Stem Cell Patents: European Patent Law and Ethics Report

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List of Commonly Used Abbreviations in the Text

COM	Commission's communication
CMLRev.	Common Market Law Review
Directive	Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions
EBA	Enlarged Board of Appeal, EPO
EC	European Community
EC Treaty	Treaty Establishing the European Community
EEC Treaty	Treaty on the Establishment of the European Economic Community
ECHR	European Convention on Human Rights and Fundamental Freedoms (1950)
ECJ	Court of Justice of the European Communities
ECrtHR	European Court of Human Rights
ECR	European Court Reports
ED	Examining Division(s), EPO
EEA	European Economic Area
ELJ	European Law Journal
E.L.Rev.	European Law Review
EFTA	European Free Trade Association
EIPR	European Intellectual Property Review, UK
EPC	European Patent Convention
EPLA	European Patent Litigation Agreement
EPO	European Patent Office
EU	European Union
EUI	European University Institute, Florence
GRUR	Gewerblicher Rechtschutz, Germany
GRUR Int.	Gewerblicher Rechtschutz und Urheberrecht, Internationaler Teil, Germany
hESC	human embryonic stem cells
IIC	International review of intellectual property and competition law
IP	Intellectual Property, Germany
IVF	*in vitro* fertilisation
Legal Affairs Committee	Parliamentary Committee on Legal Affairs and Citizens'

	Rights
MEP	Member of the European Parliament
Mitt.	Mitteilungen der deutschen Patentanwälte
OD	Opposition Division(s), EPO
OJEU	Official Journal of the European Union/European Communities, Brussels
O.J.E.P.O.	Official Journal of the European Patent Office, Munich
TBA	Technical Board(s) of Appeal, EPO

Introduction

The *Directive on the Legal Protection of Biotechnological Inventions*[1] (the Directive) was officially adopted on July 6 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 realise as 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 ethics and morality as evaluative criteria within patent law led to its rejection of an earlier text in March 1995.[2] The final text was the outcome of a legislative process[3] which 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 which 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.[4] 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.[5] Paradoxically, it is precisely in relation to the interpretation of some of the listed exceptions,

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[1] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213 of 30.07.98, p. 12.

[2] March 1995 OJ C 68 of 20.3.95. This was the first time that a Directive had been rejected by the European Parliament. See History of the Directive in Chapter one.

[3] By Article 249 (ex Article 189) of the EC Treaty 'the European Parliament, acting jointly with the Council, the Council and the Commission' are empowered to 'make regulations and issue directives, take decisions, make recommendations or deliver opinions'. The Directive was adopted in accordance with the co-decision procedure, defined in Article 251 (ex Article 189b) of the EC Treaty. .

[4] Although moral exclusion clauses existed in previous international law, the exclusion had always been formulated in general terms and did not include specific examples of inventions declared unpatentable on moral grounds. For instance, Article 4^{quater} of the Paris Convention provides that: "The Contracting States shall not be bound to provide for the grant of patents in respect of: inventions the publication or exploitation of which would be contrary to *ordre public* or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by a law or regulation; […]". Similarly, Article 27.2 of the TRIPS Agreement provides that: "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law." Article 53(a) EPC "European patents shall not be granted in respect of inventions the publication or exploitation of which would be contrary to *ordre public* or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States."

[5] The ECJ has held that the very purpose of Article 6(2)(c) is to give definition to the exclusion set out in 6(1) in Case C-456/03 *Commission v. Italy*, ECR 1-5335, at para. 78.

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 this study is to determine the scope of exclusion 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 diverging interpretations which have emerged and the range of legal considerations which are relevant to the resolution of the differences.

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.

The starting hypothesis is 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 which are relevant to the interpretation of the Directive under each legal system. In particular, the report considers:

- 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 legal instruments on the protection of the human embryo
- 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 which 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 patentatibility of hESC.

The Current Legal Environment in Europe

The legal uncertainty surrounding the Directive originates from several sources. In the first instance, the Directive has been the subject of legal controversy from its inception. Immediately following its adoption in 1998, the Directive survived a legal challenge in the ECJ, by Member States alleging that the Directive was illegal and contravened fundamental principles of the EU legal order[6]

Further legal challenges followed, this time led by the Commission which invoked its powers to refer Member States to the ECJ for failing in their obligation to implement the Directive into their own national laws by the stipulated date of 30 July 2000.[7] As late as July 2005, in its second report to the European Parliament and Council,[8] the Commission's expert committee noted that four Member States had still not implemented the Directive at the time[9] Whilst all Member States have now incorporated the Directive into their own national laws, a comparative analysis of the legislative texts incorporating the Directive into national laws carried out for this project, reveals significant differences in the wording of the moral exclusion clause, notably on the specified scope of exclusion of uses of human embryos under Article 6(2)(c). These differences are analysed in Chapter two of this Report.

Increasing legal uncertainty is also the inevitable consequence of the emerging range of national interpretations of Article 6(2)(c). Analysis of the interpretations of Article 6(2)(c) by national patent offices and the EPO reveals a fragmented view of which, if any, hESCs or processes are patentable in Europe. In July 2002, the EPO refused to grant an application for a patent on

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[6] The applicant (Netherlands) put forward six pleas which were rejected by the ECJ, notably that "…. Article 100a of the EC Treaty was the incorrect legal basis for the Directive, breach of the principle of subsidiarity, breach of the principle of legal certainty, breach of obligations in international law, breach of the fundamental right to respect for human dignity and breach of procedural rules in the adoption of the Commission's proposal." (at para. 12). Case C-377/98 *Netherlands v. European Parliament and Council* [2001] ECR I-07079.

[7] Article 15 of the Directive provides: "1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 July 2000. They shall forthwith inform the Commission thereof."

[8] COM(2005) 312 final. Commission Report of 14th July 2005: *Development and implications of patent law in the field of biotechnology and genetic engineering* at http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/com/2005/com2005_0312en01.pdf

[9] Italy, Luxembourg, Latvia and Lithuania.

pluripotent stem cells on the grounds that the specific exclusion was intended to preclude the granting of a patent on any process or cell obtained from a human embryo which had necessitated the destruction of a human embryo, whether directly or not.[10] In so doing, the EPO also rejected Opinion No. 16 of the EGE,[11] mandated under the Directive to issue guidance on the applicable ethical principles.[12] The majority of the EGE in Opinion No. 16 distinguished modified isolated hESC, which it advised should not be patentable, from modified hESC which should. Not only did the Opposition Division (OD) of the EPO reject the majority's reasoning *in toto* in the *Edinburgh* case, but it also chose to adopt instead a view which seemingly relates to the reasoning of the one single minority view in the EGE Opinion.[13]

Further divisions have since emerged between the EPO and the policy and practice of national Patent Offices in Europe, whose interpretation of the Directive has led to the adoption of a much narrower policy which excludes from patentability totipotent hESC only and processes to obtain cells from human embryos, but otherwise allows patents on pluripotent hESC and other processes.[14] Although data disaggregating applications for patents on hESC from other types of stem cells is difficult to access, research conducted for this project shows that following the restrictive ruling of the OD in the *Edinburgh* case, applicants have become even more unsure about the scope of exclusion of Article 6(2)(c) and seek to protect their claim by trying different wording strategies.[15]

Meanwhile, other national patent offices, whilst lacking a formal policy, have adopted a practice of granting patents on pluripotent hESC.[16] This includes national patent offices in

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[10] *Edinburgh* case, European Patent No. EP 0695351. See the EPO press release dated 24th July 2002.

[11] EGE, Opinion No. 16: *Ethical Aspects of Patenting Inventions Involving Human Stem Cells*, 7th May 2002.

[12] Recital 44 of the Directive: "Whereas the Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology; whereas it should be pointed out in this connection that that Group may be consulted only where biotechnology is to be evaluated at the level of basic ethical principles, including where it is consulted on patent law."

[13] Prof. Günter Virt, in a dissenting opinion stated:
"Human embryonic stem cells and also embryonic stem cell lines are excluded from patentability because we cannot get embryonic stem cell lines without destroying an embryo and that means without use of embryos. This use as material contradicts the dignity of an embryo as a human being with the derived right to life. If the condition for patentability is the industrial and commercial use and if the use of human embryos for industrial and commercial purposes is not patentable, then every exception, which cannot exclude industrial and commercial purposes, is against the ethical sense of the directive. Patenting is an incentive. Patentability of human embryonic stem cells and stem cell lines would push research towards embryonic stem cells and thus undermine the priority of research using non embryonic stem cells. Despite the relatively clear regulations in the directive this incentive for research will lead to forms of "bypasses" which makes it impossible to guarantee an ethically tolerable situation in the field of patentability" EGE, Opinion No. 16: *Ethical Aspects of Patenting Inventions Involving Human Stem Cells*, 7th May 2002.

[14] See for instance: Practice Note, UK Patent Office, April 2003.

[15] See Porter, G. Denning, C., Plomer, A., Sinden, J. and Torremans, P., 'The patentability of human embryonic stem cells in Europe', *Nature Biotechnology* 24, 653 - 655 (2006).

[16] Swedish patent No. SE 526490, (Applicant: Wisconsin Alumni Research Foundation, Priority: US 1999-11-08 09/435578) and German patent DE 10136702 B4: "System zur zell- und entwicklungsspezifischen Selektion differenzierender embryonaler Stammzellen, adulter Stammzellen und embryonaler Keimbahnzellenatent".

Member States with regulatory regimes which have 'mixed' approaches, which proscribe and criminalise the derivation of hESC in their own territory whilst permitting research on human embryonic cell lines which are *imported* from other countries.[17] As a result, it is currently possible in Europe to obtain a national patent for hESC notwithstanding the fact that the same claim has been refused by the EPO. Chapter two provides a detailed comparative analysis of the divided interpretations of the Directive.

Needless to say, the fragmented legal landscape and the resulting legal uncertainty on the scope of application of the moral exclusion clause to hESCs carries the risk of a threat to research and investment in the life sciences and innovation in Europe, both of which have been earmarked as a strategic priority for Europe.[18]

The resolution of the legal uncertainty regarding the scope of exclusion of Article 6 requires an understanding of the complex legal framework within which the Directive is to be interpreted. For instance, in October 2005, the European Parliament adopted a resolution calling on the EPO to adhere to a strict restrictive interpretation on the patentability of hESC.[19] Notwithstanding this, the European Parliament is not an institution vested with legal authority over the interpretation of the Directive in the EU legal order, nor indeed under the EPC. Legal authority over the interpretation of the Directive within the EU legal order lies with the national courts of Member States in the first instance and ultimately with the ECJ.[20] At the same time, the ECJ has no legal authority over the European Patent Office.[21] Further, the Opinions of the EGE are strictly advisory and not legally binding on any of the national or European patent offices or courts. Finally, whilst the EPO administers the European patent system and has the authority to issue a European patent which translates into a bundle of national patents, this is done under the aegis of the EPC, which is an independent international treaty whose contracting Member States includes States which are not members of the EU.

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[17] Such 'mixed' policies have given rise to accusations of 'double-standards' and hypocrisy. See Wiedemann, P. M., Simon, J. Schicktanz, S. and Tannert, C., *EMBO reports* 5, 10, 927–931 (2004).

[18] COM (93) 700 final Commission Communication to Parliament and Council *Community Growth, Competitiveness and Employment: the Challenges and Ways forward into the 21st Century.* White Paper from the European Commission to the Council of Ministers: See also SEC (91)/629 *Promoting the Competitive Environment for the Industrial Activities based on Biotechnology within the Community.*

[19] Resolution of 26th October 2005. The resolution welcomes the decision of the OD in the *Edinburgh* case and "Insists that the creation of human embryonic stem cells implies the destruction of human embryos and that therefore the patenting of procedures involving human embryonic stem cells or cells that are grown from human embryonic stem cells is a violation of Article 6(2)(c) of the Directive;" at para. 14. P6_TA(2005) 0407.

[20] Article 234 of the EC Treaty.

[21] Although national courts may request guidance from the ECJ on the interpretation of the Directive, which may include questions in relation to European patents national patents that have been issued within the 'bundle' of national patents.

Thus, whilst the list of moral exclusions contained in Article 6 of the Directive have been transposed into Rules 23d(a) to (d) of the EPC, the interpretation of Rules 23d(a) to (d) by the EPO operates within the legal framework established by the EPC system, which is a legal order that is independent from the EU legal order. In order to analyse the legal effect of the moral exclusions contained in the Directive, it is therefore essential to understand that the Directive is operating within two distinct and separate legal frameworks, and furthermore, that under the present dual legal structures, there are no inter-institutional links or procedures to integrate the two legal frameworks and therefore no integrated European judicial system to resolve differences of interpretation.[22] It follows, that in order to determine which (if any) of the existing interpretations of the scope of exclusion of patentability of hESC is legally correct, it is necessary to identify the respective overarching legal frameworks within which the Directive is to have legal effect and the corresponding applicable legal principles of EC law and European patent law respectively. Such an analysis is provided in Parts II and III of this report.

Report Outline

The report begins with a detailed analysis, of the history of the Directive and the legislative intent of the Community legislators. The Community legislators' intent is then further analysed by reference to the overarching principles of EC law, together with a textual analysis of the Directive itself in order to identify both the scope and the limits of the harmonisation sought under Article 6. This framework then provides the basis for a more detailed analysis of sources of European moral norms, as envisaged in the Directive, so as to identify the specific nature and scope of exclusion from patentability of uses of human embryos for industrial or commercial purposes.

The analysis highlights the range of norms reflected in national laws and international Treaties to which Member States are signatories, most notably the European Convention on Human Rights of 1950 (ECHR), to assist in defining the legal contours of moral exclusions on human embryos in European law.

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[22] The shortcomings of the existing fragmentation of the EU patent system and the urgent need to redress these have been acknowledged both within the EU and the EPC system: See EPO *Assessment of the impact of the European patent litigation agreement (EPLA) on litigation of European patents,* February 2006 at:
http://www.european-patent-office.org/epo/epla/pdf/impact_assessment_2006_02_v1.pdf
The EU and the EPC have each proposed alternative solutions to integrate European patent law. The EU favours the introduction of a Community patent with a judicial system of its own. Whilst the EPO is in favour a European Patent Judiciary set up by EPC Contracting States.

Although the ECJ has stressed that the moral exclusions contained in the Directive concern patentability and are not therefore coextensive with moral exclusions on research reflected in national laws,[23] an understanding of the range of legal regimes on research on human embryos in Europe is nevertheless required to help identify the precise scope of the moral consensus captured in the examples listed in Article 6, since the derivation of hESC necessarily involves procedures on human embryos usually controlled by research regulations. The analysis in this report has been carried out against the well documented evidence of the diversity of legal regimes on regulations concerning the derivation of hESC in Europe, and more generally human embryonic research, both before and since the adoption of the Directive.[24] As is well documented, regulatory regimes in Europe vary from the most restrictive regimes which have a total prohibition on research on human embryos, to the majority of regimes which permit research on surplus embryos originally created for IVF purposes, to the most liberal regimes which permit research on human embryos specifically created for research purposes but subject to a very strict limit of fourteen days after fertilisation. Along this spectrum are to be included a number of 'mixed' regimes in which national laws prohibit research on human embryos and derivation of hESC, but allow research on hESC lines imported from other countries. Two of the leading technologically advanced countries in Europe currently have such 'mixed' regimes.

Whilst the precise nature of the link between the moral norms reflected in national and supra national regulations and laws and the moral norms precluding patentability of hESC is not altogether clear in the Directive, it is nevertheless essential to note that there is a diversity of legal regimes on hESC research in Europe and furthermore that the contracting Member States of the EU have not divested themselves of their constitutional power to continue regulating research on human embryos so as to reflect national cultural and social norms. Chapters four and five analyse the limitations on the scope of patentability exclusion in Article 6 which arise from recognition within EU law, and European Human Rights law, of the diversity of national legal regimes on human embryos and the need to allow flexibility to accommodate differences in national moral cultures in this sensitive area.

More specifically, Chapter four argues that within the EU legal order, arguments based on human dignity to identify the scope of moral exclusions relating to human embryos or the rights

[23] In Case C-456/03 *Commission v. Italy*, the Commission had alleged breach of Article 15 of the Directive by Italy for failing to implement the Directive by the stipulated date of July 2000. The respondent contended that existing general exclusions on morality in its national law, together with the adoption of restrictive research laws on human embryonic research precluded the exercise of patent contrary to Article 6(2)(c). The Court disagreed and noted that the specific exemptions listed in the Directive concerned patentability and not research had to be incorporated as such into national law (at para. 78).

[24] See for instance, Commission Staff Working Paper Report on Human Embryonic Stem Cell Research, Brussels, 3.4.2003 SEC(2003) 441. Data has been updated by Isasi, R. and Knoppers, B., 'Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 countries'; *European Journal of Health Law 13(1)* April 2006.

of the human embryo, have to be carefully construed against judicial understanding of this fundamental value within European Human Rights law, and in particular the jurisprudence of the European Court of Human Rights (ECrtHR). The Chapter draws the implications of this analysis for the construction of Article 6(1) of the Directive.

Chapter five analyses the scope of exclusion of Article 5(1) and the list of exclusions in Article 6(2). The Chapter pulls together the main conclusions of the previous chapters to define both the areas of consensus and the limits of the scope of exclusion of Article 6(1) and Article 6(2)(c) in particular relation to the patentability of hESCs and processes for obtaining hESCs.

Chapters six and seven conduct a parallel analysis of the construction of the Directive within the EPC system, highlight the areas of convergence and divergence and conclude by drawing the implications of the analysis.

Part I: General Background

Chapter One: History of the Directive

Introduction

The Directive was officially adopted by the Council of the European Union and the European Parliament under the co-decision procedure on July 6 1998.[25] The Directive's adoption came after ten years of controversy and difficult negotiations, and followed the European Parliament's rejection of an earlier draft in March 1995.[26] The Commission's rationale for the Directive was to improve the competitiveness of the European biotechnology industry by clarifying and harmonising European patent laws. After extensive discussions between the Commission, the Council and the European Parliament, the final version also included a more prominent role for ethics and morality as evaluative criteria within European patent law. Most notably, this resulted in the inclusion of a 'morality clause' in the form of Article 6, which provides a non-exhaustive list of specific examples to be excluded from patentability on the grounds of *ordre public* or morality. As will be seen, the inclusion of Article 6 is the outcome of a political compromise between the EU institutions which share the legislative power under the co-decision procedure – the Council of Ministers and the European Parliament.[27]

1.1 Rationale for the Directive

The first draft of the Directive was introduced by the European Commission in October 1988.[28] The original justifications for the Directive were primarily economic in nature. The

[25] Legislation dealing with certain defined policy areas, including the internal market, must be adopted by the "*co-decision procedure*". Under the co-decision procedure, the European Commission submits a proposal to the European Parliament, which then shares the power to adopt legislation with the Council of the European Union. The two bodies are free to amend each other's proposals to the draft legislation, but both bodies are required to agree on an identical text before any proposal for a directive can become law. The co-decision procedure, as defined in Article 251 of the EC Treaty, is now the most common legislative procedure by which law is adopted in the European Community.

[26] OJ C 68 of 20.3.1995.

[27] Under Article 251 (ex 189 b) EC Treaty.

[28] COM(88) 496 final/SYN 159 of 21 October 1988, OJ C 10 of 13.1.1989.

biotechnology industry was – and still is – viewed as being a commercial sector poised for dramatic growth during the 21st century.[29] The EC needed to be strategically positioned in order to take maximum advantage of the opportunities for the generation of wealth and job-creation that the promised growth of the biotechnology industry presented. Patent law was to play a key role in this process.

The European patent system was seen by the Commission as being deficient for the purpose of fostering the European biotechnology industry,[30] partly because the standards of patentability throughout Europe were unclear in relation to the legal protection of many of the products of biotechnology, such as isolated and purified cells, proteins and DNA sequences. Whilst Article 52(1) EPC allows patents for inventions that are new, involve an inventive step and are capable of industrial application, Article 52(2) EPC specifically prohibits the patenting of "discoveries". In the field of biotechnology, drawing the legal distinction between an 'unpatentable discovery' and a 'patentable invention' can sometimes be a conceptual challenge for patent offices and the courts. The lack of guidance from Article 52 EPC and national patent laws on how to approach this issue meant that European researchers and companies were unsure if their work could be legally protected within Europe or not.

The Commission further identified the possibility of the *fragmentation* of European patent laws as a potential problem. As early as 1985, the Commission's White Paper on the completion of the internal market had noted that differences in existing IP laws were an obstacle to the development of the internal market. In addition, uncertainties in European patenting criteria could become exacerbated if individual Member States were to adopt separate and uncoordinated legislation and administrative practices for biotechnology patents; or if national case law interpreting such legislation developed differently.[31] This was seen especially

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[29] SEC (91)/629 Communication from the Commission to the European Parliament and Council: *Promoting the Competitive Environment for the Industrial Activities based on Biotechnology within the Community* and
COM (93) 700 final *Growth, Competitiveness and Employment: the Challenges and Ways forward into the 21st Century* White Paper from the European Commission to the Council of Ministers.
See also COM(2002) 27 final Communication of the European Communities 'Life Sciences – A Strategy for Europe' Brussels, 23.1.2002 at: http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0027en01.pdf Also, Opinion of the Economic and Social Committee on the 'Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions', OJ C 295 of 7.10.1996. For commentary, *see* Straus, J., 'Patenting Human Genes in Europe - Past Developments and Prospects for the Future', [1995]*IIC* p. 920. Also see Gold, R. and Gallochat, A. 'The European Directive on the Legal Protection of Biotechnological Inventions: History, Implementation and Lessons for Canada', prepared for The Canadian Biotechnology Advisory Committee Project Steering Committee on Intellectual Property and the Patenting of Higher Life Forms, February 2001.

[30] COM(85) 310 final *Completing the Internal Market: White Paper from the Commission to the European Council (*Milan, 28-29 June 1985), p. 37, at para. 149.

[31] COM(85) 310 final Completing the Internal Market: White Paper from the Commission to the European Council (Milan, 28-29 June 1985), p. 37, para. 145: "Differences in intellectual property laws have a direct and negative impact on intra-Community trade and on the ability of enterprises to treat the common market as a single environment for their economic activities" at: http://ec.europa.eu/comm/off/pdf/1985_0310_f_en.pdf

problematic in an area where great future technical and medical as well as economic developments were expected.

Given the nature of the Commission's objectives, one might expect that the drafting of the Directive would be a relatively straightforward administrative exercise in harmonising the legal criteria of novelty, industrial utility and inventive step in the context of biotechnological products and processes. Indeed, the first draft of the Directive framed the problem solely in these terms. The legal standards proposed largely reflected the permissive patenting practice of the US Patent and Trademark Office and the Japanese Patent Office, which had for many years viewed isolated and purified natural products as patent-eligible subject matter.[32] A Directive on patentable biotechnological inventions would clarify the distinction between inventions and discoveries by stating that whilst biological material in its natural state would remain an unpatentable discovery, biological material that has been isolated from its surroundings or produced in an artificial way would be patent-eligible subject matter, even if the structure of that element is identical to a natural element. This was intended to provide the incentives and legal certainty required for the European biotechnology industry to flourish.

1.2 The 1995 Proposed Directive

The Commission's proposal for a Council Directive on the legal protection of biotechnological inventions of October 1988 had its legal basis in the *Treaty on the Establishment of the European Economic Community* (EEC Treaty) Article 100a (currently Article 95 EC), which confers upon the EC the powers to deal with the establishment and functioning of the European internal market.[33] In accordance with the legal basis under which it was proposed, the Directive was not intended to radically overhaul or alter the European patent system. Rather, it would simply build upon the existing general principles of patent law, and clarify how they should be applied throughout Europe in a uniform manner. However, the project soon ran into problems. On its first reading of the Commission's proposal, the European Parliament took the view that the Directive would need to pay greater attention to what it saw as the "moral and ethical aspects" of biotechnology patenting.[34] The Economic and Social Committee's opinion of 26 April 1989 criticised the Commission's first draft of the Directive for what it perceived as a refusal to "face up to all the issues" pointing to the need to draw "ethically appropriate

[32] Trilateral Co-operation of the US, European, and Japanese Patent Offices, reported in 1988, 7 *Biotechnology Law Review*, pp. 159-193..
[33] Article 95 EC (ex Article 100a), Treaty on European Union, originally, done at Rome, 25th March 1957, as revised 1st July 1987, 1st November 1993, and 1st May 1999.
[34] OJ C 305 of 23.11.1992, p.160.

boundaries" as to what could and could not be commodified and expressing regret that "human beings *per se* are not expressly mentioned in the Directive as not being patentable."[35]

After numerous rounds of amendments, the legislative process ground to a halt when the Council rejected the Parliament's amendments to the Draft Directive in September 1994, leading to mandatory conciliation proceedings between the Council and the Parliament. Although the Conciliation Committee was successful in producing a joint text in January 1995, this text was ultimately rejected by the Parliament on 1st March 1995.[36] This was the first time that the European Parliament had used its veto powers to reject draft legislation – a fact that is testament to the degree of political controversy that the Directive had generated.

1.3 The 1998 Directive

Following the rejection of the draft Directive in March 1995, the European Commission considered it appropriate to present an amended proposal soon after. In the absence of a unifying EU-wide framework for patent law, the risk of fragmentation now seemed even greater than before. France had passed a new bioethics law in 1994, and it seemed likely that other EC Member States would also follow suit by adopting divergent individual strategies to regulate biotechnology.[37] Despite the March 1995 rejection, substantial amendments had already been made to the initial proposal during the conciliation procedure, and the Commission was of the optimistic view that one further attempt to clarify the text would draw the whole exercise to a successful conclusion.

The Commission submitted a second proposal for a Directive to the European Parliament on the 25th January 1996.[38] This proposal did not contain any reference to the exclusion of the human embryo from patentability. On the 25th June, 1997, the Parliamentary Committee on Legal Affairs and Citizens' Rights (Legal Affairs Committee) produced a report on the Commission's proposed draft of the Directive.[39] This report introduced the first mention of the human embryo within the Directive's morality clause. Amendment 55 of the Legal Affairs Committee's report stated that "*Methods in which human embryos are used*" were to be unpatentable on moral

[35] OJ C 159 of 26.6.1989.
[36] OJ C 68 of 20.3.1995.
[37] Loi n° 94-653 du 29 juillet 1994 relative au respect du corps humain.
[38] Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions/COM/95/0661 FINAL, OJ C 296 of 8.10.1996.
[39] Report on the proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions (COM (95)0661-C4-0063/96-95/0350(COD)) Committee on Legal Affairs and Citizens' Rights. 25 June 1997. A4-0222/97.

grounds.[40] The vast majority of the amendments, including Amendment 55, were then subsequently accepted by the European Parliament on 16th July 1997[41] and the Commission on 29th August 1997.[42] However, in its Common Position[43] of 26th February 1998, the Council altered the wording of the reference to the non-patentability of the human embryo so as to state that only certain uses of human embryos should be excluded from patentability, namely "*uses of human embryos for industrial or commercial purposes*" (Article 6(2)(c). The Council's wording of Article 6(2)(c) was subsequently accepted by Parliament and remained in this form in the final legislative act officially adopted by the Council and the Parliament on 6th July 1998.

The final version of the Directive drew 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. In addition, a number of 'ethically-focussed' Recitals were added to the Directive, as well as Article 6(2), which provides a non-exhaustive list of unethical inventions that would be excluded from patentability. The text of Articles 5 and 6 of the approved final version of the Directive state the following:

Article 5

> 1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
> 2. 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.
> 3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

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[40] The Report acknowledged the European Parliament's Resolution on the Protection of Human Rights and Dignity with regard to the Application of Biology and Medicine, OJ C 320, of 28.11.1996, p. 268. The Resolution stated that "all trade in human embryos, fetuses and foetal tissue without exception must be prohibited by law" and also that "consumptive research on and the production of human embryos for research purposes must be prohibited". Reference was also made to Opinion No. 8 of the Group of Advisers on Biotechnology (GAIEB), para. 2.3 stating that: "The human body, at different stages of its constitution and development, as well as its elements, do not constitute patentable inventions. Such exclusion does not come only from the usual conditions of patentability, but it is also inspired by the ethical principle of non-commercialisation of the human body. Therefore no patent can be given on the human body or on its elements ..."

[41] EP: Legislative opinion, 1st reading or single reading, COD/1995/0350, 16/07/1997.

[42] Amended proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions, COM/97/0446 final, OJ C 311 of 11.10.1997.

[43] Common Position (EC) No. 19/98 adopted by the Council on 26 February 1998 with a view to adopting Directive 98/.../EC of the European Parliament and of the Council on the legal protection of biotechnological inventions. OJ C 110 of 8.4.1998 p. 17.

Article 6

> 1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
> 2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
> (a) processes for cloning human beings;
> (b) processes for modifying the germ line genetic identity of human beings;
> (c) uses of human embryos for industrial or commercial purposes;
> (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Although the final wording of the text was intended to guide the interpretation of the general moral exclusion in Article 6(1), the emerging range of divergent interpretations of the specific exclusions under Article 6(2) have since cast considerable uncertainty on the scope of exclusion of the exceptions, most notably Article 6(2)(c). The emerging fragmented legal landscape is surveyed in chapter 2.

Chapter Two: Divergent Interpretations

Introduction

Whilst the Directive was intended to harmonise patent law in the field of biotechnological inventions, the wording of the text finally adopted has left uncertain the precise legal scope of exclusion in regard to hESC. Acute differences have emerged in the interpretation of the morality clause in Article 6 of the Directive, and especially Article 6(2)(c), by Member States, the European Patent Office and individual national patent offices. The aim of this Chapter is to evidence the range of divergent interpretations that have emerged in relation to hESC patenting in Europe.

The history of the Directive, as described in Chapter one of this Report, tells us that attitudes among Member States were not the same during the negotiations, even if they were able to reach a compromise on the text which was finally adopted. But to the drafters of the Directive an obvious and long term aim was to find and approximation of the widely accepted European standards of morality in areas that effect the smooth functioning of the Internal Market, including giving exceptions to patentability approximate definitions. An examination of the differences which have emerged over the interpretation of the morality clauses in the Directive reveals that areas of uncertainty remain.

2.1 Implementation of the Directive in National Laws

Not surprisingly, in view of the moral controversies generated by "patents on life" in public debates across Europe, the national implementation of the Directive has been a protracted process in many countries. Although Member States were obliged to implement the Directive by 30 July 2000,[44] as of 2003, only seven Member States had implemented the Directive.[45] Non-implementation was thought by the Commission to have created trade barriers and

[44] Article 15.
[45] European Commission press release IP/03/991,10/07/2003 at: http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/991&format=HTML&aged=0&language=EN&guiLanguage=en

hampered the Internal Market.[46] Consequently, infraction proceedings were brought against several Member States for non-implementation.[47] Member States found by the ECJ to have breached their obligations under Article 15 included France,[48] Belgium,[49] Luxembourg,[50] Germany,[51] Austria,[52] and Italy.[53] However, as of 9 June 2006, all EU Member States had finally implemented the Directive in their national laws.[54] The Directive has also had an impact on patent legislation in non-EU countries. The acceding and candidate countries of Bulgaria, Croatia, Romania and Turkey have implemented or are in the process of implementing the Directive.[55] Amongst EEA countries, Norway and Iceland have also adopted legislation implementing the Directive. On the other hand, the legislative process has been delayed in Switzerland (EFTA).

The majority of the EU (and non-EU) Member States follow the exact wording of Article 6 in the Directive in their national law, having done no specific amendments or additions to the provision. Belgium[56,] Croatia[57], Cyprus[58], Czech Republic[59], Denmark[60], Finland[61], France[62], Greece[63], Hungary[64], Iceland[65], Ireland[66], Italy[67], Latvia[68], Lithuania[69], Luxembourg[70], Malta[71],

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[46] COM(2002) 545 final Commission Report of 7 October 2002, Development and implications of patent law in the field of biotechnology and genetic engineering. [Not published in the Official Journal]; http://europa.eu/scadplus/leg/en/lvb/l26026a.htm Under Article 16c of the Directive, the Commission is obliged to produce a yearly report on development and implications of patent law in the field of biotechnology and genetic engineering.

[47] See COM(2005) 312 final. The Commission's second report notes that as of June 2005, 21 EU Member States had transposed or were in the process of transposing the Directive.

[48] Case C-448/03, *Commission v. France*, OJ C 217 of 28.08.2004, p. 10.

[49] C-454/03*, Commission v. Belgium*, OJ C 262 of 23.10.2004, p. 11.

[50] C-450/03, *Commission v. Luxembourg*, OJ C 262 of 23.10.2004, p. 11.

[51] C-5/04, *Commission v. Germany*, OJ C 6 of 08.01.2005, p. 18.

[52] C-4/04, *Commission v. Austria*, OJ C 6 of 08.01.2005, p. 18.

[53] C-456/03, *Commission v. Italy* [2005] ECR 1-5335, OJ C 217 of 03.09.2005, p. 14.

[54] European Commission, State of Play of the Implementation of Directive 98/44/EC (Last revision 9-06-2006), available at: http://ec.europa.eu/internal_market/indprop/docs/invent/state-of-play_en.pdf

[55] *Ibid.*

[56] Article 4(2), Loi du 28 mars 1984 sur les brevets d'invention/Patent Act of 28th March 1984, *Belgisch Staatsblad – Moniteur belge,* 9th March 1985, as amended by the Act of April 28th 2005, published in *Belgisch Staatsblad – Moniteur belge,* 13th May 2005.

[57] Article 7 of the Patent Act (NN 173/2003).

[58] Section 5A(4) of the Patent Law CAP.266, as amended by Law 163(l)/2002.

[59] Section 3, Act No. 206/2000 Coll. of 21st June 2000 on the Protection of Biotechnological Inventions.

[60] Section 1b of the Danish Patents Act, No. 451 of 10th June 2003 (LBK No. 1136 of 16th November 2004) as amended by Act No. 412 of 31st May 2000.

[61] Section 1b of the Finnish Patents Act of 15th December 550/1967 amended by 650/2000.

[62] Article L. 611-17-18, Le Code de la Propriété Intellectuelle/Partie Législative as amended by Article 17 Loi nº 2004-800 du 6 août 2004 relative à la bioéthique, available at: http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SANX0100053L, published in Journal Officiel de la Republique Français du 7 août 2004.

[63] Section 5, Greek Patent Law 1733/1987, as amended by Presidential Decree 321/2001.

[64] Sections 5 & 6, Chapter 1, Part 1 of the Act XXXIII of 1995 on the Protection of Inventions by Patents, amended by Law No. XXXIX of 24th October 2002, available at: http://www.hpo.hu/

[65] Section 1b of the Icelandic Patents Act No. 17/1991, amended by Act No. 22/2004.

[66] See Article 6(2), S.I. No. 247 of 2000, European Communities (Legal Protection of Biotechnological Inventions).

