PATENTING AND LICENSING IN GENETIC TESTING, with a focus on DIAGNOSTICS

Legal, Social and Ethical Issues

ESHG – June 2008

BACKGROUND INFORMATIONS

European Patent Convention (EPC) (1973)

For a patent to be granted, the claimed invention MUST BE:

- novel
- inventive or non-obvious
- have industrial application
- must be fully disclosed in the application

A DISCOVERY cannot be patented

European Patent Office

- Isolated genes with known utility constitute patentable inventions under the EPC.

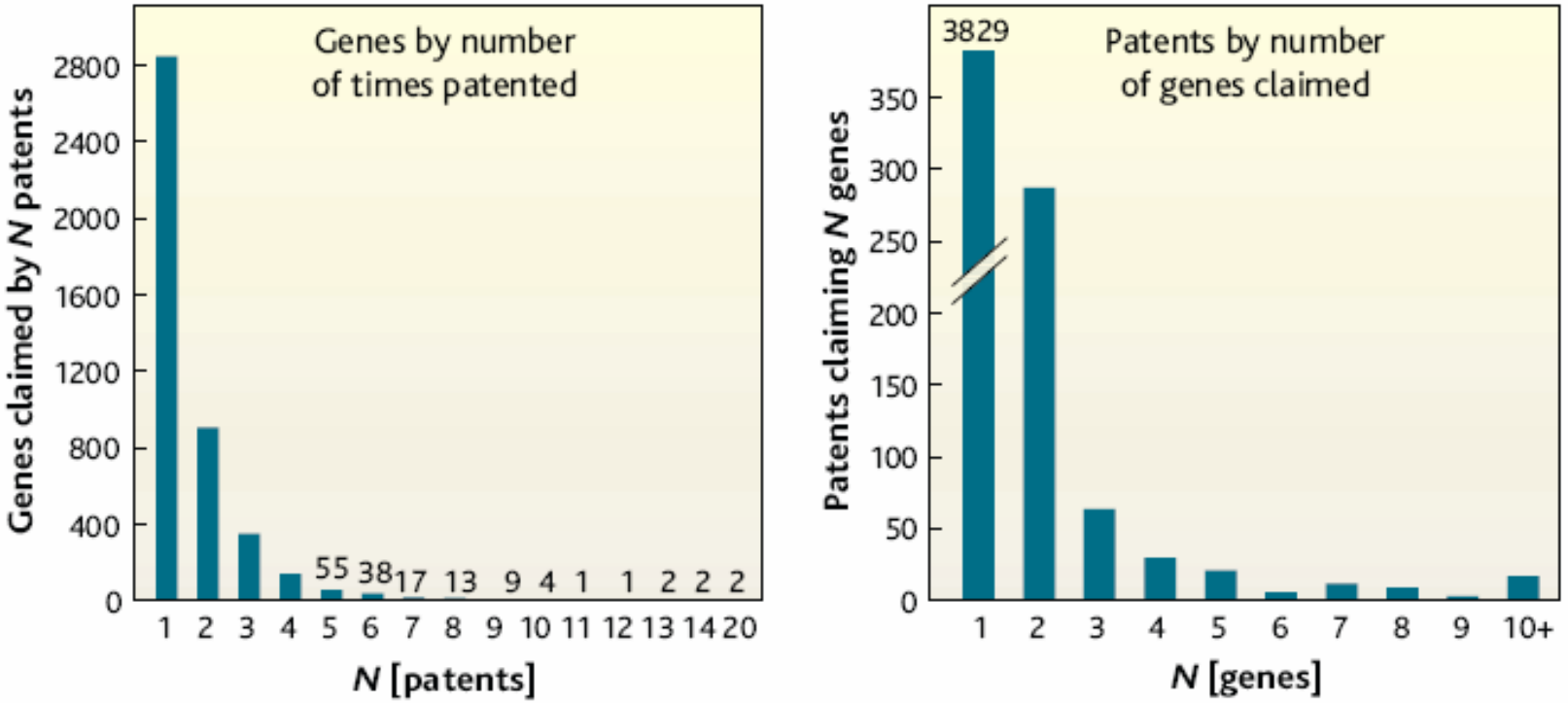
European Directive (98/44) (1998)

"An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."

