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Institut Gustave-Roussy
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Diagnosis of predisposition to breast and ovarian cancers linked to the BRCA1 gene

The European Patent Office has revoked the Myriad Genetics patent

Following a hearing on 17 and 18 May 2004 in Munich, the Opposition Division of the European Patent Office (EPO) revoked European patent EP 699 754 held by Myriad Genetics relating to a "method for diagnosing a predisposition for breast and ovarian cancer". Having successively rejected all the claims made by Myriad Genetics, the Opposition Division revoked the patent on the grounds that it does not meet the requirements of the European Patent Convention.

- This is a victory for all those whose conception of public health puts the principle of equal access to care before commercial interests.
- It is also a victory for advocates of basic and clinical research founded on public-private partnerships in the drive for innovation in Europe and around the world.
- It is a victory too for ethics and rights over monopolistic abuses leading to unjustified appropriation of key know-how likely to lead to health improvements for people around the world.

This is a success for the Institut Curie, the Assistance Publique-Hôpitaux de Paris, and the Institut Gustave-Roussy, as well as for other European opponents, who since 2001 have been contesting the monopoly imposed by the excessively wide-ranging claims made by Myriad Genetics. Our aim is to guarantee:

- access to quality tests: 10 to 20% of mutations are not detected by the Myriad tests and testing is three times more expensive at Myriad than in France;
- an approach to public health based on comprehensive and multidisciplinary care (from initial counseling to care and follow-up of at-risk patients);
- further research growth and development of new diagnostic tests: in particular, avoidance of the "mandatory" sending of DNA test samples to Myriad Genetics in the United States.

The EPO's Opposition Division examined the arguments for and against this controversial patent at a public hearing over two days.

In filing this patent application in 1994, Myriad Genetics acted alone and precipitately, and against the prevailing spirit of international scientific cooperation. In view of many shortcomings in the patent highlighted during the hearing, notably in the sequence of the gene, and because of the unwarranted monopoly claimed, the Opposition Division revoked the patent and its numerous additional claims, on the grounds of lack of inventiveness.

The written statement of the Opposition Division's verbal ruling will be published within two to six months. Myriad Genetics will then have two months to challenge the ruling in second-instance proceedings before one of the EPO's technical boards of appeal.

Background:

In October 2001, several notices of opposition to this January 2001 patent were filed at the EPO. In France, a joint notice of opposition was filed by the Institut Curie, the Assistance Publique–Hôpitaux de Paris and the Institut Gustave-Roussy. This initiative was supported by the Fédération Nationale des Centres de Lutte Contre le Cancer (French Federation of Cancer Centers) and the Fédération Hospitalière de France (French Hospital Federation), the French Ministries of Public Health and Research, and the European Parliament. Further notices of opposition were filed by a group led by the Belgian Society of Human Genetics that included Belgian and Dutch human genetics centers, as well as by the genetics societies of Germany, Denmark and Great Britain.

Further information is available at: www.curie.fr/ (under “press and publications”)

NB:

The EPO examines the technical information contained in the 160 000 or so patent applications that it receives each year. Any member of the public can present his or her observations at any stage of the examination procedure and file a notice of opposition to the patent within nine months after it has been awarded. The patent files can be consulted at: www.european-patent-office.org

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