PART III. PATENT LAW AND HUMAN STEM CELLS

The European Patent Convention is the authoritative legal instrument on patent protection in Europe. However, for a long time, the European Patent Convention did not include detailed guidelines with regard to the patenting of inventions based on the use of 'living' material or elements from human origin. The case law of the European Patent Office was not extensively developed on this point, either.

In an effort to put an end to this legal vacuum, a proposal for a European Directive on the legal protection of biotechnological inventions was laid down in 1988. This proposal received much public attention, because of the delicate question to which extent 'life' and 'living material' is appropriate by way of patents. The issue was somewhat settled with the adoption of a substantially rewritten Directive in 1998. Since 1998, when human pluripotent stem cells were first isolated, the patent issue gained growing interest in civil society again, because of the legal and ethical implications patents on human stem cells entail.

Part III offers an overview of former and current patent law with regard to inventions based on elements from human origin, and makes an attempt to assess the many and varied questions which emerge when human stem cells are involved.

CHAPTER 1. PRE-98 PATENT LAW FRAMEWORK

A. The European Patent Convention of 1973

1. Background

For the time being, it is possible to obtain patent protection in Europe by separate application to each of the national Patent Offices within Europe (the so-called National Route). Almost every country in the world has its own patent system as well as a Patent Office or equivalent bureaucracy to screen patent applications and to decide whether patents should be awarded. However, the disadvantage of a national patent is that it only offers protection in one country, and hence it is mostly a European patent that is opted for at the European Patent Office (the so-called European Route). On the basis of a single application and examination procedure one can protect an invention in up to 20 European countries, all contracting states which have ratified the European Patent Convention of 1973.

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128 Convention on the Grant of European Patents of 5 October 1973 (European Patent Convention). The texts of the 1995 version of the Convention on the Grant of European Patents, its Implementing Regulations, the Protocol on Centralisation, the Protocol on Recognition, the Protocol on Privileges and Immunities and Rules relating to Fees in their versions as of June 1995, have been published in European Patent Convention, Munich, European Patent Office, 1995, 455 p (Also see http://www.european-patent-office.org). The Member States of the European Patent Organisation are the 15 EU Member States (Austria, Belgium, Denmark, Finland, France, Germany, Greece,
The term European patent, however, is misleading from two points of view. Firstly, it is not a single patent that is valid for the whole of Europe: the application and granting procedures are uniform, after which the patent is broken up into a 'bundle' of national patents which are further subject to national legislation and, more particularly, to national regulations with regard to nullity and infringement. Nor is it a patent granted by the EU: European patents have nothing to do with the EU apart from the fact that all EU Member States have also signed the European Patent Convention (EPC).

Secondly, it is on the basis of the European Patent Convention that the European Patent Office was brought into being (EPO), for dealing with European patent applications. It might be repeated that the European Patent Office is not an EU institution, either.

Recently, the European Commission proposed, however, to create a true Community patent to give inventors the option of obtaining a single patent legally valid throughout the European Union. On August 1, 2000, the Commission laid down a proposal for a Regulation on the Community patent, but this regulation is not in force yet.

2. Eligible subject matter

a. General

In principle, a European patent shall be granted for an invention which is new, which involves an inventive step and which is susceptible of industrial application (article 52 (1) EPC). The EPC does not contain a specific provision concerning the admissibility of patents on human material. In view of the question of the patentability of biological material in general and human (stem) cells in particular, two exclusionary provisions appear to be highly relevant. The first provision is article 53 (a) EPC which stipulates that European patents shall not be issued, either, in respect of inventions the publication or exploitation of which would be contrary to 'ordre public' or morality. The second provision is article 53 (b) EPC which states that European patents shall not be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals, which provision does not apply to microbiological processes or the products thereof. The full text of article 53 EPC reads as follows:

"European patents shall not be granted in respect of:
(a) 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;
(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof".

Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, United Kingdom) and Cyprus, Liechtenstein, Monaco, Switzerland and Turkey (Status on 1 November 2001).


b. Human stem cells

Article 53 (b) EPC does not give a clear-cut answer, to the question of whether or not human stem cells could be subject of patent protection. Article 53 (b) EPC second sentence stipulates that the exclusion of plant and animal varieties does not apply "to microbiological processes or the products thereof". It is generally accepted that the purpose of the second sentence of article 53 (b) EPC was to make clear that neither microbiological processes for the production of metabolites, nor methods for the culturing and producing of micro-organisms, were to be considered as unpatentable because of the first exclusionary sentence. The same was true for new strains or species of micro-organisms. So, article 53 (b) does not offer much further guidance to the question of whether or not human stem cells can be the subject of patent protection.

One might turn back to article 52 (1) EPC for some further clarification. In this context, the EPC repeatedly clarified that if a new property of a known material or article is found out, that is mere discovery and unpatentable because discovery as such has no technical effect and is therefore not an invention within the meaning of article 52 (1) EPC. If however that property is put to practical use then this constitutes an invention which may be patentable. For example, the discovery that a particular known material is able to withstand mechanical shock would not be patentable, but a railway sleeper made from that material could well be patentable. To find a previously unrecognised substance occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature can be shown to produce a technical effect it may be patentable. An example of such a case is that of a substance occurring in nature which is found to have an antibiotic effect. In addition, if a micro-organism is discovered to exist in nature and to produce an antibiotic, the micro-organism itself may also be patentable as one aspect of the invention. Similarly, a gene which is discovered to exist in nature may be patentable if a technical effect is revealed, e.g. its use in making a certain polypeptide or in gene therapy.\footnote{Guidelines for substantive examination of the European Patent Office, Part C, Chapter IV, 2.3 (Also see http://www.european-patent-office.org/legal/gui_lines/e/c_iii_3.htm)}

The EPC Guidelines further make clear that "treatment of body tissues or fluids after they have been removed from the human or animal body, or diagnostic methods applied thereon, are not excluded from patentability in so far as these tissues or fluids are not returned to the same body. Thus the treatment of blood for storage in a blood bank or diagnostic testing of blood samples is not excluded, whereas a treatment of blood by dialysis with the blood being returned to the same body would be excluded"\footnote{Guidelines EPC, Part C, Chapter IV, 4.3.}. This point of view raises the question of the patentability status of human embryonic stem cells which have been extracted from a particular individual and then further cultured and propagated in view of tissue replacement in that same individual.

c. 'Ordre public' and morality

With regard to article 53 (a) EPC, it is interesting to note that various member states already contained a ‘ordre public’ and morality clause in their national patent act

\footnote{Guidelines for substantive examination of the European Patent Office, Part C, Chapter IV, 2.3 (Also see http://www.european-patent-office.org/legal/gui_lines/e/c_iii_3.htm)}
\footnote{Guidelines EPC, Part C, Chapter IV, 4.3.}
before it was enacted in European patent law 133. For other member states, the ‘ordre public’ and morality clause was not included in the law itself 134, but resulted from the general principles guiding the doctrine, which principle was formally implemented in an effort to model national patent to the EPC 135.

