

P R E S S R E L E A S E

Breast and ovarian cancer predisposition

New European victory in the opposition to American patents: the Board of Appeal of the European Patent Office rejects the appeal of Myriad Genetics

Paris, 1 October 2007. Following the appeals procedure of 24 to 27 September 2007 in Munich (Germany), the Board of Appeal of the European Patent Office (EPO) has rejected the appeal of Myriad Genetics/University of Utah and upheld the revocation of the patent regarding the BRCA1 gene and its applications.

This decision of the Board of Appeal confirms the ruling pronounced by the Opposition Division of the EPO in January 2005.

After over six years of European procedures, this is a new victory for the Institut Curie, the Paris Public Hospitals, and the Institut Gustave-Roussy, as well as other European opponents who since 2001 have been contesting the monopoly imposed by the excessively wide-ranging claims of Myriad Genetics.

This patent claimed the isolated BRCA1 gene (chemical molecule), the corresponding protein, and the conceivable therapeutic applications (gene therapy, drug screening, transgenic animals) and diagnostic kits (use of probes or primers specific to certain mutations).

In January 2005, the Opposition Division revoked basic points of the patent, which led Myriad Genetics/University of Utah to lodge an appeal.

Revocation upheld regarding the patent of the BRCA1 gene and its applications

At a four-day public hearing, the Board of Appeal of the EPO examined the arguments for and against the disputed patent EP 705 902.

As in 2005, the Board of Appeal rejected the principal claim relating to the gene itself, because of noncompliance with the European Patent Convention (EPC), and refused priority. The BRCA1 gene and its protein are defined by their sequences. Now, these sequences are wrongly indicated in the first patent applications made by Myriad in 1994 (called "priorities"). As a result, the reference sequences can no longer be those of September 1994, but those of March 1995, which therefore becomes the real date of "priority" that the patentee can claim. Now, on this date, the BRCA1 gene had already been isolated and its complete correct sequence had been published in scientific databases. The principal claim of the patent (gene and protein sequences) as registered can not, therefore, be validated.

Only the secondary claims relating to a nucleic acid probe and to vectors comprising certain parts of the gene sequence are accorded.

Continuation of diagnostic tests in European laboratories

Thus revoked, patent EP 705902 is no longer a hindrance to the pursuance of diagnostic tests in our institutions and in all French laboratories performing such tests. This is a gratifying for all those involved who favor an ethical and conceptual view of public health based on equal access to healthcare for all, over and above commercial interests. The revocation is also encouraging for all those who defend a conception of basic and clinical research based on real public-private partnerships in the drive for innovation in Europe and beyond. Thus respect of the law has prevailed over monopoly abuse, which leads to unwarranted appropriation of methods of prime importance likely to benefit public health.

There are two other patents related to the BRCA1 gene which will be examined later by the EPO Board of Appeal, as Myriad Genetics/University of Utah has also lodged an appeal against decisions made by the Opposition Division in May 2004 (EP 699 754) and January 2005 (EP 705 903).

*For more information: see the **press file** "Against the monopoly on tests of predisposition to breast and ovarian cancers linked to the BRCA1 gene: the latest on French opposition at the European Patent Office" of September 2007 (www.curie.fr > heading "press and publications").*

The appeals procedures are supported financially by the National Cancer Institute (INCa) and the Ministry of Health.

Patent EP 705 902

BRCA1 gene of breast and ovarian cancer predisposition

28 November 2001: award of the patent by the EPO
27 August 2002: French and European opposition
20 January 2005: partial revocation of the patent by the Opposition Division of the EPO
27 September 2007: rejection of the appeal by Myriad Genetics and upholding of the revocation of the patent by the Board of Appeal of the EPO

Contents of the patent

Protection of the isolated gene itself (chemical molecule), of its corresponding protein, of the conceivable therapeutic applications (gene therapy, drug screening, transgenic animals), and of diagnostic kits of limited scope (use of probes or primers specific to certain mutations) but which potentially stop tests being performed.

Opponents

- **Institut Curie, Paris Public Hospitals, and the Institut Gustave-Roussy** supported by the National Federation of French Cancer Research Centers and the French Hospital Federation
- **Belgian Human Genetics Society**, which brings together Belgian and Dutch human genetics centers, the German, Danish, Czech, Swiss, Austrian, Italian, Finnish, and British genetics societies, the Greek National Center for Scientific Research, the Swiss Institute for Applied Cancer Research, and two patient groups (Belgium and Holland)
- **Dutch Ministry of Health**
- **Austrian Ministry of Health**
- **Swiss Social Democratic Party**
- **Greenpeace Germany**
- **Dr Wihelms (Germany)**

Arguments against

Refusal of priority and lack of originality: The BRCA1 gene and its corresponding protein are defined by their sequences, which are erroneously indicated in the first patent applications (priorities) made by the American company Myriad, in 1994. They do not correspond to the gene concerned by this patent and so are not valid. Consequently, the reference sequences are not those of September 1994, but rather those of March 1995. However, at this time, the gene had already been isolated and its correct sequence was available in databases, so there is a lack of originality.

Flawed inventiveness: when the patent application was made, it was already possible to isolate the gene using knowledge available at the time.

Insufficient description: The therapeutic applications, and notably the methods of gene therapy, are not described in the patent.

Reasons for the revocation (Opposition Division – January 2005)

The Opposition Division rejected the principal claim relating to the gene itself and the basic points of the other claims as they failed to comply with the European Patent Convention, because of refusal of priority. Only secondary claims relating to a nucleic acid probe and vectors containing certain parts of the gene sequence were accorded.

Reasons for the revocation (Board of Appeal – September 2007)

The Board of Appeal rejected the appeal and upheld the previous decision for the same reasons as in 2005: failure to comply with the European Patent Convention, because of refusal of priority. Only secondary claims relating to a nucleic acid probe and vectors containing certain parts of the gene sequence were accorded.

All the documents on the Myriad Genetics case are available at:

www.curie.fr (“press and publications” section)

The patent files can be consulted at:

www.european-patent-office.org

Copyright-free images available:

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