# US court to decide if human genes can be patented

November 30 2012, by Jesse J. Holland

The Supreme Court announced Friday it will decide whether companies can patent human genes, a decision that could reshape medical research in the United States and the fight against diseases like breast and ovarian cancer.

The justices' decision will likely resolve an ongoing battle between scientists who believe that genes carrying the secrets of life should not be exploited for commercial gain and companies that argue that a patent is a reward for years of expensive research that moves science forward.

The current case involves Myriad Genetics Inc. of Salt Lake City, which has patents on two genes linked to increased risk of breast and ovarian cancer. Myriad's BRACAnalysis test looks for mutations on the breast cancer predisposition gene, or BRCA. Those mutations are associated with much greater risks of breast and ovarian cancer.

But the American Civil Liberties Union challenged those patents, arguing that genes couldn't be patented, and in March 2010, a New York district court agreed. But the U.S. Court of Appeals for the Federal Circuit has now twice ruled that genes can be patented, in Myriad's case because the isolated DNA has a "markedly different chemical structure" from DNA within the body.

Among the ACLU's plaintiffs are geneticists who said they were not able to continue their work because of Myriad's patents, as well as breast cancer and women's health groups, patients and groups of researchers,

pathologists and laboratory professionals. "It's wrong to think that something as naturally occurring as DNA can be patented by a single company that limits scientific research and the free exchange of ideas," said Chris Hansen, staff attorney with the ACLU Speech, Privacy and Technology Project.

A call to a Myriad spokeswoman was not immediately returned, but in court papers the company's lawyers said without being able to patent and profit from their work, they would not be able to fund the type of medical breakthroughs doctors depend on. The company also said that deciding now that genes can't be patented would throw into chaos current research and profits structures for drug-makers and medical research companies, who have gotten more than 40,000 DNA-related patents from the Patent and Trademark Office for almost 30 years, according to court papers.

"Moving the goalposts of patent eligibility for these patents now would ... undermine the interests of the investing community: Clear and certain patent protection is critical to honor the interests of past investors, such as those who funded the research behind these inventions," the company said in court papers.

In 2010, a federal judge ruled that genes cannot be patented. U.S. District Judge Robert Sweet said he invalidated the patents because DNA's existence in an isolated form does not alter the fundamental quality of DNA as it exists in the body or the information it encodes. But the federal appeals court reversed him in 2011, saying Myriad's genes can be patented because the isolated DNA has a "markedly different chemical structure" from DNA within the body.

The Supreme Court threw out that decision and sent the case back to the lower courts for rehearing. This came after the high court unanimously threw out patents on a Prometheus Laboratories, Inc., test that could help

doctors set drug doses for autoimmune diseases like Crohn's disease, saying the laws of nature are unpatentable.

But the federal circuit upheld Myriad's patents again in August, leading to the current review. The court likely will hear the case in the early spring and rule before the end of the summer.