Turning to the article 53 (a) EPC itself, it is generally admitted that the notion of ‘ordre public’ and morality is rather vague. However, the Boards of Appeal of the EPO, already ruled on the meaning and extent of article 53 (a) on various occasions. The leading EPO Board of Appeal case on the ‘ordre public’ and morality issue, is case T 356/93 from February 21 1995. This case relates to a dispute between Plant Genetic Systems (PGS) and Greenpeace on a patent related to plant cells resistant to glutamine synthetase inhibitors, made by genetic engineering 136.

First of all, the Board joined the view that an exception to the general rule under article 52 (1) EPC for certain kinds of inventions must be narrowly construed 137 and underlined that the same was true with regard to article 53 (a) 138.

Secondly, the Board emphasised that under article 53 (a) the relevant question is not whether living organisms are excluded as such, but rather whether or not the publication or exploitation of an invention relating to a particular organism is to be considered contrary to ‘ordre public’ and morality 139.

The Board further observed that the second half-sentence of article 53 (a) EPC, which contains the qualification "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", makes clear that the assessment of whether or not a particular subject-matter is to be considered contrary to either ‘ordre public’ or morality is not dependent upon any national laws or regulations. Conversely and by the same token, the Board is of the opinion that a particular subject-matter shall not automatically be regarded as complying with the requirements of article 53 (a) EPC merely because its exploitation is permitted in some or all of the Contracting States. Thus, approval or disapproval of the exploitation by national law(s) or regulation(s) does not constitute per se a sufficient criterion for the purposes of examination under article 53 (a) EPC 140.

The Board further emphasised that the concept of ‘ordre public’ covers the protection of public security and the physical integrity of individuals as part of society, and

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133 This was the case for example in the Netherlands where the ‘ordre public’ and morality clause was laid down in article 5 of the 1910 Dutch Patent Act (“Geen octrooi wordt verleend voor voortbrengselen of werkwijzen, waarvan het openbaar worden strijdig zou zijn met de openbare orde of de goede zeden”) and in Germany where the ‘ordre public’ and morality clause was stated in article 1 (2) (1) of the 1877 German Patent Act.

134 This was the case for example in the Belgian Patent Act of 1854.


137 This view had already been expressed by the Board in the framework with regard to article 53 (b) EPC: see Board of Appeal EPO, Decision T 320/87 (Official Journal EPO, 190, 71); Board of Appeal EPO, Decision T 19/90 (Official Journal EPO, 1990, 476).


underlined that this concept also encompasses the protection of the environment. In the opinion of the Board 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. Accordingly, 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.

The EPC Guidelines further explain that the purpose of article 53 (a) EPC is to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour; obvious examples of subject-matter which should be excluded under this provision are letter-bombs and anti-personnel mines. In general, this provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider 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. If it is clear that this is the case, objection should be raised under article 53 (a) EPC, otherwise not.

Although the case law of the EPO Boards on article 53 (a) EPC offers observations which are considered to be very valuable with regard to the acceptability of patents on human stem cells from an ethical point of view, the case law examined does not provide a well focused answer in this delicate matter.

d. Legal doctrine

Long before the establishment of the EPC, legal doctrine raised objections against inventions based on elements from human origin. QUADE rejected “in view of general human considerations” the granting of patents for the production of products (notably immunisation serum) obtained by way of using the physiological abilities of humans. His opinion was, however, largely opposed and hardly heard in case law.

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142 See Point 6 of the aforementioned decision, Official Journal EPO, 1995, (545), 557.
146 MUMFORD reports that in 1922 the so-called ‘Friedmann patent’ was upheld in German case law. This patent contained a patent claim relating to the production of a vaccination substance against tuberculosis, by means of the passage of turtle tuberculosis bacteria through the human body. See Blatt für Patent-, Muster- und Zeichenwesen, 1924; WARSCHAUER, ‘Kann die Behandlung des lebenden menschlichen Körpers Gegenstand einer Erfindung im Sinne des Patentgesetzes sein?’, Mitteilungen der deutschen Patentanwälte, 1927, (219), 224 et seq.
B. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) of 1995

1. Background

The Uruguay Round of multilateral trade negotiations held in the framework of the General Agreement on Tariffs and Trade (GATT) led to the Agreement Establishing the World Trade Organisation (WTO Agreement). For the first time those negotiations included discussions on aspects of intellectual property rights which had an effect on international trade. The result of those negotiations was laid down in an Annex to the WTO Agreement, the Agreement on Trade-Related Aspects of Intellectual Property Rights or TRIPS Agreement, which entered into force on January 1, 1995.

The TRIPS Agreement provides minimum standards of intellectual property protection that should be provided by all WTO member states. Member states are free, however, to determine the appropriate method of implementing the provisions of the TRIPS Agreement within their own legal system and practice, and may implement more extensive protection than required (art. 1 (1) and 1 (3) TRIPS Agreement).

2. Eligible subject matter

a. General

The essential elements of the standards concerning the availability, scope and use of patent rights are laid down in articles 27 to 34 of the TRIPS Agreement. The provisions relating to eligible subject matter, which are of special interest here, are laid down in article 27 TRIPS Agreement.

The general principle with regard to patentable subject matter is laid down in article 27 (1) TRIPS Agreement which defines that patents shall be available for any invention, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. The TRIPS Agreement emphasises that patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

In the field of life sciences, biotechnology and genetic engineering article 27 (2) and article 27 (3) TRIPS Agreement contain exclusionary provisions which are highly reminiscent of article 53 (a) and article 53 (b) EPC. Said provisions read as follows:

Art. 27.2. "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

147 The Uruguay Round negotiations concluded on December 15, 1993. The WTO Agreement was adopted on April 15, 1994, in Marrakech.
148 Official Journal EC, December 23, 1994, L 336/213 (Also see http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm).
149 The Agreement specifies that for the purposes of this article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a member to be synonymous with the terms 'non-obvious' and 'useful' respectively.
serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law.”

Art. 27 3. “Members may also exclude from patentability:
(a)...
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this sub-paragraph shall be reviewed four years after the entry into force of the Agreement Establishing the WTO”.

b. 'Ordre public' and morality

With regard to the ethical dimension of patenting, the TRIPs Agreement goes one step further than the EPC in that it clearly specifies the concept of 'ordre public' and morality as including the protection of human, animal or plant life or health and the protection of the environment, whereas the EPC does not explicitly define the scope of this concept. However, this vacuum was largely remedied by EPO case law.

CHAPTER 2. POST-98 PATENT LAW FRAMEWORK. THE EU BIOTECHNOLOGY DIRECTIVE

However much the clarifications on the twin concept 'ordre public' and morality have been welcomed, nor the elucidations in the EPO case law, nor the specification in the TRIPs Agreement offered any direct guidance as to the question of whether or not biotechnological inventions and, subsequently, inventions relating to human stem cells can constitute patentable subject matter.

