

Patents on Human Embryonic Stem Cells: European Law and Ethics¹

By Aurora Plomer

The European *Directive on the Legal Protection of Biotechnological Inventions* 98/44/EC (the Directive) was officially adopted on 6 July 1998. The aim of the Directive was to promote research and development in the field of biotechnology in the European Community (EC) through the removal of the legal obstacles arising from differences in patentability standards in national legislation and case law.

The aim proved difficult to realize: it took ten years for the European legislative institutions to reach agreement on the final legislative text. The European Parliament's wish to give a more prominent role to morality within patent law led to its rejection of an earlier text in March 1995. The final text was the outcome of a legislative process that involved extensive redrafting and amendments reflecting differences in national moral and legal cultures in Europe and a political compromise between the Commission and the EC institutions that share the legislative power under the co-decision procedure. The compromise text adopted included a 'morality clause' in the form of **Article 6**, which uniquely contains a non-exhaustive list of applications of specific technologies to be excluded from patentability on the grounds of *ordre public* or morality. The specific list of examples was intended to guide the implementation and interpretation of the morality clause by 'giving definition' to the broader moral exclusion set out in **Article 6(1)** through the inclusion of illustrations of inventions considered unpatentable on moral grounds at the time. Paradoxically, it is precisely in relation to the interpretation of some of the listed exceptions, most notably, **Article 6(2)(c)** which excludes from

patentability 'uses of human embryos for industrial or commercial purposes' that acute differences have emerged.

The aim of the report – *Stem Cell Patents: European Law and Ethics* – is to determine and clarify the scope of the moral exclusion clauses in the Directive in respect of the application of the exclusion to human embryonic stem cells (hESC) through an analysis of the range of legal considerations, which are relevant to the resolution of the differences that have emerged. The report is particularly timely in the light of the forthcoming hearing by the EBA of the *Wisconsin Alumni Research Foundation (WARF)* case (Patent Application No. **96903521.1 / 0770125**. In its Referral **G2/06** OJEP 6/2006, the Technical Board of Appeal considered that the case raised

an outstandingly important point of law within the meaning of **Article 112(a) EPC** for which a decision by the Enlarged Board of Appeal is required.

The report starts from the basis that there are a number of legal instruments and legal frameworks within which the Directive is applied and interpreted. The Directive operates within 25 national jurisdictions, which have to comply with the EU legal order. At the same time, all these EU member states are contracting parties of the European Patent Convention (EPC) – a distinct legal order into which the moral exclusion clauses have also been transposed into **Rule 23d(a) to (d)**.

The report is premised on the assumption that the overarching legal frameworks within which the Directive operates, in particular the EU legal order and the EPC patent system each have distinctive legal features which bear on the legal construction of the moral exclusion clauses. The study analyses the range of legal and extra-legal sources that are relevant to the interpretation of the Directive under each legal system. In particular, the report considers:

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- The text of the Directive, including the Recitals.
- The wider principles of EU law under which the Directive has legal effect.
- Applicable national and international law on the protection of the human embryo, notably the European Convention on Human Rights.
- The implementation of the Directive in national laws.
- National and international patent law instruments.
- The policies and/or practices of national patent offices.
- The opinions of the European Group of Ethics (EGE).
- The relevant case law under each system, e.g. European Court of Justice (ECJ) case law and European Patent Office (EPO) case law, respectively.

The first part of the report analyses the operation of the Directive within the EC legal order and examines the range of sources that the national courts of member states and the ECJ are obliged to consider in the construction of the Directive under EU law. The report then conducts a parallel analysis of the range of legal sources that bear on the construction of the Articles transposed from the Directive in the EPC. The initial hypothesis is that there should be a convergence between the construction of the application of the moral exclusions clauses to hESC under both systems on the basis of the transposition of the relevant provisions in the Directive into the EPC. The report highlights the areas of convergence and divergence identified and the conclusions reached on the scope of exclusion of the morality clauses as regards patentability of hESC.

The analysis of the relevant provisions, **Articles 5** and **6** in the Directive, highlights the complexity of the legal framework(s) in which the moral exclusion clauses fall to be interpreted. The conclusions of the report also highlight the legal consequences for European patent law of the lack of integration of the EU and the EPC legal systems. The following is drawn from the conclusions of the report.

The EU legal order

Scope of Exclusion of Article 5

The Directive draws a clear distinction between the unpatentability of the human body in its natural state as against elements isolated from the human body, which could constitute a patentable invention, providing they satisfy the patenting criteria of novelty, inventive step and industrial application.

Analysis of the Preparatory Works to the Directive discloses that the intention of the Community

legislator was to exclude patents on the human embryo itself under **Article 5(1)**. Whether the exclusion was intended to apply to both the human embryo in its natural state and the human embryo *in vitro*, is not clear from the wording. But it is suggested that the aim was to include the latter too, since the final wording removed the earlier express qualification that the exclusion applied to the human body *in its natural state*.