[67] See Article 4, Decree-Law No.3 of 19th January 2006, adopted as Law No. 78 (22nd February 2006).

[68] Article 4 of the modification of the Patent Law No. 60 of 19.04.1995, as amended on 8th December 2005.

[69] Article 2 of the Law of 30th June 2005 No. 85-3135, amending the Patent Law.

Norway[72], Poland[73], Portugal[74], Slovakia[75], Slovenia[76], Spain[77] Sweden[78] and the UK[79] have all implemented Article 6 of the Directive according to its exact wording and format (in English translation).[80] On the other hand, a number of states have not strictly followed the wording of Article 6 in their domestic implementation of the provision, and instead adopted a wording which arguably has the effect of broadening the exclusion.

The qualification "uses of embryos for industrial and commercial purposes" in Article 6(2)(c) suggests that only certain uses are excluded from patentability, and that there are other uses of human embryos which may be patentable. The effect of removing the qualifications that the prohibited uses are 'industrial' and/or 'commercial' is arguably to alter and potentially widen the scope of the exclusion.

2.2 Altered Wordings of Article 6(2)(c)

Alterations which arguably have the effect of widening the scope of the exclusion by removing the qualification on uses for industrial or commercial purposes, may be found in the transposition of the Directive in the legislative provisions of several Member States. For instance, Section 2(1)(3) of the *Austrian Patents Act* excludes patents on the use of human embryos *per se* and not only on the use of embryos for industrial of commercial purposes. Similarly, Article 5 of the Dutch Patents Act excludes patents on the use of human embryos *per se*, and not for just industrial and commercial purposes.[81]

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[70] Law of 7th April, (2006 published on 19th April 2006).
[71] Section 4(5) of the Patents and Designs Act XVII of 2000, as amended by Act IX, 2003.108
[72] Section 1b of the Norwegian Law Decree 1967.12.15 (No. 9) on Patents, as amended by Law Decree 2003.12.19 (No. 127).
[73] Article 29(1) of the Act on Industrial Property Law, Journal of Laws No. 119/2003, text 1117, as amended by act of 23rd January 2004 (Journal of Laws of 2nd March 2004, No. 33/text 286).
[74] Article 49 of the Portuguese Industrial Property Code, Decree-Law No. 16/95, of 24th January 1995.
[75] 6(2) of the Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificated (SPC) and on Amendment of other Acts (the Patents Act) as amended by the Act No. 402/2002 Coll.
[76] See Article 1 and 10 in Industrial Property Act of 23rd May 2001, as amended by Decree No. 3873 on the Legal Protection of Biotechnological Inventions.
[77] Article 5 of the Patents Act 11/1986, as amended by law No. 10/2002 of 29th April 2002.
[78] Section 1c of the Swedish Patents Act (1967:837), as amended by Law No. 2004:159.
[79] Paragraph 3(d) of Schedule A2 to the Patents Act (1977), as amended by the Patents Regulations 2000 (SI 2000/2037) and the Patents Rules 1995, particularly as amended by the Patents (Amendment) Rules 2001 (SI 2001/1412).
[80] It remains to be seen whether or not the explicit wording of Article 6 is followed in Bulgaria, Romania and Turkey.
[81] Article 5 of the Dutch Patents Act (1995) of 15 December 1994, as amended by the Act of 10 November 2004 (Stb. 589) amending the Patent Act, the Patent Act 1995, and the Seed and Plant Reproductive material Law with regard to the legal protection of biotechnological inventions.

Estonia

By contrast, in the *Estonian Patents Act*[82] the exclusion relates only to commercial purposes, not industrial ones. Section 7(3) of the Estonian Patents Act, transposing Article 6(2)(c) of the Directive, states that:

> "The following biotechnological inventions shall not be protected by a patent: [...] 3) uses of human embryos for commercial purposes, including processes prohibited by the Artificial Insemination and Embryo Protection Act [...]"[83]

Arguably, here the alteration in the wording has the opposite effect of narrowing the scope of the exclusion, since only one of the two qualified uses of human embryos, namely commercial uses, is expressly retained in the legislation. Whilst the wording of the exclusion on the one hand seems less restrictive than the Directive in limiting the exclusion to 'commercial purposes' only, at the same time the exclusion might also be broadened by including other restrictions contained in national laws, which are not framed by reference to 'industrial' uses. For example, the *Embryo Protection and Artificial Fertilisation Act*, lists a number of prohibited acts on human embryos which are penalised under the Criminal Code. These acts are also unpatentable because of the direct reference to the *Embryo Protection and Artificial Fertilisation Act* within the *Estonian Patents Act*.

Austria

Another example of direct links being established between the national law implementing the Directive and the domestic provisions on human embryo research is the Austrian Patents Act.[84] Section 2 of the Act, states that the relevant provisions of the *Austrian Reproductive Medicine Act*[85] are applicable as regards (a), (b) and (c) of Section 2 (the equivalences to Article 6(2)(a) to (c), *i.e.* processes for cloning human beings, for modifying the germ line genetic identity of human beings, and uses of human embryos). The *Austrian Reproductive Medicine Act* states

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[82] Patents Act RT I 1994, 25, 406, consolidated text 08.04.05, as amended by RT I 1999, 84, 764 available at http://www.legaltext.ee/en/andmebaas/ava.asp?m=022 (14.7.2006).
[83] Section 7(3) of the Patents Act, RT I 1994, 25, 406, consolidated text 08.04.05, as amended by RT I 1999, 84, 764 available at http://www.legaltext.ee/en/andmebaas/ava.asp?m=022 (14.7.2006).
[84] .Patent Law BGBl No. 259/1970 as amended by Law BGBl. I Nr. 42/2005.
[85] Austria/Government, Federal Law of 1992 (Serial No. 275) regulating medically assisted procreation (the Reproductive Medicine Law), and amending the General Civil Code, the Marriage Law, and the Rules of Jurisdiction, 4th June 1992, (1993) 44 No. 2 Int. Dig. Hlth. Leg. 247.

that fertilised human oocytes, and cells derived therefrom, may be used only for medically assisted reproduction (Section 9); stem cells as such are not included but, according to the interpretation of the Law, the procurement of embryonic tissues is prohibited. This reference could be interpreted as indicating that what is prohibited by the *Reproductive Medicine Act* is also contrary to the concepts of *ordre public* and morality. However, since the *Reproductive Medicine Act* does not deal explicitly with research on hESC, the legal implications are unclear. There is no legal definition of the term "human embryo" either. The Act refers to "cells capable of development" as "fertilised egg cells and cells developed thereof".[86]

Whether these alterations constitute a valid interpretation of the Directive is arguably questionable. In a case brought by the Commission against Italy, the ECJ has held unequivocally that the list of exclusions has to be transposed specifically into national laws.[87] Italy had sought to argue that its failure to transpose the Directive directly into national law did not constitute a violation of its obligations under Article 15 of the Directive, because under its own domestic patent law, inventions which are contrary to *ordre public* or morality were already excluded. The ECJ disagreed. The ECJ noted that the purpose of inserting a list of inventions which are unpatentable under Article 6(2), was to guide the interpretation of the general moral exclusion clause in Article 6(1) and achieve some legal certainty by providing a list of illustrations of inventions, which the Community legislator agreed were to be excluded from patentability on moral grounds. The ECJ held that neither Article 13 of Royal Decree No. 1127/39 nor Article 5 of the Civil Code provided expressly that the processes and uses set out in Article 6(2) of the Directive are not patentable, since those provisions merely preclude in general terms, respectively, the patentability of inventions whose exploitation would be contrary to public policy and morality and acts of disposition of the human body.[88] The Advocate General had correctly argued, in point 55 of his Opinion, that an express transposition of the principle that commercial processes involving the use of human embryos are not patentable, was required.[89] As Italy had failed to expressly transpose the exclusions into national law, the ECJ concluded that Italy was in breach of its obligations.[90] Thus, alterations to the specific wording of the exclusions may potentially be invalid under EU law if the legal effect is to broaden or narrow the scope of exclusion contrary to the intent of the Community legislator. This is discussed further in Chapter five of this report.

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[86] Section 1(1) of the Reproductive Medicine Act.
[87] Case C-456/03 *Commission v. Italy* [2005] ECR 1-5335.
[88] At para. 80.
[89] At para. 81.
[90] This has later been corrected by the above mentioned Article 4, Decree-Law No.3 of 19th January 2006, adopted as Law No. 78 (22nd February 2006).

Analysis of the wording of these national legislative texts implementing the moral exclusion clauses, also reveals that the differences appear to be influenced by or reflect the respective national attitudes towards the moral permissibility of research on human embryos and hESC. In some cases, the legislative measures implementing the Directive make a direct link to national laws on human embryo research.

2.3 Links to Research Regulations

In addition to the countries already discussed, express links between national patent laws implementing the Directive and biomedical legislation is also to be found, for instance, in the *German Patents Act*. Relevant provisions of the Embryo Protection Act[91] are applicable to the German equivalent of Article 6(2)(a) to (c).[92] In the Preparatory Works the legislator has expressly mentioned that this reference is of particular importance for the interpretation of the morality clause and that violations of the *Embryo Protection Act* render an invention unpatentable, since the Act protects rights that are considered to be "fundamental principles of the legal system".

The *Embryo Protection Act* aims to prevent the misuse of artificial fertilisation and of the human embryo[93] *in vitro*. It prevents any use of the embryo that is not for its own preservation.[94] Artificial fertilisation of an egg cell, and hence the creation of an embryo *in vitro,* is permitted only for purposes of giving rise to pregnancy.[95] It is neither allowed to create *in vitro* embryos for research purposes, or to conduct research on such embryos and individual totipotent cells, nor to use supernumerary IVF-embryos for research.[96] The Act also prohibits the removal of stem cells from embryos, irrespective of these cells being totipotent or pluripotent and irrespective of the embryo being destroyed thereby.[97] However, the Act does not prohibit research on pluripotent stem cells *per se,* since those are not considered capable of

[91] Gesetz zum Schutz von Embryonen (ESchG) 01.01.1991, available at: http://bundesrecht.juris.de/eschg/index.html.
[92] Section 2(2)1-3 Patentgesetz/German Patents Act, (RGBl II 1936, 117, 1970, BGBl. No. 259) as amended by 2005 BGBl. I 2005 No. 42, avalabler at: http://bundesrecht.juris.de/bundesrecht/patg/gesamt.pdf
[93] A definition of a human embryo is found in Section 8 of the Embryo Protection Act:
"(1) An embryo already means the human egg cell, fertilised and capable of developing, from the time of fusion of the nuclei, and further, each totipotent cell removed from an embryo that is assumed to be able to divide and to develop into an individual under the appropriate conditions for that.
(2) In the first twenty-four hours after nuclear fusion, the fertilised human egg is held capable of development except when it is established before expiry of this time that it will not develop beyond the one cell stage.
(3) Germ cell lines, for the purpose of this Act, are all cells that lead of the egg and sperm cells to the resultant human being and, further, the egg cell from capture or penetration of the sperm cell until the ending of fertilisation by fusion of the nuclei."
[94] Section 2.
[95] Section 1.
[96] Sections 1, 2, 6, 9, and 11.
[97] Sections 1 and 2.

developing into a "comprehensive human being".[98] Nevertheless, it is prohibited to extract hESC from embryos, thus making it impossible to establish hESC lines in Germany. It is, however, possible to research on imported pluripotent hESC in accordance with the German Stem Cell Act[99] if the cells (among other preconditions) originate from culture lines established and cultivated before 1 January 2002.[100]

The *Embryo Protection Act* and the *Stem Cell Act* contain definitions of human embryos that are not identical,[101] and therefore leave uncertain the related scope of the exclusion pertaining to the human embryo in the Directive.[102]
The relationship between the provision in Section 2(2)(3) of the *German Patents Act*, containing the exclusion for patents on the use of human embryos for industrial or commercial purposes, and the provisions of the *Embryo Protection Act* would arguably affect the scope of exclusion of the corresponding Article 6(2)(c) and the policy of national patent offices.

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[98] Herdegen, M, ‚Die Patentierbarkeit von Stammzellverfahren nach der Richtlinie 98/44/EG', *GRUR Int.* 2000, 861.
[99] Act ensuring protection of embryos in connection with the importation and utilisation of hESCs, Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen (StZG), 28.06.2002, at http://bundesrecht.juris.de/stzg/index.html (2006-04-20).
[100] It should be observed that another definition of human embryo than in the Embryo Protection Act, *cf.* above, is found in Section 3 of the German Stem Cell Act: "An embryo means any human totipotent cell which has the potential to divide and to develop into a human being if the necessary conditions prevail."
StZG § 3 Begriffsbestimmungen:
"4. ist Embryo bereits jede menschliche totipotente Zelle, die sich bei Vorliegen der dafür erforderlichen weiteren Voraussetzungen zu teilen und zu einem Individuum zu entwickeln vermag,"
[101] English version available at:
http://www.bundestag.de/parlament/kommissionen/ethik_med/archiv/embryonenschutzgesetz_engl.pdf
[102] The therapeutic or reproductive cloning of human embryos is prohibited according to Section 6(1) of the Embryo Protection Act, expressed as a prohibition against the creation of an embryo with the same genetic information as another. However, the crucial question that is heavily debated in Germany is whether the method of therapeutic cloning results in what is defined as an embryo in Section 8 of the Embryo Protection Act. Section 8 speaks about the creation of an embryo by means of the fusion of the cell nuclei of egg and sperm cell. One position is therefore that since therapeutic cloning does not comprise a cell fusion, Section 6(1) is not applicable and an analogy would contradict the strict requirements of Article 103(2) of the German Constitution on the specificity of criminal law provisions. The other position is that the use of the word "already" in Section 8 (1) shows the intention of the law to protect the embryo from the earliest possible moment in time (the cell fusion) without giving a conclusive definition of the way in which an embryo can be created.[102] The German Federal Government also pointed out that the intention of the legislator to prohibit therapeutic cloning in Section 6 (1) is evident since the artificial (!) creation of embryos with the same genetic information as another embryo is only possible by means of the cell nuclear transplantation method. See Eser, A. and Koch, H-G., *'Rechtsgutachten zu den strafrechtlichen Grundlagen und Grenzen der Gewinnung, Verwendung und des Imports sowie der Beteiligung daran durch Veranlassung, Förderung und Beratung*' (2003) at p. 19 at: http://www.dfg.de. Hence, the main problem is to determine *when* an embryo in the meaning of Section 8 comes into being. This provision regards "the human egg cell (zygote), fertilised and capable of developing" as an embryo. The zygote is capable of development if it acquired the ability to divide. This moment in time is therefore relevant to define the earliest point that one can speak of an embryo in the meaning of Section 8. According to the current state of the art, a transplanted cell nucleus acquires the ability to divide at the time it is inserted into the enucleated egg cell and the interaction of cell plasma and cell nucleus causes the reprogramming of the cell nucleus. But since the zygote's ability to divide is principally not provable right after the cell fusion, Section 8(2) provides for a refutable assumption of the capability of development in the first 24 hours after the cell fusion. The same problem arises as regards a transplanted cell nucleus, but since there is no cell fusion, Section 8(2) is not applicable. As a result, therapeutic cloning is prohibited in Germany under Section 8 of the Act for the Protection of Human Embryos, but the short period in which the capability of the development of the egg cell is provable may be considered as a loophole which runs counter to the clear *ratio legis* of the Act to prohibit any technique of cloning human embryos. (Cloning Report of the German Federal Government…)

Further differences in the interpretation of the moral exclusion clauses in the Directive have emerged in the guidance in the policy or practice of national patent offices, the EGE and the EPO. These are examined below in turn.

2.4 National Patent Offices

The *German Patent Office* has granted one patent on a method involving the use of pluripotent hESC.[103] Unlike the UK Patent Office, the German Patent Office has not issued any policy statements clarifying its approach to hESC-related patent applications. However, it is possible that the grant of the patent reflects national laws permitting research on imported hESC produced outside Germany, if the relevant hESCs or hESC lines have been imported legally in compliance with the Stem Cell Act.[104] At the current time, it is therefore unclear if the granting of this particular patent signifies the general practice of the German Patent Office towards hESC-related applications, or is itself simply an anomaly.

The UK Patent Office, on the other hand, has adopted an express policy based on its understanding of the Directive's effect on patentability exclusions relating to hESC. In April 2003, the UK Patent Office issued a Practice Notice outlining its policy.[105] The Notice states that, on the basis of the national transposition of Article 6(2)(c) patents will not be granted for processes for obtaining stem cells from human embryos. Neither will patents be issued for human embryonic *totipotent cells*, which are claimed to be excluded by Article 5(1) on the basis that they have the potential to develop into an entire human body. On the other hand, none of the moral exclusions in the Directive are thought to exclude patentability of *pluripotent* hESC. On this basis, the UK Patent Office has issued at least fourteen patents that make explicit reference to hESC.[106]

The *Swedish Patent Office* has also granted a patent for a method of differentiation of pluripotent hESC's into haematopoietic cells.[107] The Office considered the application to fall outside the scope of the exclusion of uses of the human embryos for industrial and commercial purposes (Article 6(2)(c). The Swedish Patent Office reasoned that the particular application

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[103] German patent DE 10136702 B4: **"** System zur zell- und entwicklungsspezifischen Selektion differenzierender embryonaler Stammzellen, adulter Stammzellen und embryonaler Keimbahnzellenatent".

[104] This reasoning is supported by the German National Ethics Council (Nationaler Ethikrat). See Opinion of 6th October 2004 on "The patenting of biotechnological inventions involving the use of biological material of human origin", pp. 27 at: http://www.ethikrat.org/_english/publications/Opinion_patenting-of-biotechnological-inventions.pdf

[105] http://www.patent.gov.uk/patent/notices/practice/stemcells.htm (2006-05-05).

[106] GB2396623B; GB2407822B; GB2394958B; GB2399823B; GB2394723B; GB2392674B; GB2393733B; GB2386120B; GB2393734B; GB2385054B; GB2399819B; GB2380490B; GB2379447B; GB2386609B.

[107] Patent No. SE 526490: "Method of differentiation of pluripotent human embryonic stem cells into hematopoetic cells".

did not require direct, repetitive, use of a human embryo. Instead the application could be performed by using existing (deposited) lines. Thus the application did not fall within the scope of exclusion of Article 6(2)(c).

Thus, the emerging common view of the national patent offices which have granted patents involving use of pluripotent hESCs, is that Article 6(2)(c) which prohibits patents on inventions involving uses of human embryos for industrial or commercial purposes, is that the provision has to be read narrowly. The narrow construction thus relies on attaching considerable weight to the qualifications expressed in the clause that only certain uses of human embryos are prohibited, namely those which amount to 'industrial' or 'commercial' uses. Whether this is a correct interpretation of the Directive is further discussed in Chapter five.

2.5 The EPO

By contrast to national patent offices in Europe, the EPO has so far taken the view that Article 6(2)(c), which is transposed in the EPC rules as rule 23d(c), should be construed broadly as precluding not only patents on totipotent hESC, but also pluripotent and multipotent hESC related inventions. In the two detailed rulings that dealt with hESC-related inventions,[108] the OD in the *Edinburgh* case[109] and the Examining Division (ED) in the *WARF* case[110] have both relied on the morality exemptions imported from the Directive to refuse grants on inventions involving hESCs. In both cases the EPO has taken a broad interpretation of Article 6(2)(c), or in the EPO context Rule 23d(c) EPC, to exclude not only patents detailing the process of extracting stem cells from a human blastocyst (and therefore which directly entail a direct use of the human embryo, but also patents relying on already-established hESC lines as their starting point.[111] In the *Edinburgh* patent, although the technology was exemplified only with

[108] Also in a couple of other patents the morality issue has been raised in a significant way in the EPO proceedings. This is for instance the case with Patent application EP1302536 on "Embryonic stem cells and neural progenitor cells derived therefrom" by the University of Singapore. The application has been rejected in the First Examination Report by the Examining Division on 10th November 2004 for lack of unity, lack of novelty, impossibility of industrial application because it involves a human or animal treatment, ex Article. 52(4) and, finally, for not compliance with Rule 23d(c), as it was held to involve an industrial or commercial exploitation of an embryo, without much explanation at this early stage.

[109] European Patent No. EP0695351with the title "Isolation, selection and propagation of animal transgenic stem cells" triggered a major public debate on the patenting of stem cell technology. The patent concerns a method of genetically modifying stem cells so as to give them a survival advantage over unwanted differentiated cells. The many opponents in the case, *inter alia,* argued that term "animal" in the claims, could be interpreted as potentially extending to humans. The OD case from 21.07.03 deals expressly with the issue of hESC in regard to Article 53(a) and rule 23d(c) EPC, thus, taking into account the list of unpatentable subject matter in Article 6(2) of the Directive. More specifically, the OD dealt with the term "human embryo" in rule 23d(c).

[110] The ED refused the European Patent Application No. 96903521.1 by Wisconsin Alumni Research Foundation (*WARF*), on "Primate embryonic stem cells" on 13th July 2004, which in an interlocatory decision of 18 November 2005 by the Technical Board of Appeal 3.3.08 has been referred by the Enlarged Bord of Appeal (EBA).

[111] Laurie, G. 'Patenting Stem Cells of Human Origin' [2004]*EIPR*, pp. 59 ff.

mouse embryonic stem cells, the claims of the patent were not limited with respect to the type of stems cells, which led to serious doubts as to whether the stem cell selection procedure would work with embryonic stem cells from sources other than mouse, in particular with hESC. The claims therefore, were held insufficient so far as embryonic stem cells were concerned. However, the OD decided to maintain the patent with amended claims, including claims to stem cells per se, having a disclaimer to embryonic stem cells.

The OD then considered whether, in the absence of a disclaimer, the claims would have contravened Rule 23d(c) prohibiting the patenting of uses of human embryos for industrial and commercial purposes. The OD noted that there were no uniform moral standards in Europe on hESC. Since neither the assessment of national approaches to hESC, nor the conventionally accepted standards of conduct in Europe had revealed a uniform approach, the OD determined that a different approach had to be followed to the construction of 23d(c).[112] According to the OD, Rule 23d(c) has to be read broadly, to preclude patents not only on industrial and commercial uses patents of human embryos, but patents on hESC retrieved therefrom by destruction of human embryos, irrespective of whether the application discloses direct use of the human embryo or not.[113] In reaching this conclusion, the EPO dismissed *in toto* the Opinion of the EGE discussed below.

The decision of the OD in the *Edinburgh* case was followed in the *WARF* case.[114] The Technical Board of Appeal (TBA) has now referred to the Enlarged Board of Appeal a series of questions relating to the interpretation of rule 23d(c). Chapter seven of this Report evaluates the EPO's rulings in the OD and WARF cases.

2.6 The Opinion of the EGE

The Directive assigns to the EGE the task of evaluating all ethical aspects of biotechnology, though points out that "the Group may be consulted only where biotechnology is to be evaluated at the level of basic ethical principles, including where it is consulted on patent law."[115]

[112] At 2.5.3.
[113] At 2.5.3.
[114] T 1374/04 (*Wisconsin Alumni Research Foundation, WARF*), referral by the Technical Board of Appeal to the Enlarged Board of Appeal, case pending under Ref. No. G 2/06, see O.J.E.P.O. 2006, p. 393
[115] Article 7 and Recital 44. The status of the EGE and its future tasks are discussed more in detail in Chapter eight.

On 7th May 2002, the EGE published its Opinion No. 16 entitled "Ethical Aspects of Patenting Inventions Involving Human Stem Cells", which detailed the EGE's considerations on the meaning and scope of application of Article 6(2)(c) of the Directive in relation to hESC-related patent applications.[116]

Opinion No. 16 drew a distinction between the 'modified' and 'unmodified' stem cells and stem cell lines.[117] The report argues that *isolated stem cells* which have not been modified are not patentable, on the grounds that:

> "'...such isolated cells are so close to the human body, to the foetus or to the embryo they have been isolated from, that their patenting may be considered as a form of commercialisation of the human body".[118]

In addition, the EGE argued that such isolated stem cells cannot, in any event, satisfy the requirement of industrial application.

The Group further suggested that *unmodified stem cell lines* should not be patentable either, on the grounds that:

> "unmodified stem cell lines do not have indeed a specific use but a very large range of potential undescribed uses. Therefore, to patent such unmodified stem cell lines would also lead to too broad patents."[119]

However, if hESC lines are modified by *in vitro* treatments or genetically modified so that they acquire characteristics for specific industrial application, then in the EGE's opinion, these kinds of modified stem cell lines will fulfil the legal requirements for patentability.

Unlike the EPO's interpretation of Rule 23d(c) the majority view in Opinion No. 16 did not consider that 'embryo destruction' was the determining moral consideration on patentability of hESC. At the same time, it has to be acknowledged that it is unclear why the EGE thought that 'closeness to the human body' was a relevant moral consideration and where in European culture this particular norm is to be found.

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[116] European Group on Ethics in Science and New Technologies to the European Commission, "Ethical Aspects of Patenting Inventions Involving Human Stem Cells Opinion 16, 7 May 2002.
Available online at: http://europa.eu.int/comm/european_group_ethics/docs/avis16-en.pdf.
[117] The distinction is drawn at para. 1.3.
[118] At para. 2.3.
[119] At para. 2.3.

2.7 Emerging Questions

In the light of the differences over the implementation of the moral exclusion clauses in Article 6 of the Directive, the emerging areas of uncertainty seemingly concern two central questions..

In the *Edinburgh* case it was held that patent protection should be refused not only for any type of hESC (totipotent, pluripotent, multipotent), but also that the exclusion of human embryos from patentability under Rule 23e(1) EPC[120] equally pertains to the "uses" of human embryos for whatever purpose. Similarly, in a separate *WARF* application, the ED of the EPO refused to grant the patent on the grounds that:

> "… the present application is not directed to the isolation or culture of human ES cells but rather to their *in vitro* differentiation into cells of the haematopoietic lineage. Claims are not direct to ES cells but to methods for obtaining differentiated cells and their uses. Nevertheless, the Examining Division considers the present claims to fall under the exclusion of Article 53(a) and Rule 23d(c) EPC, since the methods of the present application as well as the products derived therefrom cannot be obtained from a source other than the human embryo. For the purpose of morality assessment it is not sufficient that the objectable method is not claimed *per se*, as long as it is the only thinkable - and workable - option of obtaining the claimed subject-matter."[121]

By contrast, the *Swedish* patent office granted the same patent on the basis that the "commercial exploitation of this method does not need the use of a human embryo – the stem cells may have been isolated, *i.e.* for legitimate research purposes, long before the invention was made."[122]

In this light, a central emerging question concerns whether the terms 'industrial' and 'commercial' uses of human embryos, confine the scope of the exclusion to certain processes or applications only, and if so which precisely.

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[120] Rule 23e: "The human body and its elements
(1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. […]"

[121] Application No. 00 957 842.8, "Hematopoetic differentiation of human embryonic stem cells", decision of the Examining Division, 18th November 2004, at para. 4.2.

[122] Further communication with the Office clarified that it chose to focus on the patent application as such, irrespective of its possible pre-stages that were regarded as irrelevant.

Another question concerns the moral values underlying the prohibitions in the list of exceptions. As put by the OD in the *Edinburgh* case:

> "The crucial question is whether the legislator when introducing this Rule into the EPC in September 1999 has intended to ban from patenting human embryos as such or human embryos together with the cells being retrieved therefrom by destruction of the embryos, namely human ES cells."[123]

Was it the intention of the Community legislator to prohibit patents on uses of human embryos which necessarily involve "embryo destruction"? And if not, what was the moral rationale for the specific exclusions?

Part II and Part III of this report consider these questions in the light of the legal parameters which define the interpretation of the moral exclusion clauses within the EC and EPC legal systems, with a view to achieving some legal certainty.

[123] Item 2.5.3, Reasons for the Decision.

Part II: The Directive in the EU Legal Order

Chapter Three: Principles of EU Law[124]

Introduction

The Directive is a legislative product of the EC. It can be properly understood only against the backdrop of the sophisticated institutional architecture of the EU, of which the Community forms the central pillar. The Community has been aptly described as a separate legal order of a 'hybrid' nature with a mixture of federalist and intergovernmental features,[125] or as a multi-level system of governance *sui generis* as recently advanced in political science and legal scholarship. Implied in the latter concept is that the powers and the resources for political action are shared by a multitude of public as well as private actors, operating at different mutually interconnected levels, not necessarily in a hierarchical relationship to each other.[126]

3.1 Principles defining Community Legislative Competence

The Community legislative competence is often said to be based on the principle of conferred or enumerated powers, meaning that the Community has the right to intervene only within those limited spheres reserved to it in the Treaties. The principle is, however, substantially relaxed through a number of constitutional rules and judicial doctrines such as the doctrine of implied powers[127] and the open-ended nature of Article 308 TEU.[128] Furthermore, the EC Treaty is not

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[124] Our special thanks to Antonina Bakardjieva-Engelbrekt for contributing this chapter and parts of chapter 6.

[125] Case C-26/62 *Van Gend and Loos* [1963] ECR 1, 12; Hartley, T., *The Foundations of European Community Law. An Introduction to the Constitutional and Administrative Law of the European Community* (Oxford University Press: Oxford 2003), 56.

[126] On the concept of multi-level governance see Scharpf, F., 'Regieren im europäischen Mehrebenensystem – Ansätze zu eine Theorie', *Leviatnan* 2002, p. 65; Barnard, C., *The Substantive Law of the EU* (Oxford University Press: Oxford 2004), 17; Bernard, N., '*Multilevel Governace in the European Union'* (Kluwer, 2002), 8.

[127] Hartley discusses a narrow and broad version of the doctrine, Hartley (2003) *supra,* at 106. On the evolution of the doctrine on implied powers in the external relations of the Community see Cremona, 'External Relations and External Competence', in: Craig, P. and De Búrca, G., 'The Evolution of EU Law' (Oxford University Press: Oxford 1999), 137 ff., at 138 ff.

[128] The latter provision authorises the Council (on the initiative of the Commission and after consultation with the European Parliament) to take the appropriate measure "if action by the Community should prove necessary to attain, in the course of the

very exacting when outlining the powers pertaining to the competence of the Community. In particular, Articles 94 and 95 EC define the Community's legislative competence for the establishment and functioning of the Internal Market in very broad terms and have been used to extend Community's competence to a multitude of interfacing areas and objectives, notably harmonisation of Intellectual Property (IP) law. Article 95 EC has also served as a legal basis for the purposes of the Directive, a choice confirmed by the ECJ in the *Netherlands v. European Parliament and Council*.[129] In the same ruling the Court also upheld the distinction drawn in its previous case law between, on the one hand, harmonisation of national laws as a means of promoting the establishing of the internal market (thus requiring Article 95 as a legal basis) and, on the other hand, creating new Community IP rights, i.e. Community title of property right, requiring in turn Article 308 as a legal basis.[130] The ECJ confirmed that the legal basis of the Directive was Article 95 and not Article 308. The difference is important not least due to the unanimity voting required under Article 308 EC.[131] As evidenced by the Directive, also issues of ethics and morality can enter the Community legislative competences provided that a measure does not exclusively or chiefly aim at harmonising ethics and morals and provided that the link with the Internal Market is sufficiently present and plausible.

Despite an overall tendency of expansion of the legislative powers of the Community, this trend is by no means unconstrained. The pendulum has also been swinging in the opposite direction, in search of a point of balance between "an ever closer union" and preserving national sovereignty. The Treaty of Maastricht in particular reinforced the principle of enumerated powers (Art. 5(1) (ex 3b(1)) Treaty on European Union=TEU) and clearly anchored the principles of subsidiarity and the supporting one of proportionality in the constitutional texture of the European Union (Art. 5 EC).[132] Moreover Article 6(3) TEU proclaims that the Union shall respect the national identities of its Member States.

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operation of the common market, one of the objectives of the Community and this Treaty has not provided the necessary powers."

[129] See Case C-377/98 *Netherlands v. European Parliament and Council* [2001] ECR I-07079; *cf.* Recitals 5, 6 and 7 Directive. On the competence of the EU over patents see Gold, E. and Gallochat, A., 'The European Directive: Past as Prologue' [2001]*ELJ, pp.* 332 ff., at 352.

[130] See in particular, Opinion 1/94. See, however, Case C-350/92 *Spain v. Council* [1995] ECR I-1985 and the critical analysis by Ullrich, H., 'Harmony and Unity of European Intellectual Property Protection' in: Vaver D., and Bently,L. (eds.) *Intellectual Property in the New Millenium*, (Cambridge University Press,(2004), 27, fn. 37. On this case see de Witte, 'Non-Market Values in Internal Market Legislation', in: Shuibhne, N. N.,*Regulating the Internal Market* (forthcoming), on file with the author, 15, fn. 37 and Ullrich, H., 'Patent Protection in Europe: Integrating Europe into the Community or the Community into Europe?' *EUI Working Paper Law* No. 2002/5 = [2002]*ELJ,* pp. 433 ff. (2002); Kaiser, K., *Geistiges Eigentum und Gemeinschaftsrecht. Die Verteilung der Kompetenzen und ihr Einfluss auf die Durchsetzbarkeit der völkerrechtlicher Verträge* (Duncker & Humblot: Berlin 2004).

[131] The distinction is regarded as untenable by a number of authors. Others insist that the distinction should be upheld since unitary rights are a formidable intervention in the national IP right system and should require the unanimous procedure of Article 308, see Ullrich (2002), *supra*, at 40-41.

[132] Article 5 EC: "In areas which do not fall within its exclusive competence, the Community shall take action, in accordance with the principle of subsidiarity, only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by

The ECJ has also more recently demonstrated increased sensitivity as to the limits of Community legislative powers in the *Tobacco Advertisement* judgment[133], as well as to the limits of its own interpretative powers and institutional role in the seminal *Keck and Mithouard* judgement.[134] These developments are important when trying to define the margin of appreciation left to the Member States in the implementation of moral exclusions in the Directive.[135]

3.2 European Community Law and National Law

Following the classical account, once a Community legislative measure such as the Directive is in place its effect on the national law of the Member States is determined *mutatis mutandi* by the basic principles of direct applicability, direct effect and supremacy. Under the first of these principles Community law becomes part of the domestic law of the Member States, not requiring a formal act of transposition and irrespective of divergent national constitutional law doctrines as to the status of international law viz. domestic law. Primary and substantial parts of secondary Community law are generally regarded as capable of producing direct effects for individuals.[136] Last, but not least, in those areas where Member States have transferred competence to the Community, Community law takes precedence over any conflicting national law, present as well as future (the principle of supremacy).[137]

At the same time, these principles alone give a rather crude description of the variety of ways in which interaction between national and Community law can be shaped. A number of constitutional doctrines and legislative techniques are employed to fine tune the balance between uniformity and differentiation. Important in determining the balance between Community law and national law, is the choice of legal act to be adopted at Community level (Directive or Regulation), the scope and type of harmonisation (selective, partial or total,

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the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community. Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty."

[133] Case C-376/98 *Germany v. European Parliament and Council (tobacco advertising)* [2000] ECR I-8419.

