Critics Question BRCA2 Patent Decision in Europe

The European Patent Office (EPO) announced its decision in late June to uphold an amended form of a BRCA2 patent licensed to Myriad Genetics, giving the company exclusive rights to test for a particular nucleic acid mutation on the BRCA2 gene that is associated with a predisposition to breast cancer in Ashkenazi Jewish women. Opponents of the patent—including genetics societies and breast cancer organizations across Europe—have criticized the ruling as discriminatory.

In clinical practice, the ruling will mean that women who wish to undergo genetic testing for breast cancer will be asked whether they are of Ashkenazi descent and, if so, will have to be referred to the patent owner for testing. In Europe, Myriad has licensed out its BRCA1 and -2 patents to Bioscientia, a medical laboratory based in Ingelheim, Germany. The price for complete screening of both genes by Myriad in the United States is somewhere between $2,500 (£2,055) and $3,000 (£2,470), and if the test is requested via Bioscientia in Europe, the costs amount to nearly €4,000 (US $4,800).

“In Europe, nobody will ask a woman whether she is of Ashkenazi descent,” said Dominique Stoppa-Lyonnet, Ph.D., head of the Medical Genetics Department at the Institut Curie in Paris. “It is a completely different culture over here and we should be extremely cautious with patents that single out ethnic groups and we should be extremely cautious with a completely different culture over here.”

The recent EPO decision marks the preliminary end of a series of appeals opposing Myriad’s patent claims on BRCA1 and BRCA2 mutations in Europe. The patents initially gave the company rights to develop diagnostic kits and therapies based on the gene sequences. Myriad’s three patents on the BRCA1 gene were opposed by a consortium of European genetics societies, research institutes, and patient organizations— spearheaded by Stoppa-Lyonnet and by Gert Matthijs, Ph.D., head of the genetics laboratory at the University of Leuven in Belgium. The result of the opposition, decided in January, led to an amended BRCA1 patent that now no longer includes claims for therapeutic and diagnostic methods. Myriad itself slimmed down its BRCA2 patent to the so-called Ashkenazi mutation as a result of challenges by the European consortium.

One of the many questions raised by the recent BRCA2 decision is what impact it may have on genetic testing in Europe. “In contrast to the USA, genetic testing is not widespread in Europe but rather carried out in controlled clinical trials,” said Matthijs, who also is heading the patenting and licensing committee of the European Society of Human Genetics (ESHG) in Vienna, Austria. In his opinion, the decision could affect European health care systems.

He said that the estimated costs for genetic testing in Belgium are currently about €1,000 (US $1,200). Individuals at risk who are getting tested pay only €9 (US $11) out of their own pocket, because the test is largely reimbursed. “If we were supposed to send our samples to Myriad, costs for genetic testing would more than triple and we would not be able to provide testing to those possibly at risk,” Matthijs said.

Other European experts, however, doubt that the maintained BRCA2 patent will have any impact at all: “I think the recent decision is grotesque, and we do not see any need to suspend our current practice of genetic testing,” said Alfons Meindl, Ph.D., head of the gynecological tumor genetics department at the Technical University of Munich, Germany. His department collaborates in a multicenter, hereditary breast and ovarian cancer study group comprising 12 university hospitals in Germany, where women from high-risk families can undergo genetic testing and counseling. “We do not just test for single mutations as the one frequently found in Ashkenazi Jewish women,” he said. “The objective of our research is to determine mutation frequencies in women at risk and to translate this knowledge into special prevention programs; therefore, we always screen both genes.”

Claus Bartram, M.D., director of the Institute of Human Genetics at the University of Heidelberg, Germany, and president of the German Society of Human Genetics, shares this view. “In my opinion, the current BRCA2 patent is nonsense. Myriad and Bioscientia have taken the wrong approach by trying to monopolize the BRCA1 and -2 patents in Europe, even though this might be understandable from a business point of view,” he said.

Neither Myriad nor Bioscientia would comment on the current BRCA2 patent decision for this article. The EPO, however, confirmed that Myriad’s BRCA1 patent is under appeal again. In March, the company filed an appeal against EPO’s January decision to maintain the narrowed-down BRCA1 patent.

For the BRCA2 patent, the situation is slightly different. Jacques Warcoin, patent attorney at the Paris-based law office Regimbeau, which represents the French members of the consortium, explained that since Myriad itself narrowed down the BRCA2 patent and it was confirmed by the EPO, “the company cannot oppose its former decision.” The EPO is preparing its written justification of the BRCA2 patent decision, and once it is published the consortium will decide how to react. “It does not seem likely that we will file an opposition, as the fragmented BRCA2 patent is weak,” said Warcoin.

—Sabine Steimle