

US judge strikes down patent on cancer genes

March 29 2010, By LARRY NEUMEISTER , Associated Press Writer

(AP) -- In a ruling with potentially far-reaching implications for the patenting of human genes, a judge on Monday struck down a company's patents on two genes linked to an increased risk of breast and ovarian cancer.

The decision by U.S. District Judge Robert Sweet challenging whether anyone can hold patents on human genes was expected to have broad implications for the biotechnology industry and genetics-based medical research.

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.

He rejected arguments that it was acceptable to grant patents on DNA sequences as long as they are claimed in the form of "isolated DNA."

"Many, however, including scientists in the fields of molecular biology and genomics, have considered this practice a 'lawyer's trick' that circumvents the prohibitions on the direct patenting of the DNA in our bodies but which, in practice, reaches the same result," he said.

The judge said his findings were consistent with Supreme Court rulings that have established that purifying a product of nature does not mean it can be patented.

He said the company deserved praise for what is "unquestionably a valuable scientific achievement," but not a patent because the "isolated DNA is not markedly different from native DNA as it exists in nature."

The ruling came in a long-running fight 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. It was almost sure to be appealed to the 2nd U.S. Circuit Court of Appeals in Manhattan.

Last March, the American Civil Liberties Union and the Public Patent Foundation sued Myriad Genetics Inc., based in Salt Lake City, the University of Utah Research Foundation and the U.S. Patent and Trademark Office.

The ACLU and the patent foundation said Myriad's refusal to license the patents broadly has meant that women who fear they may be at risk of breast or ovarian cancers are prevented from having anyone but Myriad look at the genes in question.

Myriad attorney Brian Poissant declined to comment. At a hearing before Sweet last month, Poissant said disallowing the patents would wreck the foundation of the biotechnology industry.

Chris Hansen, one of the lawyers who argued the case for the ACLU, said the ruling provides a "strong advance for women's health and for science."

He said the ruling, if upheld, would threaten many of the patents held on approximately 20 percent of the human genome.

"In our view, it would enormously increase women's opportunities to

receive testing and diagnoses and would liberate research opportunities for researchers all over the country," Hansen said.

Yusill Scribner, a spokeswoman for lawyers who argued for the U.S. Patent and Trademark Office, declined to comment.

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, which one expert says now costs nearly \$4,000.

"There are some women without insurance coverage who are not able to pay that," and have not been able to be tested, said Dr. Kelly Marcom, a breast oncologist who runs Duke University's Hereditary Cancer Clinic.

Some doctors and researchers contend that this monopoly has long held up not only competing, cheaper tests but has also hindered gene-based research.

"The evidence has mounted that human gene patents are doing more harm than good," and resulted more by accident than a well-thought-out policy, said Jesse Reynolds, a policy analyst at the Center for Genetics and Society. The center is a nonprofit policy research group advocating for oversight and responsible use of biotechnologies.

The Myriad patent "was particularly troublesome" because it was so

broadly worded, Reynolds said.

Reading the court ruling, "I saw nothing that limited it to Myriad's patents," Reynolds said. It boiled down to this, he said: "Natural things aren't patentable; inventions are."

"This has the potential to dramatically shake up the biotech industry," Reynolds said.

More information: National Cancer Institute:
<http://www.cancer.gov/cancertopics/factsheet/risk/brca>
FORCE support group: <http://www.facingourrisk.org/index.php>

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