[134] Joined Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097.

[135] In the recent and still continuing constitutional debate on the Treaty Establishing a Constitution for Europe considerable attention has been devoted to introducing more precision and clarity in the division of powers. See de Búrca and de Witte, 'Delimitation of Powers' in: Arnull, A./Wincott, D. (eds.) *Accountability and Legitimacy in the European Union* (Oxford University Press: Oxford 2002); see Weatherill, S., 'Competence' in: de Witte, B., *Ten Reflections on the Constitutional Treaty for Europe* (Florence: RSCAS, EUI, 2003); Weatherill, S., 'Better Competence Monitoring' *E.L. Rev.* 2005, 30(1), 23-41.

[136] Case C-26/62 *Van Gend and Loos* [1963] ECR 1, 12.

[137] Case C-6/64 *Costa v. ENEL* [1964] ECR, 594 ; *cf.* Case C-106/77 *Simmenthal* [1978] ECR 640, paras 17 and 24.

minimum or full harmonisation)[138] and the legislative language and style (e.g. use of vague and open concepts or direct recourse to concepts in national law).[139]

By opting for a Directive as legislative act on biotechnological inventions, the Directive indicates, at least in principle, a lower harmonisation ambition. Following Article 249 EC Directives are binding only as to the result to be achieved and leave upon national authorities the choice of form and methods of implementation.[140] However, the difference between Directive and Regulation has been considerably blurred through creative judicial doctrines of horizontal direct effect, indirect effect and state liability for non-implementation.[141] Following settled ECJ case law Member States must moreover implement Directives in a way that ensures legal certainty and full effect of Community law.[142]

The Directive does not announce explicitly the type of harmonisation aimed at. Certainly there is no express minimum harmonisation clause. Neither is there a clear statement as to possible derogations, variable norms, transition periods or the like. This circumstance points to a high ambition of achieving common conditions of patentability. At the same time, the Directive does not ensure comprehensive harmonisation of the subject matter of patenting biotechnological inventions. As indicated by AG Jacobs directives are inherently liable not to deal exhaustively with the detail of matters within their scope.[143]

An important source of regulative leeway for the Member States is achieved through the conscious use of open and vague concepts in secondary Community law. This drafting style leaves broad margin of appreciation to the Member States in the process of transposition and interpretation of Community law and ample room for adjustment of Community concepts to the specific national legal (and social) environment, admittedly at the expense of uniformity.[144]

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[138] Slot, 'Harmonisation' 21 *ELRev.*(1996), 378.
[139] For a taxonomy of methods for introducing differentiation in Community law see Dougan, M., *National Remedies Before the Court of Justice* (Hart Publishing: Oxford: 2004). See also Dougan, M., 'Minimum Harmonization and the Internal Market' 37 *CMLRev.* 2000, 853, at 855.
[140] See Article 249 EC; *cf.* Prechal, S., '*Directives in European Community Law'* (Clarendon Press: Oxford: 2005), 31, 73 ff. The ECJ has accepted implementation through already existing general principles of national law or through settled case law of national courts. Even implementation through preparatory works has been found adequate, provided, however, that the main requirements of legal certainty and full effect have been observed. See Case C-478-99 *Commission v. Sweden* [2002] ECR I-4147, *cf.* Prechal, *supra*, 75.
[141] On horizontal direct effect see Case C-41/74 *Van Duyn v. Home Office* [1974 ECR 1337; Case C-51/*76 Verbond van Nederlandse Ondernemingen (VNO) v Inspecteur der Invoerrechten en Accijnez* [1977] 113; on indirect effect Case C-14/83 *Von Colson v. Land Nordrein-Westfalen* [1984] ECR 1891 and on state liability for non-implementation *Francovich v. Italy*, Case C-6&9//90 [1991] ECR I-5357; *cf.* Weatherill, S. and Beaumont P., EU Law – The Essential Guide to the Legal Workings of the European Union,(Penguin, 1999), p. 403, Steiner, J., Woods, L. and Twigg-Flesner, Ch., *Textbook on EC Law* (Blackstone: London 2000), p. 56
[142] Prechal, *supra,* note 16.
[143] Opinion AG Jacobs, Case C-377/98 *Netherlands v. European Parliament and Council* [2002] ECR I-07079, at para 87.
[144] Dougan (2004), *supra,* p. 143.

Indeed the Directive itself does not undertake to provide an all-valid Community-wide definition of the meaning of morality or of *ordre public*. Such an ambition would certainly also have been misguided given the limitations on the legislative powers of the Community set in the provisions discussed above (notably, subsidiarity).

Beyond the varying techniques of harmonisation, an additional support for broader margin of appreciation for the Member States has been drawn from Article 6(3) TEU (as amended by the Amsterdam Treaty) requiring respect for national identity. This article, together with Article 22 of the Charter on Fundamental Rights on "Cultural, religious and linguistic diversity" has been interpreted to require due regard for and retained powers for Member States to legislate in matters of morality and ethics.[145]

3.3 Morality and *Ordre Public* in Community Law & the Role of the ECJ

Given the often open-ended and ambiguous character of both primary and secondary Community law, the role of the ECJ as an interpreter looms large. The Court is the guardian of the Treaties and has to ensure that Community law is adequately and uniformly applied. This control is exercised in several ways. The Court can be seized by the Community Institutions, notably the Commission (Article 226 EC), by a Member State and, importantly, by national courts in order to give guidance as to the interpretation of Community law. The importance in particular of the last avenue, i.e. the mechanism of reference for a preliminary ruling set out in Article 234 (ex 177) can hardly be overstated.[146] Article 234 (ex 177) EC allows national courts (and obliges last instance courts) to refer questions concerning the validity or interpretation of Community law to the ECJ. It provides a framework for a non-hierarchical co-operative communication process between national courts and the ECJ.[147]

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[145] The Charter of Fundamental Rights of the European Union has been incorporated In the EU legal order. It was proclaimed at the European Council at Nice on December 7, 2000, in the Treaty establishing a Constitution for Europe. Although the European Council approved the EU Charter at Nice in December 2000, it is limited to a political declaration, and the Charter has so far not received a formal legal status. Part II of the proposed European Constitution, signed in October 2004, but which failed to be ratified after referendum defeats in France and Holland, contained a version of the Charter. The intention was to enable the EU to accede to the ECHR, thus enabling the ECJ to rule on the basis of this Charter.

[146] Case C-6/64 [1964] ECR 585 at 592. See Jarvis, M., *Application of EC Law by National Courts. The Free Movement of Goods* (Clarendon press: Oxford 1998), 236.

[147] See Slaughter, A-M., Stone-Sweet, A. and Weiler, J.H.H. (eds.), *The European Courts and National Courts - Doctrine and Jurisprudence* (Hart Publishing: Oxford 1998). It is often noted that the duty of the ECJ under Article 234 (ex 177) EC is to interpret the relevant Community law referred to it and not to apply its interpretation to the facts. In reality, however, the dividing line between interpretation of Community law and its application to the facts is very thin and has been often crossed in the Court's judgements. The Court has in a number of cases ventured interpretations so concrete and exacting as to leave practically no space for manoeuvring to the referring national court. For criticism of this expansionist approach see Davies, G., 'The Division of Powers Between the European Court and National Courts' article available at: http://lesl.man.ac.uk/conweb; see also Schmid, Ch., 'Judicial Governance in the EU', paper at CIDEL conference, 25 September 2005, EUI, Florence.

As reminded in AG Jacobs' opinion in the Netherlands case, the concepts morality and "*ordre public*" (in English translated more often as public policy) are not foreign to Community law, although the latter concept has been employed and subject to judicial interpretation more often than the former.[148] In the following separate analyses are made of the case law of the ECJ in the area of free movement (negative integration) and in the area of harmonised Community law (positive integration).[149] This distinction appears justified since in the first situation, there is typically no Community legislative measure in place. Consequently, the institutional relationship and the margin retained by the Member States may be shaped in a different way.

3.4 ECJ Case Law in the Context of Free Movement of Goods and Services

Public morality features as an express derogation only from the prohibition of quantitative restrictions on imports and exports and measures having equivalent effects (principle of free movement of goods, Article 28 and 29 EC), but has been discussed in the context of the other fundamental freedoms as well, notably freedom to provide services. Public morality has only rarely been invoked as a separate ground of justification and then mostly in the sense of sexual and private morality (*Darby and Henn*[150], *Conegate*[151]). The Court has tended to afford Member States a relatively wide margin of appreciation although not always finding the claim to be supported by the facts of the case. In *Darby and Henn* the ECJ held that: "in principle, it is for each Member State to determine in accordance with its own scale of values and in the form selected by it the requirements of public morality on its territory."[152]

Another line of cases that touched upon morality in the sense of divergent ethical and religious traditions and outlooks was the Sunday trading cases. In *Torfaen Borough Council*[153] the defendant Torfaen Borough Council argued that the restriction on Sunday trading (arguably presenting a barrier to trade) was justifiable on grounds of public morality due to religion-based

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[148] See Opinion AG Jacobs, Case C-377/98 *Netherlands v. European Parliament and Council* [2002] ECR] ECR I-07079, para 97.
[149] On the categories: positive and negative integration as economic concepts see Molle, W., *The Economics of European Integration. Theory, Practice and Policy* (Aldershot and Brookfield: Dartmouth Publishing 1990), at 11.
[150] Case C-34/79 *Darby and Henn* [1979] ECR 3795 concerning the import in the UK of allegedly indecent articles in breach of the UK Customs Act. See Oliver P. and Garvis, M., *Free Movement of Goods in the European Community* (Sweet & Maxwell: London 2003), p. 242.
[151] Case C-121/85 *Conegate* [1986] ECR 1007 concerning the import in the UK of inflatable dolls for sale in sex shops.
[152] Case C-34/79 [1979] ECR 3795. Oliver/Garvis interpret the phrase "in principle" in this passage of the Court's ruling in Darby & Henn as indicating that Member States may only exercise discretion within the boundaries of a Community-wide concept of public morality, *supra* 242. However, a more convincing interpretation would be that the discretion afforded to the Member States is not unlimited and is always to be exercised in accordance with general principles of Community law.
[153] Case C-145/88 [1989] ECR I-3851.

objections to opening hours among certain members of the population. This argument was discarded by the AG, who submitted that prevention of offence to religious convictions did not fall within the concept of public morality. The Court, however, did not take a stand on this point in its judgement.

Public morality was also the subject of interpretation in *R. v. Ministry of Agriculture, Fisheries and Food, Ex p. Compassion in World Farming (CWF)* in the context of the Treaty prohibition of quantitative restrictions on exports.[154] The case concerned the export of calves for rearing in veal crates. A private party, an animal welfare body (CWF), had brought judicial review proceedings against the refusal of the UK Minister to prohibit the said export, arguing that it was against animal health, public policy and public morality. The Court rejected the claim, since it found that public morality and public policy were not being invoked as a separate justification ground. They were just aspects of the justification relating to the protection of animal health and the latter had been subject to exhaustive harmonisation legislation at Community level. This part of the judgment has been rightly criticised in the legal literature as reducing questions of ethical standards and morality to questions of health protection.[155]

The decision is relevant to the biotechnology debate also because the ECJ ventured to opine on the question as to how Member States are to determine what constitutes public morality. The Court held:

> In any event, a Member State cannot rely on the views or the behaviour of a section of national public opinion, as CIWF maintains, in order unilaterally to challenge a harmonising measure adopted by the Community institutions.[156]

Also on this point the Court has been criticised for foreclosing Member States' political choices as to the weight to be attached to specific groups of public opinion. It can be objected, however, that the statement was made *obiter* and that the circumstances of the case were rather specific.[157]

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[154] Case C-1/96 [1998] ECR I-1251. See Olivera nd Garvis, *supra*, at 246.

[155] Woods, L., *Free Movement of Goods and Services within the European Community* (Aldershot: Ashgate, 2004), 109. Woods transposes the Court' reasoning to the area of foetus research arguing that if EC were to agree on public health conditions for medical research on foetuses, this would not mean that there can be no discussion about whether such research is ethically right or wrong.

[156] Case C-1/96 *R. v. Ministry of Agriculture, Fisheries and Food, Ex p. Compassion in World Farming (CWF)* [1998] ECR I-1251, paras. 65-67.

[157] Woods, *supra*, note 31, at 118. The case did not concern upholding a national standard on the state's own territory, but rather prohibition of exports on grounds of alleged national morality standards, thus affecting conditions in Member States with different view on public policy and morality in respect to animal welfare. Moreover, the assessment of EC law had already been carried out by a legitimate national authority, whose decision the Court was in effect asked to substitute. This was certainly, a sensitive institutional conundrum.

Morality justifications have likewise been invoked in the context of free movement of services. The ECJ had in several cases to rule on the compatibility of national prohibitions and regulation on the advertising of lotteries with Article 49 EC. In *Schindler* the Court found the national measure to constitute a restriction to the free movement of services, but to be justifiable on public policy grounds.[158] Particular weight was given by the Court to the shared commonality or 'general tendency' of Member States to restrict gambling on religious or cultural grounds.[159] In subsequent case law (*Diego Zenatti*, *Läära and others*[160], *Anomar and others*[161]), the Court however did no longer insist on commonality. Quite to the contrary in *Zenatti* the discretion of the Italian state to choose the way to respond to a valid social policy concern was emphasised. In the *Laserdrome* case AG Stix-Hakl clearly distinguished *Schindler*, stating that the judgement gives expression to the viewpoint "that the existence of such general opinion on the need to restrict a fundamental freedom is an indication of its legitimacy and not that this general opinion is a requirement for the recognition of such legitimacy," (para 108). This interpretation was confirmed by the ECJ.[162]

Public policy is often used as a justification of a restrictive measure when all other justifications are exhausted. It is therefore rarely judged as a separate ground for derogation from the fundamental freedoms. The Court has recurrently stated that the public policy justification has to be interpreted strictly and cannot be determined unilaterally by each Member State without any control by the Community institutions.[163] In particular, the Court has held that not every infringement of national law can be regarded as a violation of public policy. For the public policy exception to obtain there has to be evidence of a 'genuine and sufficiently serious threat to the requirements of public policy affecting one of the fundamental interests of society.'[164] At the same time the Court has acknowledged that "Member States are, in principle, free to determine the requirements of public policy and public security in the light of their national needs"[165] and that an area of discretion has to be recognised for the national authorities.[166]

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[158] Case C-275/92 [1994] ECR I-1039, paras. 59 and 60: "First of all, it is not possible to disregard the moral religious or cultural aspects of lotteries, like other types of gambling, in all the Member States. The general tendency of the Member States is to restrict, or even prohibit, the practice of gambling and to prevent it from being a source of private profit …" See Oliver/Jarvis, *supra,* note 26, 245 ff.

[159] Case C-275/92 [1994] ECR I-1039, paras. 59 and 60. The particular recognition of the religious aspects of lotteries led some commentators to speculate as to whether the AG's rejection of the relevance of such considerations in Case C-145/88 *Torfaen Borough Council* [1989] ECR I-3851 is now explicitly overruled. See Oliver/Garvis, *supra*, p. 245 ff.

[160] Case C-124/97 [1999] ECR I-6067, para 31, 35, 36..

[161] Case C-6/01 [2003] ECR, I-8621, para 80.

[162] Case C-36/02 *Omega Spielhallen- und Automatenaufstellungs-GmbH v. Oberbürgermeiterin der Bundesstdt Bonn* [2004] ECR, I-9609.

[163] Case C-36/75 *Rutili* [1975] ECR 1219, para 32.

[164] Case C-30/77 *Bouchereau* [1977] ECR 1999, para 33-35.

[165] Case C-54/99 *Eglise de scientology* [2000] ECR I-1335, para 17.

[166] Case C-41/74 *Van Duyn* [1974] ECR 1337, at paras. 18, 19.

Fundamental human rights in ECJ case law are more abundant as part of the broad concepts of public policy and public order or as a separate ground for derogation. The Court has consistently held that fundamental rights – as laid down in particular in the European Convention on Human Rights – form part of the Community legal order and that the Court ensures the observance of these rights under Community law. Initially, support for this view was derived through the doctrine on general principles common to all Member States.[167] Subsequently fundamental rights have been explicitly included in the EC Treaty and the TEU.[168] Where national legislation falls within the field of application of Community law the Court, when requested to give a preliminary ruling, sees itself in principle authorised and obliged to provide the national court with all the elements of interpretation, which are necessary in order to enable it to assess the compatibility of that legislation with fundamental rights. In contrast, the Court has no such jurisdiction with regard to national legislation lying outside the scope of Community law as demonstrated by the ruling in *Grogan*.[169] The latter case also shows the deference of the ECJ to take a stand on issues involving morality. In respect to the objections of SPUC as to the qualification of termination of pregnancy as a service under EC law, the Court stated:

> Whatever the merits of those arguments on the moral plane, they cannot influence the answer to the national court's first question. It is not for the Court to substitute its assessment for that of the legislature in those Member States where the activities in question are practised legally.[170]

This position was later on confirmed in *Schindler* in respect to lotteries and in *Jany and others* in respect to prostitution.[171] At the same time in *Grogan* the ECJ found the Irish prohibition of advertising by student associations of abortion services in the UK to have too strenuous connection with the service in question to be considered as a barrier to trade in the meaning of

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[167] Hartley, T., *The Foundations of European Community Law. An Introduction to the Constitutional and Administrative Law of the European Community* (Oxford University Press: Oxford 2003), pp. 133 ff.

[168] Article 6 TEU establishes, as a general principle, that the European Union should respect human rights and fundamental freedoms, upon which the Union is founded.

1. The Union is founded on the principles of liberty, democracy, respect for human rights and fundamental freedoms, and the rule of law, principles which are common to the Member States.

2. The Union shall respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law. …

[169] Case C-159/90 *Society for the Protection of the Unborn (Ireland) Ltd. v. Grogan and Others* [1991] ECR I-4675; *Cf.* Case C-260/89 *Eliniki Radiophonia Tileorasi v Dimotiki Etairia Pliroforissis* [1991] ECR I-195, para 42.

[170] Case C-159/90 *Grogan* [1991] ECR I-4675, para 20.

[171] Case C-275/92 *Schindler* [1994] ECR I-1039, para 32; Case C-268/99 *Jany and others* [2001] ECR I-8615. See also Joined Cases 115/81 and 116/81 *Adoui and Cornuaille* [1982] ECR 1665.

Article 49 EC. In this way the Court avoided tackling the more sensitive question of the compatibility of the Irish prohibition with Community fundamental freedoms.

Finally, despite the determination of the ECJ to provide guidance to national courts on the interpretation of fundamental rights under Community law, the ruling in the *Laserdrome* case suggests that when local social and historical context gives rise to specific and genuine national concerns for protection of fundamental rights, such concerns are respected by the Court even if not shared by all Member States.[172] In this case respect for human dignity, being central in the German constitution and acknowledged to permeate all other fundamental rights and freedoms, was allegedly impaired by the commercial organisation of 'killing games'.[173] Methodologically important is the Court's insistence that it interprets the notion of human dignity as part of the Community system of fundamental rights and not as part of national, i.e. German, law. Within this common Community notion, however, the ECJ recognised again a considerable margin of discretion of Member States as to the precise way in which the right is being protected. As commentators note, however, the ECJ had already prior to its judgement in *Laserdrome* rejected an "expansive" approach of pegging the Community level of protection to the greatest level offered among the Member States.[174] While accepting the German prohibition as justified on grounds of conflict with human dignity and public policy, the ECJ did not suggest that similar restrictive policy should be imposed on the UK where the said "killing games" had been allowed.

What could the implication of this jurisprudence be for the possible position of the ECJ on its jurisdiction to rule on divergent implementations of the morality exception in the Directive in national law? The analysis points in a direction of greater sensitivity to national perceptions of ethics and morality. This is so even in the field of protection of fundamental rights where the Court insists on the existence of common Community principles. The margin of discretion is, however, not unlimited and the Member States are required to exercise it with discipline and respect for the interest of European integration. The principles of non-discrimination and proportionality are in particular always invoked as necessary complement and limitation to discretion.[175]

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[172] Case C-36/02 *Omega* [2004] ECR, I-9609.

[173] See Smith, C./Fetzer, T., 'The Uncertain Limits of The European Court of Justice's Authority: Economic Freedom versus Human Dignity' *10 Colum.J.Eur.L.*, 445. On the principle of human dignity as a possible guidance to the ECJ see Jones, J., 'Common Constitutional Traditions": Can the Meaning of Human Dignity under German Law Guide the European Court of Justice?', *Public Law* 2004, pp. 167-187.

[174] Smith/Fezer, *supra,* note 49, at 458 with reference to Weiler, Human Rights: in Dinan, D. (ed.) *Encyclopedia of the European Union*, 265, 267.

[175] Case C-268/99 *Jany and others* [2001] ECR I-8615. See also Joined Cases C-115/81 and C-116/81 *Adoui and Cornuaille* [1982] ECR 1665; Case C-55/94 *Gebhard* [1995] ECR I-4165, at para. 37.

3.5 ECJ Case Law on Secondary Community Law

In contrast to the jurisprudence which has evolved in the context of free movement of goods and services, the Court must, in the case of the Directive, interpret secondary and not primary Community law. It may therefore be helpful to see how the ECJ has treated morality and public policy exceptions once they are incorporated in Community Directives and Regulations. As noted by AG Jacobs in the case *Netherlands v. European Parliament and Council* the concepts *ordre public* and morality are habitually included in all harmonising and unifying measures in the area of IP rights, such as the Community Trade Mark Directive and Trade Mark Regulation, the Plant Variety Regulation, the Community Design Directive and more recently Community Design Regulation.[176] References to *ordre public* and public policy can likewise be found in harmonising legislation in other areas of Community policy, typically providing Member States with a possibility to derogate from harmonised measures as a last resort.[177]

The case law on interpreting these public policy exceptions and on the margin of discretion left to the Member States is relatively limited though. Therefore attempts to elicit a uniform, all-valid approach would seem misguided. The position of the Court will rather depend on the relevant policy area, on the precision of the legislative act and on the employment of the differentiation techniques discussed above. As a general observation, it appears that when the public policy exception is fleshed out in more detail in the Community instrument in point, then these more specific provisions set stricter limits to Member States' discretion. In contrast, if the reference is made to public policy without further specification, then similar logic as in the case law on free movement applies.[178]

Still a distinction has to be made between harmonisation measures and Community legislation which establishes a separate Community title of IP rights, as is the case with the Community Trade Mark Regulation and the Community Design Regulation. Both regulations include

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[176] See Opinion AG Jacobs, Case C-377/98 *Netherlands v. European Parliament and Council* [2001] ECR I-7079, para 96.

[177] See a long list of such measures in AG Jacobs Opinion, *ibid.*, at para. 98, *e.g.* Article 11(2)(b) Directive 68/151 EEC; Article 10(2)(a) Directive 89/592/EEC on insider dealing (public policy); Article 14(5) Directive 90/619/EEC on direct life assurance (public policy), etc. So for instance First Council Directive 68/151/EEC in the field of company law stipulates in its Article 11(2)(b) that nullity of companies may be ordered among other things on grounds that "the objects of the company are unlawful or contrary to public policy".

[178] This is illustrated by the ECJ judgement in the case *Oteiza Olazabal* C-100/01 *Oteiza Olazabal* [2002] I-10981 concerning Directive 64/221/EEC. The Directive deals with Member States measures on entry, expulsion and residence permits taken on grounds of public policy, public security or public health. The Directive specifies that measures taken on grounds of public policy or of public security shall be based exclusively on the personal conduct of the individual concerned and that previous conviction shall not in itself suffice for justifying such measures. In its ruling the ECJ sustained these requirements, but for a more general analysis of the scope of the public policy exception in the Directive the Court invoked its case law developed in the context of free movement of services

morality exceptions, whereby the Community judiciary is the sole institution to make the balancing act and to give a Community-wide interpretation of the exception clauses.[179]

Although harmonisation measures often aim at abolishing obstacles to trade, in view of the many different types and degrees of harmonisation, primary Community law, notably Article 28 retains its validity even after harmonisation. This is so because (i) the Community measure itself may be imperfect and may contribute to erecting and maintaining of trade barriers,[180] or (ii) because harmonisation was only at a minimum level or incomplete.[181]

3.6 Implications for the Morality Exclusions in the Directive

The Directive is certainly a good example of a legislative measure working with open and vague concepts. In the light of the analysis above it follows that the Directive consciously seeks to accommodate the divergent ethical and public interest concerns of the Member States. A number of distinctions have to be drawn, however. First, the Directive operates with different degree of precision, leaving thus different margin of discretion to the Member States. For instance, whereas Article 6(1) by reiterating the general exception from patentability on grounds of morality and *ordre public* leaves wide scope of manoeuvre to the Member States, the list of exceptions in Article 6(2) employs more specific concepts that would require unequivocal implementation by the Member States and more stringent interpretation on the part of the ECJ. This was evident from the *Commission v. Italy* ruling of the Court.[182] The scope for

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[179] The Court of First Instance has so far had to rule in two cases invoking the morality exception in the Trade Mark Regulation. The circumstances in these cases, however, are specific and the rulings provide no guidance as to the readiness of the Court to search for a general all-valid definition of morality. In *Sportwetten* and *Durferrit* the morality exception was invoked in relation to the intended or actual use of the trademark and the lawfulness of the services offered under the trademark. The Court of First Instance had no difficulty of concluding that the morality provisions of the Community Trade Mark Regulation envisaged the intrinsic qualities of the mark claimed and accorded no significance to the prior conduct of the applicant or the possible use of the mark post registration.

[180] See Case C-47/90 *Delhaize v. Promalvin* [1992] ECR I-3669; Case C-315/92 *Verband Sozialer Wettbewerb v. Estee Lauder* [1994] ECR I-317. It may be, however, that the Community enjoys greater margin of freedom in designing its legislation. See Oliver, *supra*, 66 ff. with references to relevant case law.

[181] *Cf.* Case C-39/90 *Denkavit Futtermittel v Land Baden-Würetenber*g [1991] ECR I-3069. Less certain is whether Member States can still invoke derogations from common market freedoms on the basis of Article 30 EC after a harmonisation measure has been adopted. The classical view supported by case law from the ECJ (Case C-148/78 *Criminal proceedings against Ratti,* [1979] ECR 1629) is that once the Community has legislated, Member States may no longer rely on Article 30 justifications (especially under total harmonisation). The balance between internal market concerns and other public policy concerns is arguably to be exercised by the Court and not by Member States. This is however, a truth with modifications. Given that a measure has not comprehensively taken into account all relevant justifications under Article 30, then Member States may still retain certain margin of appreciation (*cf.* Oliver/Jarvis, *supra*, note 26, 233). Even more nuanced is the situation when a Community measure takes the form of minimum *supra* harmonization, *cf.* Dougan (2000) *supra*, at 866 ff.

[182] See Case C-377/98 *Netherlands v. European Parliament and Council* [2001] ECR I-07079, at paras. 37 and 38, *cf.* Case C-465/03 *Commission v. Italy*, judgement of 16 June 2005, nyr., para 78. Note, however, the different attitude of the Court in proceedings concerning the correct transposition of a Directive into national law (Art. 269 EC) and in preliminary ruling proceedings, Johnston and Unberath, 'Law at, to or from the Centre? The European Court of Justice and the Harmonization of Private Law in the European Union' in: Cafaggi, F., *The Institutional Framework of European Private Law* (Oxford University Press: Oxford 2006), p. 149 ff.

manoeuvre opened in Article 6(1) is consequently curtailed *inter alia* by the guidelines provided in Article 6(2).

Second, the Directive gives different signals, and consequently the attitude of the Court as to the autonomy of Member States and national judiciary may differ, depending on whether it is a question of fundamental human rights, or of other aspects of public morality and public policy. It appears that the Directive is consistent with the settled case law of the ECJ and with Article 6(2) TEU in that it accords fundamental human rights a special status. This is evident among others from Recital 43. In the *Netherlands* ruling the ECJ restated its view of fundamental human rights as falling within its sphere of competences and once again emphasised its own role as the guarantor of these rights' sufficient integration in Community law. In respect in particular to the right to human dignity and integrity, the Court held:

> It is for the Court of Justice in its review of the compatibility of acts of the institutions with the general principles of Community law, to ensure that the fundamental right to human dignity and integrity is observed.[183]

In this judgement the Court further elaborates on the different ways in which the Directive, as an act of Community law, ensures respect for human dignity, referring to Article 5(1), Recitals 20, 21, Article 5(3), Article 6(1) and Recital 38. The reference to the open nature of Article 6(1), however, comes to underscore that the Directive does not provide the final say on this point. An answer will rather be sought in dialogue with national courts.

A more nuanced view is expressed in respect to other aspects of the morality exception. The Directive itself recognises the need to keep some of the categories open and to give Member States sufficient leeway to adapt these categories to their constitutional laws and dominant perception of morality. According to Recital 38 the list of inventions excluded from patentability is only "illustrative" and cannot presume to be exhaustive. The function of the list is seen as a general guide to interpreting the reference to *ordre public* and morality.

Furthermore, Recital 39 employs an open *renvoi* to the ethical and moral principles in the Community Member States:

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[183] Case C-377/98 *Netherlands v. European Parliament and Council* [2001] ECR I-07079, paras. 69-81 (right to human dignity and integrity).

> … *ordre public* and morality correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter.

In conclusion, it is submitted that the ECJ would make a serious attempt to distil a Community wide interpretation of the specific clarifications and exceptions in Article 5 and 6 of the Directive, using a logical and systematic interpretation of the two articles and the related recitals. Likewise, there is likely to be a search for common ground in finding a Community concept of human dignity in patenting (human rights) relying on the institutional reinforcement by the EGE. However, where Community law offers no conclusive answer due to conscious option not to harmonise (for instance the concept of human embryo), open *renvoi* to national legal orders, or vagueness of the Directive's provisions, and where differences persist as a result of genuine cultural, ethical and religious diversity or different historical context (ex. *Laserdrome*), national differences would be upheld and there would be preserved broad margin of appreciation. Again in the case of human dignity the differences would most likely be methodologically treated by the Court as national variations within a common Community framework of fundamental rights.

Chapter Four: European Moral Norms on the Human Embryo and Article of the Directive

Introduction

This Chapter analyses the range of sources on European morality from which the appropriate moral norms relevant to the interpretation of the moral exclusion clause in Article 6 are to be found. As has been shown in previous Chapters, a diversity of views has emerged on the relevant moral norms to be applied under Article 6. In order to determine which, if any, of the applied norms is correct, it is necessary in the first instance to determine how the relevant moral standards are to be identified in the Directive. In this Chapter, it is suggested that the Directive itself points to the range of sources of applicable principles, most notably the moral norms reflected in the ECHR, which carries special weight as indicative of European wide moral norms on embryo protection to which Member States have agreed and which further defines the Member States rights and obligations on moral questions cognate to the Directive. The Chapter concludes with an analysis of the relevance of the Council of Europe's Convention on Human Rights and Biomedicine (1997) as an additional source.

4.1 Moral Norms in the Directive & National & Supra National Laws

Recital 14 of Directive makes an important point:

> "Whereas a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes; whereas, consequently, substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results ..."[184]

The same provision also thus indicates that the Directive does not put in place moral norms that supersede the existing national or supranational norms.

[184] Recital 14, emphasis added.

Recital 39 reinforces the need for there to be a correspondence or link between the concepts of '*ordre public*' and 'morality' in the Directive and the particular ethical or moral principles 'recognised' in a Member State:

> "Whereas *ordre public* and morality correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter."

The term '*recognised*' is significant because it limits the range of sources from which moral norms are to be identified to those sources which are acknowledged as such in Member States, *e.g.* national constitutions, laws or regulations, administrative rules or professional Codes of Practice reflecting the relevant moral norms. Excluded or irrelevant sources may, for instance, include particular ethical or religious treatises, studies or surveys which have not been incorporated into public policy, and which reflect sectional interests or the views of particular groups in society rather than nationally accepted norms.

In addition, Recital 39 also indicates that the moral standards identified from these recognised sources are to *correspond* to ethical moral principles recognised in a Member State, as well as supplement the standard legal examinations under patent law. Thus, the wording of Recital 39 suggests that patent offices were not intended to become separate moral censors under the Directive, but to draw the applicable moral principles and norms from the moral principles recognised and reflected in the national laws, regulations and constitutional traditions of Member States and to supplement their examinations accordingly.[185] This has been further emphasised by the ECJ giving Member States a wide margin of discretion in applying the exclusion from patentability of inventions whose commercial exploitation would be contrary to *ordre public* and morality under Article 6(1) of the Directive.[186]

On the other hand, the scope and normative content of one or more determinate national/territorial prohibitions on biotechnological inventions cannot conclusively determine the scope and normative content of extra-territorial, European wide prohibitions, since the

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[185] This suggests that it is at least doubtful whether national patent offices or the EPO may refuse a patent on the basis of a general moral norm under Article 6(1), when the moral norm in question is not recognised as immoral in a Member State, even less so when the Member State in question specifically authorises and recognises as lawful practices which are contrary to the enunciated moral norm. The logical consequence, in the view of some academic commentators , is that there can be no legal basis the EPO to refuse an application on moral grounds as long as there is at least one European Member State which has adopted laws authorizing the relevant uses of human embryos. See Straus, J. 'Patenting Human Genes in Europe - Past Developments and Prospects for the Future', [1995]*IIC* p. 920

[186] Case C-456/03 *Commission v. Italy* [2005] ECR 1-5335, at para. 78.

patent application cannot be refused "merely because it (the exploitation of the invention) is prohibited by law or regulation."[187]

More specifically, the fact that one or several Member States may have adopted morally restrictive national laws on the use of human embryos in biotechnological applications is not sufficient to support the finding of a European wide norm that the uses in question, and consequently their patenting, is generally immoral. The Directive thus envisages exclusionary moral norms invoked under Article 6 to 'correspond' to or reflect national laws, whilst at the same time implying that a European wide moral exclusion norm cannot automatically be deduced from the existence of one or several national exclusionary norms.

This raises the question of how the applicable European moral norms on the protection of the human embryo are to be identified.

The starting point for the identification and application of the relevant European exclusionary moral norms on human embryos/hESC, are the overarching, fundamental moral and legal principles identified in the Directive. Recital 16 of the Preamble stipulates that:

> "Patent law shall be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the human person"

Furthermore, Recital 43 of the Directive also indicates that the fundamental principles of human *dignity*[188] *and integrity* have to be interpreted in accordance with the legal rights and obligations of Member States arising from international treaties, most notably the ECHR:

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[187] Article 6(1). Also Preamble, article 36, reiterates the principle agreed in TRIPs: "Whereas the TRIPs Agreement provides for the possibility that members of the World Trade Organisation may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law;" (Article 27.2 TRIPS). Article 53(a) of the EPC states that "inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States".

