KIRKLAND **ALERT**

June 2013

U.S. Supreme Court *Myriad* Decision Strikes a Compromise on the Patentability of Human Genes

35. U.S.C. § 101 sets forth a threshold requirement for obtaining a patent in the United States: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent …." It is well settled that man-made inventions such as telegraphs, televisions and pharmaceutical compounds fall squarely under this rubric; abstract concepts such as $E=MC^2$ and other laws of nature do not. *Ass'n for Molecular Pathology et al. v. Myriad Genetics, Inc.* No. 12-398, slip op. (June 13, 2013) considered whether isolated portions of human DNA met the threshold definition for patentability under § 101. On June 13, 2013, the U.S. Supreme Court unanimously held that: (1) a naturally occurring DNA segment, though isolated in a laboratory, is a product of nature and not patent-eligible; and (2) cDNA is patent-eligible because it is not naturally occurring. The opinion, written by Justice Clarence Thomas, is sweeping, applying to both human and non-human forms of DNA.

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In the mid 1990s, respondent Myriad Genetics, Inc. ("Myriad") discovered the precise location and sequence of two human genes, BRCA1 and BRCA2, mutations of which substantially increase the risks of breast and ovarian cancer. This information enabled Myriad to develop medical tests useful for detecting BRCA1 and BRCA2 gene mutations, thereby assessing a patient's risk of developing cancer. Myriad obtained a number of patents on its discovery, including patents with claims directed to isolated strands of naturally occurring DNA sequences, synthetically created strands of DNA derived from naturally occurring DNA but excluding portions that do not code for amino acids (known as complementary DNA or "cDNA"), and various method claims.

Rather than license their patented diagnostic testing services to other laboratories, Myriad chose to perform exclusive testing for the BRCA genes, at a cost of about $3,000 per test. In order to remain the sole commercial provider of BRCA testing in the United States, Myriad enforced its patents against other would-be competitors.

The Association for Molecular Pathology ("AMP") is a not-for-profit scientific society dedicated to the advancement, practice and science of clinical molecular laboratory medicine based on the applications of genomics. Leading a myriad of other advocacy groups, doctors and medical patients, AMP filed a declaratory judgment action in the U.S. District Court for the Southern District of New York alleging invalidity of Myriad's BRCA patents under 35 U.S.C. § 101.

The complaint challenged fifteen specific claims in seven of Myriad's BRCA patents pertaining to isolated genes, diagnostic methods and methods for identifying drug

candidates. AMP alleged invalidity on the bases that the isolated genes were unpatentable products of nature, and that the method claims were mere thought processes seeking to patent a basic scientific principle. In defending its patents, Myriad argued, *inter alia*, that transformation of naturally occurring compounds into a purified form that does not exist in nature renders such isolated compounds patent-eligible. The district court disagreed, granting summary judgment of invalidity in favor of AMP on all claims. *Ass'n for Molecular Pathology v. United States Patent and Trademark Office, et al.*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

The Court reasoned that Myriad did not create anything; it merely uncovered the precise location and genetic sequence of the BRCA1 and BRCA2 genes within the chromosomes.

Myriad appealed to the Federal Circuit, which upheld the invalidity of the method claims but overturned the district's decision that isolated DNA and cDNA were patent-ineligible. The Supreme Court granted a petition for certiorari, vacated the judgment and remanded the case in light of *Mayo v. Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012).

On remand, the Federal Circuit again held that claims to isolated DNA and cDNA were patent-eligible. Each member of the panel wrote separately, with Judges Lourie and Moore concluding that isolated DNA was patent-eligible, and Judge Bryson concluding that it was not. 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. Judge Lourie concluded that the act of isolating DNA creates a nonnaturally occurring molecule; severing chemical bonds in the naturally occurring DNA to create isolated segments of DNA created new molecules with unique chemical compositions. Judge Moore agreed with Judge Lourie but also relied on the past practices of the Patent Office in granting such patents, and the reliance interests of existing patent holders. Judge Bryson, in contrast, found that the identical genetic structure of the isolated DNA segment from its corresponding natural form "dwarfs the significance of the structural differences between isolated DNA and naturally occurring DNA." All three judges, however, agreed that the synthetic nature of cDNA rendered it patent-eligible.

In the Court's 18-page opinion issued on June 13th, Justice Thomas overruled the Federal Circuit by holding that a naturally occurring DNA sequence is not patent-eligible. The Court reasoned that Myriad did not create anything; it merely uncovered the precise location and genetic sequence of the BRCA1 and BRCA2 genes within the chromosomes. While the discovery itself might be groundbreaking, innovative or even brilliant, the Court ruled that it is not patent-eligible if the genetic sequence remains unaltered. Without a creative component, discovery of a naturally occurring gene is insufficient to satisfy the demands of 35 U.S.C. § 101.

The Court rejected Myriad's argument that isolating the DNA from the human genome necessarily severed chemical bonds, thus creating a nonnaturally occurring molecule. Myriad's patent claims were not expressed in terms of chemical composition, nor did they rely on the chemical changes resulting from the isolation of the gene sequence. Rather, the claimed invention was the sequence itself, which occurs naturally. The Court also rejected Myriad's argument that the PTO's past practice of awarding gene patents was entitled to deference.

Unlike naturally occurring DNA sequences, the Court found cDNA to be patent-eligible. cDNA is synthesized in a laboratory to modify what is found in nature by removing nucleotides that do not code for amino acids ("introns"). The resulting strand of cDNA consists only of nucleotides that code for amino acids ("exons"). Though there may be "unusual and rare phenomenon that *might* randomly create a molecule similar to one created synthetically by a human," cDNA is not found in nature but is purely a product of human ingenuity, and thus is patent-eligible. Nevertheless, the Court left the door open for situations where cDNA may not be patent-eligible under § 101: if a very short strand of DNA naturally contained no introns, a corresponding cDNA strand "may be indistinguishable from natural DNA."

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While no method claims were at issue, the Court noted that had Myriad created an innovative method of manipulating the genes while searching for the BRCA1 and BRCA2 genes, "it could possibly have sought a method patent." The Court also noted that its opinion does not concern new applications of knowledge about the genes, nor does it consider the patentability of naturally occurring DNA whose nucleotides have been altered.

The Court's decision concerned isolated DNA and cDNA, but has the potential to impact patents to isolated polypeptides. The impact of the Court's ruling on other biotechnology areas will undoubtedly play out over time.

If you have any questions about the matters addressed in this *Kirkland Alert*, please contact the following Kirkland authors or your regular Kirkland contact.

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