

## ***RESEARCH PROJECT 'GENE PATENTS AND PUBLIC HEALTH' 2004-2007***

**Promotor: Prof. Dr. Geertrui Van Overwalle**

**Co-promotor: Prof. Dr. Gert Matthijs (Centre for Human Genetics, K.U.Leuven)**

**Post-doc: Dr. Birgit Verbeure**

**PhD researcher: Esther van Zimmeren LL.M.**

### **Background**

In recent years, many human genome related patents have been filed, also in Europe. Patents in the field of clinical diagnostics are not novel, patents on genes and methods for human molecular diagnostics, however, are a more recent development. The grant by the European Patent Organisation (EPO) of several patents covering the breast cancer genes, their mutations, as well as diagnostic and therapeutic applications based on the genes' sequence, evoked strong reactions both from the public and from the genetic community, and led to the questioning of the nature, legitimacy and scope of gene patents and diagnostic methods in relation to public health.

Despite the wide interest in human genetics and the controversy surrounding the BRCA1 and BRCA2 patents, there has been very little systematic and consistent description of the patented subject matter, the type of patent claims and the licensing practice for human genome related patents (hereafter referred to as "gene patents"). Even though commentators have exhaustively discussed the legal framework for gene patents, there is an urgent need to reassess, refine and strengthen the patent system for gene patents, to adapt concepts and definitions to current genetic testing methods and the increasing use of bio-informatics, and to further develop legal instruments to counter undesirable licensing practices.

### **Empirical survey**

The research project will conduct an empirical survey of European human genome related patents and aims at establishing a catalogue of granted patents with a detailed typology and classification of claims, plus an overview of licensing practices in this field. We expect this survey to provide new and detailed information and representative

statistics on the drafting of gene patent claims, enabling the establishment of a detailed classification of the types of human patents and their claims. Subsequently, the project will investigate the licensing practices of a number of human genome related patent proprietors.

### **Impact analysis**

Based on the empirical data gathered in the first stage of the project, the project will examine the impact of current patenting and licensing practices on scientific research and diagnostics. Various studies have pointed at the possible negative effects of genomic patents on development and validation of clinical tests, medical progress, diagnostics and health care in particular on the one hand, and on scientific (publication) output and on scientific research on the other hand. We note that the effect of patents on scientific research is already somehow tempered by the research exemption. The project will review the specific interpretation problems of the research exemption in the field of genome related patents. We aim at establishing some acceptable parameters, which could be useful in determining the precise borderline between activities falling inside or outside the scope of the research exemption. However, it will be worthwhile to further explore how patenting and licensing practices have influenced new product development, clinical dissemination and use of novel diagnostic tools in the field of human genetics. The current research project aims at identifying (systematic) problems encountered in view of the possible constraints that might be triggered by licensing.

### **Legal framework**

At the same time, the project will study the current Belgian, European and international legal framework with regard to patenting of genes and diagnostic methods and the licensing of patented technology for public health purposes. This will include a critical examination of the current European patent system as to the patentability of DNA, taking into account the shifting landscape of discovery in genomic research. In this regard the project will analyse to which extent existing IPR systems (copyright law, database protection) and alternative systems may be useful in creating acceptable protection for genome related inventions. Like any other patent, gene patents must meet the criteria of novelty, inventive step and industrial applicability (Art. 52 EPC) and

must disclose the invention in a manner sufficiently clear and complete (Art. 83 EPC). Several studies suggest that many existing patents may be invalid for reasons of lack of novelty, inventive step and enabling disclosure. The project will briefly review case law and legal doctrine on this issue.

As far as licensing is concerned, the project aims at studying the compulsory licensing concept, the common procedures and terms with regard to genetic diagnosis in some developed countries, as a tool to temper the consequences of an extreme monopoly. We will investigate as well to what extent a system of non-exclusive, broad licensing in the field of genetic diagnostics could be realised and would be allowable and workable. We intend to find and define a licensing regime that finds an acceptable balance between access to genetic diagnostics and screening tests in return for a reasonable royalty fee. In this regard also the impact of competition law will be analysed.

