Federal Circuit Decision on Patent Eligibility of Isolated DNA

The Federal Circuit further delineated the boundaries of the judicially created exception to 35 U.S.C. § 101 in its decision in *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.* One of the issues before the Court was whether isolated DNA molecules are patent eligible. Myriad Genetics, Inc. ("Myriad") owns patents claiming isolated *BRCA*1/2 genes and their uses. Plaintiffs, comprised of breast cancer researchers and patients, challenged the patent eligibility of isolated DNA molecules, contending that they are a "products of nature." The Court concluded that isolated DNA molecules are indeed patent eligible because they are "markedly different" from native DNA.

Judge Lourie, writing for the majority, stated that "[t]he distinction, therefore, between a product of nature and a human-made invention for purposes of § 101 turns on a change in the claimed composition's identity compared with what exists in nature."

According to the Court, the issue was whether the claimed isolated DNAs are distinctive chemical molecules different from DNA molecules in the human body, *i.e.*, native DNA. In its analysis, the Court focused on the structural differences between native DNA molecules and isolated DNA molecules. The Court determined that isolated DNA molecules have a distinctive chemical identity and nature compared to that of native DNA, whether the isolated molecule is a cleaved portion of native chromosomal DNA or synthesized. One of the examples used by the Court to illustrate this distinction was *BRCA*1. The native *BRCA*1 gene is on chromosome 17, which has around 80 million nucleotides. The claimed isolated *BRCA*1 gene is around 80,000 nucleotides, and without the introns, it is around 5,500. The claimed molecules' smaller molecular size distinguishes them from the molecules occurring in nature.

The Court also emphasized that patent eligibility for isolated DNA is not because isolated DNA has been purified. The distinctive molecular structure of isolated DNA molecules makes them patent eligible. Purification of a composition from a physical mixture found in nature does not give the composition a distinctive chemical identity. In nature, genes are covalently bonded within the chromosome, so purification is not enough to "isolate" them. "Although isolated DNA must be removed from its native cellular and chromosomal environment, it has also been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body."

In its analysis, the Court also pointed to the long-standing practice of the Patent and Trademark Office of issuing patents to isolated DNA molecules. The Court stated that if the law is to change to make isolated DNA patent ineligible under § 101, the change should come from Congress, not the courts.

The Court also analyzed the patent eligibility of the method claims at issue. The Court concluded that the method claims directed to "analyzing" or "comparing" were abstract mental steps, and thus patent ineligible, whereas the method claim directed to screening potential cancer therapeutics encompassed transformative steps, and thus was patent eligible. According to the Court, "comparing" or "analyzing" is a series of abstract mental steps that only require looking at nucleotides and determining whether they are the same or different. On the other hand, the Court held that the method claim directed to screening potential cancer therapeutics encompassed transformative steps that are central to the claim. The objective

of the claim was to evaluate a compound's potential as a cancer therapeutic, and growing cells and determining growth rate are central to reaching the objective.

In a partially concurring opinion, Judge Moore expressed that the reasoning should include a determination as to whether the differences between the isolated DNA and the native DNA "impart a new utility which makes the molecules markedly different from nature." However, Judge Moore did not rely on this line of reasoning to support her conclusion that longer strands of DNA that encompass most or all of the entire gene should be patent eligible. She looked to the substantial history of patenting isolated DNA molecules, and deferred to Congress to change the law. Judge Bryson concurred with the Court regarding the patentability of cDNA, but not Myriad's gene claims or gene fragments. In disagreeing with the majority, he dismissed the distinction the majority drew between chemical and physical extraction. Judge Bryson concluded that "extracting a gene is akin to snapping a leaf from a tree."

The practical import of the Federal Circuit's *Myriad* decision is that the majority of the Court declined to find that isolated DNA molecules are patent ineligible since they are chemically distinct, and thus are "markedly different" from DNA molecules found in nature.

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