On this basis, it is concluded that the **Article 5(1)** exclusion extends to *in vitro* embryos *per se*, irrespective of the purposes for which the embryo may have been originally created, or the particular national regulatory framework regulating the creation of *in vitro* embryos. This means that the exclusion would extend not only to human embryos which were created in accordance with national laws permitting the creation of human embryos for research purposes, but also extend to supernumerary embryos originally created for the purpose of assisting procreation through IVF.

In addition, some national patent offices (*i.e.* UK) have interpreted **Article 5(1)** as also excluding patents on totipotent hESC. For the scope of the exclusion of **Article 5(1)** to extend to totipotent hESC, the text has to be read as presupposing that both the human embryo *in vitro* from which the cells are extracted, and the totipotent cells themselves, fall under the description of a stage of development of the 'human body'. This is not obvious from a natural reading of the text. But since totipotent hESC has the potential to develop into a human being if implanted, and the intention of the Community legislators was to proscribe the grant of related patents on human reproductive cloning, it is suggested that totipotent cells are also excluded from patentability under **Article 5(1)** as subject-matter of a patent.

Against this background, an important finding of the report is that the considerations that prompted the Community legislator to exclude from patentability totipotent hESC do not extend to pluripotent hESCs. This is because unlike totipotent hESC, pluripotent hESC lack the potential to develop into a human being. Furthermore, *qua* elements isolated from the human body by means of technical process, pluripotent hESC fulfil the patentability criteria under **Article 5(2)**. Hence, if such cells were to be excluded from patentability on the grounds that their derivation necessarily involves an immoral use of the human embryo, the exclusion would have to be based on the morality exclusions in **Article 6**.

Article 6

Whilst **Article 6(1)** reiterates an accepted international principle of patent law that precludes

patents on inventions that are contrary to *ordre public* or morality, **Article 6(2)** Article provides a non-exhaustive list of unethical inventions that would be excluded from patentability. Among these is the non-patentability of 'human embryos for industrial or commercial purposes' in **Article 6(2)(c)**. The conclusions of the Report on the scope of moral exclusions in chapter 4 highlight the areas of convergence and divergence in the construction of the exclusionary provisions within the EU and EPC legal orders respectively. The range of legal considerations bearing on the construction of general moral exclusions under **Article 6** is dependent on the place of the Directive in European Community law.

The most significant aspect of the EU legal system lies in the entrenched principles of European law, which set the legal parameters for the identification and interpretation of moral norms in the Community. The fundamental principle is that the Community has the right to intervene only within those limited spheres reserved to it in the treaties and then only subject to the principles of subsidiarity and of proportionality anchored in the constitutional texture of the EU. Moreover, the EU is obliged to respect the national identities of its member states. Together, these principles point to the need for considerable deference to national constitutional traditions and cultures on questions of morality.

As a legislative instrument of the Community, the Directive is to be interpreted in accordance with these fundamental legal principles. In accordance with these principles, the ECJ has ruled unequivocally in the *Netherlands*² case that member states are to be granted a wide margin of discretion in the interpretation of the general moral exclusion clause in **Article 6(1)** in the light of the diversity of national cultures in Europe on morally sensitive questions.

A similar deference to national constitutional traditions and cultures is also required under the European Convention on Human Rights (ECHR) and the jurisprudence of the European Court of Human Rights (ECtHR). The report highlights the legal significance of the ECHR in the interpretation of the moral exclusions in the Directive, as indicated by the express recognition of the ECHR in the Directive itself, and the fact that the ECHR enshrines the fundamental moral values to which contracting member states are parties to in Europe. On the level of protection and rights granted to the human embryo under the ECHR, the jurisprudence of the ECtHR, converges with the ECJ on the conclusion that member states enjoy a wide margin of discretion in recognition of the diversity of moral traditions and cultures in Europe. Of particular importance is this year's decision of the ECtHR in

the *Evans v UK*³ case, in which the ECtHR unanimously declared that the question of whether the frozen embryo has a right to life under **Article 2** is a matter left to the discretion of member states. The report also analyzes the legal provisions in other European human rights instruments, particularly the Convention on Human Rights and Biomedicine (1997) adopted the year before the Directive, and concludes that whilst the instruments indicate the existence of a moral consensus in Europe on the impermissibility of human reproductive cloning, the same is not the case for human therapeutic cloning, on which there is a diversity of views in Europe.

Consequently, the compelling emerging conclusion on the scope of exclusion of **Article 6(1)** is that considerable deference to national traditions on the protection of the human embryo and the related moral exclusions on patentability of uses of the human embryo is required. This conclusion inevitably follows if the provisions on morality in the Directive are to be interpreted in the light of all the other provisions in the text and the wider legal context of European Community law and European human rights law.

