

Despite Gene Patent Victory, Myriad Genetics Faces Challenges

Date: 24 August 2011

Source: The New York Times

Link: http://www.nytimes.com/2011/08/25/business/despite-gene-patent-victory-myriad-genetics-faces-challenges.html?_r=1

Myriad Genetics retained its monopoly on a lucrative genetic test for breast cancer risk when a federal appeals court recently upheld the company's patents on two human genes — and the validity of gene patents in general.



Dan Cappellazzo for The New York Times

Kathleen Maxian of Pendleton, N.Y., with a group that is planning ovarian cancer awareness events in western New York. She says a supplemental test may have helped her fight her cancer.

But it is only a matter of time before the company's business faces severe challenges, some experts say, because that \$3,340 test is technologically outmoded, incomplete and too costly.

"Science has moved beyond what these folks do," said Mary-Claire King, a professor of genome sciences and medicine at the University of Washington. "It's not good for the science and it's not good for the patients and their clinicians if they cannot have the most complete, up-to-date information."

Myriad sequences the two patented genes, known as BRCA1 and BRCA2, for mutations that raise the risk of a woman getting breast and ovarian cancer.

But newer DNA-sequencing techniques are far faster and only a fraction of the cost of the 1990s technology that Myriad uses. Indeed, it will soon be possible to sequence a person's entire genome, all 22,000 or so genes, for less than Myriad charges for just two genes.

Executives at Myriad say they are preparing for changes. Although its major patents start expiring in 2014, the executives say the company's patent protection should last until at least 2018.

They say that will give the company time to adopt new technology and to diversify beyond the breast cancer test, which accounted for \$353 million, or 88 percent, of Myriad's \$402 million in revenue in the fiscal year that ended in June.

The company also plans to rely less on patents and more on trade secrets. Because it has done so much more testing than anyone else, Myriad has more information on which of the thousands of possible mutations in the two genes actually raise the risk of getting cancer.

Myriad used to share such information with a public database maintained by the National Institutes of Health, and it cooperated with academic scientists trying to analyze the mutations. But a few years ago, the company quietly stopped contributing and cooperating, in favor of building its own database.

An academic consortium, relying on data from European labs or from individual patients, is trying to catch up, but "it's kind of slow going," said Sean Tavtigian, a former Myriad scientist who is now an associate professor of oncological sciences at the University of Utah and is involved in the consortium.

Myriad, which is based in Salt Lake City, is hoping to use that advantage first in Europe, where it will open a testing laboratory next year.

"If I had my druthers, I would not want to go into a new market in a heavy-handed fashion, trying to enforce patents," Peter D. Meldrum, Myriad's chief executive, told analysts in January. Instead, he said the company would exploit its quicker turnaround time for testing and its "vastly superior information."

Myriad executives have said that when a European laboratory finds a mutation in either of the two genes, 20 to 40 percent of the time it does not know if the mutation raises the cancer risk. They say that Myriad's rate of uncertain findings is just 3 percent.

Daniel B. Vorhaus, a New York lawyer and editor of the Genomics Law Report, a Web site, said there were ethical questions about whether Myriad should be withholding the mutation information, important for public health, that it has gathered by dint of its patents to essentially extend its monopoly beyond the life of the patents.

Mark C. Capone, the president of Myriad's laboratory division, said in an interview that the company had invested heavily in characterizing the various mutations. He said that the company became uncomfortable sharing its information with a public database when it realized the information might be used to compete against it.

Ever since Myriad and its partner, the University of Utah, beat other researchers, including Professor King of the University of Washington, in identifying the BRCA1 gene in 1994, Myriad has been the target of those opposed to the patenting of genes.

In 2009, the American Civil Liberties Union and the Public Patent Foundation filed a lawsuit challenging Myriad's patents on behalf of various medical researchers, medical societies and patients.

A federal district judge last year said genes could not be patented. But his decision was reversed in late July by a 2-1 decision from the Court of Appeals for the Federal Circuit. The plaintiffs are considering appealing to the Supreme Court.

The lawsuit contends that the patents, by giving Myriad a monopoly, have limited testing options for patients and led to lower-quality tests.

The latest controversy concerns a supplemental test that Myriad is offering.

In 2006, Professor King and colleagues published a paper showing that Myriad's test, known as the Comprehensive BRACAnalysis, actually failed to detect a significant number of genetic alterations in the two genes.

Keywords: Breast Cancer / Gene / Patent