

ALERTS AND UPDATES

District Court Invalidates Claims to Isolated DNA Molecules and Methods of Their Use; Finds Subject Matter Ineligible for Patent Protection

March 31, 2010

On March 29, 2010, in a ruling that may have a tremendous impact on the biotechnology community, the U.S. District Court for the Southern District of New York held that patent claims related to the *BRAC1* and *BRAC2* genes, as well as claims to methods of using nucleotide sequences within those genes to assess susceptibility to cancer, were invalid, in *Association for Molecular Pathology v. USPTO, Myriad Genetics, et al. (Myriad)*. The patent claims were challenged by the ACLU and the Public Patent Foundation, whose motion for summary judgment was granted on the basis that the isolated DNA was a product of nature and the methods constituted nothing more than a mental process, neither of which are eligible for patent protection.

To analyze whether the claims covering DNA were valid—a representative claim was directed to "isolated DNA coding for a BRCA1 polypeptide"—the *Myriad* court applied a "markedly different" test. Relying on language from *Diamond v. Chakrabarty*,¹ as well as the holdings in *American Fruit Growers*,² and *Funk Brothers*,³ the *Myriad* court asked whether the claimed, isolated DNA possessed markedly different characteristics than the same DNA *in vivo*. The court noted that DNA possesses characteristics that are distinct from other chemical compounds because DNA encodes protein and is therefore "a physical embodiment of information." Despite the fact that DNA may have to be isolated in order to be used, the court found that "the purification of native DNA does not alter its essential characteristic—its nucleotide sequence—that is defined by nature and central to both its biological function within the cell and its utility as a research tool in the lab." Accordingly, the court concluded that the isolated DNA claimed was not markedly different from native DNA as it exists in nature and, therefore, constituted unpatentable subject matter under 35 U.S.C. § 101.

Myriad asserted that the motion for summary judgment should be dismissed in deference to the U.S. Patent and Trademark Office (USPTO), which has awarded numerous patents directed to isolated or purified DNA sequences under the guidelines it adopted in 2001 to resolve controversies over the patentability of gene sequences discovered in the Human Genome project.⁴ *Myriad* also relied on *Parke-Davis*, as establishing that purification of a natural product necessarily renders it patentable.⁵ The *Myriad* court, however, determined it owed no deference to the USPTO and that reliance on *Parke-Davis* was misplaced because the question there was one of novelty, not of patentable subject matter. The court ruled that the statement upon which *Myriad* had focused—"even if it [adrenaline] were merely an extracted product without change, there is no rule that such products are not patentable"—was *dicta* in *Parke-Davis*.

Other invalidated claims were directed to methods of "analyzing" a *BRCA1* sequence to determine whether it includes mutations associated with an increased risk of certain cancers. The *Myriad* court used the "machine or transformation" test set out in *Bilski*, under which a claimed process is eligible for patent protection where it is tied to a particular machine or apparatus or transforms a particular article into a different state or thing.⁶ Upon applying the "machine or transformation" test, the *Myriad* court found that there was nothing in the challenged method claims to limit their scope to an application of a principle and thereby exclude claiming only the principle itself. The method claims were considered directed to only the abstract mental processes of "comparing" or "analyzing" gene sequences.

The *Myriad* court discussed *Prometheus*, where the Federal Circuit held that methods of optimizing therapeutic efficacy were transformative and therefore eligible for patent protection where those methods required a step of determining the level of a metabolite in a sample obtained from a patient.⁷ In that case, the act of determining metabolite levels was construed to include extracting and measuring the metabolite, and that extraction and measurement was found to be transformative. In *Myriad*, however, the court pointed to the claim terms "analyzing" and "comparing," and argued that these terms could not be read to include a physical transformation associated with obtaining the DNA from a subject or a tissue sample. In addition, the court held that even if the challenged method claims were construed to include isolating and sequencing the DNA, this would constitute no more than data-gathering, which is not central to the purpose of the claim.

The anticipated U.S. Supreme Court decision in *Bilski*, which involves business method claims, is unlikely to address the standard for determining whether a claimed composition is patent-ineligible as a product of nature. Similarly, the *Prometheus* case, which is awaiting a decision on a petition for *certiorari*, involves only diagnostic method claims. If appealed, *Myriad* would require the Federal Circuit to address the standard for determining whether an isolated DNA is patent-eligible or a product of nature and might also ultimately impact the patent-eligibility of other purified biochemical products.

The *Myriad* decision is an interesting development in the controversy over whether patents covering biological molecules promote or impede research and commercial development in the art. As part of that debate, the February 5, 2010, report by the Secretary of Health and Human Services' (HHS) Advisory Committee on Genetics, Health and Society (SACGHS), concluded earlier this year that the Secretary of HHS should work with the Secretary of Commerce to advance an exemption from liability for infringement of patent claims on genes for anyone using those genes in research or for patient care purposes.

For Further Information

If you have any questions about this *Alert*, please contact [Vicki G. Norton, Ph.D.](#), [Lee Crews, 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. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
2. *American Fruit Growers, Inc. v. Brodgex Co.*, 283 U.S. 1 (1931).
3. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).
4. See Fed. Reg. 66(4) 1092-1099 (2001).
5. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F.2d 95 (S.D.N.Y. 1911).
6. *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008).
7. *Prometheus Laboratories Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009).