ALERTS AND UPDATES

Federal Circuit Reverses N.Y. District Court: Claims to "Isolated" DNA Are Eligible for Patent Protection

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On July 29, 2011, the U.S. Court of Appeals for the Federal Circuit reversed in part the U.S. District Court for the Southern District of New York's ruling in *Association for Molecular Pathology v. USPTO, Myriad Genetics, et al.*[1] *("Myriad")* and held that claims to "isolated" DNA molecules were patent-eligible. The district court ruling had unsettled the biotechnology industry by invalidating certain patent claims directed to the genes *BRCA1* and *BRCA2*, which, if mutated, increase susceptibility to breast cancer, and to methods of diagnosis using BRCA sequences. The plaintiffs, including the ACLU, a number of medical associations and doctors, and the Public Patent Foundation, challenged Myriad's patents as invalid and unconstitutional, and the district court granted their motion for summary judgment. The district court reasoned that isolated DNA was patent-ineligible because it is a product of nature and the claims to diagnostic methods were ineligible because they constituted nothing more than natural phenomena. Myriad appealed.

On appeal, the Federal Circuit applied the same test as the district court: Isolated DNA would be considered patent-eligible if it was "markedly different" from naturally occurring DNA. However, the Federal Circuit focused on chemical properties rather than the genetic information properties of the "isolated" DNA. Because the chemical properties of the isolated DNA were markedly different when compared to its natural context, the district court's ruling was overturned with respect to the claims to isolated DNA. The Federal Circuit also reversed the district court's decision that Myriad's claim to screening potential cancer therapeutics via changes in cell growth rates was directed to a patent-ineligible scientific principle. However, the Federal Circuit affirmed the district court's finding that method claims reciting only "comparing" or "analyzing" DNA sequences are patent-ineligible because those claims do not include transformative steps and cover only patent-ineligible, abstract mental steps.

Not surprisingly, the Federal Circuit reviewed U.S. Supreme Court decisions such as *Chakrabarty* and *Funk Brothers*, in which the Court faced questions of patent eligibility for genetically modified bacteria and mixtures of plant seeds, respectively. An apparent distinction was developed between compositions that, even if combined or altered in a manner not found in nature, nevertheless have characteristics similar to the compositions as found in nature and, on the other hand, compositions to which human intervention has imparted "markedly different," or "distinctive," characteristics.[2] Although Myriad contended that the district court "erroneously divined" the markedly different legal standard from *Chakrabarty*, the Federal Circuit also adopted the markedly different test in its analysis, declining to adopt *Myriad*'s proffered legal standard as "a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'"

As noted, the Federal Circuit looked to the chemical identity and nature of isolated DNA, and expressed disapproval with the district court for looking not at whether isolated DNAs are markedly different from naturally occurring DNAs, but instead for looking at one similarity. The Federal Circuit noted that it is the distinctive nature of DNA molecules as isolated compositions of matter that determines their patent eligibility—not the physiological use or benefit of the isolated DNA. Accordingly, the Federal Circuit found that isolated DNA molecules that have been synthesized, or removed from their native cellular and chromosomal environment by breaking covalent chemical bonds to produce a molecule a fraction of the size of the naturally occurring DNA from which it was obtained, are markedly different from DNA molecules that occur in nature.

To further support its holding, the Federal Circuit cited the long-standing practice of the U.S. Patent and Trademark Office. Numerous patents directed to isolated or purified DNA sequences have been granted, and the Supreme Court has repeatedly stated that changes to long-standing practice should come from Congress, not the courts.

With respect to the method claims, the Federal Circuit affirmed the district court's decision that the claims directed to comparing or analyzing DNA sequences are patent-ineligible because those claims include no transformative steps; the steps were abstract or purely mental.

If appealed to the U.S. Supreme Court, it will be interesting to see whether the Court will restrict its comments to the subject matter Myriad claimed or make broader comments likely to impact the patent-eligibility of other biologics, such as proteins and stem cells. The *Prometheus* case, for which the Supreme Court has granted a petition for certiorari involves only diagnostic method claims, and is therefore unlikely to clarify the standard for determining patent-eligibility for biological compositions (*Mayo Collaborative Services, dba Mayo Medical Laboratories, et al., Petitioners v. Prometheus Laboratories, Inc.*).

