Europe to pay royalties for cancer gene

It has been one of the toughest, and most impenetrable, biological patent cases in the history of the European Patent Office. But the University of Utah in Salt Lake City has finally won its battle to keep some European patents on BRCA1 — a gene associated with breast and ovarian cancer.

The ruling means that the patent owners now have the right to collect royalties on tests carried out on tens of thousands of women across Europe every year. The tests identify those who have a high risk of developing breast cancer because they have a mutated BRCA1.

"It is disappointing after our 7-year fight even though we have managed to reduce the scope of the patents," says Dominique Stoppa-Lyonnet, a clinical geneticist at the Curie Institute in Paris. "We had all been freely testing the BRCA genes since they were first described in the early 1990s," she says.

Between 10% and 15% of all heritable breast and ovarian cancers have a mutation in BRCA1 or BRCA2, another gene linked to breast cancer, leading to as many as 5,000 new cases of both cancers in the European Union every year.

An inexact sequence
Clinical geneticists do not agree with monopolies on diagnostic testing of genes for such diseases because they believe they block the competition that could lead to the development of better, cheaper products. Some of those contacted by Nature say that they will continue to test for the mutations in defiance of the patent.

Gert Matthijs, who heads the Centre for Human Genetics at the University of Leuven in Belgium, says that no European clinic has paid royalties for BRCA1-related diagnoses since the European Patent Office first granted three BRCA1 patents to the biotech company Myriad Genetics in 2001. Myriad, which is based in Salt Lake City, transferred ownership of the patents to the University of Utah in November 2004. It was facing growing opposition to its patents from genetics clinicians in neighbouring France and the Netherlands, where testing could now start to cost a lot more.

Myriad holds very broad patents on both BRCA1 and BRCA2 in the United States, where it charges US$3,120 for a full analysis of both genes and US$460 for a single mutation test. The single test is usually done in large academic institutions and hospitals at a cost of up to €1,500 ($1,900) for both genes. "We will wait to see what royalties the University of Utah might demand of us, but it won't stop us testing the gene in France," says Stoppa-Lyonnet.

Patent patchwork
William Hockett, a spokesman for Myriad, says that the company is keen to discuss the test's costs with national health systems, pointing out that "our analysis is covered by insurance in the United States because it is highly cost-effective to the insurers".

The patent office granted Myriad a broad patent on BRCA2 in 2003. That patent was reduced in scope to cover just one mutation, common in Ashkenazi Jews, in 2005. Myriad is challenging a second, broader, patent on BRCA2 that is co-owned by the charity Cancer Research UK. Mike Stratton of the Wellcome Trust Sanger Institute in Cambridge, UK, who is one of the inventors behind the patent, says that they "took the patent to defend the gene against other patent approaches. We offer free licensing to any reputable laboratory who wants to use it," he says.

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