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In *Assoc. For Molecular Pathology*, The Federal Circuit Holds Isolated DNA Sequences Remain Patent-Eligible Subject Matter

On July 29, 2011, the Court of Appeals for the Federal Circuit held that isolated DNA molecules are indeed eligible for patent protection under 35 U.S.C. § 101, reversing a lower court's ruling that isolated DNA does not alter the "fundamental quality" of DNA. *Assoc. for Molecular Pathology v. USPTO*, No. 2010-1406 (Fed. Cir. July 29, 2011).

The three-judge panel also held that method claims directed to "analyzing" and "comparing" DNA sequences cover mental processes and thus are not patent-eligible subject matter. Further, the panel held that since at least one of the plaintiffs in the case had standing to bring the suit, the district court did have declaratory judgment jurisdiction.

The Southern District of New York

The plaintiffs brought suit against Myriad Genetics, Inc. and the Directors of the University of Utah Research Foundation ("Myriad") seeking a declaration that certain composition and method claims from patents assigned to Myriad are drawn to patent-ineligible subject matter under 35 U.S.C. § 101.

Specifically, the composition claims cover isolated human genes called *BRCA1* and *BRCA2*, as well as common mutations in these genes which are associated with a predisposition to breast and ovarian cancer. The method claims cover methods of analyzing a subject's *BRCA1* and/or *BRCA2* sequence or comparing it to the normal sequence in order to identify the presence of the mutations.

After the plaintiffs initiated the suit, the defendant argued that they in fact did not have standing to bring the action, and moved for summary judgment dismissing the complaint. The plaintiffs joined in the action ranged from scientists researching cancer to doctors and patients involved or interested in offering or undergoing breast cancer testing. Since the plaintiffs were merely third parties, the defendants argued, there was no actual "case or controversy" at issue. In a 2009 decision, however, J. Sweet of the Southern District of New York held that there existed a "sufficiently real and immediate injury or threat of future injury" resulting from the fact that, among several other factors, Myriad had previously initiated litigation to enforce the patents-in-suit. Accordingly, at least some of the plaintiffs had standing to bring the action.

On the issue of patent-eligible subject matter, J. Sweet held on March 29, 2010 that since isolating DNA does not alter the "fundamental quality" of DNA – namely, that DNA is the physical embodiment of biological information – then patents directed to isolated DNA "containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 U.S.C. § 101." J. Sweet also held that since the steps of "analyzing" or "comparing" a patient's DNA sequence to isolated DNA sequences do not involve any transformation (i.e., do not require the isolation or sequencing of a DNA sample), they are merely abstract mental processes.

J. Sweet therefore granted the plaintiff's motion for summary judgment, and Myriad appealed the case to the Federal Circuit.

The Federal Circuit

The Plaintiff's Standing

On the issue of the plaintiff's standing, the Federal Circuit applied the "all-the-circumstances" test set forth by the Supreme Court to hold that at least one plaintiff, Dr. Harry Ostrer, had established standing because Myriad had demanded he pay a royalty under its patents for *BRCA* testing he had performed. Although ten years had passed since the demand, the court found that "the relevant circumstances surrounding Myriad's assertion of its patent rights have not changed despite the passage of time," and that neither Myriad nor Dr. Ostrer has altered their respective position since "Myriad's enforcement efforts eliminated all competition." Accordingly, Dr. Ostrer had standing to bring the suit.

Unfortunately, the court did not address a July 27, 2011 letter from Myriad's lawyers noting that Dr. Ostrer is no longer affiliated with the university where he conducted his genetic research.

Patentable Subject Matter

On the issue of "isolated" DNA molecules, the court focused on the physical differences between the *BRCA* genes in the human body and the isolated *BRCA* sequences purified for analysis. Rather than simply a purified *BRCA* sequence obtained from a biological sample, the claimed composition was often just a fragment of these genes and eliminated several extraneous insertions found in the genes in their native state. Accordingly, the court, noting that "the PTO has issued patents directed to DNA molecules for almost thirty years," reversed the district court's decision and held that "isolated" DNA molecules cover patent-ineligible products of nature under § 101.

Regarding the method claims, the panel concluded that Myriad's claims to "comparing" or "analyzing" two gene sequences fall outside the scope of § 101 because they claim only abstract mental processes. The panel asserted that an individual could complete the steps simply by aligning two sequences and comparing them, nucleotide-by-nucleotide. The panel declined to read into the claims the potentially transformative requirement that the comparison and analysis steps required that DNA be extracted from a biological sample and subsequently sequenced, as was argued by Myriad, since these steps were not included in the claims.

The Concurrences

In a concurring opinion, Judge Kimberly Moore noted that while an isolated DNA molecule is "a distinct molecule with different physical characteristics than the naturally occurring polymer containing the corresponding sequence in nature," it is also important to consider whether these differences impart a new utility which makes the molecules markedly different from nature. In Judge Moore's opinion, using isolated DNA molecules for diagnostic genetic testing represented a new utility as compared to nature, and thus constituted patent-eligible subject matter.

In the second concurrence, Judge William Bryson agreed with the majority as to the issue of standing and the patent-eligibility of the method claims, but disagreed with the majority's holding as to the patent-eligibility of isolated DNA molecules. In his view, isolated genes are not materially different from native genes. Although purifying a mineral from nature may result in some physical or chemical changes to the natural substance, he argued, these changes do not make the extracted mineral patentable.

The Future

It is unlikely that the Federal Circuit's recent decision will remain the final word in this case. In light of the disparate opinions among the three-member panel and the significance of this decision on the biotechnology sector of the U.S. economy, for example, the parties are likely to request an *en banc* review by the entire Federal Circuit or petition for review by the Supreme Court; a request that will likely draw a significant group of amici on both sides of the issues involved.

If you have any questions, please contact George R. McGuire, Chair, Intellectual Property Practice Group, at 315.218.8515 or gmcguire@bsk.com.

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