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September 24, 2012

Isolated Human Genes Still Patentable in the United States

By: Serge Lapointe, Ph.D. | Montréal

On remand from the Supreme Court, the United States Court of Appeals for the Federal Circuit released its second opinion in *Assoc. Molecular Pathology (AMP) et al. v. Myriad Genetics*[1]. The Court was asked to reconsidered its prior decision on patent eligibility under 35 U.S.C. §101 in view of the recent Supreme Court's decision in *Mayo v. Prometheus*[2] and thus, determine whether Myriad's patent claims were patent-ineligible products of nature. The 2-1 split panel stuck to its previous decision and concluded once again that isolated BRCA 1/2 DNA molecules patented and used by Myriad Genetics Inc. for diagnosing increased risks of breast and ovarian cancer are patent eligible, that claims on methods of using DNA transformed cells to screen for cancer therapeutics are also eligible but that diagnostic claims directed to "analyzing" and "comparing" DNA sequences are ineligible.

Regarding Myriad's isolated DNA molecules, the Court concluded that these DNA molecules are not found in nature because they "are obtained in the laboratory and are man-made, the product of ingenuity" even if they are ultimately derived from natural materials. Indeed, the Court concluded that these molecules "have been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body".

The Court also reiterated its previous observation that the United States PTO has been issuing patents on DNA molecules for almost 30 years and that Congress has not indicated that the PTO's position is inconsistent with §101: "If the law is to be changed, and DNA inventions excluded from the broad scope of §101 contrary to the settled expectation of the inventing community, the decision must come not from the courts, but from Congress".

In the second step of its analysis, the Court considered the diagnostic-related claims which consist of "analysing" and "comparing" BRCA sequences from a tumor sample to detect genetic mutations associated with a predisposition to cancer. The District Court reaffirmed its prior holding that these claims fall outside §101 because they claim only abstract mental processes: "[l]imiting the comparison to just the BRCA genes or […] to just the identification of particular alterations, fails to render the claimed process patent-eligible […] [a]ltough the *application* of a formula or abstract idea in a process may describe patent-eligible subject matter […] **Myriad's claims do not apply the step of comparing two nucleotide sequences in a process**. Rather, the step of comparing two DNA sequences is the entire process that is claimed" (italics in original, our bold). Therefore, Myriad's challenged method claims were found indistinguishable from the claims the Supreme Court found unpatentable in *Mayo v. Prometheus* (natural laws).

Only one of Myriad's method claims was found eligible for patenting, that claim being directed to a method of screening potential cancer therapeutics. That claim was considered differently because it includes transformative steps of "growing" transformed host cells, "determining" the growth rate of the cells with or without the potential anticancer drug and "comparing" the growth rates of the cells. Accordingly, the Court concluded that the claim does not simply apply a law of nature.

Comment: The holding is only a partial victory for the biotechnology and biopharmaceutical industries. Many predict that the whole issue is not settled and that this case will most likely go to the Supreme Court. Although the Court recognized the patent eligibility of isolated DNA and pharmaceuticals screening methods, there is still uncertainty with respect to diagnostic methods which may or may not be patent eligible depending on the steps recited in the claim. To maximise chances of patentability, diagnostic-related method claims should comprise more than the mere identification or comparison of sequences and also include "transformative" steps such as obtaining or processing a human sample, extracting or purifying DNA or sequencing the DNA, etc.

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[1] The first decision was discussed in prior Bulletin *Isolated Human DNA Molecules are Patent Eligible, Cancer Screening Methods are Not*. Current decision: *Association for Molecular Pathology and ACLU v. USPTO and Myriad Genetics Fed. Cir.* (PDF), No. 2010-1406, August 16, 2012.

[2] Please refer to our Bulletinhttp://www.fasken.com/en/publications/detail.aspx?publication=6009 *U.S. Supreme Court Raises the Patent-Eligibility Bar for Diagnostic Methods* for details about the decision of the Supreme Court in *Mayo v. rometheus.*

FASKEN MARTINEAU
www.fasken.com

Contacts

VANCOUVER

Roger A.C. Kuypers
+1 604 631 4880
rkuypers@fasken.com

TORONTO

Timothy Squire
+1 416 868 3462
tsquire@fasken.com

MONTRÉAL

Lucie Dufour
+1 514 397 4321
ldufour@fasken.com

Serge Lapointe, Ph.D.
+1 514 397 5219
slapointe@fasken.com

LONDON

Paul Ranson
+44 20 7917 8624
pranson@fasken.com

PARIS

Christophe Fichet
+33 1 44 94 96 98
cfichet@fasken.com