

High court throws out human gene patents

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(AP) -- The Supreme Court on Monday threw out a lower court ruling allowing human genes to be patented, a topic of enormous interest to cancer researchers, patients and drug makers.

The court overturned patents belonging to Myriad Genetics Inc. of Salt Lake City on two genes linked to increased risk of breast and <u>ovarian</u> <u>cancer</u>.

Myriad's BRACAnalysis test looks for mutations on the breast <u>cancer</u> <u>predisposition</u> gene, or BRCA. Those mutations are associated with much greater risks of breast and ovarian cancer.

The <u>American Civil Liberties Union</u> has been arguing that genes couldn't be patented, a position taken by a <u>district court judge</u> but overturned on appeal.

The justices' decision sends the case back down for a continuation of the battle between the 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.

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 nor the information it encodes.



But last year, a divided panel of the <u>federal appeals court</u> in Washington that handles patent cases reversed Sweet's ruling. The appeals court said 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. The high court said it sent the case back for rehearing because of its decision in another case last week saying that the laws of nature are unpatentable.

In that case, the court unanimously threw out patents on a Prometheus Laboratories, Inc., test that could help doctors set <u>drug doses</u> for <u>autoimmune diseases</u> like Crohn's disease.

"The question before us is whether the claims do significantly more than simply describe these natural relations," said Justice Stephen Breyer, who wrote the opinion in the Prometheus Laboratories case. "To put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural law? We believe the answer to this question is no."

The U.S. Patent and Trademark Office has been awarding patents on human.genes for almost 30 years.

Testing for mutations in the so-called BRCA genes has been around for just over a decade. Women with a faulty gene have a three to seven times greater risk of developing breast cancer and a higher risk of ovarian cancer.

Men can also carry a BRCA mutation, raising their risk of prostate, pancreatic and other types of cancer. The mutations are most common in people of eastern European Jewish descent.



Myriad Genetics Inc. sells the only BRCA gene test.

The case is Association for Molecular Pathology v. Myriad Genetics, 11-725.

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