U.S. Supreme Court Rules That Isolated Human Genes Are Unpatentable

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Summary

On June 13, 2013 in a much-anticipated decision, the U.S. Supreme Court in Association for Molecular Pathology v. Myriad Genetics, 569 U.S. ___ (2013) unanimously held that claims for isolated DNA sequences are not patent eligible subject matter under 35 U.S.C. §101, but that claims for complementary DNA (cDNA) sequences are patent eligible subject matter.

The Supreme Court held that naturally occurring DNA is a product of nature and not patent eligible merely because it has been isolated. In contrast, cDNA is patent eligible because it has been synthetically created and is not naturally occurring.

Myriad History

The long-standing battle over gene patents began in May 2009 when The Association for Molecular Pathology along with other medical associations, researchers, and patients sued Myriad and the United States Patent and Trademark Office (USPTO) to challenge several patents claiming human genes.

The challenged patents, licensed to Myriad, claim isolated human BRCA1 and BRCA2 genes and methods of using these genes. More specifically, the Myriad claims fall into three main categories: 1) composition claims directed to cDNA and isolated DNA molecules coding for all or a portion of either of the BRCA genes; 2) method claims for comparing or analyzing DNA sequences to detect mutations in the BRCA genes; and 3) method claims for screening potential cancer therapeutics.

Mutations in the BRCA genes correlate with increased risk of breast and ovarian cancer. Thus, detection of BRCA mutations is critical to the diagnosis and treatment of these cancers. Myriad provides a diagnostic test, BRACAnalysis®, which detects the presence of a BRCA1 or BRCA2 gene mutation.

1. The District Court Decision

On March 29, 2010, Judge Sweet of the U.S. District Court of the Southern District of New York declared all of the contested claims invalid. Judge Sweet reasoned that "DNA's existence in an 'isolated' form alters neither this fundamental quality of DNA as exists in the body nor the information it encodes. Therefore, the patents at issue directed to 'isolated DNA' containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable under 35 U.S.C. §101." With respect to the method claims, Judge Sweet, applying In re Bilski 545 F.3d 943 (Fed. Cir. 2008), stated that a) methods of comparing DNA sequences are merely abstract mental processes and therefore not patent eligible; and b) drug screening claims are unpatentable as merely encompassing a “basic scientific principle”. Myriad appealed to U.S. Court of Appeals for the Federal Circuit.
2. The CAFC Decision

On July 29, 2011, in a first decision, a CAFC panel (Judges Lourie, Moore and Bryson) reversed the District Court in part and affirmed in part. Specifically, the CAFC disagreed with the District Court holding that isolated DNA sequences, cDNA sequences (exon-only DNA sequences artificially synthesized from mRNA templates) and methods of screening cancer therapeutics are patent eligible. However, the CAFC agreed with the District Court holding that method claims for comparing DNA sequences to detect mutations are not patent eligible under §101.

Regarding the patent-eligibility of isolated DNA molecules, the CAFC described the legal framework for patent eligible subject matter in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) and *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), where the Supreme Court stated that the distinction made “between a product of nature and a human-made invention for the purposes of §101 turns on a change in the claimed composition’s identity compared with what exists in nature.”

In upholding the claims directed to isolated DNA, Judge Lourie reasoned that isolated DNA is “markedly different” because an isolated DNA molecule no longer contains the chemical bond that the naturally occurring gene has with other genetic materials. Judge Moore concurred in part but did not rely exclusively on Judge Lourie’s conclusion that chemically breaking covalent bonds was sufficient to render isolated DNA patent eligible. Judge Bryson concurred in part and dissented in part concluding that isolated DNA is not patent eligible. He emphasized that the breaking of chemical bonds was not dispositive. Instead, he relied on the fact that the “nucleotide sequences of the claimed molecules are the same as nucleotide sequences found in naturally occurring human genes.”

The CAFC panel unanimously agreed that patent claims related to cDNA were patent eligible. On August 16, 2012, the same CAFC panel reaffirmed that isolated DNA molecules are patent eligible subject matter. The court maintained the position that isolated DNA is markedly different and has a distinctive chemical structure and identity as compared to naturally occurring DNA. The court agreed unanimously that cDNA may be patented, since cDNA is a form of DNA that never occurs naturally.

3. The Supreme Court Decision

Justice Thomas delivered the unanimous opinion of the Court holding that extracted and isolated DNA from a human body is a product of nature and thus an exception to the statutory subject matter under 35 U.S.C. § 101. cDNA, in contrast, is synthetically created and thus not naturally occurring. Accordingly, cDNA is patent eligible. The ruling thus affirms in part and reverses in part the decision of the CAFC.

The Court noted that “patent protection strikes a delicate balance between creating ‘incentives that lead to creation, innovation, and discovery’ and ‘imped[ing] the flow of information that might permit, indeed spur, invention’.”

The Court acknowledged that “Myriad’s principal contribution was uncovering the precise location and genetic sequence of the *BRCA1* and *BRCA2* genes.” However, the Court also acknowledged that it was undisputed that “Myriad did not create or alter either the genetic information encoded in the *BRCA1* and *BRCA2* genes or the genetic structure of the DNA. It found an important and useful gene, but groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry.”

In addressing the CAFC’s decision, the Court noted that the central dispute among the panel members was whether the act of isolating DNA – separating a specific gene or sequence of nucleotides from the rest of the chromosome – is an inventive act that entitles the individual who first isolates it to a patent. In that regard, the Court stated that the “Myriad claims are not saved by the fact that isolating DNA from the human genome severs the chemical bonds that bind gene molecules together. The claims are not expressed in terms of chemical composition, nor do they rely on the chemical changes resulting from the isolation of a particular DNA section. Instead, they focus on the genetic information encoded in the *BRCA1* and *BRCA2* genes.” The Court went on to state that in this case “Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.”

In contrast, the Court held that “cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA.” The Court stated the creation of a cDNA sequence from mRNA results in an exons-only molecule
that is not naturally occurring. cDNA is not a product of nature so it is patent eligible under §101.

The Court was careful to note that the decision does not address method claims, hands-on new applications of knowledge about the BRCA1 and BRCA2 genes, or the patentability of DNA in which the order of naturally occurring nucleotide has been altered. With respect to altered DNA, the Court specifically stated that “scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of §101 to such endeavors.”

Justice Scalia provided a brief concurrence, where he did not join portions of the opinion regarding the underlying molecular biology.

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Endnotes

1 On the method claims, the CAFC applying Bilski v. Kappos, 130 S.Ct. 3218 (2010) held that claims directed to methods of comparing or analyzing DNA sequences to detect mutations merely amount to “abstract mental process of comparing two nucleotide sequences” and therefore were not patent eligible. In contrast, the court held that the method claims directed to screening for potential cancer therapeutics by measuring changes in cell growth rates, included two transformative steps, which render them patent eligible.

2 Following the CAFC decision, The Association for Molecular Pathology petitioned for a writ of certiorari to the Supreme Court. On March 26, 2012, the Supreme Court vacated the decision and remanded the case to the Federal Circuit for reconsideration in view of the Supreme Court’s decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S.Ct. 1289 (2012).

3 On the method claims, the court also reaffirmed that the method of screening drugs using genetically modified cells is patent eligible and unanimously supported its earlier decision that the methods of comparing DNA sequences to detect mutations is not patentable subject matter.

4 On September 25, 2012, the American Civil Liberties Union and the Public Patent Foundation requested certiorari to address the question “are human genes patentable?” and oral arguments were heard before the Supreme Court on April 15, 2013.