Two recent US Supreme Court rulings have led to speculation that the patentability of gene-based inventions may become uncertain.

First, in *Mayo Collaborative Services v. Prometheus Laboratories*, the Court held that certain medical inventions are non-patentable, calling into question the USPTO's long-standing practice of recognizing the patentability of isolated gene and amino acid sequences and methods of their use. In light of *Prometheus*, the Court vacated the Federal Circuit's judgment in *Association for Molecular Pathology v. Myriad Genetics* that had confirmed the patentability of Myriad's isolated gene sequences and methods, remanding the case for further consideration.

The Federal Circuit's disposition of *Myriad* (and any subsequent Supreme Court appeal) could have a momentous impact on biotechnology patent rights and on the biotechnology industry.

Myriad's composition claims cover isolated genes associated with breast cancer (BRCA genes). The Association for Molecular Pathology (AMP) challenged these claims on the grounds that they cover products of nature. The Federal Circuit disagreed, confirming the patentability of the composition claims and, applying the “markedly different” test set forth in *Diamond v. Chakrabarty*, found isolated DNA is “markedly different” from DNA found in nature.

Myriad's drug screening claim involves transforming cells with a cancer-causing BRCA gene and measuring the cells' growth in the presence and absence of potential therapeutics. AMP challenged Myriad's claims as being drawn to an abstract idea – the comparison of cellular growth rates; and preempts a law of nature – the correlation between a slower rate and the efficacy of a potential therapeutic. For this claim, the Federal Circuit applied the “machine or transformation” test set forth in *Bilski*, concluding Myriad's drug screening method was patentable. The court found the claimed steps were sufficiently transformative, while holding that other claims relating to diagnosing predisposition to breast cancer failed the “machine or transformation” test and thus were non-patentable.

*Prometheus* involves the patentability of claims drawn to methods of evaluating the dosing regimen of thiopurine by administering the drug, determining its metabolite levels in a patient’s bloodstream and comparing those to levels identified in the claims as too high and too low. The Supreme Court held that the claims are non-patentable, finding they were drawn to a law of nature – the naturally occurring correlation between metabolite levels and therapeutic efficacy. The Court concluded that any transformative steps in the claims were insufficient to constitute a patentable application of that natural law, finding the “administration” step simply refers to the “relevant audience.” The “determining” step, the Court said, involves nothing more than “well-understood, routine, conventional” activities. The Court also reasoned that public policy weighed against granting patents for such subject matter, because laws of nature are “the basic tools of scientific and technological work” and patents for
such laws would “inhibit future innovation.”

On remand, the parties in *Myriad* will have diametric views regarding the applicability of *Prometheus*. AMP will interpret *Prometheus* broadly to mean all biotechnology claims are patentable only if there are differences between the claimed subject matter and underlying natural laws or phenomena that are not “well-understood, routine, or conventional.” Regarding Myriad’s composition claims, AMP will likely argue that even if the claimed isolated genes are “markedly different” from naturally occurring genes, the act of isolating those genes is routine. Myriad, in contrast, will likely argue that *Prometheus* is inapplicable to its product claims because *Prometheus* involved only method claims, and that application of the “markedly different” test confirms the patentability of those claims. Myriad will also likely argue that, even if *Prometheus* governs the patentability of its product claims, isolation of the BRCA gene would have been impossible without the work that led to the identification of the gene sequence and its association with breast cancer – work which was not routine or conventional.

Regarding Myriad’s drug screening method claim, AMP will likely argue that the claim is analogous to the therapeutic claims at issue in *Prometheus*, because the steps the Federal Circuit found to be transformative are well-established lab techniques. Myriad will likely argue that those steps are not routine because the growth of cells transformed with a BRCA gene required the unconventional work that led to the first identification of the gene sequence. To inoculate its claims from the policy considerations in *Prometheus*, Myriad will likely argue that its patent claims have not been obstacles to further research on the claimed genes.

The Federal Circuit’s decision in *Myriad* (and any subsequent Supreme Court decision) will have a significant impact on patents covering biologic inventions. Parties seeking to invalidate patent claims to such inventions may be able to argue they are non-patentable under the standards set forth in *Prometheus* and *Myriad*.

These challenges will have an even greater impact in light of the Biologics Price Competition and Innovation Act of 2009, which is likely to dramatically increase patent litigation involving biosimilars and bioidenticals and may facilitate regulatory approval and market entry of competitive products and methods.

Companies seeking to protect the markets for their biologic inventions may be forced to explore new strategies – most likely emphasizing in their patent claims the human manipulation and intervention that led to the inventions, to adequately distinguish those inventions from products and laws of nature.

The best strategies for protecting biologic inventions will depend greatly on a series of events: the Federal Circuit’s *Myriad* remand decision, any subsequent Supreme Court opinion and the way the Federal Circuit and district courts apply those decisions in the next few years.

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2. At the time this article was written, briefs had not yet been filed in the *Myriad* remand. Oral argument before the Federal Circuit is currently scheduled for July 20, 2012. To follow the case, go to the Federal Circuit website and search using the appeal number 2010-1406.