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**REPORT FROM THE COMMISSION
TO THE COUNCIL AND THE EUROPEAN PARLIAMENT**

**Development and implications of patent law in the field of biotechnology and
genetic engineering**

(SEC(2005) 943)

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(Text with EEA relevance)

INTRODUCTION

This is the second report pursuant to Article 16c of the Directive 98/44/EC¹ of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions and bears the title “Developments and implications of patent law in the field of biotechnology and genetic engineering” (hereinafter the “second 16c Report”).

Its purpose is to set out the key events which have occurred since publication of the first 16c Report², and to comment on two issues identified in the latter: the scope of patents on sequences or partial sequences of genes which have been isolated from the human body; and the patentability of human stem cells and cell lines obtained from them. The Commission’s analysis is based on the Commission staff working paper SEC(2005)943.

1. LATEST DEVELOPMENTS IN THE FIELD OF BIOTECHNOLOGICAL INVENTIONS

1.1. State of progress with transposition of Directive 98/44

As of June 2005, 21 Member States of the European Union had notified the Commission of the instruments implementing the Directive. Legal proceedings for failure to transmit transposition measures were initiated in 2003 before the Court of Justice against the countries which had not transposed the Directive³. Infraction procedures have been opened in December 2004 against two new Member States which have not completed the transposition of the Directive⁴.

1.2. Group of Experts

As announced in the first 16c report, a Group of Experts has been set up, its remit being to advise the Commission on the preparation of future 16c Reports through the examination of important issues relating to biotechnological inventions. The Group comprises specialists in patent law and highly qualified persons in the field of biotechnologies⁵.

¹ OJ L 213, 30.7.1998, pp. 13-21.

² COM(2002) 545 final, http://europa.eu.int/eur-lex/en/com/rpt/2002/com2002_0545en01.pdf

³ <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/991&format=HTML&aged=1&language=EN&guiLanguage=en>

⁴ Lithuania and Latvia.

⁵ <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/127&format=HTML&aged=1&language=EN&guiLanguage=en>

1.3. Community action on cross-licences

The first 16c Report indicated that the provisions of Article 12 of the Directive and Article 29 of Regulation 2100/94 on Community plant variety rights⁶ were not compatible with each other and that Article 29 of the Regulation should be amended.

Accordingly, on 11 December 2003, the Commission presented a draft Regulation amending Regulation 2100/94 on Community plant variety rights⁷. The draft was adopted by the Council on 29 April 2004⁸. The provisions of the Regulation and the Directive are now mutually compatible.

2. ANALYSIS OF ISSUES RAISED IN THE FIRST REPORT

It was stated in the conclusions of the first 16c Report that the Commission should revisit two questions:

- the scope to be attributed to patents on partial sequences or sequences of genes which have been isolated from the human body;
- the patentability of human pluripotent embryonic stem cells and stem cell lines obtained from them.

The following analysis is based on the articles and recitals of the Directive, but also, *inter alia*, on preparatory work and the decision of the Court of Justice of 9 October 2001⁹, in which the Court rejected an application for annulment of the Directive. In line with the intention stated in the first 16c Report, the analysis also takes account of the contributions made by the informal Group of Experts mentioned under 1.2.

2.1. Scope of patents on gene sequences

The issue to be reviewed according to the first report under Article 16c is the question of whether patents on gene sequences (DNA sequences) should be allowed according to the classical model of patent claim, whereby a first inventor can claim an invention which covers possible future uses of that sequence, or whether the patent should be restricted so that only the specific use disclosed in the patent application can be claimed (“purpose-bound protection”).

On examination of the detailed provisions of the Directive, it can be seen that Articles 8, 9, 10 and 11 make up Chapter 2 of the Directive which is entitled “Scope of protection”. However none of these articles addresses the concept of a restricted scope of protection relating to the specific use identified for the gene sequence concerned. Indeed Articles 8 and 9 establish that the protection conferred by a patent extends to any biological material obtained from the claimed product or in which the claimed product is incorporated and the same genetic

⁶ Council Regulation (EC) N° 2100/94 of 27 July 1994 on Community plant variety rights, OJ L 227, 1.9.1994, pp. 1-30.