Article 6(2)

By contrast, the report shows that different considerations apply to the construction of the list of excluded inventions in **Article 6(2)** which were intended by the Community legislator to provide illustrations of inventions considered to be unpatentable on moral grounds. The ECJ has ruled in the *Italy*⁴ case that, unlike **Article 6(1)**, which allows member states a wide margin of discretion in the implementation of moral exclusions, **Article 6(2)** has to be transposed specifically into national laws. The ECJ reasoned that member states have no discretion over the implantation of **Article 6(2)**, because the list of illustrations cited in **6(2)** reflects the existence of a moral consensus on the unpatentability of the invention listed under the specific exclusions. The report suggests that the ECJ's analysis implies a different methodological approach to the construction of the list of exceptions in **Article 6(2)**, which requires a focus on the elucidation of subject-matter excluded under each of the listed specific exclusions, and more specifically the terms 'embryo', 'industrial' and 'commercial'. This approach is also consistent with the aim of the Community legislator, which the report shows, was to exclude from patentability only certain uses of human embryos and not to render unpatentable other uses of human embryos which are lawful in member states. The report concludes that the moral consensus captured by the prohibition

relates to inventions in which the human embryo is used directly as a raw material in a repetitive chemical, mechanical or technical process, or alternatively inventions which involve trade in human embryos.

On this basis, the prohibition on patents involving uses of human embryos for industrial or commercial purposes does not preclude the patents on pluripotent stem hESC or processes for their derivation, unless the claims fall within the terms of the exclusion. Thus, where the claim relates to an invention involving the use of an embryo for industrial or commercial purposes, the scope of the exclusion must be considered by reference to the claim itself product/cell or process, and should not reach out to the historical use of the human embryo in research, which preceded the object of the patent claim.

The proposed interpretive approach is also consistent with the view of the ECJ that the accepted principle of patent law that the patent is confined to the claimed invention, and does not extend to the activities before or after, is not displaced by the Directive. In the *Netherlands* case,² the ECJ noted at para. 79 that the Directive:

concerns only the grant of patents and whose scope does not therefore extend to activities before and after that grant, whether they involve research or the use of the patented products.

Altogether, the analysis of the relevant EU, European human rights law and related jurisprudence of the ECJ and ECtHR point to the conclusion that there is no legal basis under the Directive for the approach adopted by the Opposition Division (OD) in the *Edinburgh*⁵ case whereby inventions involving destruction of the human embryo, whether directly in the claim itself, or at any prior point in time, are unpatentable on moral grounds.

The report further suggests that the current policies and practices of national patent offices – which have granted patents on pluripotent hESC processes – are consistent with the aims of the Directive and therefore valid according to EU law. Equally valid would be national policies that would seek to rely on **Article 6(1)** to preclude patents on pluripotent hESC to reflect different national traditions in this morally sensitive sphere. More generally, since outside the list of specific exceptions, the scope of moral exclusions on patentability is largely to be determined under national law, and national laws reflect different moral traditions, it follows that different national interpretations of the morality exclusion may validly co-exist under the Directive.

Moral exclusions in the EPC

Following the transposition of the list of moral exclusions contained in the Directive into the Implementing Regulations to the European Patent Convention, the exclusionary provisions also fall to be applied and interpreted separately by the EPO under the EPC Treaty. The starting hypothesis was that the transposition of the morality exclusions from the Directive into the EPC Implementing Regulations should ensure some degree of convergence on the question of whether hESC inventions are excluded from patentability under each system. A strong reason for this is that in the event of the EPO's interpretation of the Rules corresponding to the Directive being inconsistent with the ECJ's, there is no institutional mechanism to resolve the matter. The legal validity of a patent granted by the EPO is ultimately a matter for national law. The ECJ has no jurisdiction over the Organisation, since the Organisation is not a party to or creature of the EU. In the event of a clash between the EPO's construction of the provisions imported from the Directive and the ECJ's construction of the same provisions, EU member states are still bound by the ECJ's interpretation of the Directive because of the supremacy of Community law over national law.

In respect of the interpretation of the moral exclusions incorporated from the Directive in the Implementing Regulations to the EPC, the Report suggests that because under **Rule 23d** the Directive is to be used as a supplementary means of interpretation, the relevant criteria are to conform to other provisions in the text of the Directive guiding the interpretation of morality. There should be a convergence between the conclusions reached under the EPC system and Community law, to the effect that flexibility is required to accommodate differences in national cultures and moral traditions. However, the Report shows that, whilst there is some convergence between the two legal systems on the construction of the moral exclusion clauses, there are also differences which arise from the distinct legal architecture of the EU and EPC systems.

