ISOLATING GENES IS NO LONGER SUFFICIENT TO GET A PATENT IN THE UNITED STATES*

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On June 13th 2013, the Supreme Court of the United State reversed two decades of United States Patent Office (USPTO) past practice and delivered its long awaited decision in the Myriad case (Association for Molecular Pathology v. Myriad Genetics. Inc.).Myriad is the holder of multiple patents pertaining to the BRCA1 and BRCA2 genes and their applications. The inventors of the Myriad patents determined the exact location and nucleotide sequence of the BRCA1 and BRCA 2 genes along with the fact that certain mutations in the BRCA1 and BRCA2 genes considerably increase breast or ovarian cancer risk. The Association for Molecular Pathology (AMP) brought a suit against Myriad seeking a declaration that some of Myriad's patents are invalid for non-statutory subject-matter.

In a unanimous decision, the Supreme Court partially reversed the Federal Circuit prior decision and ruled that:

- Isolated human genes fall under the laws of nature and are not patent eligible subject-matter. The Supreme Court took the position that the chemical changes resulting from the isolation of a gene were not sufficient to render an isolated gene patentable.
- Synthetically made complementary DNA molecules (cDNA) comprising coding only DNA-segments (exons) are eligible to patent protection. The Supreme Court took the position that cDNAs are not naturally occurring since non-coding DNA segments (introns) present in genes must be omitted in order to obtain cDNAs.

After the Supreme Court decision was rendered, Ambry Genetics announced that it would begin offering BRCA testing. Myriad responded by filing a lawsuit against Ambry Genetics for infringing Myriad's patent claims directed to BRCA analysis. In its submissions, Myriad argued that it was still the holder of more than 500 valid claims. It is important to point that the only issue before the Supreme Court was whether claims directed to isolated genes were eligible for patent protection. The Supreme Court did not rule on Myriad's gene testing claims.

The Supreme Court was careful in identifying what was not affected by its decision. More specifically the decision states that:
"This case, it is important to note, does not involve method claims, patents on new applications of knowledge about the BRAC1 and BRCA2 genes, or the patentability

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of DNA in which the order of naturally occurring nucleotides has been altered" (emphasis added).
In a prior Federal Circuit decision, certain method claims directed to identification of cancer therapeutic agents were held to be eligible to patent protection while other method claims directed to comparing or analyzing DNA sequences and including no transformative steps were determined not to be eligible to patent protection.

In the Ambry litigation, Myriad is taking the position that while the Supreme Court invalidated a small number of claims, Myriad is still the holder of synthetic DNA and method of use claims that were not affected by the Federal Circuit and Supreme Court decisions. The validity of Myriad's BRCA1 and 2 patents will most likely be revisited since Ambry is seeking a declaratory judgment that Myriad's patents are invalid and not infringed and that Myriad has violated U.S. antitrust laws through bad faith enforcement of these patents.

What is next?

On the same day the Supreme Court decision was delivered, the USPTO issued a memorandum instructing patent examiners to reject product claims drawn solely to naturally occurring nucleic acids and fragments therefor, whether isolated or not. The memorandum also stated that cDNA and man-made variants will continue to be patent eligible while claims directed to methods involving naturally occurring nucleic acids may give rise to eligibility issues under the current rules.

Interestingly, the Myriad decision and the USPTO memorandum are silent on how claims directed to isolated naturally occurring biomolecules, other than genes, should be considered. Based on the position taken by the Supreme Court, there is a possibility that claims directed only to isolated naturally occurring biomolecules may not be eligible to patent protection in the US.

While isolated genes continue to be patentable in many countries including Canada, patentees should carefully review their patent portfolios in order to add claims that are more likely to meet the threshold for eligible patent subject-matter in the United States. Patentees should consider adding claims directed to novel applications, cDNA and modified variants of the genes if possible

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