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Supreme Court to Hear Case on Patentability of Human Genes

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—By Jen Uscher, special to the Reporter

A lawsuit that has been winding its way through the federal court system since 2009 is challenging the controversial practice of gene patenting. On April 15, the U.S. Supreme Court will hear arguments in Association for Molecular Pathology v. Myriad Genetics, Inc. The case focuses on patents held since the 1990s by the biotech firm Myriad Genetics and the University of Utah Research Foundation covering the BRCA1 and BRCA2 genes, which are linked to a greatly increased risk of both breast and ovarian cancer.

Myriad developed the blood test that can detect mutations in these genes and is the only company in the United States that offers it. The patents give Myriad exclusive right to conduct diagnostic tests on BRCA1 and BRCA2 in the United States.

The practice of gene patenting continues to fuel debate despite a process that has been in place for more than 30 years. The United States Patent and Trademark Office (USPTO) has granted patents for an estimated 3,000 to 5,000 genes. Universities, biotechnology companies, and other companies and organizations have patented about 20 percent of the genes in the human genome.

In 2009, the American Civil Liberties Union (ACLU) and a coalition of plaintiffs that included medical researchers, medical professional associations, and patients sued Myriad Genetics, the University of Utah Research Foundation, and the USPTO, charging that the patents on BRCA1 and BRCA2 are invalid and unconstitutional.

Judge Robert Sweet of the U.S. Federal District Court for the Southern District of New York ruled in favor of the plaintiffs in 2010, declaring that isolated DNA molecules are a product of nature and therefore cannot be patented. The U.S. Court of Appeals for the Federal Circuit (CAFC) heard Myriad's appeal in 2011 and ruled that isolated DNA can be patented, but some of Myriad's patents on methods of comparing gene sequences were invalid.

After ruling in a separate case—Mayo v. Prometheus—that patents on a method for analyzing a patient's response to a drug were invalid because they involved observations of natural phenomena, the U.S. Supreme Court instructed the CAFC to reconsider its decision in the Myriad case. In 2012, the CAFC once again upheld Myriad's right to patent isolated DNA, and the plaintiffs asked the Supreme Court to hear the case again.

The Association for Molecular Pathology (AMP), one of the plaintiffs in the case, takes the view that genes should not be patentable because no company or institution should be able to exclude others from testing for gene sequences or mutations in genes.

"We're optimistic that the Supreme Court will find that a company doesn't have the right to prevent pathologists from examining their patients' DNA," said Roger D. Klein, M.D., J.D., chair of AMP's Professional Relations Committee. "A gene is a natural product and examining a gene—reading its DNA sequence—is not different from other types of medical examinations, like using X-rays to look at bones or looking at tissues under a microscope."

Opponents of gene patenting also point out that such patents may be used to prevent patients from being able to get a second opinion on a test result from an independent laboratory and the patent holder can in some cases block other scientists from conducting research on the patented genes.

In addition, gene patents loom as a potential threat to the widespread clinical use of whole-genome sequencing, Klein noted. Laboratories that offer whole-genome sequencing services may be reluctant, for example, to report mutations in patented genes because they fear infringement lawsuits.

Conversely, Myriad Genetics and many others who support gene patenting say that patents give investors a much-needed incentive to fund research that can lead to new diagnostic tests and other technologies. Such incentives, after all, have been a cornerstone of the pharmaceutical industry, particularly in the development of novel therapeutics.

In a statement, The Wisconsin Alumni Research Foundation (WARF), which patents and

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licenses the discoveries of University of Wisconsin-Madison researchers, said, “When significant investment is needed to advance a basic discovery into a new medical therapy or other product, universities have properly considered patenting. For instance, the patents on genetic testing for cystic fibrosis were granted to several research universities that have widely licensed them to many diagnostic labs.”

Problems can arise not from a patent itself, but when a university grants a broad exclusive license to a diagnostic technology to a particular company, said Robert Cook-Deegan, M.D., research professor at the Institute for Genome Sciences and Policy and the Sanford School of Public Policy at Duke University. “Exclusive licensing needs to be thought about carefully. You need to do it with due diligence and be open about it, and that’s not the norm.” What may matter most about the Supreme Court’s ruling this spring, he explained, is the extent to which it establishes criteria for what constitutes an “invention” that is patentable versus a “discovery” that is not patentable.

Myriad’s stance is that the isolated DNA sequences it patented are “product(s) of human ingenuity” and eligible to be patented. Others think that the mere isolation of a gene from the body should not be a sufficient basis for a patent.

“My opinion is that patenting a gene is like patenting a metal after extracting it from the earth,” said David Korn, M.D., professor of pathology at Harvard Medical School; co-chair of the National Academies’ Committee on Science, Technology, and Law; and former AAMC chief scientific officer. “You can’t patent the naturally occurring elements in the periodic table like copper, iron, or nickel. Extracting DNA from cells and purifying it and identifying its sequence is equivalent to extracting a metal and purifying it from its attached salts.”

While the Supreme Court’s decision is unlikely to resolve all the questions surrounding the patentability of genes, many who work in academic medicine—particularly in technology transfer roles—are closely following the case.

Stephen J. Heinig, AAMC director of science policy, noted that the AAMC has never taken a position on the patenting of DNA sequences. “I think that the leadership of medical institutions wants to know what the rules are for patenting and testing for DNA sequences or variations, so they can move ahead confidently,” he said. “The Supreme Court’s decision, especially to the extent that it focuses on the distinction between discoveries of natural phenomena and actual invention, may have far broader implications.”