188 There is a growing body of critical literature on the concept of 'human dignity' in biomedicine. For a defence of th principle see: President's Council on Bioethics. Human cloning and human dignity. Washington, DC: President's Council on Bioethics, 2002 available at: http:// bioethics.gov/reports/cloningreport/index.html , and Kass L. R., Life, liberty and the defense of dignity (Encounter Books: San Francisco, CA, 2002). For a critique see: Brownsword R., 'Bioethics today, bioethics tomorrow: stem cell research and the ''dignitarian alliance'. Notre Dame Journal of Law, Ethics and Public Policy 2003;17, at 15–51, Macklin R, 'Dignity is a useless concept', BMJ 2003;327, at pp. 1419–20 and Caulfield, T., 'Human cloning laws, human dignity and the poverty of the policy making dialogue', BMC Medical Ethics 2003, 4:3.. Ashworth provides an illuminating review of the literature in Aswhorth, A., 'Making Sense of Dignity,', J. Med. Ethics 2005;31, at pp. 679-682.

> "Whereas pursuant to Article F(2) of the Treaty on European Union, the Union is to respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law;"

As the interpretation of the moral norms invoked in the Directive is presupposed to be compliant with the rights and obligations of Member States guaranteed by the ECHR, the answer to the question of which uses of human embryos are contrary to morality under the Directive has to be such that the applicable moral norm(s) comply with the fundamental values and moral norms reflected in European human rights law.

More specifically, in the light of the TBA's interpretation of the morality exclusion clauses in the *WARF* referral[189] and the prior interpretation adopted in the *Edinburgh* case[190], the first question which arises is whether it is possible to find in the ECHR and its interpretation by the ECrtHR, authority for the claim that there is a European wide moral norm reflected in the Convention and the jurisprudence of the ECrtHR, to the effect that "embryo destruction" is immoral, irrespective of the stage of development of the embryo and the circumstances or reasons for the destruction.

4.2 The ECHR & the Rights of the Embryo in Europe

A review of the jurisprudence of the European Court of Human Rights (ECrtHR) on the rights and level of protection accorded to the human embryo under the Convention, conclusively establishes that the existence of a diversity of traditions and moral cultures amongst Member States precludes the imposition of a uniform moral standard, whereby any procedure or use of a human embryo, irrespective of its purpose or stage of development of the embryo, is immoral if it necessitates the destruction of the human embryo.

Reflecting the intention of the drafters Member States on the scope of application of Article 2 ECHR, guaranteeing the right to life, the ECrtHR has consistently held that the question of

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[189] T 1374/04 (*Wisconsin Alumni Research Foundation, WARF*), referral by the Technical Board of Appeal to the Enlarged Board of Appeal, case pending under Ref. No. G 2/06, see O.J.E.P.O. 2006, p. 393.
[190] Decision of the OD of 21st July 2003 on European patent No. EP0695351 (*University of Edinburgh*).

whether the human embryo has a right to life, comes with the 'margin of appreciation' of Member States.[191] Article 2 of the ECHR states:

> "1. Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law.
> 2. Deprivation of life shall not be regarded as inflicted in contravention of this Article when it results from the use of force which is no more than absolutely necessary: (a) in defence of any person from unlawful violence; (b) in order to effect a lawful arrest or to prevent the escape of a person lawfully detained; (c) in action lawfully taken for the purpose of quelling a riot or insurrection.".[192]

The question of whether the human embryo *in vitro* has a right to life under Article 2 of the Convention, has recently been considered specifically by the ECrtHR in the case of *Evans v. UK*.[193] Mrs Evans had embryos frozen for future IVF treatment after being diagnosed with serious pre-cancerous tumours in the ovaries. After the couple split-up, the partner refused her access to the frozen embryos for treatment. Under UK law, she could not proceed without his consent. She argued that, in denying her access to the frozen embryos, which were thereby destined to die, the UK was in violation of its obligations under Article 2 to protect the embryo's right to life. The Court rejected her submission. The Court reasoned that:[194]

> "… in the absence of any European consensus on the scientific and legal definition of the beginning of life, the issue of when the right to life begins comes within the margin of appreciation which the Court generally considers that States should enjoy in this sphere. Under English law … an embryo does not have independent rights or interests and cannot claim – or have claimed on its behalf – a right to life under Article 2.

The legal significance of *Evans v. UK* is that it extends the margin of appreciation consistently applied by the ECrtHR in relation to human embryos or foetuses *in utero*[195] to the human

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[191] Plomer, A., 'A Foetal Right to Life?: The case of *Vo v. France' Human Rights Law Review* 2005 5(2):311-338. More generally see Janis, M, Kay, R., and Bradley, A.W., *European Human Rights Law: Text and Materials,* 2nd edn, (OUP: Oxford 2000), Harris, D.J.., O'Boyle, M, and Warbrick, C., *Law of the European Convention on Human Rights,* (Butterworths: London 2005) and Mowbray, A *The Development of Positive Obligations Under the European Convention on Human Rights by the European Court of Human Rights* (Hart Publishing: Oxford, 2005).
[192] Emphasis added.
[193] Case 6339/05, March 2006.
[194] Para 46.
[195] 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.

embryo *in vitro.*[196] The unequivocal, unqualified and unanimous nature of the judgment makes the judgment legally unassailable. The judgment authoritatively establishes that there is no European wide consensus on the question of the level of protection to which the human embryo is morally and legally entitled in Europe.

The level of legal protection granted to the human embryo, including the circumstances under which it is considered morally permissible to conduct research on human embryos resulting in the destruction of the embryo, varies across Europe, as do the limiting criteria on the stage of development or purposes for which the research is permitted.[197] Currently, thirteen Member States in Europe allow for the procurement of hESC from supernumerary embryos by law under varying conditions[198] whilst four Member States prohibit (by law) the procurement of hESC from supernumerary embryos.[199] Two Member States prohibit the procurement of hESC from supernumerary embryos but allow by law the import and use of hESC under certain conditions.[200] Three Member States allow for the creation of human embryos for research purposes (by law) under strict conditions.[201]

Under the European Convention, there is therefore no legal basis to support the application of the broad, unqualified, moral norm on human embryos invoked by the OD in the *Edinburgh* case. The jurisprudence of the ECrtHR also establishes that where there is a divergence of moral cultures and traditions, the Court has consciously refrained from imposing a uniform norm. *A fortiori*, the legal effect of the Directive, which must be interpreted consistently with the ECHR,[202] cannot be to vest on the European authorities charged with the administration of patent applications, the legal authority to invoke and apply a uniform moral norm precluding the granting of patents on processes or materials derived from the human embryo in circumstances where there is no moral agreement or consensus on the specific moral norm in Europe. The jurisprudence of the ECJ, which is vested with the legal authority to interpret the Directive,

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[196] For a comparative analysis of the rights of the human embryo in Europe before the *Evans* ruling, see Mathieu, B., *The Right to Life in Europe* (Council of Europe 2006) and Plomer, A., *The Law and Ethics of Medical Research: International Bioethics & Human Rights,* (Cavendish: London 2005)

[197] See for instance, Commission Staff Working Paper Report on Human Embryonic Stem Cell Resaerch, Brussels, 3.4.2003 SEC(2003) 441. The data has been updated by Isasi, R. and Knoppers, B in Appendix I & II of tis Report. See Isasi R. and also Knoppers, B., 'Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 countries'; *European Journal of Health Law* 13(1) April 2006. For a comparative cultural analysis see Walters, LR., Human Embryonic Stem Cell Research: An Intercultural Perspective *Kennedy Institute of Ethics Journal* Vol. 14, No. 1, 3–38, 2004.

[198] Belgium, Denmark, Estonia, Finland, France, Greece, Hungary, the Netherlands, Spain, Slovenia, Switzerland, Sweden and the United Kingdom.

[199] Austria, Ireland , Italy, Norway, Poland.

[200] Germany and France.

[201] Belgium, Sweden and the UK.

[202] The ECJ has held that it has competence to interpret the ECHR and that in doing so it draws inspiration from the jurisprudence of the ECrtHR: "It is for the Court of Justice in its review of the compatibility of acts of the institutions with the general principles of Community law, to ensure that the right to human dignity and integrity is observed" (Case C-377/98 *Netherlands v European Parliament and Council* [2001] ECR I-07079).

further confirms that fundamental principles and rights form and integral part of the general principles observed by the Court, and that in this respect the EHCR "has special significance."[203]

The jurisprudence on the Convention thus suggests that, as regards general moral exclusions in the Directive on inventions involving the human embryo or processes applied to it, or products or materials derived therefrom, the identified applicable norms must show sensitivity to national moral cultures in acknowledgement of the diversity of moral views held across Europe. In the absence of clear and incontrovertible evidence of the existence of a European wide moral consensus on a particular norm, it is suggested that the moral norm in question cannot be validly relied upon or invoked to refuse an application under Article 6 of the Directive.

4.3 Additional European and International Agreements

The Convention on Human Rights and Biomedicine

Whilst there is no legal basis under the ECHR to support the view that European states share uniform moral values on the protection of the human embryo, the same cannot be said of the Convention on Human Rights and Biomedicine (*Bioethics Convention*), done at Oviedo, 1997, which contains specific prohibitions on the creation of human embryos for research purposes (Article 18). However, the legal weight to be ascribed to the *Bioethics Convention* in the interpretation of the Directive, is doubtful, notwithstanding the reliance put on the *Bioethics Convention* by those seeking to uphold a morally restrictive interpretation of Article 6 of the Directive.[204] The reasons are these.

In the first instance, it should be noted that there was no agreement amongst the Member States at the time of the adoption of the Directive that the applicable norms in the Directive should be derived from or interpreted consistently with the *Bioethics Convention*. When, on 25th June 1997, the first exclusion on human embryos appeared in the text of the Directive, the Legal

[203] Furthermore in the *Omega* case (C-36/02), [2004]ECR I-9609, at para. 33 the ECJ held that: "…fundamental rights form an integral part of the general principles of law the observance of which the Court ensures, and that, for that purpose, the Court draws inspiration from the constitutional traditions common to the Member States and from the guidelines supplied by international treaties for the protection of human rights on which the Member States have collaborated or to which they are signatories. The European Convention on Human Rights and Fundamental Freedoms has special significance in that respect." For an insightful analysis of the difficulties raised by the overlap in jurisdiction and competence of the ECJ and the ECHR see Smith, C. and Fetzer, T. 'The Uncertain Limits of the European Court of Justice's Authority: Economic Freedom versus Human Dignity', 10 *Colum. J. Eur. L.* (2004) p. 445. Also, Weiler, J., 'A Constitution for Europe? Some Hard Choices', *40 J. Common Mkt. Stud.* 563, 573 (2002) and 'A. Williams, A., 'The (Im)possibility of the European Union as a Global Human Rights Regime' in R. Brownsword: *Human Dignity and Human Rights (*Hart 2004).

[204] Resolution of the European Parliament on the Protection of Human Rights and Dignity with regard to the Application of Biology and Medicine Official Journal C 320, 28/10/1996 p. 268 and European Parliament Resolution on patents for biotechnological inventions 27-10-2005, P6_TA(2005)0407.

Affairs Committee proposed other Amendments, calling for the newly adopted *Bioethics Convention* to be respected.[205] However, the Amendments including references to the Convention were subsequently dropped in the Common Position and final text. The *Bioethics Convention* does not figure amongst the list of international Treaties recognised in the Directive. This in itself is indicative of the absence of an agreement amongst Member States at the time to grant *the Bioethics Convention* special weight in the interpretation of the moral exclusion clauses in the Directive.

Notwithstanding this, the *Bioethics Convention* has the potential to carry considerable weight in the interpretation of the fundamental rights protected through the Articles in the ECHR.[206] This is because the object of the *Bioethics Convention*, as indicated by its preamble, is to give a specific application in the field of biomedicine to the general rights contained in the ECHR. On this basis, *the Bioethics Convention* could have strong persuasive authority where it signifies widespread and formal endorsement amongst the parties on the interpretation of the main Treaty (*i.e.* the ECHR) on specific provisions in the field of biomedicine.[207]

However, *the Bioethics Convention* arguably currently lacks the required level of endorsement amongst Member States to establish the existence of a consensus on the level of protection of the human embryo in relation to research. It is well known that one of the areas of contention in *the Bioethics Convention* at the time of its adoption was Article 18 on the scope of protection of human embryos in research.[208] Whilst a substantial number of European States have ratified the Convention and thereby subscribe to Article 18(2) prohibiting the creation of human embryos for research purposes, ten years after its adoption, there is still only a minority of Member States which have ratified the *Bioethics Convention*.[209] Of the 44 four Members of the Council of Europe, only one third have signed and ratified the *Bioethics Convention.*. Another third have

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[205] Report on the proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions (COM (95)0661-C4-0063/96-95/0350(COD)) Committee on Legal Affairs and Citizens' Rights. 25 June 1997. A4-0222/97. Amendment 10 (Recital 12a). See also Amendment 33.

[206] The Explanatory Report to the *Bioethics Convention* (Strasbourg, 1997) expressly canvasses such a possibility in a note to Article 29. Article 29 of the *Bioethics Convention* states that: 'This Convention does not itself give individuals a right to bring proceedings before the European Court of Human Rights. However, facts which are an infringement of the rights contained in this Convention may be considered in proceedings under the European Convention of Human Rights, if they also constitute a violation of one of the rights contained in the latter Convention'(Explanatory Report, note 165). See Plomer, A., *The Law and Ethics of Medical Research: International Bioethics & Human Rights*, (Cavendish: London, 2005), Chapter one.

[207] Further to the general rules of international law on the interpretation of Treaties contained in Articles 31 to 33 of the Vienna Convention on the Law of Treaties of 23 may 1969.[207] Article 31(1) of the Vienna Convention directs the court to interpret a treaty in its context and in the light of its object and purpose. Article 31(3) specifies that there shall be taken into account, together with the context3(a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions; and 3(b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;

[208] ref.

[209] Austria, Bulgaria, Croatia, Czech Republic, Cyprus, Denmark, Estonia, Greece, Georgia, Hungary, Iceland, Lithuania, Moldova, San Marino, Romania, Slovakia, Slovenia, Spain and Turkey.

signed but not ratified. Significantly, this latter category includes several technologically advanced countries which signed the Convention at the time of its adoption in 1997 (*e.g.* France and Sweden[210]) but have not completed the process. The remaining States which have neither signed nor ratified the Convention also include some of the most technologically advanced countries in Europe, most notably Germany and the UK.

Uses of Embryos in Research

Even if the creation of human embryos for research purposes specified in Article 18 (2) is prohibited, the *Bioethics Convention* does not require prospective signatories to align their own national laws with Article 18 and to repel existing legislation allowing embryos to be created for research purposes. Instead, the Convention allows Member States with laws which are incompatible with Article 18 to retain these laws by entering a reservation under Article 36 'to the extent that any law then in force in its territory is not in conformity with the provision.' The only requirement is that 'any reservation made under this article shall contain a brief statement of the relevant law'.

Furthermore, the precise degree of protection of the human embryo in research required by Article 18(1) is left open:

> Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.

Para. 115 of the Explanatory Report merely reiterates that where national law allows research on embryos *in vitro* the law must ensure adequate protection of the embryo. No explanation is offered, neither is there any attempt to stipulate the kind of limits stipulated in other parts of the Convention in respect of persons who are already born, namely that the research should only be conducted for the benefit of the individual herself or if conducted for the benefit of others should be subjected to a minimal risk requirement (see articles 5, 17). Para. 116 expressly notes that the article does not take a stand on the admissibility of the principle of research on *in vitro* embryos but that paragraph 2 of the Article prohibits the creation of human embryos with the aim to carry out research on them. There is no allusion to prohibition of research which would

[210] In Sweden there is a recommendation to adhere to the Convention with a reservation to Article 18.

result in ending the life of the embryo under Article 18(1). Such research may therefore be permissible, particularly in circumstances in which signatories to the Convention are permitted to derogate from their obligations under Article 26 (1) and place restrictions on the exercise of the rights and protective provisions contained in the Convention as prescribed by law and if necessary in a democratic society, *inter* alia, for the protection of public health.

Finally, the differences between national cultures in Europe over the moral permissibility of research on human embryos *in vitro* which had emerged at the time of the adoption of the *Bioethics Convention*, far from narrowing with the passage of time have become more engrained since. The *Bioethics Convention* was originally to be followed by four Protocols, including a Protocol on the human embryo *in vitro*. Whilst the Council of Europe's Working Party on the human embryo was able to reach agreement very quickly on the moral impermissibility of human reproductive cloning, leading to the adoption of a Protocol on the Prohibition of Cloning Human Beings, in 1997, the Working Party was unable to reach a consensus on a range of issues relating to the protection of the human embryo *in vitro* and concluded that "there remains a great diversity of opinion that makes it difficult to identify a common approach." A report was issued on 19th July 2003 detailing the process of reflection which had led the Working Party to conclude that a consensus could not be reached on a Protocol on the human embryo *in vitro*.[211]

In this light, the interpretation of moral exclusions in the Directive relating to the morality of the use of human embryos calls for considerable sensitivity to national moral cultures in acknowledgement of the diversity of moral views held across Europe. The analysis of the European moral values on the protection of the human embryo in research reflected in the international and European human rights instruments indicates that there is no European wide consensus on the moral principle endorsed by the minority opinion in Opinion No. 16 of the EGE and its subsequent application by the OD of the EPO in the *Edinburgh* case to the effect all uses of human embryos which necessarily involve its "destruction", are contrary to morality and more generally on the limiting circumstances under which research on human embryo may be permissible.

However, it is of important to note that the *Bioethics Convention*, together with supplementary evidence, reflects the existence of a European wide moral consensus on other aspects of the uses

[211] Council of Europe, Working Party on the protection of the human embryo and foetus CDBI-CO-GT3 (2003) 13 http://www.coe.int/t/e/legal_affairs/legal_co-operation/bioethics/activities/human_embryo_and_foetus/CDBI-CO-GT3(2003)13E.pdf.

of human embryos, most notably the prohibition on commercialisation and reproductive cloning.

Commercialisation

Article 21 of the *Bioethics Convention* stipulates that the "human body and its parts shall not, as such, give rise to financial gain". The principle of non-commercialisation of the human body, by extension also arguably may entail non-commercialisation of the human embryo, for the reasons given by the EGE in Opinion No. 15 of 14th November 2000:

> The potential for coercive pressure should not be underestimated when there are financial incentives. *Embryos a*s well as cadaveric foetal tissue *must not be bought or sold not even offered for sale*. Measures should be taken to prevent such commercialisation.

The argument presupposes that, in so far as commercial practice is concerned, the human embryo is morally comparable to the human body. Hence, the moral consensus that human bodies may not be bought or sold and do not have a market price or monetary value, extends to human embryos.

As far as the human body is concerned, the view of the EGE in Opinion No. 8 ("Ethical aspects of patenting inventions involving elements of human origin") of 25th September 1996 was that the exclusion on patentability of the human body did not come only from the usual conditions of patentability, but

> "… it is also inspired by the ethical principle of non-commercialisation of the human body. Therefore no patent can be given on the human body or on its elements. Also it follows that no remuneration to the person from whom the samples are retrieved, or to his/her eligible party, can be allocated."[212]

[212] At para. 2.3. The traditional distinction between discovery (not patentable) and invention (patentable) involves, in the field of biotechnology, a particular ethical dimension. It follows from this distinction that the knowledge related to the human body or its elements is relevant to scientific discovery and cannot be patented. It has to be clearly specified that the simple knowledge of the complete or partial structure of a gene cannot be patented". The same principle of non-commercialisation of the human body also plays a prominent role in the earlier EGE Opinion 2 (12/03/1993) "Products derived from human blood or human plasma", where it was stated that "no one should have additional profits from blood donations that contradict the principle of non-marketability of human body. Article 3.1. of the EGE's Opinion 2 states that: "Apart from the obvious payments that are acceptable for administrative purposes and industrial developments, no one should have additional profits from blood donations that contradict the principle of non-marketability of human body."

From this it logically follows that the moral prohibition on commercialisation of the human body, and by extension, the human embryo, precludes patents on the human body itself, and by extension on the human embryo itself.

Opinion No. 8 was specifically relied upon in the Rothley Report to the European Parliament and is also mentioned the Recitals in the final text of the Directive. As such, it provides an important point of reference in determining the scope of moral exclusions involving the human embryo in the Directive (see infra).

Human Cloning (Protocol)

Similarly, there is clear evidence of a consensus in Europe on the moral impermissibility of human reproductive cloning. As mentioned earlier, the Council of Europe's Working Party on the protection of the human embryo was able to reach very quickly an agreement on a Protocol on the Prohibition of Cloning Human Beings (1998). Article 1 of the Protocol provides that:

1. Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.
2. For the purpose of this article, the term human being "genetically identical" to another human being means a human being sharing with another the same nuclear gene set.

The natural reading of Article 1 suggests that the prohibition relates to reproductive cloning and does not include so called 'therapeutic cloning'. The distinction has important implications for the attending limitations on embryo research. As the EGE explained in its Opinion No. 15, cloning technology could be used to produce human embryos which are genetically identical to another and if transferred into a woman's uterus, could therefore develop into a human being identical to another. Alternatively, a 'cloned' embryo could be produced by "embryo splitting or nuclear transfer. In the latter case they would be derived by introducing the nucleus of an adult somatic cell into an enucleated human oocyte (sometimes misleadingly termed "embryo cloning" or "therapeutic cloning"). There is no doubt that Article 1 of the Protocol prohibits human reproductive cloning. But does the prohibition really extend to 'therapeutic cloning'?

'Human Being'

The ambiguity lies in the scope of application of the term ‘human being’. In its natural meaning, the term normally refers to individuals who are already born. On this basis, Article 1 would proscribe the creation of human clones, i.e. persons who are genetically identical to others. The context in which the Protocol was adopted, namely the publication of the successful cloning of Dolly the sheep, and the concerns expressed in the Recitals to the Protocol are consistent with this interpretation. The Recitals state, that the considerations leading to the prohibition on cloning are “that the cloning of human beings may become a technical possibility;” and “Considering however that the instrumentalisation of human beings through the deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes a misuse of biology and medicine;”.

For Article 1 to be stretched beyond its natural meaning, the expression ‘human being’ would have to be construed as including ‘human embryo’ and the Protocol as a whole would have to be read as intending to prohibit not only human reproductive cloning but ‘therapeutic cloning’ too. There are additional indications in the Preparatory Works to resist this expansive reading. Whilst noting that the Protocol is to be read as an addition to the *Bioethics Convention*, and the restrictions in Article 18, the Preparatory Works also note that,

> “This Protocol does not take a specific stand on the admissibility of cloning cells and tissue for research purposes resulting in medical applications. However, it can be said that cloning as a biomedical technique is an important tool for the development of medicine, especially for the development of new therapies. The provisions in this Protocol shall not be understood as prohibiting cloning techniques in cell biology.” (para. 4)

Furthermore, as regards the scope of application of the expression “human being”

> “In conformity with the approach followed in the preparation of the Convention on Human Rights and Biomedicine, it was decided to leave it to domestic law to define the scope of the expression "human being" for the purposes of the application of the present Protocol.” (para. 6).

Finally, whilst the wording of the Cloning Protocol could theoretically be read as being consistent with the most restrictive national laws precluding all forms of human embryonic cloning, irrespective of their purpose, it should also be noted that the drafters of the Protocol did not claim that there was a consensus on such a restrictive reading. Quite the contrary, para. 2 of

the Preparatory Works distinguishes between three types of cloning "cloning of cells as a technique, use of embryonic cells in cloning techniques, and cloning of human beings, for example by utilising the techniques of embryo splitting or nuclear transfer" and then goes on to note that whereas the first situation is fully acceptable ethically, *the second should be examined in the protocol on embryo protection.* The consequences of the third situation, that is the prohibition of cloning human beings, are within the scope of this Protocol. However, as was noted earlier, the Working Party on the protection of embryo protection was unable to reach agreement on a text. Together, all these considerations strongly suggest that the Protocol on Cloning does not preclude human embryonic cloning and the derivation of hESC for biomedical research purposes.

4.4 Implications for the Construction of the Moral Exclusions

As a conclusion from the analyses of the European moral norms on the human embryo, there is an obvious need for considerable caution and a carefully qualified approach on the identification of European wide moral values which may be applicable under Article 6(1) on the morally sensitive questions relating to the circumstances under which the commercial exploitation of inventions involving the human embryo may be classified as immoral under the Directive. All the evidence from the cognate European human rights instruments points to some limited areas of consensus on an otherwise diverse moral spectrum.

Article 6(1)

The application of the morality test to biotechnological inventions in Article 6 of the Directive requires the application of two distinct tests. On the one hand, Article 6(1) states a *general* morality test. On the other, Article 6(2) lists a series of *specific* applications which are to be excluded on morality grounds. The ECJ has held that the interpretation of the general moral exclusion clause in Article 6(1) calls for different considerations from the interpretation of the specific exclusions listed in Article 6(2)(c).[213]

Regarding the interpretation of the general morality exclusion in Article 6(1), the ECJ has held that Member States and national courts are to be granted a wide margin of discretion and scope

[213] Case C-377/98 *Netherlands v European Parliament and Council* [2001] ECR I-07079.

of manoeuvre in the implementation and interpretation of the provision.[214] The ECJ considered this is necessary in order to:

> "…take account of the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State"[215]

The considerations which have led the ECJ to give Member States flexibility in the construction of the general moral exclusion clause echo precisely the considerations which have led the ECrtHR to adopt the same interpretative technique in relation to the application of provisions on which there is a need to acknowledge the diversity of national traditions and moral cultures. It is suggested that the analysis and identification of the areas of moral consensus and diversity on the human embryo reflected in the European human rights instruments should inform the delineation of specific rules and prohibitions invoked under Article 6(1).

In general, it follows from what has been said that, whilst some Member States may justifiably rely on Article 6(1) to refuse a patent application for certain processes or cells derived from human embryos, it may be equally be permissible for other Member States with different national cultures to grant the same application. Whilst the validity of each of these diverse national interpretations would ultimately be legally reviewable by the ECJ, it is clear that the ECJ will refrain from imposing a uniform moral standard where there is instead a diversity of national moral cultures.

Article 6(2)

The position under Article 6(1) is altogether different to the construction of the specific lists of exclusions listed under Article 6(2). In this regard the ECJ emphasis that,

> "Article 6(2) allows the Member States no discretion with regard to the unpatentability of the processes and uses which it sets out, since the very purpose of this provision is to give definition to the exclusion laid down in Article 6(1) … It is apparent from the 40th recital in the preamble to the Directive that processes for cloning human beings must be excluded 'unequivocally' from patentability, since there is a consensus on this question within the Community. It follows that, by expressly excluding from patentability the

[214] At para 37.
[215] At para. 38

> processes and uses to which it refers, Article 6(2) of the Directive seeks to grant specific rights in this regard".[216]

The next Chapter analyses the scope of exclusion of Article 6(2) and other provision in the Directive, in the light of the findings in this Chapter.

[216] C-456/03 *Commissions v. Italy*, at paras. 78-79.

Chapter Five:
Scope of Moral Exclusions on hESC in the Directive

Introduction

In this Chapter, a comprehensive analysis of the legal restrictions in the Directive on the commercial exploitation or unpatentability of hESC is conducted in the light of the preceding analysis of the areas of moral consensus in Europe on the protection of the human embryo. The starting point is whether the human embryo itself and totipotent hESC are excluded from patentability under Article (5).

5.1 Article 5

Article 5 of the Directive states that:

> 1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
>
> 2. 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.

The natural reading of Article 5(1) is that *patenting of human embryos* is precluded, since a human embryo constitutes one of the *stages in the formation and development* of the human body. Analysis of the Preparatory Works discloses that this was indeed the intention of the legislators. The final wording of Article 5(1) resulted from concerns voiced by the Economic & Social Committee on 11th July 1996 that: "the human embryo, which is a special case, should be excluded from patentability". The previous wording of the Article, which referred to the human

body 'in its natural state' was said by the Committee not to offer this guarantee "since the notion of the human body can be interpreted as not including the embryo."[217]

'Human Embryo 'in vitro'

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 the Preparatory Works suggest that the intention was to include the latter, since the final wording removed the earlier express qualification that the exclusion applied to the human body *in its natural* state.[218] Further support for this reading may be found in the debates in Parliament, where MEPs supporting embryo research stressed that there was never any disagreement with their opponents on the question of patenting the human embryo: "there was never any question of patenting the embryo."[219]

It should be noted that the 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. Hence, the exclusion would extend not only to human embryos who 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.

Totitpotent Cells: Article 5(1)

Totipotent hESC are elements isolated from a human embryo by means of a technical process. Therefore, the question of whether *totipotent hESC* are necessarily excluded by Article 5 is perhaps less clear cut, as in order for totipotent cells to be used for the derivation of therapeutic tissues or products, the cells have to be extracted from a human embryo at the blastocyst stage. As noted by Webber, once extracted, totipotent hESC cannot strictly be said to be a "stage" of development of the human body, and if so, should *prima facie* be patentable under Article 5(2).[220]

Thus, for the scope of 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,

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[217] Opinion of the Economic and Social Committee on the 'Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions'. OJ, C 295 of 7.10.1996, p. 11. (Opinion adopted on 11th July 1996).
[218] At the time Article 3 of the Directive.
[219] Debates of the European Parliament, Cot (PSE) (FR), Sitting of Tuesday, 15 July 1997.
[220] Webber, P.M, 'Patentability of Human Embryonic Cells under the EPC', *Bioscience Law Review* (28 June 2005).

and the totipotent cells themselves, fall under the description 'human body'. This would arguably not necessarily be the case if the words were given their natural meaning.

The UK Patent Office's policy, adopted in April 2003 may be read as an attempt to reconcile the tensions in the text.[221] The policy of excluding patents on totipotent hESC is said to be justified because a totipotent hESC has "the potential to develop into an entire human body", and "in view of this potential, such cells are not patentable because the human body at the various stages of its formation and development is excluded from patentability."[222] Hence, the view of the UK Patent Office is that totipotent hESC are excluded from patentability under Article 5(1).

Similarly, the Second Report from the Commission to the Council and the European Parliament on Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering[223] suggests that 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. The basis of the exclusion thus has to lie on the cell's "potential", since totipotent hESC cannot legally be used under international (or under many national laws) to produce human 'bodies' or human beings.[224]

The exclusion of totipotent cells also reflects most accurately the focus of the moral debates on the adoption of the Directive which, as argued in Chapter four, focused on the moral impermissibility of human reproductive cloning, that is the cloning of human beings. Since totipotent cells have the potential to develop into a human being if implanted, and the intention of the Community legislators was to proscribe the grant of related 'product' and 'process' patents on reproductive cloning, totipotent cells are excluded from patentability under Article 5(1) as subject matter of a patent.

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[221] http://www.patent.gov.uk/patent/notices/practice/stemcells.htm
[222] http://www.patent.gov.uk/patent/notices/practice/stemcells.htm
[223] COM(2005) 312 final Report from the Commission to the European Parliament and the Council; Development and implications of patent law in the field of biotechnology and genetic engineering, Brussels 14.7.2005 (SEC(2005) 943).
"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 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 EGE considered (in its opinion No. 16) 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 2003."
[224] *Cf.* Chapter four.

Pluripotent Cells: Article 5(2)

It is an important finding that the above considerations do not extend to pluripotent hESCs, which lack the potential to develop into a human being and, *qua* elements isolated from the human body by means of technical process, fulfil the patentability requirements under Article 5(2). If such cells were to be excluded from patentability on the grounds that the derivation of pluripotent hESC cells necessarily involves an immoral use of the human embryo (*i.e.* it's destruction), the exclusion would have to be based on the general morality provision in Article 6(1).[225]

The moral considerations would have to be weighed against and displace the unequivocal indications in the Directive that elements isolated from the human body, which fulfil the technical criteria of novelty, inventive step and industrial application, are patentable. In particular, Recital 20 clearly indicates that inventions based on elements isolated from the human body by means of a technical process, are patentable:

> "Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment;"

Furthermore, Recital 21 clearly indicates that the elements themselves are patentable, providing their isolation is the result of a technical process:

> "Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself;"

Finally, Recital 17 states that the patent system should be used to encourage research on obtaining and isolating elements which may be valuable for medicinal purposes:

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[225] *Cf. infra.*

> "Whereas significant progress in the treatment of diseases has already been made thanks to the existence of medicinal products derived from elements isolated from the human body and/or otherwise produced, such medicinal products resulting from technical processes aimed at obtaining elements similar in structure to those existing naturally in the human body and whereas, consequently, research aimed at obtaining and isolating such elements valuable to medicinal production should be encouraged by means of the patent system;"

It follows from these Recitals together with Article 5(2) that pluripotent hESC and the associated processes to derive or isolating the cells are *prima facie* patentable providing the invention fulfils the technical criteria of novelty, inventive step and industrial application. Hence, pluripotent hESC and processes to derive them could only be excluded from patentability if patenting would be contrary to *ordre public* or morality under Article 6(1). This is further discussed below.

5.2 Article 6

Cloning of Human Beings: Article 6(2)(a)

The related exclusion for processes involving the use of totipotent cells or human embryos is listed under Article 6(2)(a), which prohibits the granting of patents on "processes to clone human beings" and which is further affirmed in the Recitals, most notably, Recitals 40 and 41. It is apparent from Recital 40 in the preamble to the Directive that "processes for cloning human beings" must be excluded 'unequivocally' from patentability since, the Recital states, there is a consensus on this question within the Community.[226] In the *Italy* case,[227] the ECJ has further adverted to moral consensus too as the basis for the exclusion. It follows that the consensus on the moral prohibition on human cloning has to define the limits of the scope of the specific exclusion listed under Article 6(2)(a) since the rationale for the inclusion of the particular item in Article 6(2)(a) is the existence of a moral consensus on the unpatentability of the invention listed under the specific exclusion.

The scope of the moral consensus is partly indicated by Recital 41, which further defines processes for cloning human beings as follows:

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[226] Case C-456/03 *Commission v Italy* [2005] ECR 1-5335, at para. 78.
[227] Case C-456/03 *Commission v Italy* [2005] ECR 1-5335.

> Whereas a process for cloning human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as a another living or deceased human being...

The natural reading of the wording "*to create a human being with the same nuclear genetic information as a another living or deceased…*" suggests that the exclusion is confined to processes for human reproductive cloning, which in turn, reflects the prevailing European moral consensus, as reflected in the obligations to which Member States had agreed in European and international instruments, discussed in Chapter four.

An alternative, broader construction which would also preclude so-called 'therapeutic' cloning would have to treat as equivalent the terms 'human embryo' and 'human being'. But as was shown in the previous Chapter, there is no moral consensus in Europe on this sensitive matter, and the interpretation of the exclusion has to reflect the prevailing European moral consensus.

