

European-wide opposition against the breast cancer patents

In 2001, the European Patent Office (EPO) granted 3 patents on the BRCA1 gene, the first known gene with a role in familial breast- and ovary cancer, to Myriad Genetics, a US based company.

In one joint opposition, filed on August 28, 2002, Genetic Societies and Cancer Research Institutes from 11 European countries have filed opposition against the third patent (EP 705902) on BRCA1, granted to Myriad Genetics in November 2001. Oppositions against the first and second patents had already been filed in October 2001 and February 2002, respectively.

The opponents represent molecular and clinical geneticists from Austria, Belgium, Czech Republic, Denmark, Finland, Germany, Greece, Italy, the Netherlands, Switzerland and the United Kingdom. Two Dutch and Belgian patient organizations ("Borstkanker Vereniging Nederland" and "Vlaamse Liga tegen Kanker vzw") have also joined the opponents.

Specifically, the third patent broadly claims all possible uses of the BRCA1 gene and its gene product. In our view, the patent lacks inventive step and novelty. From a diagnostic standpoint, we emphasize that the European Patent Convention excludes a "diagnostic method practised on the (human) body" from patenting. Moreover, the specific nature of DNA as a carrier of genetic and private information requires special considerations. Actual patent law and the evidently narrow and strict interpretation by the EPO do not sufficiently reflect this special status.

Through the patents, Myriad Genetics obtained the monopoly on diagnostic testing for BRCA1. However, since 1994, many European laboratories have been offering BRCA1 testing in a clinical context. As a result of the monopoly on this gene, this testing will either become impossible in the laboratories in the public sector, or become exceedingly expensive.

Moreover, the BRCA1 gene patents may create a precedent. Many patent applications on genes have been filed over the last few years. If not stopped, monopolies on genes and genetic testing will wreck the reimbursement systems and negatively influence healthcare all over Europe.

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