www.eshg.org
European Society of Human Genetics
Administrative Office:
ESHG c/o Vienna Medical Academy
Alser Strasse 4, 1090 Vienna, Austria
Phone: +43 1 405 13 83 20
Fax: +43 1 407 82 74
Email: eshg@eshg.org

For immediate release
15 June 2005

Geneticists oppose singling out Jewish women in European breast cancer patent

Jewish women in Europe may face genetic discrimination in access to breast cancer diagnosis if the patent on the BRCA2 gene, which is currently being disputed, is not withheld by the European Patent Office (EPO) on June 29. The European Society for Human Genetics (ESHG) is strongly opposed to the selection of a particular racial group as a diagnostic target in a gene patent claim and is calling on the EPO to take action to prevent this situation.

On June 29 the EPO will hear the opposition of several European genetic societies and research institutes against the patent on the second breast cancer gene, BRCA2, to which the US-based Myriad Genetics holds the exclusive, worldwide license. In preparation of these hearings, the patent owners have now rewritten the original claims in the patent, to specifically protect the identification of one particular mutation – frequent in the Jewish population - "for diagnosing a predisposition to breast cancer in Ashkenazi-Jewish women". This is the first time that a racial or ethnic group has been specifically singled out as a diagnostic target in this way.

"This is not the way to go for genetic testing", said Professor Gert-Jan van Ommen, from the Center of Human and Clinical Genetics, at the Leiden University Medical Center, The Netherlands. "What it means in practice is that genetic centres that do not have licences for this test – or where the healthcare systems cannot afford to pay for it – may be forced to deny it to Ashkenazi Jewish women." One of 100 Ashkenazi Jewish women carries the BRCA2 mutation which predisposes her to breast cancer, and gives a 65-70% chance of developing the disease.

Administrative Office: Phone: +43 1 405 13 83 20
ESHG c/o Vienna Medical Academy Fax: +43 1 407 82 74
Alser Strasse 4, 1090 Vienna, Austria Email: eshg@eshg.org

The ESHG is calling on the EPO to rescind this patent claim on ethical and practical grounds. At their recent meeting in Prague, the board and members agreed their strong opposition to this development.

"Almost all European geneticists are very unhappy about the introduction of specific racial, ethnic or familial references in patent claims", said Professor Andres Metspalu, from the Estonian Biocentre at the University of Tartu, Estonia, and President of EHSG. "This is genetic discrimination, as the consequence of this practice would be that some individuals and patients could find themselves legally denied clinical diagnostic services, based on their belonging to a specific genetic heritage. While this particular mutation in the BRCA2 gene is frequent in the Ashkenazi population, we are equally opposed to similar claims on mutations in this and other genes that may be prevalent in other populations or specific to individual families.".

The ESHG is calling on the European Patent Office (EPO) to thoroughly consider the legal, economical and social consequences in its decision in June and to revoke this patent on the basis of the following considerations:

- It is against 'ordre public' and morality to introduce genetically discriminating considerations in patent language, and thus in breach of Article 53 (a) of the European Patent Convention
- The definition of a racial, ethnic of otherwise hereditarily determined groups is fraught with technical uncertainties and lack of precision, which, once introduced in patent language, will lead to a burgeoning of poorly determined terms.
-

While the latter would further inflate the cost of intellectual property protection, "both aspects may well unfavourably affect the perception of the work of the patent authorities by European citizens and the genetics community" said Professor Gert Matthijs, from the Department of Human Genetics, Catholic University of Leuven, Belgium, and chair of the ESHG Patenting and Licensing Committee.
(ends)

For further information:
Prof. Helena Kääriäinen, Department of Medical Genetics, University of Turku, Finland
Tel: +358-2-333 7453 – Email: hkaaria@utu.fi

Prof. Gert-Jan van Ommen, Department of Human Genetics, Leiden University Medical Center, The Netherlands
Tel: 31-71-527 6293 - Fax: 31-71-527 6075 - Email: gjvo@lumc.nl

Administrative Office:
ESHG c/o Vienna Medical Academy
Alser Strasse 4, 1090 Vienna, Austria
Phone: +43 1 405 13 83 20
Fax: +43 1 407 82 74
Email: eshg@eshg.org

Prof. Gert Matthijs, Department of Human Genetics, Catholic University of Leuven, Belgium
Tel: 32-16-346070 – Fax: 32-16-346060 - Email: gert.matthijs@med.kuleuven.be

A copy of the 'main request' to the patent EP785216 on BRCA2, as made available through http://ofi.epoline.org/view/GetDossier

Background:
Between 2001 and 2003, the European Patent Office (EPO) has granted several patents to Myriad Genetics Laboratories in the US on familial breast cancer genes BRCA1 and BRCA2. The breast cancer gene patents relate to research done in the early nineties which led to the identification of these genes in 1994 and 1995 respectively. The basis for these breakthroughs in familial breast and ovary cancer research had largely been laid in the years before by academic research groups and by a world-wide international collaboration between those groups through the so-called Breast Cancer Linkage Consortium (BCLC). Consequently, soon after these genes were identified, many genetic laboratories and cancer institutes in Europe included BRCA mutation testing in their service, and many women with a family history of breast cancer have now been analysed. However, the legal situation of this service became uncertain when the patents were granted. Indeed, the patents have allowed Myriad Genetics Laboratories to gain and retain monopoly on BRCA1 and BRCA2 testing. This has met with strong opposition in the European genetics community as it was seen to interfere with national policies regarding DNA-based diagnostic services.

Following opposition to the three BRCA1 patents by several European genetic societies and research institutes, led by the French Institut Curie, l'Assistance Publique-Hôpitaux de Paris and the Institut Gustave-Roussy, and by the Belgian and Dutch societies for Human Genetics, one of the patents was revoked in May 2004, and in January 2005 the second and third patents were restricted in scope.

Currently, scientists and health care providers do not consider the patents a threat to diagnostic practice in Europe, but the patent holders have appealed the decision, so the BRCA1 dispute is still ongoing. However, Myriad Genetics also holds exclusive worldwide license rights on the second gene, BRCA2, and the opposition hearings of this patent are to be held on June 29 at the EPO in Munich. With the recent changes described above, aiming this patent to a specific ethnic group, this patent, like the BRCA1 patents, is generating major concern amongst European geneticists, which has led to the current reaction of the ESHG.

About the society:
The European Society of Human Genetics (ESHG) is a non-profit organisation and its aims are to promote research in basic and applied human and medical genetics and to facilitate contacts between all persons who share these aims. The Society will encourage and integrate research and professional and public education in all areas of human genetics. See www.eshg.org