According to the ECJ, this in turns limits the margin of discretion granted to Member States in the implementation and interpretation of the specific exclusion. Unlike Article 6(1) of the Directive, which allows the administrative authorities and courts of the Member States a wide discretion in applying the exclusion from patentability of inventions whose commercial exploitation would be contrary to *ordre public* and morality, Article 6(2) allows the Member States no discretion with regard to the unpatentability of the processes and uses which it sets out, since the very purpose of this provision is to give definition to the exclusion laid down in Article 6(1) (see, to this effect, *Netherlands* v *Parliament and Council*, paragraphs 37 to 39). In the *Italy* case, the ECJ ruled that Italy was in breach of its obligations under the Treaty in failing to take measures to implement the Directive because it had, *inter alia*, failed to expressly transpose into national law the specific list of exemptions listed under Article 6(2).[228]

Uses of Embryos for Industrial or Commercial Purposes: Article 6(2)(c)

According to the ECJ, the same methodology has to be applied for construing the scope of exclusion of the other illustrations in the list in Article 6(2), "since the very purpose of this provision is to give definition to the exclusion laid down in Article 6(1)."[229] Article 6(2)(c) proscribes:

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[228] Case C-456/03 *Commission v Italy* [2005] ECR 1-5335, at paras.79–82.
[229] Case C-456/03 *Commission v Italy* [2005] ECR 1-5335, at para. 78.

(c) uses of human embryos for industrial or commercial purposes;

Since the same interpretive approach applies to Article 6(2)(c), the uses of human embryos listed under this provision have also to be expressly transposed into the national laws of Member States and excluded unequivocally.

However, as the previous Chapters have shown, even when the provision has been specifically transposed into national law, diverging approaches have been adopted by national patent offices and the European Patent Office on the scope of exclusion of this Article.

In the *Edinburgh* case,[230] the EPO defined the scope of exclusion of Article 6(2)(c) through the application of a moral exclusion norm which, we argued earlier, is questionable in the light of the prevailing moral consensus in Europe. By contrast, the policy or practice of national patent offices has been to interpret the scope of exclusion in terms of whether the subject matter of the invention, *e.g.* pluripotent cells, fell within the definition of the exclusion. According to the UK Patent Office, Article 6(2)(c) excludes processes for obtaining hESC from embryos.[231] The Swedish Patent Office instead interprets the exclusion as referring to 'repetitive' use of the embryo.[232] Thus the question arises of how differences on the construction of the scope of exclusion of Article 6(2)(c) and ambiguities on the meaning of some of the terms in the exclusion, are to be settled. The following analysis suggests that whilst it is possible to give the terms 'industrial' and 'commercial' purposes a uniform meaning, the same is not the case with the term 'human embryo'.

There is an important distinction between these two different types of approaches taken by the EPO and the national patent offices. The approach taken by the OD in the *Edinburgh* case requires that the scope of the listed exclusion be determined by reference to a moral norm (*e.g.* "embryo destruction"). The approach by the national patent offices instead, requires a consideration of whether the uses of the embryo in the particular invention amount to uses for 'industrial' or 'commercial' purposes. If the ECJ ruling on Article 6(2) of the Directive is to be understood as implying that the criteria to be applied for determining the scope of application of 6(2)(c) are not primarily 'moral' criteria, since the specific exclusions were inserted as

[230] Decision of the OD of 21st July 2003 on European patent No. EP0695351 (*University of Edinburgh*).
[231] UK Patent Office, Practice Notice "Inventions involving human embryonic stem cells", April 2003 at: http://www.patent.gov.uk/patent/notices/practice/stemcells.htm
[232] Personal communication with a representative of the Swedish Patent Office, February 10 2006.

illustrative examples because there was a moral consensus, it follows that the applicable criteria in 6(2)(c) are primarily definitional or "technical" criteria.

'Industrial' & 'Commercial'

In line with the reasoning of the ECJ in the *Italy* case,[233] the construction of Article 6(2)(c) should proceed on the basis that whilst the justification for the specific exclusion of 'industrial' or 'commercial' uses of the human embryo undoubtedly has a moral or ethical basis, the scope of the exemption itself is to be determined by reference to whether the excluded subject-matter of the invention falls under the terms of the description in the list. This in turn, requires an examination of the meaning or definition of the qualifying terms.

An initial possibility is to read the expression 'industrial and commercial purposes' as equivalent to the requirement that the claimed invention should have an 'industrial application'[234] It could be argued that the terms 'industrial and commercial purposes" cannot have a different meaning from "industrial application." Since a patent can only be granted on an invention if the invention has an "industrial application" it would seem to follow from this reading that the terms "industrial and commercial purposes" in 6(2)(c) are superfluous. There are several reasons to resist this conclusion.

In the first instance, the Preparatory Works indicate that the intention of the legislator in inserting the qualification "industrial and commercial" was to confine the excluded uses to certain uses only. The original wording of the exclusion on uses of human embryos proposed by the Legal Affairs Committee, favoured a broader definition which excluded "Methods in which human embryos are used.[235] The wording was altered in the Common Position expressly to exclude only certain uses of human embryos, namely 'industrial and commercial uses'. The meaning of the terms was not therefore considered to be superfluous by the legislators but was intended instead to narrow down the range of excluded uses of human embryos to reflect the moral consensus on human embryos amongst Member States.

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[233] Case C-456/03 *Commission v Italy* [2005] ECR 1-5335.
[234] Article 3 of the Directive and Article 57 EPC.
[235] The specific exclusion was introduced by the Legal Affairs Committee on 25th June 1997, in amendment 55 (of Article 9); Committee on Legal Affairs and Citizens' Rights, 25 June 1997, A4-0222/97. *Report on the Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions/COM/95/0661* PRELEX Document EP //218021/ LEGISLATIVE OBSERVA: 18 june 1997 EP PE 218.021/DEF.

Furthermore, the expression "industrial and commercial purposes" occurs in another part of the Directive in which the meaning of the expression cannot be equivalent to 'industrial application'. Recital 14 states that:

> Whereas a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes;

Thus, where a patent has been granted, the inventor is entitled to prevent others from exploiting the invention for industrial or commercial purposes. Since the granting of the patent necessarily requires that the claimed invention should have an industrial application it follows that where an invention fulfils this technical requirement only the patentee or those authorised by him are entitled to exploiting the invention for industrial and commercial purposes. Thus the expression 'industrial and commercial purposes' has a distinct meaning from 'industrial application', since the latter is a technical criterion for patentability which when satisfied, entitles the patentee to exploit the invention for certain defined purposes (industrial and commercial) and also prevent others from doing the same. The expression 'industrial and commercial purposes' thus defines the type of exploitation which is protected by the patent right.

The term '*commercial*' ordinarily refers to market transactions in which products are traded for money or profit.[236] Whereas the term '*industrial*' in patent law, has historically been used to refer to processes which involve repetitive mechanical, chemical or technical processing of raw materials.[237]

In this light, it is suggested that the terms 'industrial and commercial purposes' in Article 6(2)(c) should thus be read as precluding the granting of a patent on inventions which as such involve either the direct, repetitive use of a human embryo as a raw material in a mechanical, chemical or technical process and/or any uses involving a trade in human embryos *per se*.

A logical consequence of this approach is that the scope of exclusion of the listed invention is primarily defined by the terms 'industrial' or 'commercial' uses. Thus, inventions involving the use of human embryos which fall outside these qualifications cannot be excluded under 6(2)(c), although they may still be conceivably excluded under the general moral exclusion in Article

[236] See Chapter four.

[237] Moufang has argued that the interpretation of the term has its origin in German and UK patent law,'Methods of Medical Treatment Under Patent Law', [1993]*IIC* pp. 18 ff., at 22. See also Bostyn, S., 'No Cure without Pay? Referreal ro the Enlarged Board of Appeal Concerning the Patentability of Diagnostic Methods', [2005]*EIPR.* p. 412 ff. explaining how the history of the term 'industrial' and its early rationale have influenced the creation of the exemption on diagnostic methods.

6(1). More specifically, it follows that 'uses' of the embryo or processes to derive pluripotent hESC cannot be excluded from patentability under Article 6(2)(c), unless the uses or processes in questions involve direct, repetitive use of the human embryo as a raw material in a chemical, mechanical or technical process. To the extent that that the derivation of hESC from a human blastocyst involves direct or repetitive use of the human embryo as a raw material, it comes under the scope of exclusion of Article 6(2)(c) Both the interpretations of the UK and the Swedish patent offices are consistent with this analysis.

The interpretive approach suggested here is further confirmed by examination of the debates in Parliament on the adoption of the final wording of 6(2)(c) and the scope of the moral consensus on the human embryo amongst Member States. Some MEPs pointed out that the language of 6(2)(c), by introducing the qualification that the excluded uses of the human embryo where industrial or commercial **'**will allow the patenting of processes which use embryos and the embryos themselves' whereas Parliament had earlier (on 16th July 1997) stated that 'the human embryo is never patentable, either as the product of a process or as an instrument of a process'.[238] The broadening and narrowing of the moral exclusions on human embryos in the final legislative stages of the Directive, reflected the inter-institutional differences within the EU and Member States. The European Parliament favoured a comprehensive ban on any research involving human embryos but ultimately agreed with the changes introduced by the Council of Ministers in the compromise reached in the Common Position, which limited the exclusion to *certain* uses of embryos for industrial or commercial purposes.[239] According to the Rapporteur, the compromise reached through the qualification of the terms 'industrial' and 'commercial' was intended not to render unpatentable inventions which were lawful in Member States:[240]

> "In relation to the use of embryos, the Council has set some limitations: they are not to be used for industrial or commercial purposes. But I would only ask you to remember that this was done with the United Kingdom in mind. We cannot as European legislators decree that something which does not contravene the underlying legal principles of all Member States is a contravention of public order, and we cannot brand something that we do not jointly regard as abhorrent as a contravention of common

[238] Debates of the European Parliament, Casini (PPE) (IT), Sitting of Monday 11 May, 1998,
[239] The Common Position reached by the Council and the European Parliament states that under the Agreement, the Directive "categorically excludes from patentability processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, certain uses of human embryos, and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal as well as animals resulting from such processes", Bulletin EU 11-1997 - 1.3.47.
[240] Other than those which the Member States specifically agreed to exclude (in the exercise of their rights under the general principles of Community law explained in Chapter three).

> decency. That is not acceptable! It is only exemplary in any case, that is to say, other ways of using embryos may be investigated with the proviso that they do not contravene public order and common decency for other reasons."[241]

As defined in Recital 42, one such obvious non industrial or commercial use of the human embryo is "inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it".

But other the types of inventions are also permissible, for instance, inventions involving the use of embryos for the therapeutic purposes listed under UK legislation at the time, which limited the purposes for which human embryos could lawfully be used to research on the causes of infertility, congenital diseases and methods to detect genetic abnormalities before implantation.[242] The purposes were extended in 2001 to include: to increase knowledge about the development of embryos; to increase knowledge about serious disease; and to enable such knowledge to be applied in developing treatments for serious disease[243]

Comparable restrictions defining the purposes for which research on human embryos may be lawfully conducted are to be found in the national laws of other Member States. For instance, French, Finnish, Hungarian and Spanish laws all permit research on supernumerary human embryos, but only for certain legally defined purposes which range from diagnostic or therapeutic purposes for the benefit of society, *e.g.* the prevention or treatment of serious or incurable diseases to basic research or the acquisition of scientific knowledge on the human embryo.[244] This includes countries like Germany, which prohibit research on human embryos created in its own territory, but permit research on imported hESC/hESC lines, providing the research shall not be conducted "unless it has been shown by giving scientific reasons that such research serves eminent research aims to generate scientific knowledge in basic research or to increase medical knowledge for the development of diagnostic, preventive or therapeutic methods to be applied to humans…", and that "the scientific knowledge to be obtained from the

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[241] Debates of the European Parliament, Rothley (PSE), rapporteur. – (DE), Sitting of Monday 11 May, 1998.
[242] Human Fertilisation and Embryology Act 1990.
[243] The Human Fertilisation and Embryology (Research Purposes) Regulations No.188, 2001: http://www.hmso.gov.uk/si/si2001/20010188.htm
[244] For instance, Spanish law "Law No. 35/1988 on Assisted Human Reproduction Techniques" authorises research on *in vitro*, biologically non-viable human embryos under certain conditions, listed in sections 13.3(d) and 15.2(b) that any therapeutic intervention, investigation or research activity on either pre-embryos *in vitro*, pre-embryos, embryos or foetuses in utero, will be authorised only if such an intervention or activity does not alter its genetic make-up (in so far as it does not contain any anomaly), or if it is not aimed at individual or race selection. Embryo Protection Law, 1990 and *cf* .Section 5 of the Stem Cell Act, 28 June 2002, http://217.160.60.235/BGBL/bgbl1f/BGBl102042s2277.pdf (in German) on the protection of embryos imported for research.

research project concerned cannot be expected to be gained by using cells other than embryonic stem cells."[245]

Arguably, patents on hESC-related inventions for therapeutic purposes or other purposes considered lawful by Member States can only contravene the prohibition on patents in Article 6(2)(c) if the invention in question contravenes the specific uses listed in that Article, namely uses of human embryos for industrial or commercial purposes, as defined above.

Additional support from the Parliamentary debates about the intended scope of the exclusion in 6(2)(c) also confirm this analysis. The report by the Legal Affairs Committee of 25th June 1997 indicates that the scope of application of moral exemptions on patentability was thought to be determined by the *binding* legal framework for the Directive which in turn was defined by the legal obligations and rights of Member States under both the TRIPS agreement and EU law.[246] The report noted that Article 27.2 of the TRIPS agreement permits member states to exclude from patentability inventions whose commercial exploitation is contrary to *ordre public* or morality and stressed that under 27.2:[247]

> "1. To secure exclusion from patentatibility, it is not sufficient that the national law of the Member States should contain other prohibitions on exploitation.
> And even more important:
> 2. Exclusion from patentatibility is possible only if the industrial application of the invention is prohibited in the Member State in question."

From this, the report concluded that:

> "An invention whose industrial application is permitted can never be excluded from patentatibility"

The example then cited in the report indicates that it was thought that the TRIPS Agreement not only precludes the application of a moral guillotine on patent claims for inventions whose

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[245] Section 5 of the Stem Cell Act.
[246] Committee on Legal Affairs and Citizens' Rights, 25 June 1997, A4-0222/97. *Report on the Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions/COM/95/0661* PRELEX Document EP //218021/ LEGISLATIVE OBSERVA: 18 june 1997 EP PE 218.021/DEF.
[247] *Article 27 Patentable Subject Matter.* "2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."

industrial application is permitted in Member States, but that the denial of a patent in such a case would constitute a *violation* of the Agreement:

> "the idea of permitting a new medicine which would benefit human genetic information but denying the inventor a patent would constitute a manifest violation of Article 27(2)."

According to the report, the denial of the patent would have to be reserved exclusively to inventions which are "manifestly contrary to morality" "… for example, banned biological weapons - do not enjoy patent protection."[248] Another example cited was "anti-tank" mines. The grant of a patent on an "anti-tank" mine does not authorise the patent holder to use the invention for any purpose he chooses, since the uses will be restricted to those which are not contrary to the relevant criminal and civil laws.[249]

Finally, it must also be stressed 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,[250] 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."

It follows that 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.[251]

Overall, the suggested reading of Article 6(2)(c) arguably reflects most accurately the background moral considerations reviewed in Chapter four which prompted the legislator to

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[248] Report on the proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions (COM (95)0661 - C4-0063/96 - 95/0350(COD)), 25 June 1997, PE 218.021/fin. A4-222/97, note 4, at p. 31.

[249]- For a supporting legal analysis, see Straus, J., ‚Ethische, rechtliche und wirtschaftliche Probleme des Patent- und Sortenschutzes für die biotechnologische Tierzüchtung und Tierproduktion', (1990) *GRUR Int.*, .91

[250] Case C-377/98 *Netherlands v European Parliament and Council* [2001] ECR I-07079

[251] Such reasoning can also be substantiated by the "German solution" *supra* to allow reasearch (and patents) on imported hESC/hESC lines, whilst the use of HESC of German origin is precluded under Section 4 of the Stem Cell Act, and *cf.* also *supra* Chapter two.

exclude patents involving commodification of the human embryo, whilst acknowledging national differences on the reach of moral prohibitions on the human embryo

In conclusion, the above analysis of the scope of exclusion of Article 6(2)(c) suggests that none of the patents granted for human embryonic pluripotent cells by the Swedish Patent Office, the UK Patent Office and the German Patent Office are in violation of Article 6(2)(c) of the Directive, because they do not involve an industrial or commercial use of the human embryo. In view of the ECJ's case law so far in this field,[252] and knowing that the Court interprets the wording of articles in the light of the recitals, it is suggested that this too would be the conclusion of the ECJ, should national courts refer the matter to the Court under Article 234 EC.[253]

'Human Embryo'

Assuming an application for a patent falls under Article 6(2)(c) because it involves repetitive, direct use of a human embryo as a raw material in a mechanical or chemical process, or alternatively trade in human embryos, some residual uncertainty may still remain in circumstances where it is unclear whether the organism in question falls within the definition of 'human embryo'. The reason for this residual uncertainty arises from the fact that Directive itself does not contain a legal definition of the term 'embryo', neither is there a legal definition to be found in European or international law instruments.[254] Furthermore, where legal definitions exist in national laws, these definitions vary considerably.

Whilst we have suggested that it is possible to determine the meaning of the terms 'industrial' and 'commercial' with reasonable certainty, no such determinate meaning may similarly be attached to the term 'human embryo'.

At one end of the spectrum some of the definitions, like the ones in Germany, include moral evaluative criteria whereby the human embryo is defined in terms of its potential to develop into a human being:

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[252] Case C-377/98 *Netherlands v European Parliament and Council* [2001] ECR I-07079; Case C-456/03 *Commission v Italy* [2005] ECR 1-5335

[253] On Member States "obligations" to ask for preliminary rulings see Chapter three *supra*.

[254] On the other hand, on the national level there exist some such definitions, and as has been pointed out in Chapter two *supra,* German law even contains two different embryo definition.

> "Embryo means any human totipotent cell which has the potential to divide and to develop into a human being if the necessary conditions prevail,"[255]
>
> or
>
> "An embryo already means the human egg cell, fertilised and capable of developing, from the time of fusion of the nuclei, and further, each totipotent cell removed from an embryo that is assumed to be able to divide and to develop into an individual under the appropriate conditions for that."[256]

Most commonly, in the few instances where legal definitions of the human embryo exist, the definitions are framed in scientific terms. For instance, under UK law:

> (1) In this Act, except where otherwise stated—
> (a) embryo means a live human embryo where fertilisation is complete, and
> (b) references to an embryo include an egg in the process of fertilisation, and, for this purpose, fertilisation is not complete until the appearance of a two cell zygote.257

Under UK law, the definition of the human embryo in the Act only covers human embryos *in vitro*.[258]

Under Finnish law, the definition is vaguer and broader:

(2) 'embryo' means a living group of cells resulting from fertilisation not implanted in a woman's body" [259]

In Spanish law, currently under revision, the term 'pre-embryo' is used where other European laws refer to the embryo. A 'pre-embryo' is defined as the fertilised egg up until 14 days from fertilisation or implantation. The human embryo is then considered to exist – following general practice – from 14 days to two and a half months.[260]

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[255] Section 3 Stem Cell Act (2002.).
[256] Section 8(1) of the Embryo Protection Act (1990).
[257] Human Fertilisation and Embryology Act 1990.
[258] Schedule 1(2) (2): "This Act, so far as it governs bringing about the creation of an embryo, applies only to bringing about the creation of an embryo outside the human body.";
[45] Section 2 lag (488/1999) om medicinsk forskning. (Act on Medical Research).
[260] Law No. 35/1988 on Assisted Human Reproduction Techniques and the Law No. 42/88 on the donation and use of human embryos, foetuses and cells, tissues and organs.

As pointed out in Chapter two of this Report, doubts as to whether the organism which is the subject matter of an application, falls within the definition of a 'human embryo' are likely to arise due to the pace of development of scientific advances in this field. Even where national definitions exist, because of the fast developing pace of scientific developments on human embryonic research, the legal definitions may not have kept pace with scientific advances. The difficulties encountered by national courts in the determination of whether unforeseen scientific developments fall within the regulatory scope of existing national laws may be gauged from the litigation which has taken place in the UK. In legal proceedings which concluded in the highest court in the land, the House of Lords held that embryos cloned for 'therapeutic' purposes, and therefore not strictly created by a process of fertilisation as defined under the Act, nevertheless fell under the definition of the human embryo in the UK HFE Act 1990.[261] The House of Lords took the view that the intent of the legislators could not have been to leave this unforeseen research unregulated, notwithstanding the fact that this research arguably raised moral issues distinct from those originally considered by legislators.

In the US, the Hurlbut proposal[262] has sought to avoid the moral controversies surrounding cloning of human embryos for biomedical research purposes and related patents with the suggestion that research should be conducted instead on organisms created by a technique of "altered nuclear transfer" which, it is suggested, would not strictly fall within the definition of a 'human embryo' The Hurlbut proposal has its origins in the enactment by the US Congress in 2004 of a measure to prohibit the granting of patents on claims "directed to or encompassing a human organism"[263] and the inability of the US Council on Bioethics to reach a consensus on the question of when human life beings and acquires moral standing. Hurlbut reports that this led Council Members to consider whether it may be possible to create a biological entity that cannot rightly be called a living organism, or a human embryo, and yet that has the generic organic powers necessary to produce ES cells:

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[261] The alternative view that the cloned embryos did not fall within the ambit of definition of the embryo under the Act, was put forward by the High Court judge in *R (Quintavalle) v. Secretary of State for Health,* [2001] 4 All ER 1013. For an analysis supporting *the* High Court ruling see Plomer, A., 'The Regulation of Stem Cell Research in the UK' *Med.Law.Rev,* (2002) 10:2 132-164..

[262] *Science and Engineering Ethic,* (2005) 11, at pp. 21-29.

[263] In 1997, the US PTO decided, in relation to a speculative claim concerning a human-animal chimera that could be up to (but not more than) 50 percent human, that the claim should be rejected on the grounds that it 'encompassed a human being". The claim was rejected notwithstanding the fact that the stated intention of the inventors was not to produce such creatures but to control and preclude their production, 58 BNA Patent, Trademark & Copyright J. 1430 (Jun 17, 1999).

> "Such a proposal shifts the ethical debate from the question of: When is a normal embryo a human being? to the question of: What component parts and organised structure constitute the minimal criteria for considering an entity a human embryo?"[264]

Hurlbut notes that the creations of these organisms would require 'pre-emptive' interventions which may involve a range of techniques:

> "… from the use of short interfering RNA to silence genes essential for early intercellular organisation or formation of extra-embryonic structures to the deletion of genes for angiogenesis (such that the stem cells procured could produce differentiated cell types with therapeutic potential, but would have to rely on the host into whom they were placed for their vascular connections)."[265]

However, the main difficulty with Hurbult's proposal is that it is not clear that it finally avoids the definitional and moral difficulties it seeks to address. As one commentator, puts it, is it the case that the organisms created are not human embryos, or are we instead faced with human embryos purposely created with a defect?[266] That view was voiced by one senator who wondered "[i]f it's not an embryo, what is this Frankenstein-like thing we're creating?"[267] For those opposed to research on human embryos, is the latter any more acceptable ethically than the former?[268] In short, the US debate surrounding the term 'human embryo' shows that definitional issues surrounding the scientific meaning of the terms "human embryo" may conceal distinct moral perspectives. Furthermore, attempts to avoid the ethical dilemmas by converting the problem into a seemingly strictly 'scientific' question, may also be illusory, precisely for the same reason.

5.3 Implications

The implications of the definitional difficulties attaching to the term 'human embryo' suggests that, within the EU legal order, in the absence of agreed European definitions on the 'human

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[264] *Science and Engineering Ethic,* (2005) 11, p. 21 p. cit. at. p. 27

[265] *Ibid*.

[266] Statement of Richard Doerflinger of the United States Conference of Catholic Bishops. Cited by Dolgin,J. L. in 'Surrounding Embryos: Biology, Idealigy, and Politics*,* 16 *Health Matrix,* at 27. See also Robinson , C. 'Recent Developments in the Law and Ethics of Embryonic Research: Can Science Resolve the Ethical Problems it Creates?',, 33 *J.L. Med. & Ethics* at p. 384. Robinson also highlights the shortcomings of a related proposal by Columbia University scholars Howard Zucker and Donald Landry, to harvest stem cells from dead embryos.

[267] Cited by Dolgin *ibid*.

[268] Conversely, from the perspective of scientists who support research on human embryos, the proposals are perceived as ideologically driven attempts to influence science with the risk that where ideology "trumps" science experience from history suggests a loss of good science for generations. See report by Irving Weissman, biology professor at Stanford, comparing the US restrictions on hESC research to misguided State driven policy in Russia in the 1920's: 'The Future of Stem Cells: The Ghost of Lysenko'*, SCI, AM*, July 2005.

embryo' a residual margin of discretion would fall on Member States to determine the scope of the 6(2)(c) exclusion where there are doubts as to whether the organism in the application is a human embryo. This is because Member States have not divested themselves under the EU Treaty or in the Directive, of the power to continue to define what counts as a human embryo under national laws.[269]

Article 6

> 1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

Article 6(1) reiterates an accepted general principle of patent law which precludes patents on inventions which are contrary to *ordre public* or morality. As was seen in Chapter four, the ECJ, which has jurisdiction over the Directive, has further stressed that a wide margin of discretion has to be given to Member States in the interpretation of the exclusion "to take account of the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State."[270] Similarly, the ECrtHR has held that, in the absence of any European consensus on the scientific and legal definition of the beginning of life, the issue of when the right to life begins comes within the margin of appreciation which the Court generally considers that States should enjoy in this sphere.[271]

The range of moral considerations applicable under Article 6(1) to patents involving the human embryo, and the intention of the Community legislator have specifically been canvassed in the previous Chapter. The main conclusion which carries through is that, in the absence of a uniform view amongst European societies on the point in time from which the life of the human embryo should be protected, there can be no legal basis for reading Article 6(1) of the Directive as conferring a license for the imposition of the uniform moral bar on patents on hESC whose derivation necessarily involves embryo destruction are contrary to *ordre public* or morality. The application of such a moral bar would also be inconsistent with the legal reality on the range of national regimes in Europe which permit the derivation of stem cells from human embryos, most notably supernumerary embryos.

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[269] *Cf.* also Recital 14: "... whereas, consequently, substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards;"

[270] Case C-377/98 *Netherlands v European Parliament and Council* [2001] ECR I-07079, at para. 38.

[271] Case C-377/98 *Netherlands v European Parliament and Council* [2001] ECR I-07079, at para. 46.

Patentability of Pluripotent hESC

This leaves the question of whether pluripotent hESC may otherwise be considered generally excluded under the general moral exclusion clause in Article 6(1). But this would require the application of a European wide norm on the moral impermissibility of exploiting inventions involving human embryos. Instead, as shown in Chapter four, beyond the consensus identified on human reproductive cloning and trade on embryos, the level of protection conferred on the human embryo itself and on research involving the human embryo varies across Europe.[272]

The derivation of pluripotent hESC can take place lawfully in a large number of countries in Europe, although the precise circumstances and purposes for which the research is permitted vary from country to country. Not only is there no evidence to suggest that it is contrary to European views on morality to derive pluripotent cells from human embryos, but as was argued earlier, the Preparatory Works on the Directive further confirm that the intention of the legislator was not to render unpatentable research on human embryos which was at the time lawful in Member States. It is therefore suggested that there is no legal basis for the exclusion of patents on human embryonic pluripotent stem cells or related process for their derivation under Article 6(1).

[272] *Cf.* Recitals 36 – 40.

PART III: The Directive in the EPC legal system

Chapter Six:
Moral Exclusions in the EPC System

Introduction

In the previous Chapters of this Report, we have outlined a methodology for the interpretation of Article 6 of the Directive from the perspective of the EU legal order within which the Directive was originally conceived and adopted. In this Chapter, we highlight the fact that the implementation of the Directive also falls upon the EPO, and discuss the implications that arise in terms of the EPO's interpretation of the exclusion of uses of the human embryo from patentability. As has been emphasised in the introduction to this Report, it is important here to note that the EPO is independent of the EU, and operates within the legal framework established by the EPC. However, as is well known, the EPO voluntarily transposed the wording of the provisions of the Directive into the EPC in the form of amendments to the EPC Implementing Regulations on 16th June 1999.[273] The degree to which the EPO, operating within the EPC legal framework which also includes the Directive and its morality provisions, is also bound by the general operating principles of EU law is unclear. A question which therefore arises in the EPO context is whether the EPO is also obliged to adopt the same construction of the exclusionary moral rules on human embryos and the patentability of hESC,[274] and this Chapter will examine whether the interpretation of the exclusionary moral rules under the EPC system lead to the same conclusions on the scope of the exemptions under the EU legal system as made in Chapter five.

[273] Decision of the Administrative Council of 16th June 1999, see Notice dated 1 July 1999 concerning the amendment of the implementing regulations of the European Patent Convention, O.J.E.P.O. 1999, 437, 573.
[274] *Cf.* Rule 23d(c).

6.1 The European Patent Organisation

The European Patent Organisation (the EPO) was established on 7th October 1973 on the basis of the European Patent Convention (EPC), which was signed in Munich in 1973 and entered into force in 1978. The EPO has the nature of a classical intergovernmental organisation based on an international treaty, the EPC, which has to be interpreted in compliance with the Vienna Convention on the Law of Treaties.[275] The EPO is independent of the EU and is an example of the alternative, intergovernmental approach to integration in post-war Europe.

All EU Member States plus the EU candidate countries Bulgaria, Romania and Turkey, as well as Switzerland, Cyprus, Liechtenstein, Iceland, Malta and Monaco are members of the European Patent Organisation with the European Patent Office (EPO) in Munich. By joint association of the group of Central and Eastern European Countries to the EPC in mid 2004, the Organisation today comprises 32 Member States.[276] Moreover, as a consequence of the Extension Agreements signed with Albania, Croatia, Bosnia and Herzegovina, the Former Yugoslav Republic of Macedonia, as well as with Serbia and Montenegro, European patents may now also be obtained in most of these countries and soon in all of them, once the necessary parliamentary ratifications are completed. All these countries will also be Member States of the European Patent Organisation in due course. When these accessions are completed, the EPC area will form the largest single patent region in the world – a single grant procedure which can lead to patent protection in a potential market of more than 500 million people, considerably larger than that of the USA and Japan together.[277]

In contrast to the European Community, the EPO only has powers in a specific and well defined field of activity.[278] Judging from the Preamble, the main objectives of the EPC are to strengthen

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[275] Paterson, G., *The European Patent System, The Law and Practice of the European Patent Convention* (Sweet & Maxwell: London 1992), 24 ff. On supranational elements in the structure of the Organisation and its financial autonomy see van Empel, M., *The Granting of European Patents* (A.W.Sijthoff: Leyden, 1975), 27.

[276] See at: http://ceec.european-patent-office.org (last visited July 17 2006).

[277] *Ibid*.

[278] The EPO has no formal legislative powers in the proper sense of the word, recognised in the text of the EPC. However, probably because amendments to the articles of the Convention are so difficult, considerable powers have been given to the Administrative Council, notably to amend the Implementing Regulations of the Convention (Article 33(1)(b) EPC). Decision on such amendment can be taken with qualified majority of three-quarters of the votes of the Contracting States represented and voting (*cf.* Article 35(2) EPC). The Administrative Council is moreover competent to authorise the President of the EPO to negotiate and, with its approval, to conclude agreements on behalf of the Organisation, with States and with intergovernmental organisations (Article 33(4) EPC). The impressive rule-making and decision-making powers vested in the EPO have not been subject to much scholarly or political attention, but are indeed remarkable since they give the EPO broad freedom in setting patent philosophy and economic policy in both the national and the European context, and since both governments and EU have little control over the functioning of the EPO. (See however, Ullrich, H., 'Patent Protection in Europe: Integrating Europe into the Community or the Community into Europe?' [2002]*ELJ, ,p.* 433, at 491; Leith, P., Harmonising European patent laws: Why so little call for a European appellate system?, in: Craig, P. and Harlow, C., *Lawmaking in the European Union* (ed.) (Kluwer:

co-operation between the States of Europe in respect of the protection of inventions. Its more specific objective is to ensure that protection may be obtained in the Contracting States by a single procedure for the grant of patents and by the establishment of certain standard rules governing patents so granted.[279] The EPC establishes a centralised application procedure for the countries adhering to the Convention. As the validity of national laws is restricted to the territory of each country, the main rule on the grant of patents is that an application for a patent must be filed in each country where patent protection is desired. The exception to this is the EPO[280] and some similar joint Offices in other parts of the world, such as the African Regional

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London/Cambridge, 1998), 511 ff., at 526. For the more detailed study, see Leith, P., *Harmonisation of Intellectual Property in Europe: A Case Study of Patent Law* (Sweet & Maxwell: London 1998).

[279] The grant of European patents is a complex process which may go through several stages and involves numerous administrative and quasi-judicial bodies of the EPO. The departments charged with the procedure are the following: (a) a Receiving Section; (b) Search Divisions; (c) Examining Divisions; (d) Opposition Divisions; (e) a Legal Division; (f) Boards of Appeal; (g) an Enlarged Board of Appeal. Whereas all the departments are technically speaking part of the Office, the institutional and procedural rules show an attempt for securing the independence of the Boards of Appeals in view of their, in essence, judicial functions. In particular, in their decisions the members of the Boards "shall not be bound by any instructions and shall comply only with the provisions of this Convention" (Article 23) (COM (2002) 545 final, Report from the Commission to the European Parliament and the Council, Development and implications of patent law in the field of biotechnology and genetic engineering, p. 7.) In many respects, thus the Boards of Appeal meet the requirements for a court in the meaning of Article 6 ECHR. (Article 116(4) and 128(4) EPC.) (See Messerli, P., Die organisatorische Verselbständigung der Beschwerdekammern des Europäischen Patentamts, in: Festschrift Kolle/Stauder (Carl Heymanns Verlag 2005) p. 441 ff.) Nevertheless, critics have observed that in the present institutional architecture of the Organisation, more is needed in order to guarantee the independence of the Boards and to convince the public of this independence. The position of the President of the EPO as administratively responsible for the management of the Boards but also as having a right to nominate members of the Boards is given as an example of one arrangement which undermines the confidence in the fairness of the system. (See Messerli, *supra*) Finally, in the particular context of biotechnology patenting it may deserve mention that the procedure on the grant of individual patents includes the possibility for opposition and appeal. Any person may give notice of opposition to the European patent granted on the grounds laid down in the Convention (Article 99 EPC) or submit third party observations according to Article 115 EPC. The notion "any person" in Article 99 has been broadly construed in the practice of EPO. The Enlarged Board of Appeal has held that the EPC legislator had expressly designed the opposition procedure as a legal remedy in the public interest, which under Article 99(1) EPC was open to "any person". Consequently an opponent does not have to establish any kind of interest in the opposition. (See G 3/97 and G 4/97, O.J.E.P.O. 1999, 245, 270. *Cf.* Case Law of the Boards of Appeal of the EPO, 466, available at:http://db1.european-patent-office.org/dwl/legal/case_law/clr_all_en.pdf).

