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Patenting and Licensing of Genes for Diagnostic Purposes in Europe

The least one could say about the BRCA1 case, it that it has caused a stir in the field of genes and patenting. In contrast to the colleagues in the US, the geneticists in Europe had never worried about, nor considered, the possibility that genes and genetic tests could become the exclusive property of a laboratory or a company. Under the existing legislation, based on the European Patent Convention (EPC) and supported by the European 'Biodirective' 98/44/EC, genes and genetic sequences are patentable. However, the debate has never been closed, i.e. many people and organisations are still questioning the patentability of genes and genetic tests. Many professionals, mostly those who are familiar with gene patenting, including the experts at the European Patent Office (EPO), have commented that the problem is in licensing, not in patenting. The only way out is to define pragmatic solutions, that respect the rights of the patent owners and the users, and at the same time, warrant the patient's right and access to affordable health care provisions.

Patents are meant to reward the inventors who have undertaken research as well as to encourage innovation. Patent owners and the industry argue that this form of protection of intellectual property is a prerequisite for investment. But, for the identification of novel genes, the patent owners have often heavily relied on the data generated through other, mostly publicly funded, research activities. In addition, it seems that the market system does not always operate properly in the case of patents on genes, probably because genes and genetic sequences are different from classical chemical compounds. At the same time, the compulsory licensing system, which is the traditional safeguard against excesses in licensing, is not effective, and may have to be replaced by other systems.

During a special session on 'Patenting and Licensing of Genes for Diagnostic Purposes in Europe' on Monday, June 14 in Room 13a, the different topics will be presented by speakers that represent the different stakeholders. The session is organised in collaboration with the German Technology Transfer Agency of National Genome Research Network (TT-NGFN). From 10.30 am to 12.45 pm, the focus is on patenting. The legal context will be situated by Dr. B. Stolz from the EPO, and the related aspects will be highlighted by other patent specialists. Legal specialists will present the different aspects of licensing in the session from 1.15 pm to 3 pm. The keynote speaker will be Prof. J.F. Merz from Philadelphia, who will present empirical insights into the effect of patents in the field of genetic diagnostics.

The aim of these sessions is to inform and then commit the European human genetics community to take part in the discussions on the practical, ethical and societal aspects on this matter.

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