VOL 310 14 OCTOBER 2005

Intellectual Property Landscape of the Human Genome

Kyle Jensen and Fiona Murray*



Global characteristics of the patent map. (**Left**) Distribution of genes by the number of times they are patented. (**Right**) Distribution of patents by the number of unique genes they claim.

Evidence and anecdotes: an analysis of human gene patenting controversies

Timothy Caulfield, Robert M Cook-Deegan, F Scott Kieff & John P Walsh

When it comes to gene patenting, policy makers may be responding more to high-profile media controversies than to systematic data about the issues.

NATURE BIOTECHNOLOGY VOLUME 24 NUMBER 9 SEPTEMBER 2006

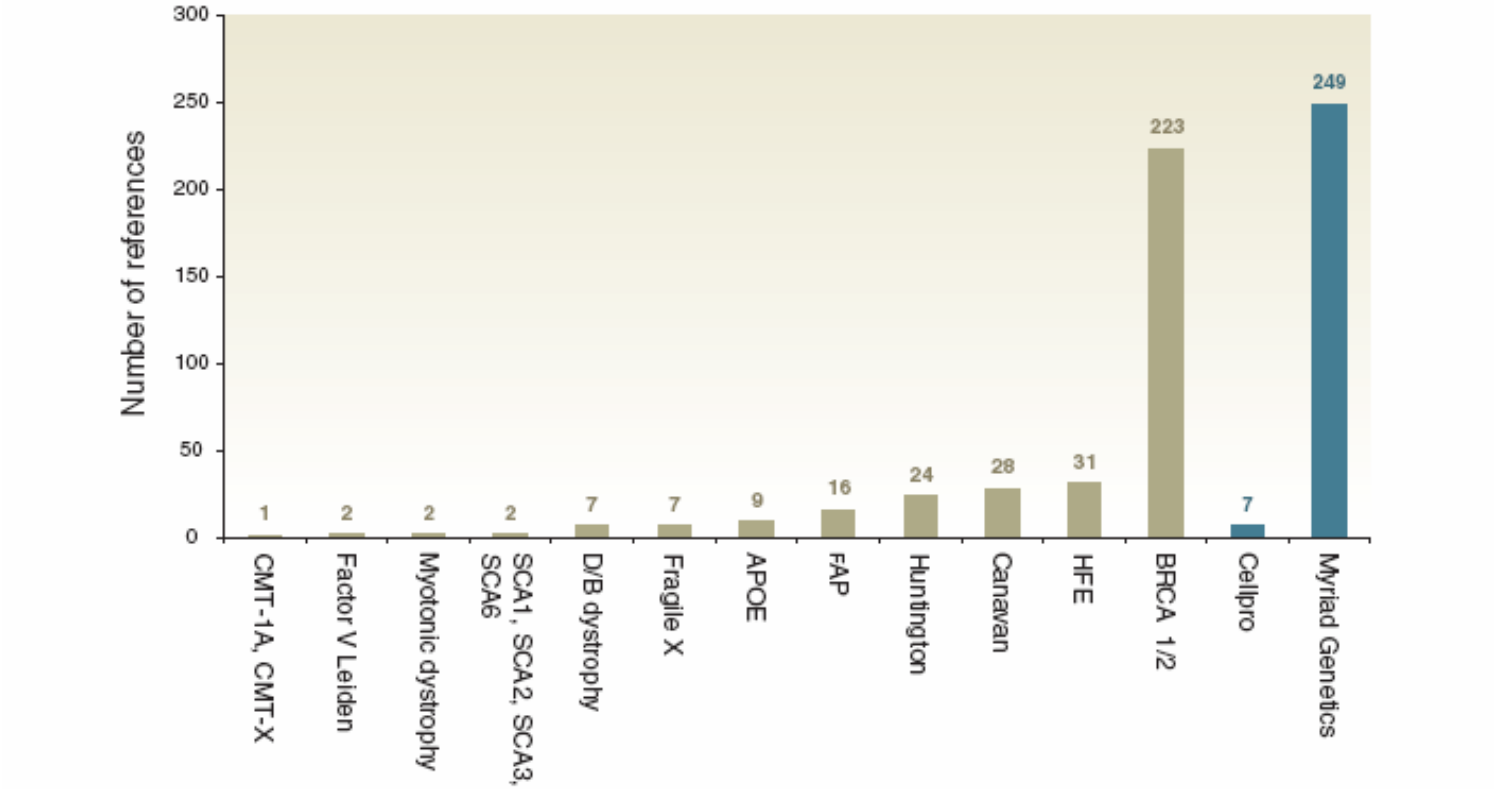


Figure 2 Explicit references to controversial biotechnology patents and firms in major policy documents after 2002.