Unlike the entrenched principles of Community law limiting the rights of the Community *vis-à-vis* member states in matters concerning morality, the rules guiding the interpretation of morality exclusions in the EPC system are to be found mostly in the case law of the EPO. The EPO case law on the patentability of hESC inventions is reviewed in this light.

It is suggested that it follows from firm case law of the EPO's TBA that the exploitation of inventions may be excluded on moral grounds, only when it

is consistent with an applicable European-wide standard or a uniform European norm. However, the EPO's case law also indicates that there is some lack of clarity as to how the existence of such European wide standards or norms is to be ascertained under the EPC system. In particular, there is some uncertainty as to the nature of the evidence that the EPO considers adequate to identify the relevant applicable European moral standards under existing EPC rules. Be that as it may, the Report suggests that as regards the relevant standards to be applied under the specific provisions imported from the Directive, the EPO is obliged to apply moral standards which are in conformity with the fundamental principles of the EU Treaty, the ECHR and the constitutional traditions of member states.

The Report suggests that there is a convergence between the TBA's methodology on the construction of moral exclusions imported from the Directive and the approach taken by the ECJ. In *Oncomouse II*,⁶ the TBA considered the relationship between the general moral exclusion in **Article 53(a)EPC** and the specific exclusion in **Rule 23d(a) to (d)**. If a case falls within one of the four categories of exceptions set out in **Rule 23d**, it must be denied a patent under **Article 53(a)**. However, cases not falling within **Rule 23d(a) to (d)** are to be considered under the general exclusion under **Article 53(a)**, which requires identification of the relevant European moral norms.

The Report thus suggests, that from either the EC or EPC perspective, the specific moral exclusion in **Article 6(2)(c)** or its equivalent in **Rule 23d(c)**, only precludes patentability of inventions involving certain specific and qualified uses of human embryos, which do not extend to pluripotent hESC or their derivation, unless falling under the terms of the exception.

The special difficulty facing the EPO arises from the fact that it is charged with issuing a European patent, which could be valid in all European states. Having reviewed the options in circumstances where there is no uniform European view on morality, the Report concludes that the jurisprudence of the EPO interpreting the EPC requires that, in the absence of a European wide moral norm, the patent should be granted. Member states may, thereafter, exercise their right to invalidate the patent to reflect distinctive national moral considerations precluding the grant of the patent. This seems to be the most adequate way of safeguarding all interests involved, including giving applicants, opponents and courts of EU member states the possibility of referring sensitive and unsolved morality questions of a European dimension for preliminary ruling by the ECJ.

The overall logical implication of this analysis is that applicants should follow the national route to seek patent protection for hESC related inventions in the event of the current EPO ban being upheld by the Enlarged Board of Appeal.

The EGE

The last part of the report reviews the future role of the European Group on Ethics (EGE) in the light of the disputes which have arisen in connection with Opinion No. 16⁷ and its failure to persuade the OD in the *Edinburgh* case. The report suggests that, for the views of a minority in the opinions issued by the EGE to be followed in preference to those of the majority, as the OD did in the *Edinburgh* case, there must be overwhelming evidence to displace the views of the majority. There was no such evidence in this case.

The report makes recommendations on the working methodology of the Group and stresses the importance of the continuing need for the Group to be perceived as independent for its advice to carry the requisite authority in the future.

Equally, it should be clear from the detailed discussion of the legal principles guiding the interpretation of the morality clauses under Community law and EPC law, that the question of when morality may be used as a basis to exclude patents on biotechnological inventions is not purely an 'ethical' question but is closely interconnected with fundamental constitutional matters. Community law is premised on recognition and respect for the diversity of moral traditions and cultures in Europe. The limitations of the EGE's Opinions, ultimately also have to be understood in this light.

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- 1 This paper represents the summary conclusions of the Report: *Stem Cell Patents: European Law and Ethics* (28 July 2006). The project was funded by the European Commission under the Framework 6 program, Contract no. 005251. A copy of the Report may be accessed via: www.nottingham.ac.uk/law/StemCellProject/reports.htm
 - 2 Case C-377/98 *Netherlands v European Parliament and Council* [2001] ECR I-07079
 - 3 Case 6339/05, March 2006. For an analysis of the leading ruling of the Grand Chamber of the European Court of Human Rights on the right to life of the human embryo in utero, applied in the *Evans* case see: Plomer, A., 'A Foetal Right to Life?: The case of *Vo v France*', *Human Rights Law Review* 2005 5(2):311-338.
 - 4 Case C-456/03 *Commission v Italy*, at paras. 78-79.
 - 5 Decision of the Opposition Division of 21 July 2003 on European patent No. EP0695351 (University of Edinburgh).
 - 6 T 315/03 (*Oncomouse II*) O.J.E.PO 2005
 - 7 'Ethical Aspects of Patenting Inventions Involving Human Stem Cells Opinion 16, 7 May 2002.