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Supreme Court to Myriad: Isolated DNA Sequences Are Not Patent-Eligible Subject Matter

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The Supreme Court of the United States has released its highly anticipated decision in ***AMP et al. v. Myriad Genetics, Inc., et al.***, on the patenting of genes. This *On the Subject* discusses the Supreme Court decision and the earlier Federal Circuit decision that address whether the subject matter is patent eligible.

In a 9–0 decision issued on June 12, 2013, the Supreme Court of the United States brought to a conclusion the closely watched case of *AMP et al. v. Myriad Genetics, Inc., et al.* The decision held that "isolated DNA sequence" composition claims do not constitute patent-eligible subject matter under 35 U.S.C. § 101, but that composition claims directed to cDNA do constitute patent-eligible subject matter.

By way of background, the "human gene" claims at issue in this case involve BRCA1 and BRCA2 genes, which have been correlated with susceptibility to breast and ovarian cancer. Respondent Myriad Genetics, Inc., successfully isolated the BRCA molecules in what has been described as a major breakthrough. Myriad claims that the isolation of these molecules was a result of significant scientific expertise and financial outlays.

The petitioners contended that the composition claims patented by Myriad cover sequences already existing in nature and therefore do not constitute patent-eligible subject matter. Myriad countered that it has not patented gene sequences *per se* (such as, for example, the sequence that naturally exists in a human being), but has instead patented sequences that are "isolated," for example, in a laboratory.

Petitioners, however, claimed that the inventive concept in Myriad's "isolated sequence" composition claims is the sequence information, not the isolation step. Thus, the petitioners argued that the fact that the claimed compositions cover "isolated" molecules is irrelevant because the claimed compositions in effect pre-empt all BRCA1 and BRCA2 molecules regardless of whether they are in a human body or created in a laboratory as long as the molecule encodes the claimed sequence. Petitioners argued that this was true for cDNA as well.

In a unanimous decision authored by Justice Clarence Thomas, the Supreme Court agreed that "isolated DNA sequences" do not constitute patent-eligible subject matter. In doing so, the Supreme

Court drew on its long-held rule that products of nature are not patent eligible. The Supreme Court reasoned that Myriad's contribution was "uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes." The Supreme Court contrasted this act with the transformed bacterium in its *Chakrabarty* decision, which contained new and "markedly different characteristics from any found in nature." Myriad's act of "separating a gene from its surrounding genetic material" failed to meet this test.

Simply discovering the location of the BRCA1 and BRCA2 genes "does not render the BRCA genes 'new . . . composition[s] of matter,' § 101, that are patent eligible." In making this determination, the Supreme Court rejected the U.S. Court of Appeals for the Federal Circuit's reasoning that severing the chemical bonds by isolating the sequence from the genomic sequence was sufficient. The Supreme Court did so because the claims focused on the sequence information itself and did not speak in terms of "chemical changes that result from the isolation of a particular section of DNA."

Finally, the Supreme Court rejected the argument that the **U.S. Patent and Trademark Office's** (**USPTO's**) past practice of awarding gene patents is entitled to deference. In part, it did so on the unusual split between the USPTO and the United States, which argued in the Federal Circuit and before the Supreme Court that isolated DNA was not patent eligible.

As to the cDNA claims, the Supreme Court held that cDNA "results in an exons-only molecule that is not naturally occurring." The Supreme Court found that the lab technician "unquestionably creates something new when cDNA is made." As a result, Justice Thomas explained that cDNA is not a product of nature and is patent eligible.

This is the second time this case is before the Supreme Court. In its previous appearance, the Supreme Court remanded the case back to the Federal Circuit in light of the Supreme Court decision in *Mayo Collaborative Services v. Prometheus Labs* (for more information, see *IP Update, Vol. 14, No. 6*. The Federal Circuit, however, retracted the decision it had previously reached before the remand, essentially rendering *Prometheus* irrelevant to composition claims.

But it is important to recall that the Federal Circuit struck down the gene correlation method claims. The panel unanimously found that Myriad's claims of comparing gene sequences did not constitute patent-eligible subject matter. Indeed, the court found the claims "indistinguishable" from the method claims struck down in *Mayo v. Prometheus*, stating that the Supreme Court "made clear that such diagnostic methods in that case essentially claim natural laws not eligible for patent." Importantly (and as noted by Justice Thomas), those claims were not before the Supreme Court in the current *Myriad* decision.

Also noteworthy, the Federal Circuit upheld as patent eligible subject matter claims directed to a method for screening potential cancer therapeutics via changes in cell growth rates of transformed cells. As for those claims, the Federal Circuit maintained its previous rejection of Mayo's argument that the method constituted an abstract idea that preempted the basic scientific principle that a slower growth rate in the presence of a potential therapeutic compound suggests that the compound is a cancer therapeutic. Instead, the Federal Circuit concluded that the cells were transformed, which reflected the "hand of man," and thus constituted patentable subject matter.

The long road for this particular suit is now at an end. Under the Federal Circuit and Supreme Court decisions, it is now clear that certain method claims and isolated DNA sequence claims are not patent eligible. The ultimate ramifications of these rulings are certain to be the focus of future litigants.

Practice Note

On the same day that the Supreme Court decision was handed down, the USPTO (Office of the Deputy Commission for Patent Examination Policy) issued a memorandum to the examining corps advising the corps that “claims to isolated DNA are not patent eligible under 35 U.S.C. § 101.” The memorandum notes that the *Myriad* decision “significantly changes the Office’s examination policy regarding nucleic acid related technology.”

Practitioners will now have the challenge of devising new ways of protecting discoveries involving genes without claiming isolated DNA,*e.g.*, what is done with a gene? How is it used?

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