The opponent's motives are likewise irrelevant in the absence of evidence of abusive conduct. (See G 1/84 O.J.E.P.O. 1985, 299; T 635/88 (O.J.E.P.O. 1993, 608), T 635/88, O.J.E.P.O. 1993, 608, *cf.* Lunzer, R. and Singer,R., *The European Patent Convention* (Sweet & Maxwell: London 1995), 465.) There are provisions for oral proceedings at the request of any party or at the instance of the EPO if expedient. Proceedings before the Boards of Appeal and the Opposition Division are as a rule public (Article 116 EPC). This rather open opposition procedure has provided access of various interest groups to the decision-making process and has turned into an important channel for influx of public interest and ethical considerations in the case law of the EPO. There is, as of now, no advisory body to the EPO to provide guidance on ethical or other non-patent issues possibly invoked in the grant procedure. (See recommendation in this respect in the EGE Opinion No. 16.)

[280] The procedure in the EPO consists generally of the following steps:
The Receiving Section is responsible for the examination on filing and the examination as to formal requirements of each European patent application. It is also responsible for the publication of the European patent application and of the European search report. An ED examines each European patent application from the time when the Receiving Section ceases to be responsible. An ED consists of three technical examiners. Oral proceedings are held before the ED itself. If the ED considers that the nature of the decision so requires, it shall be enlarged by the addition of a legally qualified examiner. An OD is responsible for the examination of oppositions against any European patent. An OD consists of three technical examiners, at least two of whom shall not have taken part in the proceedings for grant of the patent to which the opposition relates. Oral proceedings may be held. If the OD considers that the nature of the decision so requires, it shall be enlarged by the addition of a legally qualified examiner who shall not have taken part in the proceedings for grant of the patent. The Boards of Appeal are responsible for the examination of appeals from the decisions of the Receiving Section, the ED, and of the ODs. The TBA consist of combinations of technically and legally qualified members, depending on the nature of the appeal in question.

Industrial Property Organisation, ARIPO[281], as well as the procedure established by the Patent Co-operation Treaty (PCT), which offers a simplified application procedure for more than 100 countries in the world.

The objectives of the EPC and the EPO indicate clearly that the intent of the founders has been to achieve uniformity (a single procedure) only in the pre-grant phase, whereas to limit the influence of the EPC in the post-grant phase only to "certain standard rules", leaving the rest to the national patent law of the Contracting States.[282] The EPC regulates the grant but not the legal effects of a patent. With only one application to the EPO, patents are granted in as many of the Member States as the applicant wishes. After a uniform examination procedure, the EPO grants patents in the countries designated in the application. However, the patent granted is not a unitary European patent as such, but a bundle of national patents resulting from the joint application procedure. Once a European patent has been granted, it exists as a national patent in each country designated in the application, where it also has been validated, and is then subject to each national jurisdiction.[283] Questions on infringement and validity of the patent right are matters for the national courts.[284]

Membership in the EPC does not involve formal harmonisation of laws. The Convention establishes "a system of law, common to the Contracting States, for the grant of patents for invention" (Article 1). Contracting States are only committed to accept a European patent issued by the EPO when it is granted for their territory and to treat it as national patent.[285] While ratification of the EPC does not bind the Contracting States to bring their national patent laws in conformity with the EPC, most of the Member States have actually amended their laws to achieve such conformity.[286] This has taken place by way of emulation and voluntary harmonisation and partly due to mechanisms built into the design of the EPC.[287] An important impetus for harmonisation has been provided by Article 138 establishing common and binding grounds for revocation of European patents.[288] Member States' authorities and courts have consequently been bound to ensure the conformity of huge portions of their national patent law

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Decisions of a TBA may be applied to the EBA. However, the EBA rules only on points of law, referred to it by the TBA, or gives opinions on points of law referred to it by the President of the EPO.

[281] http://www.aripo.wipo.net/index.html.

[282] Paterson, G., *supra*, 25.

[283] Articles 2 and 135 ff. EPC.

[284] *Cf.* Article 138.

[285] Article 2 EPC "The European patent shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that State, unless otherwise provided in this Convention".

[286] This represents the "cold harmonisation" as it was called by Haertel, K., Harmonisation of National Patent Law by European Patent Law, [1983] p. 719..

[287] See Waage, E., Beyond the Harmonisation of Statute Law: Adapting the National Court's Exercise of Discretion to the Practice of the EPO, in: Festschrift Kolle/Stauder, (Carl Heymanns Verlag, 2005) p. 487 ff.

[288] On the importance of this solution see van Empel, *The Granting of European Patents* (A.W.Sijthoff: Leyden, 1975).

with the Convention. A further vehicle for harmonisation has been the availability of full-fledged contentious post-grant opposition procedure and the proclivity of national courts to follow the decisions of the EPO Boards of Appeal, probably due to the perceived high professional expertise and quality of the decisions of these bodies.[289] More generally, the explanation for this much celebrated emulation effect lies partly in the efforts of national law-makers to reduce transaction costs for local industry and local administration and judiciary that would otherwise ensue from the necessity to follow two different sets of rules in national and European procedure.[290]

In accordance with the intergovernmental nature of the cooperation it establishes, the EPC can only be amended by a full diplomatic conference and in accordance with a complex procedure laid down in Article 172 EPC.[291] Given the increasing number of contracting states, Advocate General Jacobs' qualification of the revision procedure as "very cumbersome" appears justified.[292] Revision of the articles of the EPC has so far only been carried out twice.[293]

6.2 The EPO – EU Relationship

Needless to say, the objectives of the EPC and the EPO are much more limited and specific than those of the EU/Community. As the EPC establishes a single unitary system only for the examination and grant of patent applications, it is not a complete system covering the lifespan of a patent. As mentioned, once a European patent has been granted, questions of infringement and the assessment of validity under Article 138 EPC fall back on the national systems. In view of validity, it is thus obvious that national courts can invalidate a patent granted by the EPO, thereby providing for a system where different national views on some issues (such as e.g. *ordre public* and morality) can be upheld. Even though the EPO has been engaged in the discussions

[289] However, the question of the indepence of the TBA/EBA from the EPO is still unresolved.
[290] Ullrich, 'Patent Protection in Europe: Integrating Europe into the Community or the Community into Europe?' [2002] *ELJ,* pp. 433 ff., at 491.
[291] Following this provision, the EPC may be revised by a Conference of the Contracting States at which three-quarters of the Contracting States are represented. For the adoption of a revised text there must be a majority of three-quarters of the represented and voting Contracting States, whereby abstentions are not considered a vote. A State that has not ratified or acceded to a revised text of the Convention ceases to be party to the EPC.
[292] See Opinion AG Jacobs, Case C-377/*98 Netherlands v. European Parliament and Council* [2001] ECR I-07079; para 53.
[293] The second and comprehensive revision of the EPC, with the EPC2000 as a result, took place in September 2000 and submitted to the Conference of the Contracting States convened under Article 172 EPC and held in Munich from 20 to 29 November 2000, where among others the rules for rule-making by the Administrative Council were amended. The planned revision by integrating the rules of the Convention into the text of the Convention notoriously failed and other open questions concern the patentability of computer programs. Ullrich, H., 'Patent Protection in Europe: Integrating Europe into the Community or the Community into Europe?' [2002] *ELJ*, pp. 433 ff.; *cf.* Joos, U. Revisionen des Europäischen Patentubereinkommens, in: Festschrift Kolle/Stauder (Carl Heymanns Verlag, 2005) p. 429.

on a supra-national patent court system, the European Patent Litigation Agreement (EPLA), with the objectives to establish a system for enforcing a unitary approach of interpretation of EPC articles, this will need further discussion and time. Furthermore, this is rather an institutional question, and it remains to be seen whether the work on the Community patent or other types of patent co-operations will resolve these issues in the longer perspective.[294]

Within the EU, the Member States have divided competence with the Union's authorities in certain areas pertaining to the establishing of the Internal Market. As indicated in Chapter three of this Report, the ECJ developed at an early stage the crucial concepts of direct effect and supremacy of European Community law.[295] In the event of national law being inconsistent with Community law, ECJ case law asserts the supremacy of Community law over national law, including in particular domestic law introduced after accession.[296] The ECJ has held that, under the terms and spirit of the Treaty, Member States cannot accord precedence to a unilateral measure adopted under domestic law which is inconsistent with Community law:

> "Such a measure cannot therefore be inconsistent with that legal system. The executive force of Community law cannot vary from one state to another in deference to subsequent domestic laws, without jeopardising the attainment of the objectives of the Treaty."[297]

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[294] *Cf.* for instance Commissioner Charlie McCreevy, on the 12th July at the publichearing in Brussels on the future patent policy in Europe: "I will go for one big last push for the Community patent". At this instance Mr. McCreevy also acknowledged that the EPLA was "a promising route towards [a] more unitary jurisdiction" stating that the EC would be looking into ways of moving the project along." *Cf.* also the UK Statement at the Working Party on Litigation (13th December 20005)*:*

"The UK, on behalf of the member states of the European Union, recognises the importance that industry attaches to the role that the European Patent Litigation Agreement could play in improving the European Patent System. At the Competitiveness Council at the end of November, member states committed themselves to strengthen information and support services on intellectual property, especially for SMEs, support patent authorities increasing their cooperation across borders and pursue work to improve the accessibility and efficiency of Europe's patent system. A litigation system which would reduce the cost and complexity of the European Patent System could have a key part to play in delivering against the Lisbon goals. In his speech to the European Parliament's Legal Affairs Committee on 29 November, Commissioner Charlie McGreevy announced that he intended, over the coming three months, to engage in a dialogue on how to provide Europe with a sound IPR framework. While the Commission continues to believe that the Community patent is crucial, another issue to be considered is improvement of the existing framework of the European Patent Office, especially the litigation arrangements.

Our intention is as soon as possible to reach a position where a text can be put to a diplomatic conference. For this purpose, the Commission and member states plan to hold one or two meetings to discuss the technical issues relating to Community involvement in the EPLA. ″

[295] See *inter alia* Case 26/62 *Van Gend en Loos* [1963] ECR 3, Case 6/64 *Flaminio Costa v. ENEL* [1964] ECR 1141 and Case 43/*75 Defrenne* [1976] ECR 455.

[296] See Case 6/64 *Costa v. ENEL* [1964] ECR 1141and Case 106/77, *Amministrazione delle Finanze dello Stato v. Simmenthal SpA* [1978] ECR 629.

[297] Case 6/64, Costa v. ENEL [1964] ECR 585, pp. 593-94.

The ECJ has further asserted that:

> "… the laws stemming from the Treaty, an independent source of law, could not, because of it's special and original nature, be overridden by domestic legal provisions, however framed, without being deprived of its character as Community law, and without the legal basis of the Community itself being called into question."[298]

Even if directives leave to national authorities the choice of means and methods of implementation, they are nevertheless binding on Member States as to the results to be achieved. The ECJ has recognized the principles of vertical direct effect and of state liability for non-implementation of Community directives. Furthermore, the duty of Member States under Article 10 EC to take all appropriate measures, whether general or particular, to ensure the fulfilment of their obligations under Community law, is binding on all national authorities of Member States including, for matters within their jurisdiction, the courts.[299] It also follows from the Court's judgments that national courts are required to interpret a directive, so far as possible, in the light of the wording and the purpose of the directive concerned in order to achieve the result sought by the directive and consequently comply with the third paragraph of Article 249 EC (doctrine of indirect effect).[300]

As mentioned in Chapter three, to secure a uniform interpretation of Community law throughout the European Union, under Article 234 EC, national courts or tribunals may request the Court of Justice to give a ruling thereon if they consider that a decision on the question is necessary to enable them to give judgment. However, where any such question is raised in a case pending before a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law, that court or tribunal shall bring the matter before the Court of Justice (Article 234(3). That obligation is in particular designed to prevent a body of national case-law that is not in accordance with the rules of Community law from coming into existence in any Member State.[301] Thus, in order for a final court not to consult the ECJ, the correct application of Community law must be so obvious as to leave no scope for any reasonable doubt as to the manner in which the question raised is to be resolved (*acte clair*).[302]

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[298] Case 11/70 *Internationale Handelsgesellschaft* [1970] ECR 1125, at. 1134.
[299] Case 14/83 *Von Colson and Kamann v. Land Nordrhein Westfalen* [1984] ECR 1891, at para. 26.
[300] See *inter alia* Case 14/83 *Von Colson and Kamann ibid.* and Case C-106/89 *Marleasing v. La Comercial Internacional de Alimentación [*1990] ECR I-4153, at para. 8.
[301] See *inter alia* Case C-99/00 Roland Lyckeskog [2002] ECR I-4839.
[302] Case 283/81 *CILFIT v. Ministero della Sanità* [1982] ECJ 3415 at para. 16: "the national court or tribunal must be convinced that the matter is equally obvious to the courts of the other Member States and to the Court of Justice. Only if those conditions are satisfied may the national court or tribunal refrain from submitting the question to the Court of Justice and take upon itself the responsibility of resolving it."

For the EPO the Directive has been referred to as a "supplementary means of interpretation" (Rule 23b). However, 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 said 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. By contrast, as seen earlier, under the EPC system the legal validity of a patent granted by the EPO is ultimately a matter for national law.

Importantly, in the event of the EPC's interpretation of the Directive being inconsistent with the ECJ's, there is no institutional mechanism to resolve the matter. The ECJ has no jurisdiction over the EPC, since the EPC is not a party to the EU Treaty.[303] On the basis of the above analysis, the inevitable conclusion is that, as regards member states of the European Union, the ECJ's interpretation will prevail.

6.3 Moral Exclusions in Patent Law – Article 53(a) – General Principles

The possibility of excluding inventions from patentability on the basis of *ordre public* or morality concerns, i.e. so-called morality exclusions, is present in almost every international convention or national regulation on IP. *Ordre public* and morality considerations had been taken into account in many jurisdictions even before the adoption of the prevailing international and regional legal acts, (i.e. the EPC, the TRIPS Agreement[304] and the Directive). European laws and many other civil law jurisdictions have traditionally provided for explicit exceptions on terms comparable to the present morality exclusions.

Some commentators have held that the concept of "*ordre public*" means a body of positive law. This approach implies that the publication or exploitation of an invention must be prohibited by law to offend against "*ordre public*".[305] Morality, however, is seen as a body of ethical norms which are generally accepted by those concerned with these norms, for example ethical principles generally recognised in the different branches of the medical profession or codes of conduct observed in industry and business.[306] Under U.S. case law, inventions were considered

[303] COM(2002) 545 final Report from the Commission to the European Parliament and the Council; Development and implications of patent law in the field of biotechnology and genetic engineering, p. 10.
[304] WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, available at: http://www.wto.int./english/docs_e/legal_e/27-trips.pdf
[305] See *e.g.* Schatz, U., 'Patents and morality', in:, Sterckx, S. (ed.), '*Biotechnology, patents and morality'* (Ashgate: Aldershot 1997) p. 161.
[306] *Ibid.*

to be contrary to *ordre public* if they were "frivolous or injurious to the well-being, good policy, or sound morals of a society".[307]

The morality exclusion in the EPC is found in Article 53(a),[308] which stipulates that:

> "European patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to *ordre public* or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.

The morality exception in Article 53(a) is based on Article 2(a) of the Strasbourg Convention,[309] which provided for the exclusion of inventions from patentability on the basis of *ordre public* and morality concerns.[310] This Convention has had considerable influence on the legislative development of patent laws in Europe, both national and international, even before the Convention actually came into legal effect in 1980.

Article 53(a) EPC also follows Article 4*quater* of the Paris Convention for the Protection of Industrial Property and indicates that the mere fact that something is prohibited by law or by regulation in some, or even all, of the Contracting States, does not of itself preclude patentability.[311] The patent right is a negative right, stipulating that the patent holder may prevent third parties from using the invention. A mere prohibition by law of the use of the invention does not matter or hinder the grant of the patent. One reason for this is that a product

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[307] UNCTAD Resource Book on TRIPS and Development: An authoritative and practical guide to the TRIPS Agreement, available at: http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm (2005-08-03), updated version as of 1 June 2005, p. 376, with further reference to *Lowell v. Lewis*, 15 (a. 1018 No. 8568) (C.D. Mass. 1817), quoted in Chisum and Jacobs, p. 2.5. In the United States, "the trend is to restrict this subjective public policy approach to utility".

[308] Article 53(b) contains the exclusion from patentability for living matter in the form of plant or animal varieties, together with the methods for their production.

[309] "The Contracting States shall not be bound to provide for the grant of patents in respect of: inventions the publication or exploitation of which would be contrary to *ordre public* or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by a law or regulation; […]" It shall be noted that also the original text of Article 53(a) EPC contained the reference to 'publication', which has been omitted in EPC2000 because it being regarded as superfluous.

[310] Many of the essential concepts of substantive patent law in the EPC were adopted from the Strasbourg Convention on the Unification of Certain Points of Substantive Law of 27th November 1963. The participating countries agreed that the provisions of this Unification Convention should be drawn upon for the purpose of formulating the EPC. The Strasbourg Convention in turn drew extensively upon the preparatory works undertaken by the Scandinavian countries on a Nordic patent law and of the work by the six original members of the EEC on a common European Patent Law, see Lunzer, R. and Singer, R., *The European Patent Convention A Commentary* (London 1995), p. 108. The morality exception was included in the Strasbourg Convention at a relatively late stage, see Mills, O., *Biotechnological Inventions. Moral Restraints and Patent Law* (Aldershot Burlington: Ashgate, 2005 p. 26.)

[311] Moufang, R. 'The Concept of Ordre Public and Morality in Patent Law', in: in van Overwalle (Ed.), *Patent Law, Ethics and Biotechnology* (Katholieke Universiteit Brussel 1998), p.72. The Brussels draft of the TRIPS Agreement contained a reference to "publication", but this was deleted because in the view of some authorities this would be irreconcilable with Article 27.2 of TRIPS in TRIPS only refers to "commercial exploitation", and does not make reference to "publication". Also see Lunzer and Singer *supra*, p. 125 and *cf.*. Article 27.2 of the TRIPS Agreement.

could still be manufactured under a European patent for export to countries in which its use is not prohibited.[312] Mere marketing restrictions as such cannot justify exclusions from patentability. There has to be a specific link between the commercial exploitation of an invention and the respective Member's approach to *ordre public* or morality.[313]

The historical background of the provision shows that its main purpose was, and is, that a country should not give protection to something that would be contrary to its laws or ethical values. No country should have to contribute to legalise such phenomena. The grant of an official protection such as patents for these kinds of inventions would be beneath the country's dignity.[314]

The Guidelines for Examination in the EPO[315]provide some guidance on the interpretation of Article 53(a). The purpose of Article 53(a) is to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour.[316] Traditional examples of such subject matter are letter bombs and anti-personnel mines.[317] According to the Guidelines, a fair test to apply is whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.[318]

The provision is centred on the criteria of 'exploitation' of an invention. An assessment should be made whether or not the use of an invention would be contrary to *ordre public* or morality. Nearly all inventions may have different purposes, and it is quite easy to find uses that would be contrary to *ordre public* or morality. However, Article 53(a) only applies when the non-permissible use of the invention can be deduced from the very nature of the invention.[319] In other words, the approach is narrow.

The wording of Article 53(a) EPC probably inspired the drafters of the TRIPS Agreement,[320] to which both the EU and its Member States are contracting parties. Based on a long established tradition in patent law (particularly in the European context), TRIPS allows (but not mandates)

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[312] Guidelines for Examination in the European Patent Office, Part C, Chapter IV, 3.1.
[313] UNCTAD Resource Book on TRIPS and Development: An authoritative and practical guide to the TRIPS Agreement, http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm (2005-08-03), updated version as of 1 June 2005, p. 381.
[314] Konph, R., *Åndsretten* (Oslo 1936) p. 285.
[315]. Guidelines for Examination in the European Patent Office, Part C, Chapter IV, 3.1.
[316] Guidelines for Examination in the European Patent Office, Part C, Chapter IV, 3.1.
[317] Guidelines for Examination in the European Patent Office, Part C, Chapter IV, 3.1.
[318] Guidelines for Examination in the European Patent Office, Part C, Chapter IV, 3.1.
[319] http://www.european-patent-office.org/legal/gui_lines/e/c_iv_3_3.htm
[320] UNCTAD Resource Book on TRIPS and Development: An authoritative and practical guide to the TRIPS Agreement, http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm (2005-08-03), updated version as of 1 June 2005, p. 376.

exceptions to patentability based on *ordre public* and morality. The implementation of these exceptions, which need to be provided for under national law in order to be effective, means that a WTO Member may, in certain cases, refuse to grant a patent when it deems it necessary to protect higher public interests.[321] Article 27.2 of the TRIPS Agreement reads as follows:

> "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."

In relation to the TRIPS Agreement, the term *ordre public* is held to express concerns about matters threatening the social structures which tie a society together, i.e., matters that threaten the structure of civil society as such.[322] "Morality" is "the degree of conformity to moral principles (especially good)".[323] The concept of morality is relative to the values prevailing in a society. Such values are not the same in different cultures and countries, and change over time. Some important decisions relating to patentability may depend upon the judgement about morality. It would be inappropriate for patent offices to grant patents to any kind of invention, without any consideration of morality.[324]

Article 27.2 clarifies, unlike equivalent precedents in national laws, that protection of *ordre public* or morality includes the protection of "human, animal or plant life or health or to avoid serious prejudice to the environment", thereby explicitly allowing for exceptions to patentability when any of these interests may be negatively affected by patent grants. The concept of "health" may be deemed to encompass not only medical care, but also the satisfaction of basic requirements such as adequate food, safe water, shelter, clothing, warmth and safety.[325] The "environment" refers to the "surrounding objects, region, or conditions, especially circumstances of life of person or society".[326] The TRIPS morality clause represents

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[321] *Ibid.*
[322] *Ibid.,* p. 375.
[323] *Ibid.* with further reference to The Concise Oxford Dictionary, p. 637.
[324] *Ibid.* with further reference to Bercovitz, A., 'Panel Discussion on Biotechnology' in Hill, K. and Morse, L. (eds.), *Emergent Technologies and Intellectual Property. Multimedia, Biotechnology & Others Issues*, ATRIP (CASRIP Publications Series No. 2, Seattle 1996) p. 53.
[325] UNCTAD *ibid.* p. 376 with further reference to Robert Beaglehole and Ruth Bonita, *Public Health at the Crossroads. Achievements and prospect*, Cambridge University Press, Melbourne 1999) p. 45 and Mustard, F., Health, health care and social cohesion, in: Drache, D. and Sullivan, T. (ed.), *Health Reform. Public Success. Private Failure* (Routledge: London and New York 1999).
[326] UNCTAD *ibid.* with further reference to The Concise Oxford Dictionary, p. 323.

an extension of morality issues to modern and global values as a sustainable development, environmental concerns and animal welfare.

The next Chapter examines whether the transposition of the morality exclusions from the Directive into the EPC Implementing Regulations has achieved a degree of convergence on the question of whether hESC inventions are excluded from patentability under each system.

Chapter Seven:
The Construction of the Directive's Moral Exclusions under the EPC

Introduction

To ensure a coherent European approach on the patenting of biotechnological inventions, the Directive's articles were inserted in Rule 23 of the Implementing Regulations of the EPC by way of a decision of the Administrative Council on 16th June, 1999,[327] For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the EPC are to be applied and interpreted in accordance with the provisions of Rules 23b to 23e of the Implementing Regulations.[328] The moral exclusions contained within Articles 6(1) and 6(2) of the Directive were transposed as Rule 23d EPC, which states that:

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;

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[327] O.J. EPO 1999, 437; O.J. EPO 1999, 574 for an official commentary. The legitimacy of this type of rule-making has rightly been questioned in the literature. Bossung (Bossung, O., 'A Union Patent Instead of the Community Patent. Developing the European Patent Into an EU Patent', [2003]*IIC,* p. 14) wonders whether the executive was not "overstepping its competence by assuming a legislative role or anticipating decisions which are the prerogative of the judiciary." Ullrich (Patent Protection in Europe: Integrating Europe into the Community or the Community into Europe?, EUI Working Paper Law No. 2002/5, 26, fn. 88 = 8 *ELR* 2002, 433 ff.; Ullrich, H., 'Harmony and Unity of European Intellectual Property Protection', in: Vaver, D. and Bently, L. (ed.) *Intellectual Property in the New Millennium. Essays in Honour of William R. Cornish* (Cambridge University Press: Cambridge 2004), pp. 20 ff.) notes with regret the failure of the revision conference of the EPO to deal with the biotechnology issues since he also sees a decision of the executive as democratically deficient. Indeed, given that the implementing regulations are in Article 164 EPC characterised as being integral part of the Convention, an amendment leading to substantial concretisation of major concepts of the Convention appears to represent "legislating in disguise".

[328] The cumbersome procedure for amendment of the Convention has at many places been officially recognised as one decisive reason to proceed to change by way of amended Implementing Regulation. While acknowledging the practicality of the latter approach as a sort of a short-cut around lengthy processes of intergovernmental law-making, this does not compensate for its major deficiencies in terms of democratic legitimacy. The legitimacy should be questioned not least due to the divergent circle of states, participating in the elaboration of the Directive as part of EU law and those accepting the Directive as a source of interpretation of the EPC convention through a decision of the Administrative Council. At the time of drafting the Directive, divergence may not have been perceived as a problem, because of the overall overlap in membership in the two organisations. Yet, with the current 31 EPO Member states and several more accession candidates, the system will soon comprise a number of countries, whose membership to the EU is uncertain, to say the least.

> (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

The methodology for the construction of the moral exclusion provisions under the EPC system involves reliance on EPC rules, relevant international Treaties such as the Vienna Convention, and the jurisprudence of the TBA.

7.1 The Vienna Convention on the Law of Treaties (1969)

Since, the EPC is an international Treaty, the starting point is the Vienna Convention governing the interpretation of Treaties.[329] The Vienna Convention defines in Articles 31 and 32 the principles of interpretation to be applied. Article 31(1) of the Vienna Convention states that a treaty "shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose". Article 31(2) further states that the 'context' for the purpose of the interpretation of a treaty shall comprise, amongst other things, the text of the treaty itself, including its preamble and annexes.[330]

In the referral questions to the EBA in the *WARF* case, the TBA noted that the established jurisprudence of the EBA has acknowledged that the rules on the interpretation of treaties incorporated in the Vienna Convention on the Law of Treaties may be relied upon to provide guidance in matters pertaining to the interpretation of the EPC.[331] On this basis, the interpretation of the specific list of exclusions incorporated under the EPC should be construed by reference to the wording of the legislative text as well as the legislative intent in introducing the provisions.[332]

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[329] T 1374/04 (*Wisconsin Alumni Research Foundation, WARF*), referral by the Technical Board of Appeal to the Enlarged Board of Appeal, case pending under Ref. No. G 2/06, see O.J.E.P.O. 2006, at para. 35). In instances where the text of the EPC is ambiguous, the EPO may adopt the approach outlined in Articles 31 and 32 of the Vienna Convention on the Law of Treaties (the Vienna Convention) in order to clarify the meaning and scope of particular provisions.

[330] Article 31(2): "The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:
(a) any agreement relating to the treaty which was made between all the parties in connexion with the conclusion of the treaty;
(b) any instrument which was made by one or more parties in connexion with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty."

[331] G 5/83, O.J.E.P.O. 1985, 64 and more recently G 2/02 and G 3/02, O.J.E.P.O. 2004, 483, point 5.2 of the reasons.

[332] T 1374/04 (*Wisconsin Alumni Research Foundation, WARF*), at paras. 33-35.

7.2 Text, Context and Purpose of Exceptions

In the *WARF* case the TBA has held that the construction of the Directive's list of moral exclusions, which have been transposed into the EPC rules, should proceed on the basis of the wording of the legislative text and the intentions of the legislators in drafting the specific exclusions.[333] In its earlier decision in G 1/98 concerning the patentability of genetically modified plants, the EBA arrived at its "narrow" construction of Article 53(b) EPC after having analysed the meaning of the terms used in their legislative context, in particular its historical background and the object and purpose of the provision.[334]

Furthermore, in both cases, the TBA and EBA respectively have, arguably correctly, held that since the purpose of the exclusion in each instance is closely related to considerations pertaining to the specific subject matter, the substantive tests to be applied in each case vary depending on the specific nature and purpose of the exclusion. Thus, in the *WARF* referral, the TBA noted that the correct interpretation of an exclusion relating to plant or animal varieties depends on the purpose for which legislators sought to introduce the specific provision. The TBA reasoned, arguably correctly, that the reasons for the exclusion under Rule 23d(d) are not relevant to reasons for exclusion of Rule 23d(c)[335] since Rules 23d(d) and (c) concerns substantially different subject matter.[336]

7.3 EPC Rules: the Directive as a Supplementary Guide

Further interpretive tools are to be found in the EPC Regulations themselves which state that the Directive is to be used as a supplementary means of interpretation.[337] In particular the recitals preceding the articles of the Directive are to be taken into account.[338] As pointed out in the analysis of the Directive under the EU legal system, relevant provisions in the Directive to assist with the determination of the scope of exclusion of the moral exclusion clause include Article 7 of the Directive, as well as other important provisions in the Recitals.

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[333] *Ibid*. at paras. 25 and 33 citing the *Oncomouse* case (T 19/90) and the G 1/04 decision of 16th December 2005 (to be published in the O.J.E.P.O., *cf.* Point 6 of the reasons) respectively, with a narrow exclusion to patentability under Article 52(4) EPC concerning diagnostic methods.
[334] *See* T 1374/04 (*Wisconsin Alumni Research Foundation, WARF*), at para. 33.
[335] T 1374/04 (*Wisconsin Alumni Research Foundation, WARF*), at para. 43.
[336] T 1374/04 (*Wisconsin Alumni Research Foundation, WARF*), at para. 44.
[337] Rule 23b of the Implementing Regulations to the EPC states that: "For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this Chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a *supplementary means of interpretation."* (emphasis added).
[338] Guidelines for Examination in the European Patent Office, Part C, Chapter IV, 2a.2.

Article 7 states that the Commission's European Group on Ethics in Science and New Technologies "evaluates all ethical aspects of biotechnology". Recital 44 points out that that Group may be consulted only where biotechnology is to be evaluated "at the level of basic ethical principles, including where it is consulted on patent law". In the *Edinburgh* case, the EPO comprehensively dismissed the majority view in the EGE's Opinion No. 16, and seems to have construed the exception under 23d(c) on the basis of a moral principle precluding "embryo destruction", which was endorsed only by a single minority view in the EGE's Opinion.[339] Arguably, reliance on a minority opinion could only be justified in exceptional circumstances where there is other overwhelming evidence that the majority view is fundamentally flawed and misrepresents the consensus of moral opinion on the particular subject matter in Europe. However, as was argued in Part I of this Report, there is no legal basis for the view that there is a moral consensus in Europe on the prohibition of uses of technology on the human embryo *in vitro* which necessarily result in "embryo destruction", particularly in the light of other provisions in the Directive.

Among such other important provisions in the Recitals are most notably the reference to the Treaty of the EU, under whose umbrella the Directive was adopted, the EHCR and the constitutional traditions common to the Member States (Recital 43). The implications of this reference to the EU Treaty and ECHR for the interpretation of the scope of the exclusion of "uses of the human embryo" from patentability have been discussed in detail above in Chapters four and five of this Report. We have suggested that under the terms of the Treaty and the Convention, as interpreted by the ECJ and ECrtHR respectively, considerable flexibility is required in the interpretation of the general moral exclusion clause, and considerable caution is also required on the interpretation of the scope of exclusion of the specific exceptions in ascertaining the moral consensus which prompted the inclusion of the specific exceptions in the list.[340]

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[339] Decision of the OD of 21st July 2003 on European patent No. EP0695351 (*University of Edinburgh*), at pp. 21-23.

[340] From an EU law point of view, we have also demonstrated that in such cases where there is no common or commonly defined concept EU law has used the concept of a referral back to national law and standards in order to give meaning to a term used in EU legal provisions. It is submitted that this may also be the way forward when it comes to the concept of morality when one needs to apply it to the issue of the patentability of stem cell related inventions.

7.4 The Practice of National Patent Offices

Article 31.3(b) of the Vienna Convention states that "any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation" shall also be taken into account when interpreting ambiguous treaty provisions. The EPO must also therefore take due account of the practice of EPC signatory states that indicate their understanding of the scope of the exclusion of patentability of industrial or commercial uses of the human embryo when interpreting the EPC provisions.

As of June 2006, the UK patent office has issued at least fourteen patents that are directed to or at least make explicit reference to hESC.[341] In addition to the UK, the Swedish[342] and German[343] patent offices have each issued one hESC-related patent. As was noted in Chapter two, the patents which have been granted at national level have either been granted on the basis that they were in accordance with an express policy on the applicability to hESC-related inventions of the exemptions in the Directive (UK), or simply because the national patent offices involved have adopted different interpretations from the EPO on Rule 23d(c).

It is suggested that the UK Patent Office's narrow construction of the Article 6(2)(c) exclusion to patentability under the Directive, as well as other countries' less restrictive attitudes to the patenting of biotechnology inventions, and in this context especially pluripotent related hESC inventions, should be taken into account by the EPO Boards when considering the proper scope and meaning of the Rule 23d(c) exemption to patentability.

Of additional significance here, as was pointed out earlier, is the fact that Member States, within the European Union, have divided competence with the Union's authorities to harmonise

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[341] Twenty-eight applications were found that relate to human embryonic stem cells, of which fourteen have been granted. Two applications were filed directly at the UK Patent Office. The remainder derives from PCT filings.

[342] The current *WARF* application in relation to hESC-related inventions is a case in point. The patent on a method for differentiation of hESC cells into hematopoetic cells was granted, for example, in Sweden as Swedish patent No. SE 526490 (US prioriy: 1999-11-08 09/435578). When granting this patent the subject whether such claims complied with Swedish Patents Act, Section 1.c.3. (e.g. the implementation of directive 98/44/EC Article 6(2)(c) was considered. The conclusion was that it did, for the following reason: "To produce human embryonic stem cells human embryos are required. However, the present method does not require that the stem cells need to be produced from embryos as a consequence of the invention, since the method can be performed using already existing (deposited) stem cells." (Citation from a communication with the responcible officer.) Thus, the Swedish view was that the commercial exploitation of this method does not need the use of a human embryo-the stem cells may have been isolated e.g. for legitimate research purposes, long before the invention was made. The object of the provisions in *e.g.* Article 6(2)(c) was to avoid a repetitive use of the humans or parts of humans such as embryos, thus leading to an instrumentation of humans/embryos. This invention is not directly linked to the use of an embryo and moreover does not repeatedly need human embryos. Accordingly the Swedish concept of morality did not hinder the grant of the patent.

