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## District Court Holds Gene Sequences Not Patentable Subject Matter

On March 29, 2010, in the highly publicized and closely watched case of *Association for Molecular Pathology, et al v. U. S. Patent and Trademark Office, et al.* (real parties in interest patent holders Myriad Genetics and the University of Utah Research Foundation), the District Court in the Southern District of New York granted summary judgment in favor of Plaintiffs and held that 15 claims in Myriad's 7 patents relating to human BRCA1 and BRCA2 genes (Breast Cancer Susceptibility genes 1 and 2) (collectively "BRCA1/2") are invalid because they claim non-patentable subject matter.

The case was one of first impression dealing with the PTO's practice of granting patents claiming DNA sequences so long as those sequences are "claimed in the form of 'isolated DNA.'" (Emphasis added.) The PTO's practice was "premised on the view that DNA should be treated no differently from any other chemical compound, and that its purification from the body ... renders it patentable by transforming it into something distinctly different in character." The Court disagreed and, in its 152-page opinion with extensive analysis, the Court held that isolated human genes and comparisons of their sequences to detect mutations, etc. are not patentable under Section 101 because the sequences are nothing more than products of nature and, the claimed comparisons are "abstract mental processes." The Court went into painstaking detail to address the interplay between molecular biology and the fundamental principles of patent law. The Court concluded that DNA's existence in an "isolated" form does not alter its fundamental quality as it exists in the body or the information it encodes.

The Court held that "patentable subject matter must be 'markedly different' from a product of nature ... products of nature do not constitute patentable subject matter absent a change that results in the creation of a fundamentally new product ... 'purification' of a natural compound, without more, is insufficient to render a product of nature patentable." (Emphasis added.) As correctly noted by the Court, "genes and the information represented by human gene sequences are products of nature universally present in each individual, and the information content of a human gene sequences is fixed. While many inventive steps may be necessary to allow scientists to extract and read a gene sequences, it is undisputed that the ordering of the nucleotides is determined by nature." Hence, the Court's decision hinged on whether isolated DNA sequences are "markedly different" from DNA in its native form.

The Court held that "in light of DNA's unique qualities as a physical embodiment of information, none of the structural and functional differences cited by Myriad between native BRCA1/2 DNA and the isolated BRCA1/2 DNA claimed in the patents-in-suit render the claimed DNA 'markedly different.'" This conclusion was "driven by the overriding importance of DNA's nucleotide sequence to both its natural biological function as well as the utility associated with DNA in its isolated form. The preservation of this defining characteristic of

DNA in its native and isolated forms mandates the conclusion that the challenged composition claims are directed to unpatentable products of nature.” Critical to the Court’s analysis was that “the entire premise behind Myriad’s genetic testing is that the claimed isolated DNA retains, in all relevant respects, the identical nucleotide sequence found in native DNA ....” The Court noted that “were the isolated BRCA 1/2 sequences different in any significant way, the entire point of their use – the production of BRCA 1/2 proteins – would be undermined.” The ability to use isolated DNA for the various purposes cited by Myriad did not, according to the Court, “establish the existence of differences ‘in kind’ between native and isolated DNA that would establish the kind of subject matter patentability of what is otherwise a product of nature.”

With respect to Myriad's comparison claims, the Court noted that “the claimed process is not limited to any particular method of analysis and does not specify any further action beyond the act of ‘analyzing.’” Instead, a number of Myriad’s patent claims were “directed to ‘comparing’ two gene sequences to see if any differences exist and [did] not specify any limitations on the method of comparison.” However, simply specifying limitations on a method of comparison would not have been enough. The Court cautioned that “even if the challenged method claims were read to include the transformations associated with isolating and sequencing human DNA, these transformations would constitute no more than ‘data-gathering step[s]’ that are ‘not central to the purpose of the claimed process.’ Consequently, even if the method claims-in-suit were construed to include the physical transformations associated with isolating and sequencing DNA, they would still fail the ‘machine or transformation’ test under §101 for subject matter patentability.”

In light of the implications of this decision and the parties involved, this case will be appealed to the Federal Circuit and quite possibly could find its way to the United States Supreme Court. The numerous amicus briefs filed at the district court level will undoubtedly increase at the appellate level. Stay tuned for further developments.

Authored By:

[Jennifer A. Trusso](#)

(714) 424-8294

[JTrusso@sheppardmullin.com](mailto:JTrusso@sheppardmullin.com)