⁷ COM(2003) 456 final. The draft Regulation can be consulted on the Council’s web site: <http://register.consilium.eu.int/pdf/en/03/st14/st14215.en03.pdf>

⁸ Council Regulation (EC) N° 873/2004 of 29 April 2004 amending Regulation (EC) N° 2100/94 on Community plant variety rights, OJ L 162, 30.4.2004, p. 38.

⁹ Judgement of the Court of Justice, 9 October 2001, Case C-377/98, Kingdom of the Netherlands supported by Italian Republic and by Kingdom of Norway v. European Parliament and Council of the European Union, supported by Commission of the European Communities.

information expresses its function. This might be seen as arguing for a broad scope of protection rather than a restricted one, subject of course to the exclusion under Article 5(1) of claims to the human body in its entirety.

On the other hand, it might be thought from Article 5(3) and Recitals 23 and 25 that the Community legislator had intended to at least raise the possibility of a limited scope of protection covering only the specific industrial application identified in the patent, as far as this particular type of invention is concerned. Otherwise Article 5(3), which requires the industrial application of a gene sequence to be disclosed in the patent application, merely repeats a standard requirement of general patent law, as can be seen from Recital 22.

The informal Group of Experts met in March 2003 to discuss this issue. A majority of the Group felt that there were no objective reasons to create a specific regime of purpose-bound protection in this area differing from the classic patent protection. In particular, legal and technical experts felt there were no differences between DNA sequences and chemical substances which would justify different treatment as regards the scope of patent protection.

Since these discussions other arguments have been brought to the table.

First, there is the question of whether the fact that human gene sequences have been isolated from the human body implies that they should be given different treatment to chemical substances on ethical grounds. This reasoning would seem to be behind the transposition of the Directive contained in French national law and in Germany where purpose-bound protection is provided for inventions concerning material isolated from the human body (France) and human/primate gene sequences (Germany).

A second argument is an economic question: is it more valuable to society to allow the first inventor a broad scope of protection so others which build on this invention should have to seek a licence, or should a patent on a gene sequence be limited in scope to allow future uses of such sequences to be patented freely? This issue has been linked to the freedom of research, although certain research exemptions already exist in patent law. More generally it relates to the balance between investment and potential reward for the first innovator in a field compared to subsequent innovators. Economic evidence is however hard to come by and the arguments do not relate solely to gene sequence patents as distinct from any other field of technology. The Commission has launched a study¹⁰ that is analysing the extent of human DNA patenting in Europe and its potential consequences on research and innovation. The Group of Experts could be asked to consider further the impact of the research exemption.

Moreover, as a specific field of technology becomes mature, the application of the normal patent criteria of novelty, inventive step and industrial applicability means that future patents are necessarily limited in scope because the invention claimed has to be distinguished from the vast array of what is already known in the field¹¹. As it is now seventeen years since a

¹⁰ The Patenting of Human DNA: Global trends in commercial and public sector activity
<http://www.sussex.ac.uk/spru/1-4-14-1.html>

¹¹ The case of the European patents on BRCA1 gene (related to the predispositions to ovary and/or breast cancer) is an example. Indeed for the three European patents exploited by the Myriad Genetics company, the procedures of opposition carried out at the European Patent Office (EPO) led in May 2004 to the revocation of the first patent (EP0699754), then in January 2005 to a substantial limitation of the protection conferred by the second and third patents (EP0705902 and EP0705903) for the reason that these patents were not in conformity with the European Patent Convention (EPC) because they do

Directive was first proposed, it may be questionable whether attempting to further refine the scope of protection of gene sequence patents in the light of divergences between national legislations will have any significant effect on actors in the field.

Against this background, the Commission does not at present intend to take a position on the validity of transposition according to the choice between classical and limited scope of protection for gene sequences. The Commission will, nonetheless, continue to monitor whether there are any economic consequences of possible divergences between Member States' legislation.