Lost in space
'Creative' approach to Beagle 2 finds no favour with inquiry
p330

Risk factor
Tissue analysis hints at broader spread of brain disease
p331

Culture shock
Microbiologists get to grips with growing the world's bacteria
p332

Creature comfort
Britain sets out plan to improve the lot of lab animals
p334

Clinicians win fight to overturn patent for breast-cancer gene

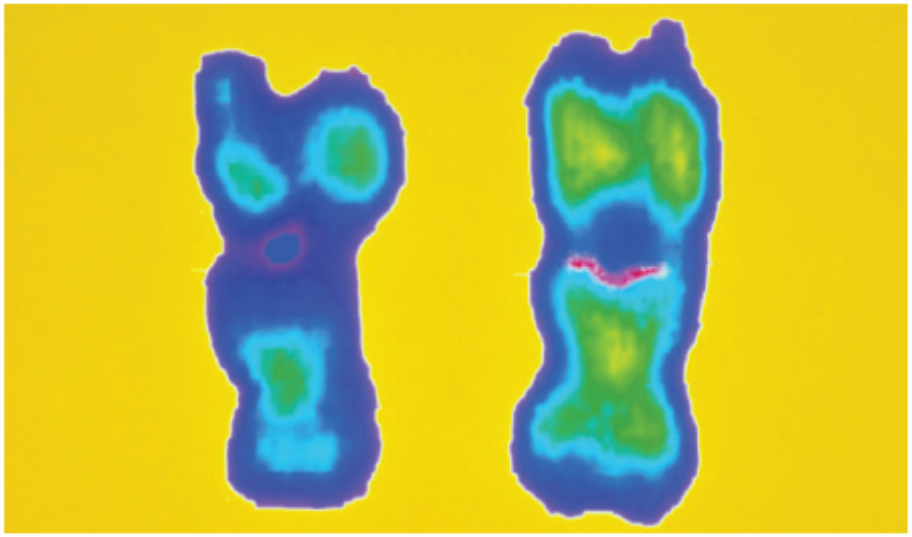
Alison Abbott, Munich

A European patent that gave a company in Utah the exclusive right to perform diagnostic tests for a breast-cancer gene has been revoked.

In a landmark ruling on 18 May, the European Patent Office (EPO) granted an appeal against Myriad Genetics of Salt Lake City over its patent on the gene *BRCA1*. The office ruled that Myriad's claim was invalid because its original submission, made in the United States in 1994, contained a number of small errors in the gene's sequence.

The finding sheds light on the race in the early 1990s to patent genes of interest, while updating their accuracy, even as other researchers put versions of the same sequences in public repositories, such as GenBank.

Mutations in *BRCA1* predispose women to some hereditary forms of breast cancer. Myriad's patent had incensed European clin-



Women with only one copy of the *BRCA1* gene (red) on chromosome 17 may be at risk of breast cancer.

CUTTSOM MEDICAL STOCK PHOTO/SPL

Vol 429
No 6990
pp329

Main Request

1. Use of an isolated nucleic acid which comprises the coding sequence set forth in SEQ ID NO: 1 from nucleotide position 229 to nucleotide position 10482 and further comprising the mutation associated with a predisposition to breast cancer, wherein T at nucleotide position 6174 is deleted, for diagnosing a predisposition to breast cancer in Ashkenazi-Jewish women in vitro.

There are instances in which the patent attorneys
(seem to be exploring / seem to have to explore) the limits of patentability.

However, within the legal framework, the EPO has no means to avoid those tricks.

