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Federal Circuit Holds that "Isolated DNA Molecules" Are Patentable Subject Matter and Method Claims Merely "Comparing" or "Analyzing" Are Not

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The Federal Circuit issued its much-anticipated decision in *The Association for Molecular Pathology v. United States Patent and Trademark Office* on July 29, 2011. The case concerns Myriad Genetics, Inc. and its patents covering two “isolated” human genes, BRCA1 and BRCA2.

In the 55-page opinion, written by Judge Lourie, the Federal Circuit held that composition claims covering two isolated human genes are patentable subject matter but method claims devoted to methods of "analyzing" or "comparing" a patient's isolated DNA sequence with the "normal" sequence are not patentable subject matter. The challenged composition claims cover isolated genes BRCA1 and BRCA2 (collectively, "BRCA1/2" or "BRCA") and certain alterations, or mutations, in these genes associated with a predisposition to breast and ovarian cancers. Representative composition claims include Claims 1, 2 and 5 of U.S. Patent No. 5,747,282 (the "'282 patent") and representative method claims include claim 1 of United States Patent No. 5,709,999 (the "'999 patent"). All but one of the challenged method claims cover methods of "analyzing" or "comparing" a patient's BRCA sequence with the normal sequence to identify the presence of cancer-predisposing mutations. The one exception is Claim 20 of the '282 patent.

The crux of the Court's finding of patent eligibility was based on its reading of the Supreme Court's holding in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). In particular, relying on *Chakrabarty*, the Court held that "the distinction between a product of nature

and a human-made invention for purposes of § 101 turns on a change in the claim composition's identity compared with what exists in nature." Based on that distinction, the Court held that the challenged composition claims are "drawn to patentable subject matter because the claims cover molecules that are markedly different-have a distinctive chemical identity and nature-from molecules that exist in nature." The Court focused on the fact that the claimed isolated DNAs exist in a distinctive chemical form-as distinctive chemical molecules-from DNAs in the human body, i.e., native DNA. "BRCA1 and BRCA2 in their isolated state are not the same molecules as DNA as it exists in the body; human intervention in cleaving or synthesizing a portion of a native chromosomal DNA imparts on that isolated DNA a distinctive chemical identity from that possessed by native DNA."[1] The Court noted that "it is the difference between knowledge of nature and reducing a portion of nature to concrete form, the latter activity being what the patent laws seek to encourage and protect."

In focusing on the structural chemical differences, the Court ignored the structural chemical similarities (i.e., the information content contained in isolated and native DNA's nucleotide sequence) and the importance of those similarities to the invention as a whole and its utility. Instead, in criticizing the lower court's focus on the similarities between native DNA and isolated DNA, the Court held that "it is the distinctive nature of DNA molecules as isolated compositions of matter that determines their patent eligibility rather than their physiological use or benefit…. [T]heir informational content is irrelevant to that fact." The Court was also troubled by what it viewed as the lower court's "categorical exclusion of isolated DNA molecules" from patent eligibility, concluding that categorical exclusions are to be left to the legislature and not the courts. The Court also deferred to the PTO's long standing practice of granting patents to isolated DNA molecules and was concerned with a disruption that may be caused to the expectations of the "inventing community" if the Court abruptly held that isolated DNA molecules were no longer patentable subject matter.

In contrast, with respect to the method claims, the Court held that the method claims devoted to "analyzing" or "comparing" two gene sequences fall outside the scope of § 101 because they "recite nothing more than the abstract mental steps necessary to compare two different nucleotide sequences." The Court, relying on the Supreme Court's *Bilski* decision, held that limiting the comparison to particular genes (i.e., BRCA genes) or particular alterations "fails to render the claimed process patent eligible."

("limiting an abstract idea to one field of use…did not make the concept patentable.") Finding no support in the claim language or the specification, the Court rejected Myriad's attempt to read into the terms "comparing" and "analyzing" the additional, transformative steps of (1) extracting DNA from a human sample and (2) sequencing the BRCA DNA molecule. The Court distinguished the method claims at issue in *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347 (Fed. Cir. 2010), on the grounds that the *Prometheus* "administrating" step was not only transformative but the "determining" step "was both transformative and central to the purpose of the claims." ("the metabolite levels could not be determined by mere inspection, the determining step necessarily required a transformation….") In contrast, the Court held, comparison between two sequences in the Myriad claims "can be accomplished by mere inspection alone."

It is doubtful that this is the last word on whether isolated DNA molecules are patent eligible since it is likely that at least Appellees will request rehearing en banc at the Federal Circuit and/or petition for certiorari to the Supreme Court.

Authored by:

Jennifer A. Trusso
(714) 424-8294
JTrusso@sheppardmullin.com

[1] "Native DNA exists in the body as one of forty-six large, contiguous DNA molecules. Each DNA molecule is itself an integral part of a larger structural complex, a chromosome. In each chromosome, the DNA molecule is packaged around histone proteins in a structure called chromatin, which in turn is packaged into the chromosomal structure."