods of Analysis and Comparison

Looking to the Federal Circuit and its *Bilski* (2008) "machine or transformation" test for guidance on when a method claim encompasses the application of a principle, not the principle or law of nature itself, the Court held the Myriad diagnostic method claims unpatentable under Section 101 as non-patentable subject matter.

In Judge Sweet's view, "analyzing" or "comparing" human DNA to Myriad's BRCA genes was no more than a mental process devoid of any machine or transformation. In reaching that conclusion, the Court distinguished cases like *Prometheus* (2009), where the Federal Circuit found that the human body was transformed by the claimed method for optimizing the therapeutic efficacy of a drug treatment and that there were physical and chemical changes in the assayed metabolites as a result of that transformation.

The impact of this prong of the Court's decision on the diagnostic industry is unclear. First and foremost, it may be possible to draft diagnostic claims to include the necessary transformation steps as a central part of the method. Second, *Bilski* is now under submission to the Supreme Court. Its decision will control how this prong of the *Myriad* case affects the future.

Methods of Screening

The Court also applied its non-patent eligible "mental process" analysis to Myriad's claim for a method of screening compounds for potential therapeutic use against breast cancer based on a comparison of the growth rates of cells containing an altered BRCA gene in the presence or absence of the compound. Judge Sweet's view was that the steps of producing and growing the transformed cells, exposing the cells to the compounds, and measuring their growth rate were mere "preparatory" and "data-gathering steps" that did not affect the "essence" of the claim: the mental comparison steps.

This prong of the Court's decision may be particularly controversial. The Federal Circuit, most recently in *Ariad* (2010) and *Rochester* (2004), held that discovery of a mechanism underlying a disease or treatment, albeit groundbreaking and important, cannot support claims to compounds that may in the future be identified using the mechanism or claims to general methods of treatment that work through the mechanism. What was left to these typically academic innovators and their pioneering discoveries was method of screening claims to identify compounds that could modulate the newly-discovered mechanism. Judge Sweet's decision calls that last hope into question.

Next Steps

Myriad is likely to appeal to the Federal Circuit. The timing and substance of the Supreme Court's *Bilski* decision will affect that appeal in many procedural and substantive ways. The views of amici may also be important in the ultimate resolution of the Section 101 issues in the context of claims to DNA and methods of diagnosis and screening. In the District Court, many amici shared their views on those questions. On appeal, we expect even more amici to present their views.

Ropes & Gray's Intellectual Property group regularly counsels clients on these issues. If you have any questions about *Myriad* and its effect on your business activities, please do not hesitate to contact your regular Ropes & Gray attorney.

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