Published on *The National Law Review* https://natlawreview.com

The Supreme Court Holds Human Genes are Unpatentable

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In a unanimous decision written by Justice Thomas, the Supreme Court held that naturally-occurring DNA sequences are unpatentable. The Court has long held that certain subject matter is not patent eligible under 35 USC § 101. Patent exempt subject matter includes laws of nature, natural phenomenon, and abstract ideas. In this case, the Court found that human genes are products of nature. The Court further found that cDNA sequences, which are copies of non-intron containing mRNA sequences created in the laboratory, are patent eligible.

The case before the Court involved several patents issued to Myriad Genetics, Inc. ("Myriad") that were directed to two genes known as BRCA1 and BRCA2. Mutations in these genes can increase a woman's risk of developing breast and ovarian cancer. The scientists at Myriad had discovered the genes, determined their nucleotide sequence and their chromosomal location. The Court found that locating and isolating the genes did not make them new compositions of matter. The Court acknowledged that the genes were important and useful, but nevertheless concluded that "Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them." Thus, the "genes and the information they code are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material."

The Court found that cDNA sequences stood on a different footing. The Court acknowledged that cDNA contains naturally-occurring coding sequences of DNA known as exons, but observed that it differs in that intervening non-coding sequences are removed by a lab technician. Consequently, the court held that cDNA is not a product of nature and may be patent eligible.

The Court went to great pains to point out that the decision was limited to the genes themselves. The Court explicitly stated that it was not passing judgment on patent claims directed to methods of isolating or manipulating genes. Although they noted that the isolation methods used by Myriad were "well understood, widely used, and fairly uniform in so far as any scientist engaged in the search for a gene would likely have utilized a similar approach."

Of paramount importance is that the Court's decision did not encompass patent claims directed to "new applications of knowledge about the BRCA1 and BRCA2 genes" or "scientific alteration of the genetic code." After all, it is the potential use of a DNA sequence that is the raison d'étre for isolating it in the first instance. The ultimate goal of all DNA research is for the gain, financial or otherwise, that is obtained in developing a new diagnostic assays, gene therapy, therapeutics, herbicide resistance,

etc. that use the DNA. The practical application of a DNA sequence has always been where the true value lies.

The *Myriad* decision will have a tremendous impact on the biotechnology industry. Tens of thousands of existing patents having claims that are exclusively directed to DNA sequences and fragments thereof can now be challenged and invalidated. The United States Patent and Trademark Office (USPTO) has already published new interim guidelines for the patent examiners. Referring to the Supreme Court's decision in *Myriad*, the new guidelines instruct the examiners to "now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C. § 101."

In the wake of the *Myriad* decision, biotech companies would be well advised to protect their intellectual property by immediately examining their patent portfolios. Claims in pending patent applications should be amended and/or new claims added that are directed to cDNA sequences and methods of using said sequences. Steps should be taken to safeguard those patents that have already issued from litigation. To that end, companies should consider amending the claims in issued patents by filing a request for reissue or reexamination.

National Law Review, Volume III, Number 213