A. Background

I. Genesis of the Directive

In view of the many unclarities which remained with regard to the patentability of inventions which make use of biological material, the European Commission expressed a clear desire to harmonise member states' legislations on this point. The Commission submitted a proposal for a Council Directive on the legal protection of biotechnological inventions in October 1988 150. Ever since its submission, this proposal has been subject to numerous discussions, which first led to a 'Common Position' adopted by the Council on February 7 1994 151 and which finally culminated in a 'Joint Text' approved by the Conciliation Committee on February 23 1995 152. The latter was eventually rejected by the European Parliament on March 1 1995 153.

152 Joint Text approved by the Conciliation Committee provided for in article 189 b (4) of the EC Treaty (0159 (COD), PE-CONS 3606/95).
When the European Parliament rejected the 'Joint Text' approved by the Conciliation Committee, the Commission announced that it intended to re-examine the matter closely in the light of the reasons put forward by Parliament, in order to find the best possible solution in this sensitive field. As a result, on January 25 1996, the Commission submitted a proposal for a Directive of the European Parliament and of the Council on the legal protection of biotechnological inventions \(^{154}\), based on article 100a of the EC Treaty. The Economic and Social Committee delivered its Opinion on July 11 1996 \(^{155}\). The Parliament delivered its Opinion on first reading on July 16 1997 \(^{156}\). Further to that Opinion the Commission sent an amended proposal for a Directive on August 29 1997 \(^{157}\). The Council adopted its Common Position in accordance with article 189b of the EC Treaty on February 26 1998 \(^{158}\), which culminated in the final approval of the European Parliament on June 6 1998 \(^{159}\).

2. Opinions of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission (GAEIB)

In the course of the process of the development of an EU Directive, the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission (GAEIB) \(^{160}\) delivered two opinions on the proposal. In the first opinion the GAEIB admitted that there are no ethical objections to the patenting of biotechnological inventions per se, but suggested that some clarifications were made on certain concepts and on the scope of certain provisions \(^{161}\). In the second opinion the GAEIB specified to which extent inventions involving elements of human origin should be patentable \(^{162}\).

The Directive underlines that account has been taken of Opinion n° 8 of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission (GAEIB) \(^{163}\).

The Opinions of the GAEIB will be examined in further detail hereafter.

3. Implementation in the EPC


\(^{155}\) Official Journal EC – C - 7 October 1996, 295/11.


\(^{157}\) Official Journal EC – C - 11 October 1997, 311/12.


\(^{160}\) The GAEIB was set up by the European Commission on November 20 1991. See EUROPEAN COMMISSION, Group of Advisers on the Ethical Implications of Biotechnology to the European Commission, 1996.


\(^{162}\) GAEIB, Opinion on the Ethical Aspects of Patenting Inventions Involving Elements of Human Origin, September 25 1996 (Opinion n° 8).

Implementation of the EU Biotechnology Directive into the EPC was necessary since a directive harmonising member states’ legislation may not directly influence the EPC, nor the EPO’s rulings. The decision of the Administrative Council of June 16 1999 incorporated the EU Biotechnology Directive into the EPC by inserting Rules 23b-23e into the Implementing Regulations to the EPC, with effect from September 1 that year.\(^{164}\)

Rule 23 b from the Implementing Regulations to the EPC stipulates in this respect 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”.

4. Implementation in the EU member states

One year after the expiration of the implementation deadline – July 30 2000 – only a few member states accomplished the implementation of the EU Biotechnology Directive in their national legislation.

Denmark (May 26 2000), Finland (June 30 2000), Ireland (July 30 2000) and Greece (October 15 2001) passed the implementing legislation, whereas the United Kingdom still has to implement some articles: effect was given to articles 1 to 11 of the Directive, whereas articles 12 to 14 still have to be implemented.\(^{165}\)

Italy (October 19 1999), Germany (October 18 2000), Luxembourg (June 2000), the Netherlands (May 28 1999), and also Austria and Portugal submitted a bill at their parliaments.

The Netherlands manifested their unhappiness with the EU Biotechnology Directive’s consequences in the form of an action for its annulment under art. 173 of the EC Treaty on October 19 1998.\(^{166}\) However, the fact that the Netherlands were opposed to the EU Biotechnology Directive did not discharge them - in accordance with art. 15 (1) EU Biotechnology Directive - of the duty to bring into force laws to comply with the Directive by July 30 2000. In an effort to avoid this duty, the Netherlands filed an action for interim measures before the Court of Justice on July 6 2000. However, on July 25 2000 the President of the Court denied the Dutch Government’s request for suspension of the implementation of the EU Biotechnology Directive.\(^{167}\)

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\(^{164}\) *Official Journal EPO, 1999, 437 ff.*


\(^{166}\) By order of the President of the Court of 28 April 1999, the Commission of the European Communities was granted leave to intervene in support of the forms of order sought by the European Parliament and the Council of the European Union. By orders of the President of the Court of 3 May 1999 the Italian Republic and the Kingdom of Norway were granted leave to intervene in support of the forms of order sought by the Kingdom of the Netherlands.

\(^{167}\) Order from the President of the Court, 25 July 2000, Kingdom of the Netherlands v Council of the European Union and European Parliament, Case C-377/98 R.
Germany on its turn, announced it would implement the directive, but at the same time initiate an amendment process on the European level to support the needed improvements and clarifications, in particular to examine the scope of product patents in the biotech field.

Belgium prepared a bill, which was sent to the national Conseil d'Etat for prior advice on July 19 2001. France equally prepared a bill which was adopted by the Government on October 31 2001. France, however, made it clear that it will implement the directive, save article 5, the reason being that in 1994 France adopted a provision which excludes human body parts from patentability and thus runs counter to article 5 of the Directive. Article L. 611-17 of the French patent law stipulates in this respect that: "The following shall not be patentable: (a) inventions the publication or exploitation of which would be contrary to public policy or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation; [in this respect, the human body, its elements and products as well as the knowledge of the whole or part of a human gene cannot as such be subject to patents]" 168.

Sweden launched the legislative process.

5. Judgement Court of Justice, October 9 2001

On October 19 1998, the Kingdom of the Netherlands brought an action for annulment of the EU Biotechnology Directive before the European Court of Justice 169. The Netherlands put forward six pleas:

1. that Article 100a of the Treaty was the incorrect legal basis for the Directive,
2. breach of the principle of subsidiarity,
3. breach of the principle of legal certainty,
4. breach of obligations in international law,
5. breach of the fundamental right to respect for human dignity and
6. breach of procedural rules in the adoption of the Commission's proposal.