### **Health care**

A major focus of the project is the effect of current patent law and patent practices on health care (costs and quality). This day, few papers have analysed the cost impacts of (predictive) genetic tests on health care costs. The present research project will examine this cost issue, be it that the work will be confined to an analysis of the overall cost of molecular diagnostic techniques. In this regard the possibility of implementing a (Anglo-American) health care provider exemption as an instrument to restrict the impact of patent law on the access to health care services will be assessed. For this part of the work, researchers and organisations with specific knowledge and skills in this field are invited to joint the project.

### **Goals of the project**

The project will generate a list of considerations with regard to patent law and (compulsory or non-exclusive) licensing, that could assist Belgian and European lawmakers, would they wish to do so, in adapting their laws to the post genomic era, while ensuring a better balance between intellectual property protection for modern molecular diagnostic techniques and the needs of public health. Moreover, it is our ambition to try and develop a 'Leuven protocol', encompassing detailed guidelines on

patenting genes and diagnostic methods, instructions on possible additional (copyright and database) protection systems and rigorous regulations on licensing practices in the field of genome related patents. This protocol may be implemented in the Leuven research institutes, (research) laboratories and spin offs. Other research groups, pharmaceutical or biotechnological companies will be invited to subscribe the protocol on a voluntary basis.

### **Key references**

- BOSTYN, S. J.R., *Enabling Biotechnological Inventions in Europe and the United States. A Study of the Patentability of Proteins and DNA Sequences with Special Emphasis on the Disclosure Requirement*, Munich, European Patent Office, 2001, 352 p.
- CAULFIELD, T.A., KNOPPERS, B.M., GOLD, E.R., SHEREMETA, L. & BRIDGE, P.J., 'Genetic Technologies, Health Care Policy and the Patent Bargain' *Clinical Genetics*, 2003, 63: 15-18
- EISENBERG, R. S., 'How Can You Patent Genes?', 2 *American Journal of Bio-ethics*, 2002, 3-11
- KNOPPERS, B. M. 'Status, sale and patenting of human genetic material: an international survey'. *Nat. Genet* 1999: 22: 23-26
- MERZ, J.F, KRISS, A.G., LEONARD, D.G.B. & CHO, M., 'Diagnostic Testing Fails the Test', 415, *Nature*, 2002, 577-579
- NELKIN, D., 'Patenting Genes and the Public Interest', 2 *American Journal of Bio-ethics*, 2002, 13-15
- NUFFIELD COUNCIL ON BIOETHICS, *The Ethics of Patenting DNA. A Discussion Paper*, 2002, ([www.nuffieldbioethics.org](http://www.nuffieldbioethics.org))
- ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, *Working Paper on Biotechnology. Genetic Inventions, IPRs and Licensing Practices: Evidence and Policies*, Paris, 2002 (DSTI/STP/BIO(2002)5/REV1)
- STRAUS, J., HOLZPAPFEL, H. & LINDENMEIR, M., *Empirical Survey on Genetic Inventions and Patent Law*, Munich, Max Planck Institute for Foreign and International Patent, Copyright and Competition Law–Federal Ministry of Education and Research, 2002

WALSH, J.P., ARORA, A. & COHEN, W.M., *The Patenting of Research Tools and Biomedical Innovation* (Discussion paper prepared for the Science, Technology and Economic Policy Board of the National Academy of Sciences), 2001, 35 p.  
(<http://ip.nationalacademies.org>)

WOLFRUM, R., STOLL, P.-T., FRANCK, S., *Die Gewährleistung freier Forschung an und mit Genen und das Interesse an der wirtschaftlichen Nutzung ihrer Ergebnisse*, Frankfurt am Main, Peter Lang, 2002, 155 p.