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Federal Circuit Reaffirms the Patentability of Isolated DNA in Association for *Molecular Pathology v. Myriad*

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On August 16, 2012, the U.S. Court of Appeals for the Federal Circuit issued another split decision in *Association for Molecular Pathology v. Myriad Genetics*, No. 2010-1406 (*Myriad*). Each of the three categories of claims under review in *Myriad* revolved around the discovery that certain mutations in the *BRCA1* and *BRCA2* genes correlate with an increased risk of breast and ovarian cancers.

Myriad arose from an appeal of a decision of the United States District Court for the Southern District of New York holding that Myriad's patent claims to isolated *BRCA1* and *BRCA2* genes and to screening for potential cancer therapeutics via changes to growth rates of transformed cells were not patent-eligible under 35 U.S.C. § 101. In addition, Myriad's claims to methods of "analyzing" or "comparing" a patient's *BRCA* sequence for detecting the presence of cancer-predisposing mutations were also held by the District Court to be patent-ineligible. After the Federal Circuit's decision last year and a further appeal to the U.S. Supreme Court, the Supreme Court remanded the case back to the Federal Circuit for reconsideration in view of the Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* 132 S. Ct. 1289 (2012) (*Prometheus*). In *Prometheus*, the Court held that claims directed to a method of optimizing 6-thioguanine therapy for treating an immune-mediated gastrointestinal disorder were patent ineligible under 35 U.S.C. § 101.

After reconsideration in view of *Prometheus*, the Federal Circuit's opinion today in Myriad again reverses the District Court, finding that the isolated DNA claims and the claims to screening for potential cancer therapeutics are patent-eligible under 35 U.S.C. § 101. However, the Federal Circuit affirms the District Court's finding that method claims involving only "comparing" or "analyzing" DNA sequences constitute patent-ineligible subject matter.

The Federal Circuit's rationale in upholding patent eligibility is based on the fact that the claimed isolated DNA molecules were man-made and the product of human ingenuity. According to the majority, as compared to native DNA, isolated DNA molecules are distinct chemical entities. The Federal Circuit was not persuaded by the government's so-called "magic microscope" test, which stood for the proposition that isolated and unmodified genomic DNAs are patent-ineligible but cDNAs are patent-eligible (i.e., if an imaginary microscope could focus in on the claimed DNA molecule as it exists in the human body, the claim covers ineligible subject matter). Since simply visualizing a DNA molecule will not cleave and isolate it from its native environment, the Federal Circuit declined to make a distinction between different types of isolated DNA claims, whether limited to cDNAs or not. In addition, the Federal Circuit rejected the argument that because isolated DNAs retain the same nucleotide sequence as native DNAs, they do not have any "markedly different" characteristics. According to the Federal Circuit, isolated DNA molecules are distinct from their natural existence as portions of larger entities, and their informational content is irrelevant to that fact.

Finally, the majority distinguished the dissent's attempt to analogize isolated DNA claims to claims directed to "elemental lithium" extracted from nature, a leaf snapped from a tree, and a kidney removed from the human body.

With regard to the method claims for screening for potential cancer therapeutics, the parties agreed that the transformed host cells arose from human effort, i.e., they are not

natural products. Nonetheless, the Plaintiff challenged the claim based on the argument that comparing growth rates of two cell populations preempts a basic scientific principle, which is that a slower growth rate in the presence of a candidate compound suggests that the compound is a cancer therapeutic. The Federal Circuit rejected this argument by pointing out that "transformed" host cells are derived by altering the cells with a foreign gene with enhanced function and utility. As such, the majority found that the claim was patent-eligible for including more than an abstract mental step of "comparing" the growth rate of two host cells.

Finally, claims to "comparing" or "analyzing" DNA sequences where held patent-ineligible, as encompassing only abstract mental processes. The Federal Circuit found these method claims to be indistinguishable from the claims the Supreme Court found invalid under 35 U.S.C. § 101 in *Prometheus*.

Myriad sustains the validity of a large number of patents directed to isolated DNA molecules, but calls into question patents merely claiming correlations and comparisons. Moreover, according to the Supreme Court in *Prometheus*, claims directed to conventional or known "pre- or post-solution activity," without more, may also be problematic.

For issued patents with potentially problematic claims under *Prometheus* and today's decision, patentees should consider pursuing claims directed to more clearly patent-eligible subject matter in a continuation or divisional application. Where an issued patent includes problematic claims but no applications in the same patent family are pending, patentees should consider the pros and cons of filing a reissue application.

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