

Myriad can patent breast cancer genes: US court

July 30 2011, by Kerry Sheridan

A federal appeals court on Friday ruled in favor of Myriad Genetics after a legal battle over whether the US company could keep its patent on genes linked to an inherited form of breast cancer.

The ruling overturns a lower court's decision and allows the Utah-based company to maintain its patents on the isolated [genes](#), known as BRCA1 and BRCA2, despite complaints from rights groups who say it creates an unfair monopoly and limits women's health choices.

The US Court of Appeals for the Federal Circuit decided such patents on isolated [DNA molecules](#) could be held, in accordance with the "longstanding practice" of the [Patent and Trademark Office](#) (PTO), over the past 29 years.

The 2-1 court ruling also said the company cannot patent five broadly framed processes of comparing or analyzing [DNA sequences](#) because they were "abstract mental processes."

However, a Myriad spokeswoman said that aspect of the ruling did not hurt the company's ability to test for the isolated genes.

"Our intellectual property position today is no different than before the ACLU ([American Civil Liberties Union](#)) even brought this case," Rebecca Chambers, head of investor relations, told AFP.

She said the company still has 232 method claims, or steps that explain

exactly how to test, "as part of 23 patents which describe how we go about doing the BRAC analysis test that were not even part of this lawsuit."

Backed by pharmaceutical company Eli Lilly, Myriad obtained a series of US patents in the mid-1990s on two genes -- BRCA1 and BRCA2 -- strongly associated with hereditary forms of breast and ovarian cancer in women.

According to the [National Cancer Institute](#), 12 percent of women in the general population will develop [breast cancer](#) in their lifetimes, compared to 60 percent of women who have inherited a mutation in BRCA1 or BRCA2.

With ovarian cancer, 1.4 percent of women may be diagnosed in their lifetimes but the number rises to 15-40 percent of women with the BRCA1 or BRCA2 mutation.

The patents held by Myriad mean the company owns the "exclusive right to perform diagnostic tests on the BRCA1 and BRCA2 genes and to prevent any researcher from even looking at the genes without first getting permission from Myriad," the ACLU said in a statement.

A key complaint in the lawsuit, was filed in 2009 by a coalition of patient advocacy and medical groups represented by the ACLU, was that the company wielded too much control over the tests and costs.

"Myriad's monopoly on the BRCA genes makes it impossible for women to access alternate tests or get a comprehensive second opinion about their results. It also allows Myriad to charge a high price for its tests," ACLU lawyer Sandra Park told AFP.

The ACLU was consulting with its clients and would make a decision

soon about whether to appeal to the full 12-member court of appeals for the federal circuit or to bring the matter before the Supreme Court, she said.

Analyst Robert Cook-Deegan of the Institute for Genome Sciences and Policy at Duke University in North Carolina, said he expected the legal battle would continue over whether human DNA is something that can be patented and owned.

"This is probably not the last stage in this game," he said. "The fact that all three judges have given very different lines of reasoning does suggest to me that there is going to be another round to go here."

If the matter reaches the Supreme Court, he said the outcome would be "very unpredictable."

But Friday's ruling was expected to make few waves in the biotech industry or on the US stock market.

"The impact of the federal circuit decision in the Myriad case on the biotech industry should be minimal," said biotech intellectual property lawyer Roberte Marie Makowski.

"At least for now, this decision provides a level of certainty for the industry's existing patents and research endeavors."

Biotech companies first began patenting genes and genetic material in the 1980s. More than 20 percent of the 24,000 human gene patents granted since then have been in the United States.

A gene inside the human body cannot be patented. But once it is identified, removed and isolated, a company can apply for exclusive rights to exploit it for commercial purposes.

Only a handful of countries -- including Brazil and Chile -- do not allow patents on genes in any form.

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