168 The text between square brackets has been inserted by the Act of 29 July 1994. The original French text stipulates: "Ne sont pas brevetables: ... (a) ... a cet titre, le corps humain, ses elements et ses produits, ainsi que la connaissance de la structure totale ou partielle d'un gène humain ne peuvent, en tant que tels, faire l'objet de brevets (Article L. 611-17 Code Propriété Intellectuelle). For the English translation, see Book VI of the Intellectual Property Code at http://www.chaillot.com/En/circ/c121.html. Also see VAN OVERWALE, G., The Legal Protection of Biotechnological Inventions in Europe and in the United States. Current Framework and Future Developments, Louvain, Universitaire Pers, 1997, 35.

169 Action brought on 19 October 1998 by Kingdom of the Netherlands against European Parliament and Council of the European Union (Case C-377/98) (98/C 378/23), Official Journal EC – C – 5 December 1998, 378/13. The applicant stated that it was acting at the express request of the Netherlands Parliament, in the light of the opposition expressed there to genetic manipulation involving animals and plants and to the issuing of patents for the products of biotechnological procedures liable to promote such manipulation (See Judgement of the Court of Justice, 9 October 2001, point 4). This action has to be distinguished from the action for interim measures, which the Netherlands brought before the Court of Justice on 6 July 2000 (see above).
On February 3 2001 the argument from the parties was heard at the oral hearing. On June 14 2001 the Advocate General Jacobs delivered his opinion¹⁷⁰. In his conclusion, the advocate general proposed to dismiss the complaint on all points.

The final judgement of the Court of Justice was rendered on October 9 2001¹⁷¹. The Court entirely rejected the application. In response to the six pleas put forward by the Netherlands, the Court replied that

1. the Directive was correctly adopted on the basis of Article 100a of the Treaty¹⁷²;
2. that the Directive stated sufficient reasons with regard to the compliance with the principle of subsidiarity¹⁷³;
3. that the two grounds relied on by the applicant to support its plea that the Directive gives rise to legal uncertainty did not justify its annulment¹⁷⁴;
4. that the allegation of breach of obligations in international law was admissible, but had to be rejected¹⁷⁵;
5. that no breach of the fundamental right to respect for human dignity could be demonstrated¹⁷⁶ and, finally,
6. that the proper procedures were followed¹⁷⁷.

In this report, only the relevant passages of the judgement will be considered notably the third and the fifth plea.

B. Eligible subject matter

1. General principle (article 3)

The EU Biotechnology Directive proclaims as a general rule the patentability of biological material. Article 3 (1) stipulates that “for the purposes of the Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used”. Article 3 (2) further emphasises that “biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature”.

For the purposes of the Directive, biological material is defined as "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system" (article 2 (1) (a)).

¹⁷¹ Judgement of the Court of Justice, 9 October 2001, Case C-377/98, Kingdom of the Netherlands, supported by Italian Republic and by Kingdom of Norway v. European Parliament and Council of the European Union, supported by Commission of the European Communities (See http://www.curia.eu.int).
¹⁷² Judgement, points 13 to 29.
¹⁷³ Judgement, points 30 to 34.
¹⁷⁴ Judgement, points 35 to 49.
¹⁷⁵ Judgement, points 50 to 68.
¹⁷⁶ Judgement, points 69 to 81.
¹⁷⁷ Judgement, points 82 to 88.
The Group of Advisers on the Ethical Implications of Biotechnology to the European Commission (GAEIB) underlined the importance for Europe to step up biotechnological research and develop the industry as a whole and, therefore, felt that the Community should have its own legislation on the legal protection of biotechnological innovation. The GAEIB admitted that there are no ethical grounds for opposing the patentability of inventions relating to living matter in principle and emphasised that the principle of patentability of inventions relating to living matter must be upheld wherever ethically possible.\textsuperscript{178}

Apparently the GAEIB shares the belief that biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and that the protection of biotechnological inventions by way of patents is of fundamental importance for the Community’s industrial and economical development.

2. Human genes and human (stem) cells (article 5)

\textit{a. Key question}

As to the patentability of human material, the Directive stipulates that “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” (article 3 (1)). However, “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” (article 3 (2)).

In view of article 3, the question arises to which extent this article applies to human stem cells. In an attempt to provide an answer to this question, we carefully examined various sources. First of all, we thoroughly screened the preparatory documents of the EU Biotechnology Directive looking for relevant information. Next, we examined the GAEIB Opinion on the Ethical Aspects of Patenting Inventions Involving Elements of Human Origin of September 25 1996 and the recent judgement of the Court of Justice of October 9 2001. We also focused on the latest position of the European Parliament as expressed in the Resolution of October 4 2001 on the patenting of the breast cancer genes (BRCA1 and BRCA2). Last but not least, we consulted some academic scholars.

\textit{b. EU documental history}

In the amended proposal for a EU Biotechnology Directive from 16 December 1992, the European Commission underlined that ‘parts of the human body’ are parts of the body that are within the body and that a human cell line used in the development of medicines can be patented: “With regard to the unpatentability of the human body or parts of the human body, the Commission wishes to make it quite clear, … that ‘parts of the human body’ per se means parts of the human body as found inside the body. It is important that this be spelled out so as to remove all possible ambiguity with

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respect to the position of certain products or parts of the human body which are already covered by patents granted in connection with the development of medicinal products. By way of example, reference is then made to a patent relating to human lymphoblastoid cell lines, human hepatocyte culture processes and a method for producing human antibody. Recital 10 of the version of the EC Proposal reiterated that point of view.

In the 'Common Position' which was adopted by the Council on February 7 1994, the Council emphasised that in the light of the general principle that the ownership of human beings is excluded "the human body or parts of the human body as such, for example a gene, protein or cell in the natural state in the human body, including germ cells and products resulting directly from conception, must be excluded from patentability, but isolated parts of the human body should not be unpatenable merely because of their human origin, it being understood that the parts of the human body from which such isolated parts are derived are excluded from patentability".

The Position seems to suggest that the patent regime for human cells is not different from the one for human genes, which leads to conclude that human cells and human stem cells which are isolated from the human body are patentable. The Position raises some doubt, however, with regard to the patentability of human stem cells from embryonic or foetal origin (so-called embryonic stem cells, embryonic germ cells, foetal stem cells), since the Position indicates that "products resulting directly from conception" must be excluded from patentability. Possibly the Position is to be understood in this way that embryos which are isolated as a whole from the human body are to be excluded from patent protection, whereas human (stem) cells originating from embryos are not to be excluded.

ROTHLEY, the rapporteur of the committee in charge, took opposite views. At various occasions he underlined in the European Parliament that "This wording is clear and unequivocal and uninterpretable! Clearly unequivocal and beyond any doubt! ... By the way this also applies - to avoid any misunderstanding - to the case that a medicament is produced with the aid of a human gene and the medicament then patented, but not the human gene. This sentence, according to which the human body or parts of the human body are not patentable, applies without reservation."

