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PRESS RELEASE FROM EUROPEAN SOCIETY OF HUMAN GENETICS

For immediate release: Friday 1 July 2005

EPO upholds limited patent on BRCA2 gene: singling out an ethnic group is a 'dangerous precedent' says European Society of Human Genetics

Following the decision of the European Patent Office (EPO) to uphold the slimmed-down version of University of Utah Research Foundation's European patent on the BRCA2 breast cancer gene, Professor Gert Matthijs, from the Department of Human Genetics, Catholic University of Leuven, Belgium, and chair of the ESHG Patenting and Licensing Committee, said:

"The patent owners have been able to rescue a small bit of their original patent on BRCA2 testing by putting Ashkenazi women into their claim. This apparently renders the test for the 6974delT mutation, which happens to be frequent in the Ashkenazi population, inventive, novel and industrially applicable. We understand that the EPO had to decide about this case within the constraints/ of the patent law, and could thus only take the above criteria into account. Nevertheless, we still believe that there is something fundamentally wrong if one ethnic group can be singled out by patenting. Women coming to be tested for breast cancer will have to be asked whether they are Ashkenazi Jewish or not. If they are, the healthcare providers will only be able to offer the test if they paid for a licence or they will have to send the women's samples abroad. Women who are not Ashkenazi-Jewish – or who just don't know that they had Ashkenazi-Jewish ancestors – will be entitled to a test which is free. This is the first time that this kind of situation has arisen in genetic testing, and we find it very worrying.

(ends)

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Notes for editors:

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 woman 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.

As far as the second gene, BRCA2, is concerned: after the opposition hearings of this patent, held on June 29 at the EPO in Munich, BRCA2 testing is now essentially free, except for Ashkenazi women. Opponents have 2 months to decide whether they will appeal against the latest decision.

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

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