2.2. Patentability of human embryonic stem cells and cell lines obtained from them

Human embryonic and somatic stem cells (the latter isolated from foetal or adult tissue) each have advantages and limitations regarding their potential uses for basic research and novel stem cell based therapies. Currently, human embryonic stem cells are of particular interest because they have the potential to differentiate into all cell types in the body (they are pluripotent) and are at present the only pluripotent stem cell that can be readily isolated and grown in culture in sufficient numbers to be useful.

A distinction can be drawn between totipotent stem cells, which are capable of developing into a human being, and pluripotent stem cells, which are not so capable. The debate has gained greater profile since the beginning of 2004 when Korean researchers announced the results of experiments leading to the development of a cell line of pluripotent stem cells¹² using the technique of "therapeutic cloning", by which cells are developed with the same genetic information as a particular patient and used to treat that patient's disease, essentially without the risk of rejection by the patient's immune system.

The question of whether the Directive specifically addressed the patentability of stem cells was raised in the first 16c Report, and referred to the Group of experts for discussion in May 2003.

The European Group of Ethics considered (in its opinion No 16¹³) that there was no ethical reason for a complete ban on patenting of inventions relating to stem cells or stem cell lines, although the normal requirements of patentability would have to be met.

The provisions of the Directive are clear in relation to totipotent stem cells, since each cell could develop into a human being on its own and under Article 5(1) the human body at the various stages of its formation and development cannot constitute a patentable invention. This principle has been reiterated in the practice notice issued by the UK patent office in April 2003¹⁴.

For pluripotent embryonic stem cells the situation is more complex. The Group of Experts considered that the question of patenting was closely linked to the definition of what constitutes an embryo, and the scope of research allowed, which is determined by national legislation. As regards research funding under the European framework programmes, such

not respect in particular the criterion of novelty. The first decision of the EPO is the subject of an appeal (T 80/05-338).

¹² <http://www.nature.com/nsu/040209/040209-12.html>

¹³ http://europa.eu.int/comm/european_group_ethics/docs/avis16_en.pdf

¹⁴ <http://www.patent.gov.uk/patent/notices/practice/stemcells.htm>

funding may be available for projects involving human embryonic stem cell research on a case by case basis.

In the light of the clear divergences which currently exist between Member States as regards the acceptability of research relating to embryonic stem cells¹⁵, the continuing and rapid developments in this field, and the fact that the Directive itself provides for Member States to refuse patents on grounds of *ordre public* or morality under Article 6(1), the Commission considers that it is premature to give further definition or provide for further harmonisation in this area. At the same time the Commission will monitor developments taking into account both the ethical aspects and the potential impact on competitiveness. It has launched a study¹⁶ looking at the ethical and legal aspects of stem cell patenting.

3. CONCLUSIONS

The first 16c Report stated that the main provisions of the Directive were clear and precise; that uncertainty could not be permitted where the patentability of plants, animals and micro-organisms was concerned; and that there was no ambiguity regarding the patentability of material isolated from the human body.

This Report introduces some new, fundamental considerations. While it can be argued from a plain reading of the provisions of the Directive that there are no objective grounds for limiting the traditional protection granted by patent law to inventions relating to sequences or partial sequences of genes isolated from the human body, other issues have also been raised relating to ethics, to research and to economics. The Commission will continue to monitor whether there are any economic consequences of possible divergences between Member States' legislation.

In the light of the Commission's analysis, it appears that totipotent stem cells should not be patentable, on grounds of human dignity.

There is no immediate answer to the question of the patentability of embryonic pluripotent stem cells and indeed at this stage it would appear premature to come to a definitive conclusion. The Commission will continue to monitor developments in this area.

¹⁵ http://europa.eu.int/comm/research/biosociety/pdf/mb_states_230804.pdf

¹⁶ Stem Cell Patents: European Patent Law and Ethics
<http://www.nottingham.ac.uk/law/StemCellProject/summary.htm>