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180 These patents have been examined in more depth, supra.
183 The European Parliament suggested to amend the wording of recital 10 in the following way: "Whereas, in the light of the general principle that the ownership of human beings is excluded, the human body or parts of the human body as such, for example a gene, protein or cell in the natural state in the human body, or isolated from it, including germ cells and products resulting directly from conception, must be excluded from patentability; whereas, however, an invention incorporating isolated parts of the human body should not be unpatenable merely because it uses material of human origin, it being understood that the parts of the human body from which such isolated parts are derived are excluded from patentability" (Official Journal EC – C – July 1994, 205/308). The Commission gave her advice on this amendment (See document COM(94) 245 def. – COD 159 of 9 June 1994). Ultimately the proposed amendment was not adopted by the Council (See Decision of the Council from 19 September 1994).
184 See the Report of the session of 26 October 1992, 69.
New amendment (n° 3) from the Committee on Legal Affairs and Citizens' Rights Session of 26 April 1994, reflected the opinion of the rapporteur. This amendment aimed at changing recital 10 in such a way that isolated parts of the human body were considered not patentable.\(^{185}\)

The 'Joint Text' approved by the Conciliation Committee on 23 February 1995\(^{186}\) emphasises that "in the light of the general principle that the ownership of human beings is excluded, the human body or parts of the human body as such, for example a gene, protein or cell in the natural state in the human body, including germ cells and products directly from conception, must be excluded from patentability; whereas, however, an invention incorporating industrially applicable parts obtained in a technical manner from the human body in such a way that they can no longer be ascribed to a particular individual may not be unpatentable because of the human origin of such parts, even where the structure of such parts is identical to a part of the human body, it being understood that parts of the human body from which such parts are derived are excluded from patentability" (Recital 12).

The Joint Text reveals that the criterion to decide whether or not an element from the human body is patentable, relates to the use of a technical manner in such a way that they can no longer be ascribed to a particular individual. Apparently, the technical intervention, the artificial process to isolate and reproduce the elements from human origin, will often be stressed as one of the major tests to decide whether an element from human origin is patentable.

Less emphasis has been put, however, on the closely related idea that such a technical process should lead to the obtaining of human body parts which can no longer be linked with a specific individual. Does this phrase aim at stressing that no physical link with a specific individual may be present anymore, or does it intend to underline that no association whatsoever with the particular individual may be present? In the light of the fact that human genes and human cells contain valuable information with regard to the genetic make up of a specific individual, it is not clear whether physical separation through a technical method is envisaged or whether complete anonymity is claimed as a criterion to decide on the patentability of elements of human origin.

Do human cells and human stem cells, not resemble human genes in this respect that cells, similar to genes, contain the entire genetic information of the person from whom the material is extracted? Can stem cells, similarly to genes, be qualified as 'genetic information carriers'?

The explanatory memorandum to the Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions from January 25 1996 emphasised on its turn that an element of the human body that has not been obtained with the aid of a technological process, but simply detached, removed or collected, may not be regarded as a patentable invention: "Thus a limb, on organ, or a bodily fluid (e.g. sperm, blood, tears or sweat) cannot be patentable"\(^{187}\). Equally the memorandum stipulates that "a gene, a cell, in their natural state, must be excluded from patentability"\(^{188}\).

\(^{185}\) EU Document, PE 181.920.
\(^{186}\) Joint Text approved by the Conciliation Committee provided for in article 189 b (4) of the EC Treaty (0159 (COD), PE-CONS 3606/95).
\(^{187}\) See 96/C 296/03, COM (95) 661 final, 95/0350 (COD), p. 13, n° 43.
\(^{188}\) See 96/C 296/03, COM (95) 661 final, 95/0350 (COD), p. 14, n° 53.
The memorandum further considers that regardless of whether the human material concerned ranks as a discovery the question arises as to what it constitutes the technical solution applied to a technical problem. Elements isolated from the human body by means of a technical process are artificial and thus qualify as inventions, since they are technical solutions invented by man in order to solve technical problems; the techniques employed in order to isolate such elements from the human body work only by means of human intervention.

The memorandum thus suggests that the decisive element to turn material from the human body from a non patentable issue (discovery) into patentable subject matter (invention) is (1) the technical process, the human intervention and (2) the way in which the biological material provides a technical solution for a technical problem. In the logic of the Directive, human stem cells probably are patentable if (1) the human stem cells are isolated from the human body by means of a technical, artificial process and (2) if the stem cells provide a technical solution for a technical problem.

The Common Position of the Council adopted on 26 February 1998 clarifies that the words “the human body, at the various stages of its formation and development” covers the human embryo.

The recitals of the EU Biotechnology Directive from 6 July 1998 on their turn underline that “it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented” (Recital 16). It is also 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” (Recital 20). And it is underlined that “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” (Recital 21).

Applying these recitals in a EU Biotechnology Directive vein in the field of human stem cell research, leads to believe that human stem cells as they appear in their natural environment would not be considered patentable, whereas human stem cells which have been isolated, identified and reproduced outside the human body would not be excluded from patentability. The touchstone to decide whether or not elements from human origin are patentable or not, whether they are to be considered as discoveries or not, lies in the technical intervention - the isolation, purification or reproduction of the element - techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself.

c. Opinion of the GAEIB

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189 See 96/C 296/03, COM (95) 661 final, 95/0350 (COD), p. 13, n° 43.
190 See 96/C 296/03, COM (95) 661 final, 95/0350 (COD), p. 13, n° 51.
Contrary to several EU Documents, which claim the distinction between discovery and invention is of a technical patent law nature, the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission (GAEIB) takes the view in its Opinion on the Ethical Aspects of Patenting Inventions Involving Elements of Human Origin of September 25 1996, that 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.\(^{192}\)

The GAEIB believes that patents for inventions issued from the knowledge of a human gene or a partial human gene sequence are acceptable "only if, on the one hand, the identification of the function attached to a human gene, or a partial human gene sequence allows new possibilities (for instance the production of new drugs), and, on the other hand, if the intended use of the patent is sufficiently specific and identified"\(^ {193}\).

The GAEIB takes the view that the decisive criterion to grant patents for elements from human origin is not the mere technical intervention of isolating and reproducing the element, but the fact that the isolation and identification of the element allows new possibilities\(^ {194}\). At first sight this viewpoint seems to be differing from various EU Documents which have been examined and discussed so far and from article 5 (2) of the Directive. Looking into the opinion more closely it appears that GAEIB is not opposed to the patenting of elements of human origin, notably genes, but demands that in the case patents are granted, new possibilities are offered. This specific requisite does not seem to add anything surplus, since it is enclosed in the standard patentability requirements of novelty and industrial applicability, as laid down in the EPC, which are equally applicable in the case of biotech patents. Thus, GAEIB's position appears to be reconcilable with the article 5 approach from the EU Biotechnology Directive.

The real diverging opinion seems to come from Dietmar Mieth. Dietmar Mieth considered that "A patent can be granted on an innovation capable of industrial application, which relates to an element of human origin, like an isolated gene, if this element has been essentially changed. It is not essentially changed if the structure of the element is identical to an element (gene) to be found in the human body or if the genetic information is identical to the information of a human gene inside the human body. The granting of a patent is justified for an innovation that shows a new therapeutic application or use of a gene or a partial sequence of an even unchanged gene. In these cases - patent on process and patent on product - the need to encourage European research and the use of its results may outweigh other aspects. The patent must not cover the gene itself, but the specific identified use of the gene"\(^ {195}\).