The Federal Circuit clearly focused on the defining characteristics of naturally occurring DNA, against which the claimed DNA was compared to determine if it was markedly different. Further, the Federal Circuit focused on chemical properties of DNA, as it did in *Regents of University of California v. Eli Lilly and Co.*, which was also authored by Judge Lourie. In *Lilly*, the Federal Circuit characterized DNA as a type of chemical compound, which could be adequately described with respect to 35 U.S.C. § 112 only by reciting the sequence of a representative number of DNAs falling within the claimed genus or by reciting structural features common to a substantial portion of the DNA molecules within that genus.

The Federal Circuit appeared careful to distinguish isolated DNA from purified DNA. The majority noted that purification simply involves removal of a substance from surrounding impurities without changing the substance itself. In contrast, isolation, as applied to DNA, requires chemical manipulation, and it is that chemical manipulation - cleavage of covalent bonds - that produces a molecule that is markedly different from one found in nature. The isolated DNA that results from the breakage of covalent bonds is not merely a purified form of a "natural material," but is in fact, a "distinct chemical entity." The Federal Circuit's distinction may leave open the door for patent eligibility challenges to claims to "purified DNA," and nucleic acids small enough to be "isolated" intact (such as viral nucleic acids).

In *Myriad*, Judge Moore concurred, but wrote separately on the patent-eligibility of isolated DNA claims, indicating that short, isolated DNA molecules in diagnostic genetic testing were clearly an enlargement of the range of utility demonstrated by naturally occurring DNAs, which did not "serve the ends nature originally provided," *Funk Bros.*, 333 U.S. at 131; and therefore had "markedly different properties which are directly responsible for their new and significant utility," *Chakrabarty*, 447 U.S. at 309–10. However, Judge Moore also noted that although she might conclude that an isolated DNA sequence including most or all of a gene was not patentable subject matter if writing on a clean slate, she believed that deference to Congress and settled expectations of patentees tipped the scale in favor of patentability.

Judge Bryson concurred with the portions of this court's judgment directed to the patentability of claims to cDNA and the ruling on method claims, but dissented from the court's holding that Myriad's BRCA gene claims and its claims to gene fragments were patent-eligible. Judge Bryson also expressed concern that those claims were not directed to patentable subject matter, and that if upheld, the majority's decision would potentially have broad consequences, such as preempting methods for whole-genome sequencing.

The parties used many colorful analogies in the opinion and in the amicus briefs that were filed in this case. Both Judge Lourie, writing for the majority, and Judge Moore, in her concurring opinion, took issue with the so-called "magic microscope" guidelines for patentability of DNA molecules presented by the DOJ. The DOJ's brief reasoned that if one could look inside a cell using a "magic microscope" and see the claimed substance, then that substance should not be patent-eligible. Consistent with his emphasis on isolated DNA as a chemical entity, Judge Lourie faulted the analogy for failing to take into account the importance of chemical manipulations. He noted that visualization alone cannot isolate a molecule and that isolation requires human intervention. Judge Moore also disagreed with the DOJ's view that the test would have limited impact on DNA claims. She noted that such a mechanical test would also call into question the patent-eligibility of fragments of naturally occurring proteins, since these too could be visualized inside a cell.

For Further Information

If you have any questions about this *Alert*, please contact Lewis F. Gould, Jr.; Vicki G. Norton, Ph.D.; or Gretchen L. Temeles, Ph.D.; any member of the Intellectual Property Practice Group; or the attorney in the firm with whom you are regularly in contact.

Notes

1. *Ass'n for Molecular Pathology v. United States PTO*, 2011 U.S. App. LEXIS 15649 (Fed. Cir. July 29, 2011).
2. See *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980); *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887); see also *Am. Fruit Growers v. Brogdex Co.*, 283 U.S. 1, 11 (1931).