[343] DE 10136702 B4: "System zur zell- und entwicklungsspezifischen Selektion differenzierender embryonaler Stammzellen, adulter Stammzellen und embryonaler Keimbahnzellen".

legislation in certain areas with the aim of establishing the Internal Market. Member States have an obligation arising from a directive to achieve the result envisaged by the directive and their duty under Article 10 EC to take all appropriate measures, whether general or particular, to ensure the fulfilment of that obligation. This is binding on all the authorities of Member States including, for matters within their jurisdiction, the courts.[344]

It is therefore suggested, that in relation to the determination of the scope of the moral exemptions falling within the field of application of the Directive, the EPO's has to weigh appropriately the interpretation adopted by national patent offices, as reflecting the competence of national member states to interpret the Directive under EU law.

7.5 TBA's Methodology on the Construction of Moral Exclusions

The methodological approach adopted by the TBA in its decision in the *Oncomouse* case (T315/03) is, arguably, consistent with the ECJ's analysis of the construction of Articles 6(1) and 6(2) in the Directive.

Having outlined the general methodology in the *Oncomouse* case, the TBA further considered the nature of the tests to be applied for the construction of the morality clauses imported from the Directive and the precise nature of the test to be applied under Article 53(a) EPC as compared to the test to be applied to the specific inventions excluded in the list of in Rules 23d(a) to (d) EPC.[345] The TBA held that:

> "[I]f a case falls within one of the four categories of exceptions set out in Rule 23d EPC… then it must *ipso facto* be denied a patent under Article 53(a) EPC. However, cases not falling within the limited exclusions of Rule 23d EPC….must then be considered under Article 53(a) EPC. There are thus in effect two quite different Article 53(a) EPC objections – on the one hand, a "Rule 23d-type" Article 53(a) objection which requires only that the invention is assessed as to whether or not it falls in one of the four limited categories set out in the Rule and, on the other hand, a "real" Article 53(a) objection which requires an assessment as to whether or not exploitation of the invention in question would be contrary to morality or "ordre public".[346]

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[344] Case 14/83 *Von Colson and Kamann v. Land Nordrhein Westfalen* [1984] ECR 1891, at para. 26.
[345] O.J.E.P.O. 2005, 246. Full text availablehttp://legal.european-patent-office.org/dg3/pdf/t030315ex1.pdf.
[346] T 315/03, Headnote II and 10.1 Reasons for the Decision. The Board further states that: "Thus, in cases falling within it, Rule 23d(d) EPC inserts an objection under Article 53(a) EPC (a "Rule 23(d) type" Article 53(a) EPC objection) which, depending on the outcome of the test, may be either additional or alternative to an objection under Article 53(a) EPC itself (a "real" Article 53(a) EPC objection) as developed by the case law."

The suggested two tests – the general and the specific – are "quite different" in that whilst a "technical" or "definitional" test is to be applied to the list of specific exclusions, a "real" moral test is to be applied under Article 53(a) EPC. Although the TBA did not expand on the reasoning behind such a "dual" test approach, there seems to be a convergence with the ECJ's analysis of the corresponding provisions of the Directive. As mentioned in Part I, in the *Italy* case, the ECJ ruled that because there was a consensus in Europe that patenting of the listed inventions was contrary to morality, member states had no margin of discretion over the implementation of the specific exclusions in domestic law. We suggested that the logical implication of this analysis is that the list of exclusions should be read primarily as excluded patentable subject matter, the test for which is primarily a technical/definitional test. The same conclusion would seem to logically flow from the dual methodological approach advocated by the TBA.

Furthermore, the suggestion that the "real" moral test falls to be applied primarily under Article 53(a) cannot be construed as an evasion of the moral considerations which led to the insertion of the specific list of exclusions. This is because the moral considerations behind the specific exclusions may still be relevant to the determination of the excluded subject matter. For instance and as pointed out in Part I, in relation to 23d(c) the purpose of excluding only 'industrial' or 'commercial' uses of human embryos reflected the limits of the moral consensus on uses of human embryos in Europe. But in addition, in the (second) *Oncomouse* case (T 315/03) the TBA also held that whilst applications which may fall under 23d(c) should in the first instance be considered under that provision, in the event that the application should be found not to be caught by Rule 23d(c), the application must then be considered under Article 53(a).[347] In short, following the suggested analysis in Part I, just because a particular application does not involve direct uses of human embryos as a raw material in a repetitive technical process, it does not follow that the application may not be excluded from patentability under the general moral test in Article 53(a).

[347] *Ibid.*

7.6 Implications for the *Edinburgh* and *WARF* Cases: Rule 23d(c)

Two consequences would seem to flow from this proposed methodology. On the one hand the "human embryo destruction" test is undoubtedly a "real" moral test, and as such logically falls primarily to be applied under Article 53(a). On the other hand, to the extent that moral considerations may still conceivably play a "background" role in helping clarify the scope of exclusion of specific provisions, such as Rule 23d(c), the relevant moral principle(s) to be applied here cannot be the principle of "embryo destruction," since as was seen in Part I, there is no moral consensus in Europe precluding uses of human embryos which necessarily involve what can be called "embryo destruction".

It follows from this analysis that, to the extent that both the decision of the OD in the *Edinburgh* case as well as the pending *WARF* case rely on the moral principle of "embryo destruction" to disambiguate 23d(c) both are questionable in:

a) failing to advert to the precise terms in which the exclusion is drafted, most notably the qualifications that the prohibited uses related to 'industrial' or 'commercial' uses; and:

b) in applying an unqualified moral norm precluding embryo destruction on which there is no moral consensus in Europe and for which there is no legal basis.

Instead, as argued in Part I, the moral purpose of the provision is to preclude instrumentalisation of the human embryo through direct use of the embryo as a raw material in a repetitive (technical) process or alternatively, embryo commodification through trade of human embryos involving monetary exchanges.

7.7 The Relevance of the Term 'Uses'

In the *Edinburgh* case, the OD held that in order for Rule 23d(c) to be read as having a purpose exceeding the one in Rule 23e(1)[348] EPC, Rule 23d(c) had to be interpreted broadly to encompass:

> "not only the industrial or commercial use of human embryos but also the human ES cells retrieved therefrom by destruction of human embryos."

[348] Rule 23e: "The human body and its elements
(1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. […]"

The OD reasoned that a narrow interpretation of Rule 23d(c) would render Rule 23e(1) redundant. However, as the analysis in Part I of this Report suggests, a narrow interpretation of Rule 23d(d) does not have the effect of collapsing the two provisions into one. The purpose behind the insertion of the two provisions, whilst related, is distinct. Whilst Rule 23e(1) was intended to preclude patents on human embryos and totipotent cells *per se*, the aim of Rule 23d(c), as expressly stated in the Common Position, was to preclude only *certain uses* of human embryos.[349] Thus, the term 'uses', far from being irrelevant as suggested by the OD, was specifically intended to direct the application of the test in 23d(c) to inventions - other than the embryo itself (or totipotent cells)- which involve using the human embryo directly in a specific manner, viz. for industrial or commercial purposes. Hence, the narrow interpretation suggested in Part I, not only preserves the distinct purpose behind the two exceptions, but it also avoids the exception to the general rule that exemptions have to be construed narrowly, which is created by the 'broad' interpretation proposed by the OD.[350]

Thus, the decision by the OD in the *Edinburgh* case takes little account of the specific wording of the text in the Directive, or the wider legislative context and intent of the legislators in inserting the specific provisions in the list.

The related *WARF* case,[351] which is pending by the EBA, concerns claims to primate embryonic stem cells. The questions in the referral include the following:

– Does Rule 23d(c) EPC forbids the patenting of claims directed to products (here: hESC cultures) which – as described in the application – at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?

– If the answer to the question above is no, does Article 53(a) EPC forbid patenting such claims?[352]

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[349] Common Position (EC) No. 19/98 adopted by the Council on 26 February 1998 with a view to adopting Directive 98/.../EC of the European Parliament and of the Council on the legal protection of biotechnological inventions. OJ C 110/17 of 8.4.1998.
[350] See T 320/87, O.J.E.P.O. 1990, 76, Reasons for the Decision, item 6, and T 19/90, O.J.E.P.O. 1990, 486. See also Bostyn, S., 'DNA Patents in Europe: Controversy Remains, in The Ethics of Patenting Human Genes and Stem Cells', Conference Report, Copenhagen 28 September 2004, www.etiskraad.dk (2005-05-05), p. 43.
[351] T 1374/04 concerning patent application No. 96 903 521.1 published as WO 96/22362 (EP Nr. 0 770 125) with the title "Primate embryonic stem cells".
[352] In the *WARF* referral (T 1374/04), the EBA has been asked to consider the following questions: "(1) Does Rule 23d(c) EPC apply to an application filed before the entry into force of that rule? (2) If the answer to question 1 is yes, does Rule 23d(c) EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which – as described in the

As noted earlier, the TBA's referral in the *WARF* case follows the methodological approach outlined by the TBA in the (second) *Oncomouse* case, whereby patent examiners have to consider in the first instance whether the application falls under the list of specific exemptions, and in the event that it does not, then consider whether patenting is precluded under the general moral test in Article 53(a).

In the light of the analysis in Part I of this Report, which discussed the scope of exclusion of Article 6(2)(c) based on the Directive's text and legislative intent, it is suggested that Rule 23d(c) should be interpreted in the same way. Of particular significance here is the methodology outlined by the TBA, which requires specific weight to be attached to legislative intent.[353] Indeed, the TBA's detailed and specific rebuttal of the applicant's contention that the distinction between Rule 23e(1) and Rule 23d(c) concerns the category of the claim relies on a review of the Preparatory Works for the Directive which largely retraces the steps and analysis followed in Part I, but it leaves to the EBA the task of considering the legal constraints relevant to the interpretation of moral exclusion clauses in a piece of Community legislation.

The analysis of the moral exclusion clauses in Part I of this Report is also consistent with the TBA's view that the purpose of the EU legislator when drafting Articles 5(1) and 6(2)(c), the equivalents to Rule 23e(1) and 23d(c) respectively, was not to insert prohibitions with a view to strictly reflecting patent law categories of 'product/process' claims.[354] Instead, as the TBA suggests, the inclusion of the specific exceptions was driven by ethical concerns resulting in the political compromise wording of the text. In the TBA's view, legislative history shows that the wording of 6(2)(c) was a political compromise, not determined by patent categories but "whose aim was to safeguard that technologies making use of human embryos for a purpose that was regarded as being ethically unacceptable".[355] Thus, the aim of the EU legislator was to "define the essence" of the inventions which it had been agreed, should not be morally patentable.[356]

It is suggested that these considerations, together with the detailed analysis of the moral and legal considerations which formed the background to the exclusions, lead to the narrow

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application – at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims? (3) If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims? (4) In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: *e.g.* derivation from available human embryonic cell lines)?"

[353] *Cf.* T 1374/04 (*Wisconsin Alumni Research Foundation, WARF*), referral by the Technical Board of Appeal to the Enlarged Board of Appeal, case pending under Ref. No. G 2/06, see O.J.E.P.O. 2006, p. 393.

[354] *Ibid*., at para. 42.

[355] *Ibid*., at para. 46.

[356], *Ibid.,* at para. 42.

interpretation of 23d(c) outlined in Part I, which in turn avoids the need to create an exception to the general principle that exemptions have to be construed narrowly.[357]

The principle that exemptions have to be construed narrowly in turn flows from a more fundamental principle that the wording of (Article 52(1), 54 to 57 EPC), which states that inventions shall be patentable if they fulfil the three basic criteria – novelty, inventive step and industrial application, creates a presumption in favour of patentability.[358] Although the EBA has held that there may be exceptions to the principle that exemptions have to be construed narrowly,[359] a departure from the normal rule would have to be justified by reference to "the wording, the object and purpose of the provision, the interests involved, the consequences of a narrow or broad interpretation, respectively, and the aspect of legal certainty."[360] As with the manner of legislation, so the *scope of legislation* is entirely a matter for the legislator.[361] The analysis in Part I shows that a broad interpretation of 23d(c) cannot be sustained on this basis.

7.8 The General Moral Exclusion: Article 53(a)

As pointed out earlier, following the methodology advocated by the TBA in both the (second) *Oncomouse* case and the TBA referral of the *WARF* case to the EBA, after having considered whether the application is within the scope of Rule 23d(c) if the patent examiners determine that the answer is 'no' the question may still arise whether the application should be refused on the grounds that it is generally contrary to 'ordre public' or 'morality', as *per* Article 53(a).

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[357] *E.g.* T 320/87, O.J.E.P.O. 1990, 71; T 19/90, O.J.E.P.O. 1990, 476; T 356/93, O.J.E.P.O. 1995, 545.

[358] T 315/03 (*Oncomouse II*) O.J.E.P.O 2005, (p. 30: "the word "shall" in the relevant sections of the EPC clearly indicates, there is a *prima facie presumption in favour of patentability*").

[359] G 1/04 (*Diagnostic Methods*) (to be published in the O.J.E.P.O.), at para. 33.

[360] In the earlier *PGS* decision G 1/98 (see *supra* Chapter six), which concerned the scope of the exclusion of plant varieties from patentability under Article 53(b) EPC, there is not even a mention of the said principle but the EBA arrived at its "narrow" construction of Article 53(b) EPC after having analysed the meaning of the terms used in it, its legislative context, in particular its historical background and the object and purpose of the provision.

[361] See the (second) *Oncomouse* case (T 315/03), at 3.308. pp. 43-44. The TBA has given more specific guidance on the methodology for construction of the Rule 23d exemptions to patentability The Board gives two statements. First, Article 53(a) EPC contains nothing which precludes or limits its own subsequent interpretation whether by case law (as in T 19/90) or by legislation (as in Rule 23d EPC). With regards to the Rule 23d(d) EPC exemption, the respondents argued that Rule 23d(d) EPC broadens the exclusion in Article 53(a) EPC contrary to the principle of narrow construction of exclusions and thus inventions which might have satisfied the T 19/90 test in the (first) *Oncomouse* case may now fail the Rule 23d(d) test. In the Board's opinion, it is only correct to say the Rule broadens the Article 53(a) EPC exclusion in as much as the Rule now specifies four limited categories of inventions which are deemed to fall within that Article. However, since it is unimaginable that cases within those four categories would not always have been considered under Article 53(a) EPC, it would be incorrect to say that the new Rule broadens the law as regards the exclusion of such cases. If a case falls within one of the four specific categories, then it must be without more be refused a patent; if it does not fall within one of those categories, it must be considered under the law as it stood prior to the new Rules. That position is no more contrary to any principle than it is *ultra vires.* It would therefore appear that questions concerning the meaning and scope of application of Rule 23d(c) EPC will be resolved through determination of the scope of the legislation that was intended by the legislator.

Thus, where the subject matter falls within one of the categories listed in Rule 23d(a) to (d), patentability is excluded and there is no more need to consider Article 53(a) further. However, a case not falling within one of those categories in Rule 23d(a) to (d) must be considered further under Article 53(a) EPC.[362]

The relationship between the two tests is explained in the following way:

> *"*As regards cases such as the present which fall within Rule 23d(d) EPC, the effect of this interpretation is to insert a test which, depending on the facts and thus on the outcome of the test, may be either additional or alternative to that previously established by the case law."[363]

7.9 '*Ordre Public*' and Morality

The case law of the EPO clearly states that 'ordre public' and 'morality' are two distinct tests.[364] On the concept of "*ordre public*" the Board held that:

> It is generally accepted that the concept of "*ordre public*" covers the protection of public security and the physical integrity of individuals as part of society. This concept encompasses also the protection of the environment."[365]

The Board concluded the following about the inventions caught by Article 53(a):

> "[U]nder Article 53(a) EPC, inventions the exploitation of which it is likely to breach public peace or social order (for example, through acts of terrorism) or to seriously prejudice the environment are to be excluded from patentability as being contrary to 'ordre public'."[366]

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[362] T 315/03 *ibid*.
[363] T 315/03, at para. 7.7, Reasons for the Decision.
[364] In the (first) *Oncomouse* case (T 19/90) of 3rd October 1990, the Board of Appeal held that Article 53(b) EPC applies to certain categories of animals but not to animals as such, and that in the absence of serious doubts substantiated by verifiable facts, there was no reason to refuse the application under Article 83 EPC on the ground that it involved an extrapolation from mice in particular to mammals in general, with claims directed at a transgenic non-human mammalian animal containing an activated oncogene in its cells. Before the expiry of the opposition period, no less than 17 oppositions were filed against the patent alleging almost any available ground for opposition. The opponents' objections were rejected except those on moral grounds under Article 53(a) EPC. The EPO's OD found that the claims directed to non-human mammalian animals could not be allowed under that Article and maintained the patent in an amended form with narrower claims directed to rodents. Six of the opponents lodged an appeal against that decision and the Board finally decided this appeal in the (second) *Oncomouse* case (T 315/03) on 6th July 2004.
[365] T 356/93 (Plant Genetics Systems, PGS), p. 4, Reasons for the Decision.
[366] *Ibid.*

In general, as to its contents the concept of *ordre public* does not seem problematic. It is quite clear what the concept embraces. However, when it comes to 'morality' the EPO's case law is much less clear on the relevant applicable standards.

Having scrutinised the history of the two concepts in the documentation of the EPC Working Party, the TBA noted in 356/93 (*PGS*)[367] that that "there was no European definition of morality". According to these Preparatory Works:

> "the interpretation of the concept of morality should be a matter for European institutions", and the same applied to the concept of "*ordre public*".[368]

In the second *Oncomouse case* (T 315(/03) the TBA upheld the test applied in the *PGS case*, whereby:

> "The concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in European society and civilisation."[369]

The TBA further stated that:

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[367] See T 356/93 (Plant Genetics Systems, PGS), where the object of the invention was plants and seeds resistant to a particular class of herbicides so that they could be selectively protected against weeds and fungal diseases. This was achieved by stably integrating into the genome of the plants a heterologous DNA encoding a protein capable of inactivating or neutralising the herbicides. The patent was opposed under Article 53(a) EPC, in particular on the grounds that the exploitation of the invention was likely to cause serious damage to the environment.

[368] *Ibid.* p.4-5, Reasons for the Decision (with further reference to document IV/2767/61-E, p. 7-8):
"As is apparent from the historical documentation, the EPC Working Party recognised that "there was no European definition of morality". Its members were, therefore, unanimously of the opinion that the "interpretation of the concept of morality should be a matter for European institutions" (*cf.* document IV/2767/61-E, page 7), and the same applies to the concept of "ordre public" (p. 8). Thus, prior to any assessment of the patentability of the claimed subject-matter under Article 53(a) EPC, the meaning of these concepts must be defined by way of interpretation."

[369], T 356/93 (Plant Genetics Systems, PGS), p. 6, Reasons for the Decision.

> "[U]nder Article 53(a) EPC, inventions the exploitation of which is *not* in conformity with the conventionally-accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality."[370]

Even though it would seem to follow from this 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, the EPO's case law also indicates that there is some unclarity as to how the existence of such European wide standards or norms is to be ascertained under the EPC system.

7.10 Determination of European norms

As the OD noted in the *Edinburgh* case, the TBA also held in the *PGS*' case that, even where a uniform standard for all contracting states exists, this would not automatically be a criterion for the purposes of examination under Article 53(a).[371] This then raises the question of which other evidence the EPO is to rely upon to identify the applicable moral standards. As seen below, the case law is of limited assistance in that it emphasises the kind of considerations which will *not* necessarily establish the existence of a European wide norm, as against the type of evidence which would.

For instance, the TBA has held that religious or economic considerations would not necessarily constitute adequate evidence unless they represented an accepted European standard:

> "The many bases (economic, religious, etc) for definitions of morality suggested by the appellants are of no assistance since no single such basis represents an accepted standard in European culture."[372]

Neither would opinion polls:

"Opinion poll evidence is of very limited value for the reasons given in
T 356/93."373

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[370] *Ibid*.
[371] Decision of the OD of 21st July 2003 on European patent No. EP0695351 (*University of Edinburgh*), at 2.5.3.
[372] T 315/03 (*Oncomouse II*) O.J.E.P.O 2005, at 10.10, Reasons for the Decision.
[373] *Ibid*.

The conclusion from this case law suggests that 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, it is suggested that as regards the relevant standards to be applied under the provisions imported from the Directive, the EPO is obliged under its own rules 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.

7.11 Implications

In circumstances such as those described by the OD in the *Edinburgh* case, where there are no European wide moral standard or conventionally accepted norms, the question arises of what the implications are for the EPO. This question is not a totally new one. The conclusion of our analysis is that, in the absence of a consensus on the morality of a particular invention, the jurisprudence of the ECrtHR, as well as the ECJ, point to the need for a margin of discretion to be granted to Member States to determine the scope of the moral exclusions to be implemented so as to reflect national moral traditions and cultures.

The question as to the jurisdiction of the EPO in interpreting the morality exceptions in the EPC in the event of a divergence in national moral cultures, has been discussed prior to the Directive, both in legal doctrine and in the practice of the EPC. There are a number of possible alternatives,[374] such as: the patent should be refused; the patent should be granted only for the Member States which do not consider the publication or exploitation of the invention to be contrary to morality; the patent should be granted for all Member States; or intermediary solutions where the applicant should be informed that the patent may be invalidated in a number of States and, thus, should have the free choice to withdraw designations of those States.

Initially, this was a purely theoretical discussion started by Bossung in 1974[375] and continued by van Empel ten years later.[376] But with the growth of biotechnology and the related, inventions and their patenting, the issues have become not only more complicated but also of great practical importance. Whilst, as shown earlier in this Report, and not least above in this

[374] Of which all are not coherent with the present structure of the EPC.
[375] See 'Erfindung und Patentierbarkeit im europäischen Patentrecht', *Mitt.* 1974, 101 ff., at 123 as quoted by Straus, J. in: 'Ethische, rechtliche und wirtschaftliche Probleme des Patent- und Sortenschutzes für die biotechnologische Tierzüchtung und Tierproduktion*, GRUR Int.* 1990, p. 913 ff, at 918 f.
[376] See van Empel, M.,*'The Granting of European Patents'* (Leyden: A.W. Sijthoff, 1975), 69, item 128. Along similar lines Dolder, F., 'Schranken der Patentierbarkeit biotechnische Erfindungen nach dem Europäischen Patentübereinkommen*'*, *Mitt*., 1984, 1 ff., 2, quoted after Straus*, supra*., 919.

Chapter with illustrations from EPO case law,[377] whilst there is little doubt on what constitutes *ordre public*, the question of how to identify European morality is a much more difficult matter. Hitherto, the EPO case law has primarily led to a discussion on morality exceptions in the context of plant- and animal-related biotech patenting.[378] The discussion shows that although the problem had rarely been defined as a conflict of jurisdictions and decision-making competences, there had been awareness about the distinction between the content of morality and *ordre public* and the question as to whose morality and *ordre public* should be of relevance and who should decide on the latter. Indeed, the views expressed in the literature have varied.

The object of the EPC is to introduce a uniform examination and granting procedure. Thus, in Bossung's view the concepts *ordre public* and morality (in German "gute Sitten") could only be interpreted as common European concepts, since otherwise the patenting would depend on the choice of designated States in the application and would contravene the main tenets of the European patent system.[379] In a similar vein, Moufang finds possible support for a unitary European standard in the ECHR, which lays down the right to life and a prohibition of treatment that violates human dignity.[380]

van Empel in turn, has argued that the philosophy of the EPC, implies that the exceptions refer, if not to common then at least, to *fairly widely* shared perceptions.[381] At the same time he points to safeguards available to Member States with stricter views on morality in the form of "the possibility of having the patent revoked by a national court with effect for that particular State."[382] According to van Empel, the EPC thus enables Contracting States to maintain their own moral traditions and standards in this field, as for instance, on contraceptives.

Straus argues along similar lines in regard to the existence of procedures within the EPC's to safeguard respect for the sovereignty of the Contracting States and their right to uphold their own moral traditions and cultures. . But he reverses the perspective. In his view, the acceptability of an invention in even one Contracting country would constitute evidence of absence of a European wide morality and *ordre public*. On this ground he considers that the patent should be granted when the invention is morally acceptable to at least one Member State.

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[377] Especially the *Oncomouse* cases (T 315/03, OD V 6/92 and T19/90),and the *PGS* case (T 356/93), OD European Patent No. EP87400141).
[378] See especially Straus, *supra* 918 f. and *cf.* Rogge, R., 'Patente auf genetische Informationen im Lichte der öffentlichen Ordnung und der guten Sitten', *GRUR* 1990, p. 303 ff.
[379] See Bossung, *supra ibid.*.
[380] Moufang, R., 'Patenting of Human Genes, Cells and Parts of the Body? – the Ethical Dimension of Patent Law', [1994]*IIC*, p. 487 ff., at 503.
[381] van Empel *supra ibid.* Along similar lines Dolder, *supra ibid.*
[382] van Empel, *supra*, at, 68.

This, according to Straus, would be the only solution which could do justice to the objective of the European Patent system and its original design.[383] This would also, in his view, lie in the interest of EPO, as patent applicants otherwise would chose the national route for what could be morality sensitive inventions.[384] It could be added that Schatz's view is no different, but Schatz finds that the difficulties involved with a European wide approach must still be acknowledged.[385]

More importantly, the granting of a unitary patent by the EPO opens the possibility of national revocation proceedings in EU Member States which in turn open an avenue for seeking guidance from the ECJ, and may provide the Luxembourg Court with the possibility of controlling the margin of discretion exercised by Member States in respect to the morality exception from biotechnology patenting. The revocation takes effect "under the law of the Contracting State" (Article 138).[386] If that State is an EU Member State, it is also bound by Community law and notably by the Directive and the morality exceptions in the Directive. This can provide a possible route to bring matters to a head and to achieve some legal certainty with the involvement of the ECJ in questions of interpretation of the morality exception as applied by EU Member States.

Considerations on the EPO's Application of Article 53(a) EPC

In the *Edinburgh* case, having reviewed national legislation to hESC and found that there was no uniform standard, or conventionally held standards of morality, the OD held that another approach had to be taken.[387] As acknowledged in the OD decision, there is no uniform approach with regard to hESC, either reflected in legislation or in other conventionally accepted

[383] *Supra* at 919. The applicant should, however, be duly warned against the existing national objections and the risk of his patent been invalidated in national proceedings.
[384] *Ibid*.
[385] These difficulties prompted Ulrich Schatz to search for compromise solution. Inspired by Straus, in his view if an invention is contrary to *ordre public* or morality prevailing in only one or a part of the designated States, the applicant may, on his own initiative or following a corresponding ruling of the examination division, withdraw the designation of the States in question while maintaining it for the others. In this way he acquires protection in the other States. If, however, the applicant does not make use of that opportunity, the expansive position should obtain and the application must be refused as a whole, see Schatz, U. in: Singer M. and Stauder, D. *The European Patent Convent. A Commentary*, Volume 1 (Carl Heymanns Verlag: Cologne 2003), Section. 22, p. 91.
[386] The post-grand life of a European patent is in principle goverend by national law. See Article 2(2) EPC "The European patent shall in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that State". This is the reason why Ullrich calls the concept "European patent" a misnomer, see Ullrich, H. 'Patent Protection in Europe: Integrating Europe into the Community or the Community into Europe?', *EUI LAW 2002/05,* p. 10 (= *ELJl* 2002 pp. 433 ff.), *cf.* van Empel, *supra at 69*.
[387] Decision of the OD of 21 July 2003 on European patent No. EP0695351 (*University of Edinburgh*), Reasons for the desision at 2.5.3.

standards of conduct in European culture. In the absence of common standards the OD has, as discussed earlier in this Report, tried to interpret the incorporated rules with the help of textual analysis, discussing but discarding the opinion of the EGE. Yet it appears, that the OD has not avoided the knotty dilemma of choosing between divergent perceptions of morality altogether. The turn by the OD to an overly restrictive interpretation of the morality exemption may not be so surprising. Being ill equipped to judge questions of morality and having no guidance in judicial precedent, the safer position for the EPO's experts may have been to try to satisfy even the strictest moral views. Alternatively, the decision can be read as an attempt to induce a more categorical answer by the TBA on a soaring issue of controversy.[388] But as shown above, the EPO's approach has no legal basis.

We have suggested that in practice, the stance adopted by national patent offices in the application of Article 6(1) to hESC-related patent applications will likely reflect local standards in the individual Member States.' Different considerations, however, pertain to the application of the general morality prohibition of Article 53(a) EPC[389] in the EPO context, due to the fact that unlike the situation for the national patent offices of individual Member States, there is no uniform European concept or standard of morality that EPO patent examiners can look to under Article 53(a) in order to fill in the concept of *ordre public* or morality. In effect and as shown in earlier in this Report and the Appendices, EPO examiners look out to a patchwork of moral perspectives in Europe, particularly reflected in the widespread differences in the regulatory criteria for research on human embryos.

It should then be born in mind that whilst the lack of European wide moral norms may be evidenced by one Member State being in opposition to the majority view, evidence of a European wide morality norm could not be based solely on the perspectives of one, two, or indeed several Member States. States have sovereignty in their own territory over these questions and the decision on morality outside a common kernel must be respected on a national basis. There is only in the enumerated cases of 6(2)(a) to (c) and 23d(a) to (c) that there is clear evidence of a European wide moral consensus on the unpatentability of certain inventions regarding human embryos, subject to the qualifications noted in Chapter five of this report on the need to defer to national traditions and cultures where doubt remains on definitional questions such as the term 'human embryo' ,

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[388] See Laurie, G., Patenting Stem Cells of Human Origin, [2004]*EIPR*, p. 59; and *cf.* http://ipgenethics.group.shef.ac.uk/conference/papers/Laurie.pdf

[389] Contained in Article 6(1) of the Directive.

The respect for national moral traditions and culture is further present within the EU legal system. In the absence of a European consensus on the relevant moral norms amongst Member States of the EU, the applicable norms can only be determined under each national jurisdiction. Neither the fundamental treaties of the European Union nor the draft Constitution provide that the Member States have placed this fundamental competence at the disposal of the European Union.[390]

The determination of moral norms is done outside patent law, and in a European Human Rights context. European and national laws are founded on the values established in human rights principles most notably the rights protected under the ECHR. Such rights are fundamental and must guide the European as well as the national legislator. This obligation is recognised by the EU Member State in the Directive itself, as well as by the ECJ in its interpretation of the same legal text. So, in the absence of a consensus, Article 53(a), which is similar to Article 6 of the Directive, has to be interpreted so as allow a wide margin of discretion to Member States to implement restrictions in a way that reflects national constitutional values and moral traditions. For the alternative, to grant the patents selectively to match the liberal or restrictive morality views, there is presently hardly any basis in the EPC.[391]

The Scope of the Rule 23d(c) EPC Exclusion

It has been suggested that the construction of Rule 23d should be based primarily on a "technical test" whereby the invention is excluded if it falls within the definition of listed unpatentable subject- matter. Where the claimed invention falls clearly within the definition of the listed exclusion, the patent *ipso facto* must be refused Where the claimed invention does not fall within the scope of definition of the listed exception, the claim must be considered under Article 53(a) EPC and the exclusion based on a European wide norm.

In general, it is suggested that if the EPO takes proper account of the broader EU legal framework within which the EPC now has to operate as a result of the transposition of the Directive as a supplementary means of interpretation, the same conclusions discussed in Chapter five regarding the interpretation of Rule 23d(c) EPC will be reached. This would mean that patents that directly claim repetitive use of the human embryo as a raw material in a

[390] The patenting of biotechnological inventions involving the use of biological material of human origin, Opinion of the 'Ethikrat'/German National Ethics Council of 6th October, 2004, availablein English at http://www.ethikrat.org/_english/publications/opinions.html (2006-04-04).

[391] This would obviously require decisions of the Administrative Council of the Organisation to amend the EPC or to insert special rules that open the possiility for Member States exclude certain areas of patentability from the European framework.

mechanical, chemical or technical process would be excluded from patentability. This would have the effect of rendering processes for extracting hESC from a human embryo non-patentable, whilst pluripotent cells as products and methods relating to their use would fall outside the scope of Rule 23d.(c), and instead be evaluated by the EPO under the general patent morality exemption contained within Article 53(a) EPC.

The practice of the EPO on the questions that have been described in this Chapter and also in other parts of this Report, shows that the further development of the EPC system on these issues is of great importance to (the majority of) patent applicants in the Member States of the EU that make use of the EPC. EPO case law so far does not seem to have created any major problems as it has been generally cautious in applying only European wide standards to the morality exclusions, as well as a narrow approach. This approach is most consistent with the need to take account of the divergent attitudes among Member States, particularly in relation to the morally sensitive field of human embryonic stem cells related inventions. Another approach would most probably also force applicants down the national route in order to secure patent protection in those parts of Europe where such patents comply with the moral cultures of individual Member States.[392] It must also be emphasised that in the fast moving field of biotechnological inventions, moral norms and societal views are changing with increasing knowledge of the potential for therapeutic applications of hESC inventions.[393]

Thus, it is submitted that where, as noted by the OD in the *Edinburgh* case,[394] the evaluation of the national legislation or the assessment of the conventionally accepted standards of conduct of European culture fail to disclose a uniform standard of morality in regard to hESC, there is no legal basis in the Directive for a "different approach" of the kind adopted in the *Edinburgh* case, where the identified moral norm bears no relation to fundamental principles of EU law and European Human Rights law.

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[392] The legal reality under the EU legal system is that Member States are given considerable flexibility in the interpretation of the general exclusion clause and also arguably some residual flexibility in the interpretation of the scope of exclusion of the listed exceptions. This will remain the case, whatever approach the EPO chooses to take, so that in the event of the EPO persisting in its broad construction of the exclusions, the legal effect will be to pave the way for a consolidation of the existing fragmentation in Europe. This means in effect the end of European Patents on hESCs, and a reversion to national systems in this area is presumably not to Europe's advantage.

[393] A recent study, Eurobarometer 64.3, May 2006, shows that although the majority of Europeans are not very or at all familiar with stem cell research, expectations are high p. 30 ff. Admittedly, there are substantial variations in levels of approval and disapproval across Europe, but even so the general acceptance of hESC research of 59 per cent. Interestingly the countries where the approval is the highest represent both catholic and protestant countries, such as Belgium and Sweden with approvals of over 70 per cent among the population, whilst the figure for Denmark, Netherlands, Czech Republic, Italy, Hungary, Spain and the UK is still more than 60 per cent. The lowest approval, often combined with "don't know" answers, are primarily found in some new Member States, along with Ireland and Portugal.

[394] Decision of the OD of 21st July 2003 on European patent No. EP0695351 (*University of Edinburgh*), at para. 2.5.3.

