'...the uncoordinated development of national laws could lead to disincentives to investment...'

editorial

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European patent law and ethics

The EU Directive on the Legal Protection of Biotechnological Inventions 98/44//EC was intended to harmonize patent law in the field of biotechnology and genetic engineering. The fear was that the uncoordinated development of national laws could lead to disincentives to investment and trade and ultimately impede the smooth functioning of the internal market. It took over a decade for the EU legislative institutions to reach agreement on the final wording of the text. However, far from achieving its stated aim, the Directive adopted in 1998 has created considerable uncertainty and an unprecedented disruption to patent law in Europe [1,2].

The aim of the EU funded project *Stem Cell Patents: European Patent Law and Ethics* is to provide a lead in the resolution of the legal uncertainty created by the Directive. The project will be carried out over a period of 18 months (Jan 05–June 06). The focus of the project is on Article 6 of the Directive which prohibits patents that are 'immoral', including 'processes for cloning human beings' [Article 6.2(a)] and 'uses of human embryos for industrial or commercial purposes' [Article 6.2(c)]. These prohibitions were imported into Rule 23(d) of the European Patent Convention in 1999.[1] The crucial question is how the prohibitions on human embryonic patents should be interpreted and applied in the light of the fundamental principle of EU law, which devolves competence to Member States in matters concerning morality and the fact that patent law is independent of national regulatory regimes on embryo research, which, in liberal states like the UK, permit embryo research[2].

The Directive does not create a separate body of law in place of the rules of national patent law but the Directive has to be implemented by Member States and applied by national patent offices and/or the European Patent Office (EPO). The first phase of the project, currently underway, is to get an update on the impact of the Directive on national laws and on the practice of national patent offices and the EPO. There are currently eight Member States (Germany, Austria, Belgium, France, Italy, Luxembourg, the Netherlands and Sweden) that have failed to implement the Directive and which have been referred to the European Court of Justice[3]. Conversely, some Member States have implemented the Directive notwithstanding their espousal of a liberal regime on embryo research. The project aims to identify

[1]See 'Decision of the Administrative Council of 16 June 1999 amending the Implementing Regulations to the European Patent Convention.' Available online at http://www.european-patent-office.org/epo/ca/e/16_06_99_impl_e.htm
[2]See the European Commission's Report on human embryonic stem cell research. Commission staff working paper. SEC(2003) 441.

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emerging trends and areas of difficulty or uncertainty in the implementation or non-implementation of the Directive in National Laws.

The comparative analysis of national laws will be complemented by an analysis of applications to the EPO and national patent offices. A comprehensive search and update on existing applications is currently underway. This will result in an analysis of the differences that have recently surfaced between the EPO and national patent offices over the grounds of rejection of specific applications[4].

The results of the comparative analysis of patent law and the practices and policies of patent offices on human embryonic stem cell patents will be combined in phase two of the project with the results of a parallel review of national and supra-national ethical and legal restrictions on embryo research, with a particular emphasis on the precise nature of the level and scope of protection of the human embryo in international and regional human rights instruments. It is anticipated that this analysis will assist in two ways.

In the first instance, a complicating factor in the implementation of the Directive has been the intervention of the European Group on Ethics (EGE), whose Opinion no. 16 on the Patenting of Human Embryonic Stem Cells[5] was rejected by the Opposition Division of the EPO in its decision on the so-called 'Edinburgh' patent (EP 94913174.2) in July 2003[6]. The first phase of the project thus aims to clarify the precise nature of the Constitutional status of the EGE and to analyze its substantive recommendations to evaluate the reasons that are casting uncertainty over its authority.

A related study, which is currently underway, involves a detailed mapping and delineation of the boundaries between ethical and legal norms on human embryonic research to clarify their precise legal effect on the Directive and its implementation. In particular, the precise nature of the relationship between the Directive and international human rights instruments in the field of embryo protection is yet to be determined in the light of Article 16 of the Directive, which imposes on the Commission an obligation to send a report to the European Parliament and the Council on any problems encountered with regard to the relationship between the Directive and international agreements on the protection of human rights to which Member States have acceded[7]. The project will analyze the *prima-facie* tension between human rights instruments, particularly the established jurisprudence of the European Court of Human Rights on the scope of application of Article 2 of the European Convention on Human Rights (1950)[8] to the human embryo, which confers on Member States discretion to define when life begins and the level of protection required[9], and the seemingly uniform standard introduced in the prohibitions on embryo research contained in the Directive and the EPC.

It is expected that the combination of the four arms of the project will cast new light on the Directive and assist in the clarification of its scope of application.

The project is conducted by a multidisciplinary and independent team of experts from Europe and Canada. Further details of the project may be found on the website: http://www.nottingham.ac.uk/law/StemCellProject/summary.htm

[3]See 'Industrial Property: Eight Member States Referred to Court for Failure to Implement Directive on Legal Protection of Biotechnological Inventions,' (Press Release of the European Court of Justice) IP/03/991,10/07/2003.Availableonlineat: http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/991andformat=HTMLandaged=0andlanguage=ENandguiLanguage=en. Also see,'Brussels Takes EU States to Court over Biopatent Law', Nature Biotechnology 21, 960 (2003).

[4]See Practice Notice of the UK Patent Office,'Inventions Involving Human Stem Cells', April 2003. Available online at http://www.patent.gov.uk/patent/notices/practice/stemcells.htm

[5]Opinion of the European Group on Ethics 2002 Opinion No.16 of 7 May 2002; www.europa.eu.int/comm/european_group_ethics/docs/avis16_en.pdf

[6]The Opposition Division rejected Opinion 16 of the EGE, stating that 'Due to its many inconsistencies, logical flaws and incompatibility with existing patent law and the EU Directive, the Opinion must be disregarded in toto'.

[7]The report is to be sent every five years.

[8]Article 2 protects 'everyone''s right to life.

[9]See for instance the judgment of the Grand Chamber of the European Court of Human Rights in the case of Vo v France 2 July 2004, accessible online through the Council of Europe's website: http://www.echr.coe.int). An analysis of the Vo case may be found in 'Foetal Rights under Article 2 of the ECHR: the case of Vo v France' Human Rights Law Review (2005) summer, forthcoming. For an analyis of European human rights law on the human embryo, including the provisions on embryo research in Convention on Human Rights and Biomedicine (1997) see A. Plomer, The Law and Ethics of Medical Research: International Bioethics and Human Rights, chapter 4, Cavendish (2005).

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