

## **The Institut Curie, the Assistance Publique-Hôpitaux de Paris and the Institut Gustave-Roussy file a joint opposition notice to the Myriad Genetics patent with the European Patent Office**

The Assistance Publique-Hôpitaux de Paris and the Institut Gustave-Roussy have decided to support the Institut Curie's initiative to institute an opposition procedure against the patent granted to Myriad Genetics for a « method for diagnosing a predisposition for breast and ovarian cancer associated with the BRCA1 gene ».

This initiative has also elicited the active support of the Fédération Nationale des Centres de Lutte Contre le Cancer (French national federation of anti-cancer centers) as well as of the Fédération Hospitalière de France (French federation of hospitals). These two bodies are however not seeking direct involvement in the opposition procedure.

In other European countries, many players in the field, geneticists and representatives of various institutions, have spoken in favor of similar approaches, or expressed support for the French initiative.

The opposition notice, drafted with the Regimbeau patent and trademark attorneys, was filed on behalf of the three joint opposing parties on October 9, 2001, the deadline set by the European Patent Office (EPO) for instituting proceedings against said patent.

Patents exist to reward individuals and institutions for work carried out in specific fields through the granting of monopoly rights to the exploitation of their discoveries. " However, should the criteria used to assess patentability be insufficiently stringent, the magnitude of means brought to bear on a given project may singly ensure monopoly rights, for which there is in fact no commercial or social rationale", to quote from the opposition notice.

The opposition notice aims to challenge the patent inter alia on the following grounds :

- **Lack of inventive step**

Myriad Genetics may have won the very last stretch in the race to breast and ovarian cancer predisposition genes in 1974, but between 1990 and 1994 the international public consortium had singly achieved detailed localization of the BRCA1 gene, and provided significant information as to its features, and its possible use in the detection of breast and ovarian cancer susceptibility. What remained to be done was the final gene sequencing, a technological procedure the outcomes of which warrant, at the most, protection by limited monopoly rights.

- **Insufficient description**

The protein sequence used for Myriad Genetics' first patent application on diagnostic methods is per se insufficient for producing a susceptibility test, as this test is based on comparing a high-risk individual's sequence (which carries a mutation) to a known (normal) gene sequence.

## **Curtailing the negative consequences which might stem from sanctioning a dubious monopoly**

In instituting this opposition procedure, the Institut Curie, the AP-HP and the IGR wish to challenge Myriad Genetics' overly broad claims, as sanctioned by a European patent which covers all diagnostic methods. This initiative aims to prevent the establishment in France and in Europe of a monopoly which would, under current circumstances :

- jeopardize the development of research and the identification of new tests and new diagnostic methods. The "compulsory" sending to Myriad of DNA samples obtained from high risk individuals would help the US corporation build up the only genetic data bank in the world. This in turn would grant it **unchallenged control over the main research materials concerning genes coding for breast and ovarian cancer susceptibility**, thereby allowing it to make further discoveries and ultimately to file further patent applications as a result of such discoveries;
- **seriously jeopardize the quality of test results**, as 10 to 20% of all mutations go undetected with the Myriad Genetics method (which only uses direct sequencing technology), **as well as hinder access to testing**, as Myriad testing is three times more expensive than testing in France;
- furthermore go **against our approach to public health**, which is based on our commitment to the comprehensive and multidisciplinary care of high-risk patients.

In practice, and despite the opposition procedure which has been initiated, **laboratories whose work is seen as contrary to the terms of this patent could be prosecuted for patent infringement, regardless of the detection technology they use.**

The initiators of the opposition procedure thus welcome the support expressed by the French **Ministries for Public Health and Research, who are currently developing a legal framework to facilitate access to diagnostic testing, through a broadening of the ex officio and compulsory licensing schemes.** Draft legislation aiming to transpose EU Directive 98/44, currently under review by the Conseil d'Etat, thus aims to extend the list of products for which ex officio licensing can be sought, and which is currently limited to drugs. Under this proposed legislation, ex officio licensing could also cover medical facilities, in vitro diagnostic systems and associated therapeutic products, as well as in vivo diagnostic methods. In addition, the draft provides for stricter identification of patent applicants' claims.

Finally, the **European Parliament has recently voiced its support for the French initiative**, in a joint resolution adopted October 4, 2001, wherein the Parliament "*associates itself with those tabling objections to the granting of these patents, such as the Institut Curie. It asks its competent services to prepare without delay an objection to be filed to European patents n° 699 754 and n° 705 903 and calls on the other institutions of the European Union and Member State governments to do likewise*».

### **Press contacts**

Institut Curie	Catherine Goupillon	01 44 32 40 63	catherine.goupillon@curie.fr
AP-HP	Thierry Girouard	01 40 27 37 22	thierry.girouard@sap.ap-hop-paris.fr
Institut Gustave-Roussy	Hélène Hartmann	01 42 11 50 59	hartmannh@igr.fr