Chapter Eight:
Issues for the Future:
The Role of the European Group on Ethics

Introduction

The role assigned to the EGE in the Directive may be traced back to the debates in the European Parliament reflecting MEP's concerns that morality may be marginalised in the Directive.[395] Calls from MEPs that a new ethics committee should be created and vested with the power to veto individual patent applications ultimately resulted in a legislative compromise which assigned to the EGE a more limited role.[396] In what turns out to be no more than a factual statement, Article 7 of the Directive states that "The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology." Recital 44 of the Preamble reiterates the same point but adds that it should be pointed out in this connection that the Group may be consulted *only* where biotechnology is to be evaluated at the level of *basic ethical principles*, including where it is consulted on patent law." The addition to the

[395] The Legal Affairs Committee ref. 18/06/97. Article 9a called for the insertion of an article in the Directive providing for the creation of a new ethics committee to 'assess all ethical aspects of biotechnology and its utilisation, in particular with regard to patents'. The Committee's report was issued just days after the European Parliament's debate on a resolution concerning the extension of the mandate of GAEIB, the forerunner of the EGE. The resolution not only called on the Commission to renew and clarify the group's mandate particularly its composition, terms of reference and duties (consulting and reporting back to Parliament) but also considered that 'Parliament should be consulted on the appointment of members of the GAEIB" and called on the Commission to "bring forward proposals to guarantee Parliament's involvement in ethical questions relating to biotechnology' EP B4-0484/97 passed on 13.6.1997. For an insightful institutional analysis of the EGE in the wider context of EC governance, see Salter, B., *Transnational governance and cultural politics: the case of human embryonic stem cells and the European Union's Sixth Framework Programme* (2005).
http://www.york.ac.uk/res/iht/projects/l218252005/SalterTransnationalGovernance.pdf

[396] The modified proposal for the Directive issued by the Commission on 29th August 1997, incorporated 65 of Parliament's 66 recommendations, but did not mention the creation of a new ethics committee. When the Council adopted the Common Position statement on the directive in February 1998, it included Article 7 stating that 'the Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology'. The Council indicated the rationale for this article stating that '…[g]iven that there was a Commission Group of Advisers on the Ethical implications of Biotechnology, and given its terms of reference, the Commission thought it more appropriate to refer to that Group in its amended proposal rather than set up a new committee.' The Council also thought that a new recital should be included stating the EGE should only be consulted 'where biotechnology is to be assessed at the level of basic ethical principles so as to remove all doubt about the possibility of the Group being involved in the procedure for issuing a specific patent.' Council of the European Union, *Common position adopted by the Council with a view to the adoption of Directive ./.../EC of the European Parliament and of the Council on the legal protection of biotechnological inventions,* OJ C 110 of 08.04.1998, p. 17.

Recital was prompted by the Council of Ministers concern to remove all doubt about the possibility of the Group being involved in the procedure for issuing a specific patent.[397]

It is clear that the role ascribed to the EGE is strictly to advise the Commission on ethical questions and the advice is not binding on either the Commission or indeed on any of the potential legal actors involved in the implementation of the Directive at national or supra national level.[398] Thus, whilst the ethical guidance issued in the EGE's Opinions, may potentially carry considerable persuasive weight, the EGE's guidance is not legally binding on national or supra national patent offices and courts. . This includes, most notably the EPO, which stressed precisely this point in the *Edinburgh* case.[399] Secondly, the EGE's role is limited to issuing ethical guidance in respect of *basic* principles and not particular 'inventions' or patent applications. Moral oversight or evaluation of individual patent applications lies outside the competence assigned to the EGE in the Directive.[400] Any future role played by the EGE under the Directive is thus to be understood as limited to publishing new Opinions offering ethical evaluations of biotechnology and its commercialisation , strictly at the level of general and basic principles.

Although not legally binding, it is anticipated that the EGE's Opinions will continue to be a persuasive point of reference in future disputes regarding the morality of biotechnological inventions and their commercialisation.[401] But as the EPO's decision in the *Edinburgh* case shows, the mere fact that the Opinion was issued by the EGE does not guarantee that it will carry the authority and credibility required to persuade those charged with the implementation of the Directive to adopt the professed guidance. Because of the potential persuasive weight of the Opinions of the Group, it is therefore necessary to examine the reasons why Opinion 16 failed to persuade and whether any lessons can be learnt for the future.

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[397] *Ibid.* It has been pointed that the role ascribed to the EGE in the Directive being questionable.and unprecedented in international patent law, see Crespi, S. R., 'Patenting and Etics: A Dubious Connection', *Bio-Science Law Review* (26 February 2003).

[398] Article 2 of mandate: Commission Decision of 11 May 2005 on the renewal of the mandate of the EGE: OJ L 127/12-19 of 20.5.2005 –, http://ec.europa.eu/european_group_ethics/mandate/docs/mandate2005_en.pdf

[399] Decision of the OD of 21st July 2003 on European patent No. EP0695351 (*University of Edinburgh*) See the EPO press release dated 24th July 2002.

[400] The EGE's suggestion in Opinion 16 that the EPO should appoint its own patent ethics committee to oversee compliance of individual patent applications with the morality exemptions stems from an acknowledgement of the institutional limitations of the role assigned to the EGE in the Directive.

[401] Some commentators have even suggested that the EGE's role is comparable to that of a supra-national court: Dubos, O., 'Community Law and Bioethics: Study of Internormativities through the Advices of the European Ethics Group', *International Journal of Bioethics* 2004; Vol. 15 2/3 pp. 101-130. The analysis in this report indicates that this view is misconceived and is based on a blurring of legal and ethical orders.

Opinion 16 failed to persuade for a number of reasons identified by the EPO. These included, *inter alia*;

- Reliance on opaque concepts such as 'closeness to the human body' to justify moral exclusion of certain types of patents.
- Reliance on concepts such as 'modified' or 'unmodified' stem cells which have no counterpart in patent law.
- More generally, failure on the part of the EGE's to advert to the significance of the distinction between hESC and other types of stem cells and the specific restrictions on human *embryonic* stem cells in Article 6 (2)(c).

The criticisms point to some methodological weaknesses in the Opinion, most notably the disjunction between taxonomy in patent law and the categories relied upon in the Opinion, as well as a blurring of legal and ethical principles.

In terms of the specific substance of each of these claims, other parts of the report have already shown that the criticisms carry some force and that the distinctions relied upon were not sufficiently well supported to stand up to critical scrutiny. The more delicate question is whether Opinion 16 is to be judged as a 'one-off' slippage confined to the specific subject matter or whether the quality of the Opinion points to structural problems or fault lines in the working methods/methodology of the Group and/or the terms of appointment and expertise of its members, which may potentially impact on the quality, credibility and authority of future Opinions issued by the Group. As will be seen, questions concerning the type of expertise required of members of ethics committees and the related issue of the methodology followed by these groups have beset similar advisory ethics commissions whether at national and supranational level.[402] To address these questions it is necessary to review briefly the history of the Group and its mandate.

8.1 History of the EGE

[402] There is a fast growing body of critical literature on the conflicts engendered by Bioethics Committees, from the perspective of political science and philosophy. See for instance Schuklenk, U. and Lott, J. P. 'Bioethics and (Public) Policy Advice' in Thiele, F. Et al. (eds.) *Bioethics in a Small World* (Springer 2004) and Cohen,C. B. (ed). 'The President's Council on Bioethics and Approaches to Public Deliberation Taken by National Bioethics Commissions' *Kenndey Institute of Ethics Journal Special Issue:* Vol. 15 No. 3 September 2005..

The creation of an advisory group on European Ethics was prompted by the regulatory challenges faced by the European Community in the wake of the rapid advances in biotechnology and genetic engineering in the late 80s and early 90s.[403] The need for an institutional mechanism to facilitate debate and address public concern on the ethical issues raised by the application of the new biotechnologies was perceived as essential to the adoption of an EU regulatory framework to promote economic investment and competitiveness.[404]

The forerunner of the EGE, was the Group of Advisers on the Ethical Implications of Biotechnology (GAEIB). Originally created in 1991, the first term of the group was set at 2 years. The group was composed of six members drawn from the fields of law, science, medicine, philosophy and theology. The group's term of office was extended 'to further clarify ethical issues in relation to the application of biotechnologies,'[405] and its membership increased to nine members in 1993. When GAEIB's mandate expired in 1997, the European Commission replaced the group with the European Group on Ethics (EGE). The membership of the EGE was enlarged to twelve members and the term of office was extended to three years to take account of the increased workload [406] The EGE's first term (1998-2000) was renewed in 2001 for another four years and the mandate revised.[407] In 2005, the group was further enlarged to fifteen members and new rules of procedure issued[408] and the Secretariat of the Group made an integral part of the Bureau of European Policy Advisers (BEPA), a Directorate General of the European Commission that reports directly to the President of the Commission.[409]

The evolving and expanding nature of the Group and its mandate follows a long-standing inter-institutional dialogue between the Commission, the Council and the European Parliament,

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[403] Barling, D., 'Regulatory Conflict and Marketing of Agricultural Biotechnology in the European Community,' pp. 1040 -1048 in: Stanyer, J. and Stoker, G. (eds.) *Contemporary Political Studies*, 1997. Nottingham: Political Studies Association of the U.K., Cantley, M. F. (1995) ' The Regulation of Modern Biotechnology: An Historical and European Perspective,' chapter 18 in Brauer, D.(ed.) *Biotechnology: Legal, Economic and Ethical Dimensions* VCH: Weinheim: 1996). and Levidow, L. et al. 'Regulating agricultural biotechnology in Europe: harmonisation difficulties, opportunities, dilemmas,' *Science and Public Policy* 1996 23(3), at 135 -357 and Lenoir,N., 'The Ethics of Biotechnology' *Journal of Biolaw Business* 2001; 4(2), pp. 6-10..

[404] See SEC (91)/629 communication paper to the European Parliament and Council in April 1991, *Promoting the Competitive Environment for the Industrial Activities based on Biotechnology within the Community*.

[405] European Commission white paper on *Growth, Competitiveness and Employment: the Challenges and Ways forward into the 21st Century*, COM (93)/700 final, stated in section 5g that the Commission would "reinforce the role of the Group of Advisers on the Ethical Implications of Biotechnology" to "further clarify ethical issues in relation to some applications of biotechnology."

[406] Commission press release IP/97/1196.

[407] For copy of mandate 1998- 2000 and rules of procedure see http://ec.europa.eu/european_group_ethics/archive/1998_2000/mandat_en.htm

[408] Commission Decision of 11 May 2005 on the renewal of the mandate of the EGE: OJ L 127 of 20.5.2005 p. 12-19 (Article 2), available at: http://ec.europa.eu/european_group_ethics/mandate/docs/mandate2005_en.pdf

[409] On BEPA's mission and activities see: http://ec.europa.eu/dgs/policy_advisers/index_en.htm

with repeated calls from MEPs for greater openness, transparency and accountability on the membership and working methods of the group.[410]

The specific issues relating to the institutional function of the EGE must also be understood against the broader backcloth of the 2001 Commission's White Paper on EU Governance[411] and the ensuing communications on good governance which were intended to address the charges of 'democratic deficit' in EU 'comitology'.[412] The EGE's revised mandate of 2005 expressly builds on the principles of good governance contained in the 2002 Commission's communication on the collection and use of expert advice "to improve the knowledge base for better policies".[413] The principles apply to all groups of experts who advise the Commission, whether on an ad-hoc basis or as part of a permanent group and thus extend to the EGE.[414]

The principles identified in the White Paper were "accountability, plurality and integrity" to be used when collecting and using expert advice. This is set in the context of other general principles for better governance: openness, participation, effectiveness, coherence, proportionality and subsidiarity. As applied to expert advice, these principles were regrouped in the Commission's 2002 communication on expert advice into three core principles of "quality, openness and effectiveness".[415] Quality is defined in the 2002 Communication in terms of

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[410] For instance, in resolution EP B4-0484/97 passed on 13.6.1997 on the mandate of GAEIB, the European Parliament, whilst formally recognising the work carried out by the group, criticised its working methods and structure, stating, 'too much attention has been paid to the interests of research and not enough to its possible effects on society' and furthermore that sometimes the statements issued by the group were lacking in clarity. The resolution not only called on the Commission to renew and clarify the group's mandate particularly its composition, terms of reference and duties (consulting and reporting back to Parliament) but also considered that 'Parliament should be consulted on the appointment of members of the GAEIB". Parliament also called on the Commission to "bring forward proposals to guarantee Parliament's involvement in ethical questions relating to biotechnology' and that an annual report on the activities of GAEIB should be presented to Parliament by the Commission.

[411] COM(2001) 428 final.

[412] On 'Comitology' see Bernard, N., Multilevel Governance in the European Union, (Kluwer: 2002). Quoting Ellen Vos, Institutional Frameworks of Community health and Safety Regulation: Committees, Agencies and private bodies, (Hart Publishing: Oxford 1999) The author distinguishes f three types of committees. The first are so called comitology committees, committees with representatives from Member States. The second are the so called 'scientific' committees, for instance in the field of consumer health and food safety, where experts do not represent Member States, but sit in their personal and expert capacity. The third category are committees made up of representatives of civil society interests (participatory democracy). According to Bernard scientific committees "differ markedly from comitology commiittees both in their membership and their status in the decision-making process. They are not made up of representatives of the Member States ... Unlike comitology committees under the management and regulatory procedures, the Commission is not bound by the opinions given by scientific committees". For a critique, see Landfired, C., 'The European Regulation of biotechnology by Polycratic Governanc', in: Joerges, C. and Vos, E , *EU Committees: Social Regulation, Law and Politics* (Hart Publishing: Oxford 1999), arguing that 'scientific' committees are an attempt to cover what are political decisions by reference to technical experts.

[413] COM(2002) 713 final.

[414] "The core principles and guidelines apply whenever Commission departments collect and use advice of experts coming from outside the responsible department. The principles and guidelines thus cover the collection of advice though *ad hoc* and permanent expert groups; external consultants (individuals, groups or companies, possibly using study contracts); and instances when these mechanisms are used in conjunction with inhouse expertise (residing in Commission departments and in the Joint Research Centre)." COM (2002) 713, at para. 2.

[415] *Ibid.*

"excellence, independence and pluralism."[416] Openness is defined in terms of "transparency and accountability" and effectiveness in terms of costs.[417] Quality and openness thus provide the Commission's own key guiding principles on the appointment and working methods of all expert advisers, including the EGE.

In terms of defining an adequate principled framework to secure future advice of the requisite quality to stand up to public scrutiny, there is nothing particularly amiss with the general threefold "core" principles. The potential difficulties come instead from the more specific provisions defining the mandate of the EGE and the practical implementation of the mandate. In particular, the potentially difficult questions concern both the nature of the expertise required from members appointed to advise on the ethical evaluation of biotechnologies and the related question of the methodology to be followed by the Group.

8.2 Delivering Quality: Expertise of Members

It is clear from the 2005 mandate that the kind of expertise required for appointment to the group is not expertise in ethics. Instead, the mandate specifies that:

> "Members are nominated *ad personam*. Members serve in a personal capacity and are asked to advise the Commission independently from any outside influence. The EGE shall be "independent, pluralist and multidisciplinary."[418]

Academic commentaries of similar national & supra national ethics committees/commissions have suggested that the rationale for not basing the appointment on expertise in ethics lies in the recognition that professional ethicists hold a diversity of moral views and the concern that over-participation of professional ethicists might unfairly strengthen preferences in moral positions.[419] Allowing ethicists to set normative standards has also been said to grant ethicists superior status and to endanger the democratic ideal of equal respect for all in a pluralistic society.[420]

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[416] *Ibid.*
[417] *Ibid.*
[418] Article 3 (2).
[419] Friele, M. B., 'Do Committees Ru(i)n the Bio-political culture? The Democratic Legitimacy of Bioethics Committees' *Bioethics* 2003, Aug;17(4), at pp. 301-318.
[420] Braun, K., 'Deliberation, democracy, and bioethics: How to democratise the politics of biomedicine?' Paper presented at the European Consortium for Political Research, Joint Session of Workshops, Turin, March 22-27, 2002.

At the same time, the stipulation that the appointments be made on a *personal* basis rules out appointments on a (party political or other) representative basis. This again may be justified on the grounds that there is no straightforward link between political affiliation and moral outlook. Hence, the Group is not intended to emulate a representative parliamentary committee whose members are drawn in proportion to their electoral share of power at any one point in time.

But if the Group is intended to be independent and not representative, and the members appointed need not have any expertise in ethics, this then opens the question of which criteria are to be relied upon to determine how these 'personal' appointments are to be made and the related question of what working methodology the Group is to adopt. Arguably, both criteria of appointment and methodology must be sufficiently robust to safeguard the quality and consequent authority and credibility of the Group's Opinions. There are two potential challenges facing the Group in the future: developing a robust and credible methodology and preserving an image of independence.

8.3 Quality, Openness & Methodology

Attached to each 'expert' discipline there is normally a distinctive methodology which is internal to the discipline and is accepted by its members as laying down the framework rules within which the articulation and evaluation of different points of view in the discipline may be made.[421] Historians, sociologists, anthropologists, philosophers, lawyers, physicists and microbiologists all have their own distinctive methodologies. Within each discipline, there are further subdisciplines with their own distinctive body of knowledge and rules. Experts from different disciplines may come together to share their own discipline's perspective on a given subject matter. They may bring in evidence as to what is considered morally accepted practice or not within each discipline. They may deliberate and establish whether there is a consensus that is shared or a convergence which emerges between the different disciplines or practices. To those engaged in this deliberative exercise, the outcome of the process may well appear like the natural end point of deliberation. To outside observers, who have not been part of the process, the public presentation of the shared reasoning behind the conclusions will be crucial to its credibility. Arguably, the early Opinions of the Group were rightly queried for the paucity and lack of clarity of argumentation needed to justify the conclusions reached by the Group.

On deliberative democracy see Fishkin, J. and Laslett, P., *Debating Deliberative Democracy* (Blackwell 2003).

[421] Philosophers have developed a range of alternative theoretical perspectives on method. Contrast Winch, P., '*The Idea of a Social Science: and its Relation to Philosophy'* (Routledge 1990) with Fay, B., *Contemporary Philosophy of Social Science: A Multicultural Approach (Contemporary Philosophy S.)* (Blackwell 1996).

The 2001 Rules of Procedure sought to address the charge by requiring the Group's Opinions to normally contain:

> a. An indication of all documentation considered by the Group in arriving at an Opinion, each item to be preceded by the words "Having regard to".
> b. An indication of any proposals, opinions and consultations of relevance also preceded by the words "Having regard to".
> c. The considerations and the reasons "for and against" relevant to the issue under discussion preceded by the word "Whereas".
> d. The wording "issues the following Opinion", followed by the text of the Opinion presented in the form of paragraphs.

The publication of the Group's Opinions around the listed headings was intended to assist public understanding of the reasoning and evidence relied upon by the Group in reaching its evaluations. The linguistic expressions for the headings will also be familiar to lawyers from the civil law tradition, and gives an air of 'quasi-legislative' proceedings to the publications. But whilst this 'semantic' structuring does indeed assist in highlighting the sources relied upon by the Group, it is also potentially misleading for the following reasons.

In the first instance, the Group is not intended to function as a legislative body or court of law. Neither do its members have the competence or authority to act in a judicial capacity. The deliberative process followed by the Group is not & cannot therefore be akin to judicial reasoning which has to conform with prescribed rules & legal method which in turn require specialised training and understanding of both substantive legal principles and interpretive rules. Whilst it may be thought that there is no risk of such a conflation taking place, it should be noted that clarity of reasoning is not assisted by the listing in the Groups' Opinions, including Opinion 16, of both legal and non-legal sources and principles amongst the documentation considered by the Group. The potential blur between moral and legal orders is liable to happen as the conclusions reached in the Opinions are not only presented formally as following from a list of both non-legal and legal instruments and sources ('whereas' followed by references to legal instruments and/or ethical principles), but could impliedly be read as being substantively necessitated by law.

Under the new 2005 mandate, the Group has the power to adopt its own rules of Procedure.[422] In the light of the above potential difficulties, this may be an opportune time for the Group to review its rules of procedure to avoid the potential risk of blur between legal and moral reasoning, not least because, as this report shows elsewhere, the interpretation of specific provisions in European legal instruments requires extensive knowledge and expertise of legally complex overlapping layers of national and EU law. Where the Group thinks it necessary to consider legal instruments to assist its moral deliberations, and call upon expert legal advice, it is suggested that the legal expert advice relied upon by the Group should be clearly distinguished from the ethical Opinions of the Group. Such an eventuality is provided for in Article 4(5) which provides that:

> "For the purposes of preparing its opinions and within the limits of the available resources for this action, the EGE:
> – may invite experts having a specific competence, to guide and inform the work of the EGE if this is deemed useful and/or necessary,
> – may initiate studies in order to collect all necessary scientific and technical information,

In order to enable the Group to deliver reports of the quality sought is therefore essential that, where needed to facilitate the gathering of technical, including legal, and scientific evidence required, the required resources should be made available to the Group.

Secondly, and more generally, whether or not the Group retains the use of the 'quasi-legal' terminology prescribed in the 2001 Rules of Procedure to structure the presentation of its Opinions, there is a need for the precise steps in the Group's reasoning and its weighing of the evidence and arguments considered, to be detailed in the Opinions. In practice, this would require lengthier, more detailed reports, perhaps with an executive summary attached.[423]

8.4 Independence & Excellence

Aside from issues concerning methodology, the main other challenge to the Group's authority and credibility comes from public perception of the Group's independence. From its inception, the Group has been beset with a number of challenges, which, to a large extent, are common to

[422] Article 4(7)
[423] Compared to the reports of the US's President's Council or the previous National Advisory Bioethics Commission, the EGE's Opinions stand out as short in the extreme.

the creation and function of other similar (bio) ethics advisory groups at national and transnational level. A major difficulty the EGE shares which other national and supra national bioethics committees is the growing concern that these committees are prone to "political capture" with the consequent risk of politicisation of bioethics debate.[424] Examples discussed in the academic literature include the German National Ethics Council, where the government installed what appeared to be a committee which competed with the committee set up by the German parliament (German Inquiry Commission) and was perceived as a tool to legitimise the liberal views of the German executive on biomedical research in contrast to the views of its elected counterpart in the parliament.[425] Another notorious example is the US President's Commission.. In contrast to its predecessor, the Commission was expressly mandated to forego the search for a consensus and concentrate instead on displaying the range of possible ethical perspectives on ethically sensitive issues. Whilst the new mandate had, in theory, the potential to foster the practice of deliberative democracy,[426] in practice, the independence, orientation and scope of deliberation of the Commission was immediately called into question by the appointment of a Chair –Leon Kass- who had gone down on record as opposed to embryo research and strongly committed to the preservation of life.[427] On the other hand, in the view of some commentators, the President's selection of appointees from a wide spectrum of ethical perspectives was in any event bound to frustrate from the beginning the practical realisation of a consensus.[428]

Similarly, the recent appointment of new members of the EGE with public religious affiliations has raised understandable concerns about the independence of the Group and seems to be at *prima-facie* at odds with the requirement that the members of the Group should be independent.[429] Arguably, this type of appointment could be justified if the Group was intended to function as a *representative* group of a spectrum of diverse ethical outlooks. But as noted earlier, that is not the basis on which the group is intended to function. A change over to turn the

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[424] See ASHB Conference Proceedings: *Bioethics & Politics: The Future of Bioethics in a Divided Democracy,* Albany,USA July 13-14, 2006.

[425] Discussed in Braun, K., 'Deliberation, democracy, and bioethics: How to democratise the politics of biomedicine?', Paper presented at the European Consortium for Political Research, Joint Session of Workshops, Turin, March 22-27, 2002.

[426] Riley, F. M. and Merrill, R. A., 'Regulating Reproductive Genetics: A Review of American Bioethics Commissions and Comparison to the British Human Fertilisation and Embryology Authority, 6 Colum. Sci. & Tech. L. Rev. 1 Spring 2004-2005.

[427] For a trenchant critique of the politicisation of the President's Council see A. Charo Passing on the Right: Conservative Bioethics is Closer than it Appears' 32 J.L. Med. & Ethics 307 Summer 2004. Leon Kass has defended the group's work in 'Reflections on Public Bioethics: A View from the Trenches' Kennedy Institute of Ethics Journal Vol. 15, 3 pp. 221-250.

[428] Riley,F. M. and Merrill, R. A. *ibid.*.

[429] The list of members appointed in 2005 is published in the OJ, available at : http://ec.europa.eu/european_group_ethics/mandate/docs/listmemberspubjo_fr.pdf. According to an article in The Scientist, five of the nine new members are practicing Roman Catholic activists or theology professors: *The Scientist* 2005, 6(1)**:**20051104-01

group into a representative body would therefore require a change to the mandate and procedures of appointment.

One of the most significant alterations in the 2005 rules relates to the working methods of the Group. Under the 2001 rules, responsibility for directing the work of the group and communications with EU institutions lay with the President who was elected by members of the group and acted as a Chair. [430] By contrast, under the 2005 rules, the office of President has disappeared along with the associated responsibilities. A Chairperson is still to be elected by the group, but the powers and responsibilities of the Chairperson are more diffuse than under the 2001 rules. The Chairperson is to act in close cooperation with the Bureau of European Policy Advisers who are charged with "organizing the works of the EGE and its Secretariat" (Article 4.2) acting in close cooperation with the EGE's Chairperson on the basis of a work programme which has been agreed by the President of the Commission (including ethical reviews suggested by the EGE under their right of self-initiative Article 4.2). Under the new text, there appears to be considerable leeway for the President of the Commission to influence the workings of the Group either directly or indirectly through BEPA.

A new section also specifically calls for increased inter-institutional links between the EGE and other departments in the Commission:

> — *will* establish close links with the Commission departments involved in the topic the Group is working on (emphasis added)

The remainder of the section authorises the EGE to establish closer links with similar bodies in the European Union:

> — may establish closer links with representatives of the various ethics bodies in the European Union and in the applicant countries. (Article 4.5)

How the workings of the new Group unfold will be a test of the Group's independence.

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[430] The President will have the following responsibilities:
a. Institutional representation of the Group;
b. Preparation of the Agenda for meetings of the Group;
c. Acting as Chairperson of meetings of the Group;
d. Direction of the Group's activities;
e. Relationships with the European Institutions and other bodies;
f. Preparation of the report of activities at the end of the mandate for approval by the Group;
g. Organisation of relations with the media.

Conclusions

The original question which has been the focus of this Report is whether hESC are excluded from patentability on moral grounds under the Directive on Biotechnological Inventions 1998. The analysis of the relevant provisions, Articles 5 and 6, in the Directive has highlighted the complexity of the legal framework(s) in which the moral exclusion clauses fall to be interpreted. The Report also highlights the legal consequences for European patent law of the lack of integration of the EU and the EPC legal systems.

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 have interpreted Article 5(1) as excluding also 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 have 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 which 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.

Moral Exclusions in the EU Legal Order

Whilst Article 6(1) reiterates an accepted international principle of patent law which precludes patents on inventions which are contrary to *ordre public* or morality, Article 6(2) 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 four 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 European Union. Moreover the Union 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 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 EHCR, which is expressly recognised in the Directive, and which enshrines the fundamental values to which contracting Member States are parties in Europe. On the level of protection and rights granted to the human embryo under the ECHR, the jurisprudence of the ECrtHR, converges on the conclusion that Member States enjoy a wide margin of discretion in recognition of the diversity of moral traditions and cultures 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.

By contrast, the Report shows that different considerations apply to the construction 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. As regards the exclusion of industrial or commercial uses of the human embryo in Article 6, our analysis suggests that the intention of the Community legislator in Article 6(2)(c) 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, Article 6(2)(c) does not preclude the granting of patents on pluripotent stem hESC or processes for their derivation, unless the claims fall within the terms of the exclusion.

The general conclusion of the analysis of the Directive in the EU legal system is that, as pointed out by the ECJ and ECrtHR, in the absence of a uniform European moral view on the level of protection and rights of the human embryo, and outside the very limited and qualified terms of

exclusion of the list of inventions contained in the Article 6(2), the question of whether hESC inventions are patentable or not, is to a large extent a matter for national laws.

Our analysis 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 Community law. Equally valid would be national policies which 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 coexist 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 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 unclarity 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.

It is suggested 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. The TBA have considered the relationship between the general moral exclusion in Article 53(a) 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 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 for in all European States. Having reviewed the options in circumstances where there no uniform European view on morality, the Report concludes that the jurisprudence of the EPO interpreting the EPC, is 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.

Issues for the Future

The last part of the Report reviews the future role of the EGE in the light of the disputes which have arisen in connection with Opinion No. 16. 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 issues. 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.

Appendices

Definitions of regulatory models:

i) ***Restrictive***: Many techniques are prohibited (i.e. reproductive and therapeutic cloning, embryonic research) via tight regulations or blank prohibitions

ii) ***Intermediate***: A wide range of techniques are allowed but controlled and closely monitored by modest state intervention. Under this approach, stem cell research on supernumerary embryos from IVF treatment is permitted, but the creation of embryos specifically for research purposes is prohibited.

Liberal: Most technologies are permitted provided procedural rules and governance are observed. These policies permit the creation of embryos for research purposes as well as for the derivation of stem cell lines and for research cloning (mostly by *de facto* or by case-by-case approval by a governmental agency or licensing authority).

Appendix I

Chronology of National Legislation Regarding HESC Research

Country	"Pre-Dolly" (Legislation adopted prior to 1997)	"Post-Dolly" (Legislation adopted after 1998)	Legislation amended ("liberalized")	Policy Model
Iceland	Artificial Fertilisation Act no. 55/1996 (May 29, 1996)			Restrictive
Latvia		Law on Sexual and Reproductive Health (July 2002).		Intermediate
Lithuania		Law on Ethics of Biomedical Research No. VIII-1679 (May 11, 2000)		Restrictive
Denmark	Act No. 460 on Medically Assisted Procreation in Connection with Medical Treatment, Diagnosis and Research (June 10, 1997)		Amendment par. 25 Act. No. 460 on Medically Assisted Procreation (May 2003, in force 1 September 2003).	Restrictive
Estonia	Embryo Protection and Artificial Fertilisation Act (1997)		Penal Code, passed June 6, 2001 (in force 1 September 2002, consolidated text January 2004)	Intermediate
Finland		Medical Research Act, No. 488/1999 (1999)		Intermediate
France	Bioethics Law (1996)		Bioethics Law No. 2004-800 (August 6,	Intermediate

Sweden	Act 1991:115 on Measures for Purposes of Research and Treatment Involving Fertilized		Act 1991:115 on Measures for Purposes of Research and Treatment Involving 2004)	Liberal
Greece	Human Ova (1991) The In Vitro Fertilization Act No. 1988:711.	Law 3089/2002 on Medically Assisted Human Reproduction (2002)	Fertilized Human Ova (amendment in force 1 April 2005).	Intermediate
Hungary	Law No. 154 of 15 December 1997 on Public Health. (23 December 1997)		The In Vitro Fertilization Act, 1988:711, May 2, 2002 (in force 1 January 2003).	Intermediate
Spain	Law No. 35/1988 on Assisted Human Reproduction Techniques, (22 November 1988)		Law No. 35/1988 on Assisted Human Reproduction Techniques, (amended by Law 45/2003).	Intermediate
Slovenia		The Law on Medically Assisted Reproduction (2001)		Restrictive
Switzerland		Federal Order of December 1998 on the revision of the Federal Constitution (1998)	Federal Act on Research on Surplus Embryos and Embryonic Stem Cells (Approved by Referendum November 2004)	Intermediate
The Netherlands			Embryos Act (September 1, 2002)	Intermediate
Belgium			Law on research on human embryos in vitro (April 2003)	Liberal
United Kingdom	Human Fertilisation and Embryology Act (1990)		Human Reproductive Cloning Act (4 December, 2001)	Liberal
Germany	The Embryo Protection Law (1990)		Act ensuring the protection of embryos in connection with the importation and utilization of human embryonic stem cells (Stem	Restrictive

			Cell Act) (June 28, 2002)	
Ireland	Irish Constitution (1937, as amended in 1983)			Restrictive
Austria	Federal Law of 1992 (Serial No. 275) regulating medically assisted procreation and amending the General Civil Code, the Marriage Law, and the Rules of Jurisdiction*, (4 June 1992)*			Restrictive
Italy		Medical Assisted Procreation Law No. 40 (19 February, 2004)		Restrictive
Norway	Law No. 79 amending Law No. 56 of 5 August 1994 on the Medical Use of Biotechnology (13 December 2002)	Law No. 100 on the Use of Biotechnology in Human Medicine (the Biotechnology Law). (5 December 2003)		Restrictive
Poland	Law on Family Planning, Protection of Human Fetuses, and the Conditions under which Pregnancy Termination is Possible (January, 1993)			Restrictive
Bulgaria		Additional Protocol to the "Biomedicine Convention" on the Prohibition of Cloning Human Beings (1998)		Intermediate
Cyprus		Additional Protocol to the "Biomedicine Convention" on the Prohibition of Cloning Human Beings (1998)		Intermediate
Portugal		Additional Protocol to the		Intermediate

		"Biomedicine Convention" on the Prohibition of Cloning Human Beings (1998)		
Turkey		Additional Protocol to the "Biomedicine Convention" on the Prohibition of Cloning Human Beings (1998)		Intermediate
Ukraine		Additional Protocol to the "Biomedicine Convention" on the Prohibition of Cloning Human Beings (1998)		Intermediate
Georgia		Additional Protocol to the "Biomedicine Convention" on the Prohibition of Cloning Human Beings (1998)		Intermediate
Moldova		Additional Protocol to the "Biomedicine Convention" on the Prohibition of Cloning Human Beings (1998)		Intermediate
Romania		Additional Protocol to the "Biomedicine Convention" on the Prohibition of Cloning Human Beings (1998)		Intermediate
Slovakia		Additional Protocol to the "Biomedicine Convention" on the Prohibition of Cloning Human Beings (1998)		Intermediate

Appendix II:

National Policies Regulating Human Embryonic Stem Cell Research

	I. Countries Allowing Human Embryo Research by LAW	**II. Countries Allowing Human Embryo Research by GUIDELINES**
General Provisions (Countries with no specific legislation regarding hESC research)	▪ Iceland ▪ Latvia ▪ Lithuania	▪ None
Allowing for Procurement of hESC from Supernumerary Embryos	▪ Denmark ▪ Estonia ▪ Finland ▪ France ▪ Greece ▪ Hungary ▪ Spain ▪ Slovenia ▪ Switzerland ▪ The Netherlands	▪ Portugal
Allowing for the Creation of Human Embryos for Research Purposes	▪ Belgium ▪ Sweden ▪ United Kingdom	
Prohibiting the Procurement of hESC from Supernumerary Embryos But Allowing for the Import and Use of hESC lines	▪ Germany	▪ Italy
Prohibiting the Creation of Human Embryos for Research Purposes and for the Procurement of Stem Cells by Law or	▪ Cyprus ▪ Ireland ▪ Georgia ▪ Slovakia	

Ratification of the 1997 Convention of the Council of Europe on Human Rights and Biomedicine		

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