Mieth states that patents for elements from human origin are only justified if the element has been essentially changed, which is not the case if the structure of the element is identical to an element to be found in the human body. This statement leads to believe that Mieth is genuinely opposed against patents on elements of human origin if the structure of that element is identical to that of a natural element, even if the element is isolated from the human body by means of a technical process.

\(^{192}\) Opinion n° 8, 2.2.

\(^{193}\) Opinion n° 8, 2.5.

\(^{194}\) The second qualification, notably 'specific and identified intended use' is discussed below.

\(^{195}\) Opinion n° 8, Addition to 2.5. from Dietmar Mieth.
According to Mieth patents can only be granted for new therapeutic applications or specific identified uses of an element of human origin. Mieth's approach manifestly clashes with the article 5 treatment of human genes envisage in the EU Biotechnology Directive. Although Mieth developed his opinion having genes in mind, one can imagine that it would equally apply to human stem cells.

d. Judgement of the Court of Justice, October 9 2001

In the nullification proceedings before the Court of Justice, the Netherlands submitted that the patentability of isolated parts of the human body provided for by article 5 (2) EU Biotechnology Directive reduces living human matter to a means to an end, undermining human dignity.

The Court of Justice stated that the respect for human dignity is in principle guaranteed by article 5 (1) of the Directive which provides that the human body at the various stages of its formation and development cannot constitute a patentable invention. Nor are the elements of the human body patentable in themselves and their discovery cannot be the subject of protection. Only inventions which combine a natural element with a technical process enabling it to be isolated or produced for an industrial application can be the subject of an application for a patent. Thus, the Court emphasised, as is stated in recitals 20 and 21, an element of the human body may be part of a product which is patentable but it may not, in its natural environment, be appropriated. The Court referred to the example of human genes to demonstrate that the distinction applies. The result of such work can give rise to the grant of a patent only if the application is accompanied by both a description of the original method of sequencing which led to the invention and an explanation of the industrial application to which the work is to lead, as required by article 5 (3) of the Directive. In the absence of an application in that form, there would be no invention, but rather the discovery of a DNA sequence, which would not be patentable as such.

The Court underlines that the protection envisaged by the Directive covers only the result of inventive, scientific or technical work, and extends to biological data existing in their natural state in human beings only where necessary for the achievement and exploitation of a particular industrial application. The Court concludes that it is clear from those provisions that, as regards living matter of human origin, the Directive frames the law on patents in a manner sufficiently rigorous to ensure that the human body effectively remains unavailable and inalienable and that human dignity is thus safeguarded.

Although the ruling of the Court is put in rather general terms, following the Court's logic seems to lead to the conclusion that human stem cells should be considered patentable.

196 Witness the fact that his final sentence underlined that "The patent must not cover the gene itself, but the specific identified use of the gene."
197 Judgement of the Court of Justice, 9 October 2001, Case C-377/98, Kingdom of the Netherlands, supported by Italian Republic and by Kingdom of Norway v European Parliament and Council of the European Union, supported by Commission of the European Communities (See http://www.curia.eu.int).
198 Fifth in law, first part.
199 See judgement of the Court of Justice, 9 October 2001, points 71 to 77.
e. Opinion of the Unesco

Lately some voices are raised again to address the issue of the patenting of human genes and cells and to express some concern as to the effect of such patents. The International Bioethics Committee of Unesco (IBC) at the conclusion of its Eighth Session on 14 September 2001 adopted by consensus an "Advice on the patentability of the human genome", which states "that there are strong ethical grounds for excluding the human genome from patentability" and further recommends "that the World Trade Organisation (WTO), in its review of the TRIPS Agreement, clarify that, in accordance with the provision of Article 27(2), the human genome is not patentable on the basis of the public interest considerations set out therein, in particular, ordre public, morality and the protection of human life and health".

f. Position of the European Parliament

Similarly, the European Parliament Resolution of 4 October 2001 on the Patenting of BRCA1 and BRCA2 ('Breast Cancer') Genes expresses its dismay at the possible consequences of the granting by the European Patent Office of a patent on a human gene, and reiterates its call on the European Patent Office 'to ensure that all ... patent applications in Europe do not violate the principle of non-patentability of humans, their genes or cells in their natural environment'.

g. Legal doctrine

The views of academic scholars differ with regard to the issue of patenting inventions based on the use of human (stem) cells. STRAUS is of the opinion that the EU Biotechnology Directive expressly allows the patenting "not only of biological material isolated from its natural environment or produced by means of a technical process e.g. cell lines, whatever their source, but also of plants and animals, if the feasibility of the invention is not confined to a particular plant or animal variety".

MOUFANG seems to be rather reluctant with regard to the patenting of human cells: "A prominent example is the patenting of human germ cells, which meets with fundamental ethical reservations: the closer the application of methods of reproductive biology (artificial insemination and fertilisation) becomes interwoven with commercial interests, the more the current bio-ethical problems in this field will become aggravated unnecessarily. The establishment of commercial sperm banks hardly appears reconcilable with the European 'ordre public' and does not earn support through patent protection. ... In addition, patent applications claiming embryonic cell lines or foetal tissue appear extremely dubious. ... Even if embryo research were to be permitted to a limited extent, the legal system has to prevent a commercialisation of the results obtained through such research. Consequently, the patenting prohibition of article 53 (a) EPC should apply in this respect".

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201 Document B5-0633, 0641, 0651 and 0663/2001, Point 2.
An in-between position seems to be taken by BERGMANS who postulates that parts of the human body can be regarded as admissible subject matter, to the same extent that the legal order tolerates their direct or indirect appropriation. Consequently, neither the human body as such, nor the complete genome, can be considered patentable, but parts of the human body, can be the subject of patent protection to the extent that they have been extracted from their source in a legitimate manner.\textsuperscript{204}

3. Processes for cloning human beings (article 6 (2) (a))

a. Key question

As has been pointed out repeatedly before, laboratory stem cell research was very successful with mice. However, laboratory mice are inbred, and humans are not. To get around the problem of host rejection, human embryonic cells might have to be modified, or doctors might be able to clone an early embryo from a patient’s somatic cells and then generate his or her own embryonic cells\textsuperscript{205}. That explains why some of the patents which have been examined, deal with both the method to create embryos and the method to harvest human embryo stem cells. In view of those cases, the patentability of the cloning phase has to be assessed.

Various sources have been consulted to assess the question of the patentability of cloning methods. First, we found some information in the recitals preceding the EU Biotechnology Directive. Next, we thoroughly examined the Edinburgh case, which reveals the manner in which the EPO interprets the EU Biotechnology Directive at this point. Last but not least, we explored the position of the European Parliament on this issue.

b. EU Interpretation

The EU Biotechnology Directive underlines that 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)).