(GM)

ESHG’S INITIATIVE AND RECOMMENDATIONS

ESHG - Patenting and Licensing Committee

The Professional and Public Policy Committee (PPPC) and the Patenting and Licensing Committee (PLC) have prepared a Draft Background Document on “PATENTING AND LICENSING IN GENETIC TESTING”.

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.

ESHG - Patenting and Licensing Committee

This work was started upon request by the President and the Board of the ESHG. After an initiatory meeting in November 2005 in Paris, and a workshop in November 2006 in Leuven, a document was prepared that would comprehensively review the background on patenting and licensing, and the current situation with a focus on genetic, diagnostic testing. During the workshops, external experts were asked for advise.

The discussions and the background document have served as a basis for the generation of recommendations, by the PPPC and PLC members. These recommendations have been submitted to the Board for approval. They are now ready for publication.

European Journal of Human Genetics (2008) 16, 405–411

www.nature.com/ejhg

POLICY

Patenting and licensing in genetic testing

Recommendations of the European Society of Human Genetics

The members of the Public and Professional Policy Committee (PPPC) and the Patenting and Licensing Committee (PLC) of ESHG who were involved in setting up these recommendations were Ségolène Aymé (Paris, France), Gert Matthijs (Leuven, Belgium), Violetta Anastasiadou (Nicosia, Cyprus), Fatmahan Atalar (Istanbul, Turkey), Suzanne Braga (Berne, Switzerland), John Burn (Newcastle upon Tyne, UK), Jean-Jacques Cassiman (Leuven, Belgium), Martina Cornel (Amsterdam, The Netherlands), Domenico Coviello (Milano, Italy), Gerry Evers-Kiebooms (Leuven, Belgium), Philippe Gorry (Bordeaux, France), Shirley Hodgson (London, UK), Helena Kääriäinen (Turku, Finland), György Kosztolányi (Pécs, Hungary), Ulf Kristoffersson (Lund, Sweden), Milan Macek Jr (Prague, Czech Republic), Christine Patch (London, UK), Jörg Schmidtke (Hannover, Germany), Jorge Sequeiros (Porto, Portugal), Dominique Stoppa-Lyonnet (Paris, France), Lisbeth Tranebjærg (Copenhagen, Denmark), Veronica van Heyningen (Edinburgh, UK) and Gert-Jan van Ommen (Leiden, The Netherlands).

In summary:

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.

Major suggestions:

It could be fairly easy to prohibit patenting of individual mutations in known disease genes, for example on the basis of an absence of novelty.

Establishing a link between a disease and a genetic sequence or defect is merely a discovery and therefore not patentable, unless the identification of this link includes a real conceptual innovation.

The ESHG proposes EPO to consider the benefit of having an ethics committee to consider issues of major interest, such as patents applied to genes.

Policy makers should work on the development of licensing guidelines, and effectively support those that have already been issued by international organizations such as the OECD.

PRESS CONFERENCE INVITATION

12.00, 24 April 2008

Academy House - Hertogsstraat 1 - B-1000 Brussels, Belgium

European experts propose solutions to gene patenting controversy

The European Society of Human Genetics (ESHG) invites the media to attend the launch of new guidelines on patenting genes. Drafted by leading European experts, it is hoped that these guidelines, which are published simultaneously in the European Journal of Human Genetics, will bring to an end the long-running controversy on this subject. The programme for the media launch is as follows:

12.00 hrs	Buffet lunch and oppportunity to mingle with the speakers
13.00 hrs	Introduction by Prof. Pier-Franco Pignatti, president of ESHG.
	Presentation of the recommendations will be briefly presented by Prof. GertJan van Ommen and Prof. Gert Matthijs, members of the Patenting and Licensing Committee of ESHG. Brief comments from important stakeholders in the field: - Dr. Siobhan Yeats, European Patent Office (Munich, Germany) - Prof. Joseph Straus, Max-Planck-Institute for Intellectual Property, Competition and Tax Law and Munich Intellectual Property Law Center (Munich, Germany), an academic patent specialist - Prof. John Burn, University of Newcastle upon Tyne (UK), representing the views of clinical geneticists - Mr. William Bird, Bird Goën & Co (Belgium), a practicing patent attorney - Mr. Denis Dambois, from the European Commission.