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POLICY

Introduction

Gert Matthijs*,[1] and Ségolène Aymé*,[2]

[1]*Center for Human Genetics, University of Leuven, Leuven, Belgium;* [2]*INSERM SC11, Paris, France*

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The European Society of Human Genetics (ESHG) wants to involve the genetics community in the analysis of, and the discussions on, the practical, political, societal, ethical and economical aspects of patenting and licensing of genes, sequences and genetic tests.

In 2005, the President and Board of the ESHG have asked the Public and Professional Policy Committee (PPPC) and Patenting and Licensing Committee (PLC) of the ESHG to create a working party and discuss the matter with experts and stakeholders. The aim of the joint work was to explore how to achieve a situation where useful tests are available at affordable costs for diagnosis of patients. The group explicitly aimed to 'go beyond the Myriad case'. Despite already available recommendations and reports on gene patenting, the ESHG found it necessary to focus further on diagnostics and public health aspects, and to define further action points to work with. With new knowledge constantly developing, such as ESTs, variants, gene expression mechanisms, genetic associations and so on; the practical framework is becoming more complicated.

The PPPC and the PLC organised an initiatory meeting on 29 November 2005 in Paris with four external experts and a workshop on 13 and 14 November 2006 in Leuven, to which 18 experts were invited. Prior to the second workshop, each participant received a working paper developed by the PPPC and the PLC for further discussion.

The first draft of the background document was produced by the first author. The method used to produce this document was the systematic review of current literature and articles on patenting and human genes in major scientific journals, after which it was submitted for comments to the four experts. It was then sent to approximately 90 experts for review, of which half responded. The list of experts was created by asking each member of the PPPC and the PLC to nominate several experts in their respective countries, such as geneticists having been involved in the public debates around gene patenting, attorneys, technology transfer officers, academic lawyers, and experts of non-governmental organisations in the field, and of the European Patent Office.

Their comments were incorporated to produce a second draft, which was sent to the group that convened at the workshop in Leuven.

In addition, during the workshop, the participants were invited to provide statements or recommendations they considered as crucial to improving the field of genetic testing. These statements and recommendations were incorporated into the document, together with the conclusions of the Leuven workshop, to produce the third version. This version was posted on the ESHG website for discussion in the late Spring of 2007, and the membership was invited to comment.

The final version of the background document, which is presented here, aims at reflecting the discussions and various opinions.

In brief, the background document reviews the current status on patenting and licensing in genetic testing. It deals with different issues of patenting: problems and remedies within the patenting system, which include the research exemption. Licensing is also approached, and novel models that could ease access to patented genetic inventions are explored. The document could serve as an introduction to patenting and licensing rules for geneticists and researchers.

The main reason for focusing mainly on diagnostics (and not on therapeutics) in the background paper is because diagnostic tools can be developed at relatively low cost, while development of therapeutic solutions requires lots of work, time and money. Consequently, the need to obtain return from investment seems to be much higher in the course of developing therapeutic inventions. Therefore, in

***Correspondence: G Matthijs, Center for Human Genetics, University of Leuven, Herestraat 49, Leuven 3000, Belgium.**
E-mail: gert.matthijs@med.kuleuven.be or
Professor S Aymé, Hôpital Broussais, INSERM SC11, 102 rue Didot, Paris F-75014, France. E-mail: ayme@orpha.net

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the field of diagnostics a consensus of new solutions or alternatives to patents could be more easily discovered.

Following the aforementioned process, the ESHG started to elaborate its own set of statements and recommendations. The PPPC and PLC presented a draft issue to the Board of the ESHG in June 2007. The Board endorsed it soon thereafter. They are presented below as the Recommendations of the European Society of Human Genetics.

Very briefly, the major problems seem to be in the breadth of the claims in genetic patents, in the criteria for patentability and in the number of (overlapping) patents. There is a need to improving the quality of the patents that will eventually be granted. The research exemption is generally unclear, and not universal. Licenses are problematic when they are exclusive. In general, licensing seems to be prohibitive, both in practical and in financial terms, partly due to the complexity of the system, and to the lack of effective guidelines.

The ultimate goal of the ESHG is to assist in the advancement and where necessary adaptation of legislation and practice to foster the patients' rights and access to affordable health care provisions and to safeguard the social health care system prevalent in European countries and elsewhere, with an open mind to the role of intellectual property right protection in translation of inventions into clinical practice, notably in therapy development.

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