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 (article 6 (2)).

The EU Biotechnology Directive explicitly considers processes for cloning human beings unpatentable (article 6 (2) (a)). According to Recital 40 there is a consensus within the Community that intervention in the human germ line and the cloning of human beings offends against ‘ordre public’ and morality and it is therefore important to exclude unequivocally processes for modifying the germ line genetic identity of human beings and processes for cloning human beings from patentability.

\textsuperscript{204} BERGMANS, B., La protection des innovations biologiques. Une étude de droit comparé, Brussel, Larcier, 1991, 189: “On peut admettre la brevetabilité des parties du corps humain en tant que telles, dans la même mesure que l’ordre juridique tolère leur appropriation directe ou indirecte. Ainsi, le corps humain entier (ou un génome entier) ne pourrait faire l’objet d’un brevet, mais bien des parties dans la mesure où elles ont été séparées de manière licite de leur source”.

This exclusion, however, raises various questions. The first question is whether the exclusion of therapeutic or reproductive cloning is envisaged. An answer can be found in Recital 41 from the Directive which stipulates that “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 another living or deceased human being”\textsuperscript{206}. Recital 41 points in the direction of the exclusion of reproductive cloning, but not of therapeutic cloning. However, the Council emphasised in its Common Position that the word ‘reproductive’ was deliberately omitted, since the adjective ‘reproductive’ could be too restrictive\textsuperscript{207}. The second question is what is to be understood by ‘human being’? Current national legislations employ differing definitions of ‘human being’. The EU Biotechnology Directive does not offer any definition, what might lead to a different scope of the exclusion in the different member states. The Council explained, however, in its Common Position that the words ‘human beings’ referred to the “human being from the embryonic state”\textsuperscript{208}. But what is to be understood by ‘the embryonic state’? One can wonder whether the addition really solves the interpretation problems, especially when one compares this definition with the one used in, for example, the Dutch translation, where it is said that the term humans beings refers to ‘human beings from the fertilisation’ (“menselijke wezens vanaf de bevruchting”).

c. Position of the EPO: the Edinburgh patent

The cloning issue brings us to the core of the heated debate surrounding European patent 695 351 entitled “Isolation, selection and propagation of animal transgenic stem cells”\textsuperscript{209}. The patent to the University of Edinburgh was granted by the EPO on December 8 1999. The issuance of the patent thus occurred after the EU Biotechnology Directive was inserted in the EPC and took effect\textsuperscript{210}. A case as high profile as the Edinburgh case thus reveals the manner in which the EPO apparently interprets the EU Biotechnology Directive in the field of human stem cell research.

Public attention was drawn to this patent by a Greenpeace demonstration, protesting against the grant of this patent which was believed to enclose human cloning methods.

\textsuperscript{206} The Council agreed with the Commission that it was better to put the definition of human cloning in the recitals, and it tried to clarify the wording proposed by the Commission, in particular by the addition of a reference to the techniques for splitting embryos (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 (98/110/02), \textit{Official Journal EC – C} - 8 April 1998, 110/(17), 30, point 34.

Some member states, however, took the view that for clarity’s sake it was desirable to integrate the Recital 41-phrase directly in the relevant patent law provisions. See e.g. the Belgian Draft Bill modifying the 1984 Patent Act, dated 31 May 2001 which stipulates: “\textit{Au titre du § 2, ne sont notamment pas brevetables: les procedes de clonage des etres humains, c’est-a-dire les procedes permettant de faire naître une copie d’un individu vivant ou ayant vecu}” (article 4 (3) of the Draft Bill).


\textsuperscript{209} Supra.

\textsuperscript{210} The decision of the Administrative Council of 16 June 1999 incorporated the EU Biotechnology Directive into the EPC by inserting Rules 23b-23e into the Implementing Regulations to the EPC, with effect from September 1 that year.
Subsequently, national and international press covered the grant of this patent, alleged to comprise human cloning.

The disputed part of the Edinburgh patent was claim 48 which related to "a method of preparing a transgenic animal, said animal comprising a selectable marker capable of differential expression in (a) desired stem cells and (b) cells other than desired stem cells, the method comprising: providing a blastocyst; providing animal cells according to any of claims 37-38, introducing the animal cells into the blastocyst, transferring the blastocyst to a recipient and allowing an embryo to develop to a chimaeric animal to enable germline transmission of the selectable marker".

The indignation surrounding this patent appears to be justifiable to a large extent. In the three practical examples elaborated in the patent description, only cell lines of mice are being used. It emerges from a careful reading from the description that human cells might be enclosed in the patent claims since the description of the patent explicitly mentions that "in the context of this invention, the term 'animal cell' is intended to embrace all animal cells, especially of mammalian species, including human cells".

On February 21 2000 the EPO admitted that the wording of the claim should have included the qualification 'non-human' because in English scientific usage the term 'animal' also includes 'human'. In its press release the EPO admitted this error and regretted that it had occurred. The declaration went on, however, to state that the patent, contrary to many accounts, and despite the omission of the qualifier 'non-human' did not extend to human cloning, because under articles 69 and 84 EPC the patent claims must be supported by the patent description, which was not the case here.

The EPO is not able on its own initiative to amend a granted patent containing an error and in the press release the EPO invited oppositions from third parties. Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the EPO of opposition to the European patent granted (article 99 (1) EPC). This procedure thus allows any necessary corrections to be made. Opposition were filed by various organisations and institutions.

On April 4 2000 a request to correct the decision to grant was filed by the University of Edinburgh. The correction related to the insertion of 'non-human' before 'animal'

211 See the Description of EP 695 351, p. 2 (0011).
213 Article 69 EPC: supra; article 84 EPC stipulates that "the claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description".
214 There have been filed various oppositions (Greenpeace Deutschland, PDS-Bundestagsfraktion, Ökumenischer Rat der Kirchen in Österreich, Bundesrepublik Deutschland - Bundesministerium Der Justiz Z.H. Dr. E. Hucko, Alliance pour les Droits de la Vie, Aktion Leben Österreich, Greenpeace E. V. Sammelentspruch, Bündnis 90 Die Grünen - Bundestagsfraktion Dr. B. Laubach, Dr. Ruth Tippe "Kein Patent Auf Leben", de Koninkrijk der Nederlanden, Deutsche Forschungsgemeinschaft, Regierung der Republik Italien Untersmatssekretär Dr. Enrico Michelli, Dr. Jürgen Kaiser, Bündnis 90/Die Grünen Ortsverband Vaihingen Kreisverband), but only four oppositions were held admissible: Greenpeace Deutschland, Ökumenischer Rat der Kirchen in Österreich, Bundesrepublik Deutschland and Regierung der Republik Italien.
in claims 47 and 48. On April 11 2000, an amended set of claims was filed as a main request in the Opposition proceedings, with the same claim amendments as made in the correction request. Simultaneously, the issuance of a Preliminary Opinion as to the merits of the claims was asked.

The Opposition Division gave their preliminary opinion on the amended set of claims on April 14 2000. According to the Opposition Division “The gist of the contested European patent is the development of a method for in vitro maintenance of a stem cell culture as a homogenous population in the undifferentiated state. Thus cultured stem cells are thus amenable to in vitro genetic manipulation. In vitro culture in general is a long practised technique that has enabled major scientific advances while circumventing the need for in vivo experimentation. Ethical concerns particularly arise when the genetic manipulation of human cell cultures is carried on into the germline of a human. However, this embodiment is explicitly disclaimed in claims 47 and 48 of the new request. Thus, the subject matter of new claims 47 and 48 does not offend against article 53 (a) and Rule 23 (d) EPC. In view of the fact that it appears of general concern whether the methodology claimed and disclosed in the contested patent could be employed for the purpose of human cloning, the Opposition Division clarified that “Cloning is a process of asexual reproduction of an organism that creates multiple genetically identical copies (a clone) of the original. This is achieved experimentally by nuclear transfer from a somatic cell into an enucleated oocyte. However, the patent in suit neither describes nor comprises nuclear transfer. Furthermore, embryonic stem cells cannot develop into an organism on their own (see e.g. Science, vol. 283, p. 1468-1470, 1999). They can only contribute to and form parts of a developing organism upon integration into a host blastocyst. The resulting animal is genetically different from both the blastocyst and the embryonic stem cell donor. Therefore, it becomes apparent that the methodology described in the contested patent is not cloning. Thus, the contested patent, being absolutely distinct – both in strategy and utility – from cloning, does not offend against Rule 23 d EPC.”

The oral proceedings opposition proceedings are expected to take place on 2 April 2002.

Two observations can be made with regard to the position taken by the EPO. Firstly, it has to be noted that the EPO press declaration did not address the claims concerning methods of isolating and propagating desired animal (read: human) stem cells (claim 1 et seq.), nor the claims relating to animal (read: human) stem cells as such (claim 37

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215 The amended claim 48 includes “a method of preparing a transgenic non-human animal, said animal comprising a selectable marker capable of differential expression in (a) desired stem cells and (b) cells other than desired stem cells, the method comprising: providing a blastocyst; providing animal cells according to any of claims 37-38, introducing the animal cells into the blastocyst, transferring the blastocyst to a recipient and allowing an embryo to develop to a chimaeric animal to enable germline transmission of the selectable marker”.

216 See the file wrapper of this case, more in particular the letter from MATHYS & SQUIRE, Chartered Patent Attorneys from London to the EPO, dated 11 April 2000. Also see SCHLICH, G., “When Ethics are Called into Question”, CIPA Journal, May 2000, 224-226.

217 See the file wrapper of this case, more in particular the communication of the Opposition Division from the EPO to G. Schlich, MATHYS & SQUIRE dated 14 April 2000 (See point 5.1.). Also see SCHLICH, G., “When Ethics are Called into Question”, CIPA Journal, May 2000, 224-226.

218 See the communication of the Opposition Division from the EPO, point 5.2.
et seq. 219). This might mean that the EPO takes the view that methods for isolating and culturing human stem cells are patentable. This also leads to believe that the EPO is of the opinion that human stem cells are patentable, supposedly within the limits of article 5 of the Directive. Secondly, the EPO press release only treated the claims concerning possible human cloning (claim 47 and 48). In doing so, the EPO firmly rejected the idea of patents on human cloning.

Both these observations lead to the conclusion that the EPO apparently favours the patentability of human stem cells, but disapproves of methods and applications in human stem cell research, which enable human cloning.

d. Opinion of the EGE

The EGE made clear in its opinion on Ethical Aspects of Human Stem Cell Research and Use from November 14 2000, that there is an interest in performing somatic cell nuclear transfer (SCNT) with the objective of studying the conditions necessary for “reprogramming” adult human cells. It is also aware that, in view of future cell therapy, the creation of embryos by this technique may be the most effective way to derive pluripotent stem cells genetically identical to the patient and consequently to obtain perfectly histocompatible tissues, with the aim of avoiding rejection after transplantation. But, the EGE underlines that these remote therapeutic perspectives must be balanced against considerations related to the risks of trivialising the use of embryos and exerting pressure on women, as sources of oocytes, and increasing the possibility of their instrumentisation. The EGE concludes that, at present, the creation of embryos by somatic nuclear transfer for research on stem cell therapy would be premature, since there is a wide field of research to be carried out with alternative sources of human stem cells 220.

e. Position of the European Parliament

The Edinburgh patent was the immediate cause for a resolution passed at the European Parliament condemning the cloning of humans beings 221. The Parliament underlined that “it was deeply shocked at the granting of a patent to the University of Edinburgh, which includes a technique for the genetic modification of the germ line of human embryos and of the embryos themselves, a patent on isolation, selection, and propagation of animal and transgenic stem cells, which could be used for the cloning of human beings” (point 1). The European Parliament further announces it “Undertakes to file without delay an objection to patent number EP 695 351 if legally possible, and calls on the other institutions of the European Union and Member State governments to do likewise” (point 2) and “Demands a review of the operations of the EPO to ensure that it becomes publicly accountable in the exercise of its functions,

219 Claim 37 reads as follows: “an animal cell capable of being cultured from a mixture of cells including desired stem cells and cells other than the desired stem cells, characterised in that all cells in the said mixture of cells contain a selectable marker and in that in the said mixture of cells, under appropriate selective culture conditions, differential expression of the selectable marker in (a) the desired stem cells and (b) cells other than the desired stem cells enables selective survival or growth of the desired stem cells to occur, so as to enable isolation and/or enrichment and/or propagation of desired stem cells”.

220 EGE, 2000, p. 16, point 2.7.

and to amend its operating rules to provide for it revoking a patent on its own initiative” (point 9).

4. Processes for modifying human germ line genetic identity (article 6 (2) (b))

The EU Biotechnology Directive also excludes processes for modifying the germ line genetic identity of human beings from patent protection (article 6 (2) (b)). According to Recital 40 there is a consensus within the Community that intervention in the human germ line and the cloning of human beings offends against ‘ordre public’ and morality and it is therefore important to exclude unequivocally processes for modifying the germ line genetic identity of human beings and processes for cloning human beings from patentability. It is commonly understood that the exclusion does not extend to somatic cell gene therapy 222.

The 'Common Position' adopted by the Council on February 7 1994 suggested that not all processes for modifying the genetic identity of the human are to be excluded, but only those which are contrary to the dignity of man 223. Even in the case a process would enable a modification of the human genetic code to be controlled in connection with in vitro fertilisation intended to correct certain genetic deficiencies, such a process should be compatible with the dignity of man, taking into account the therapeutic aims which the process would enable to be achieved. Even if this condition were fulfilled, that would in no way imply automatic recognition of the patentability and legitimacy of what is known as germ gene therapy since, if such a patent were to be granted, the national or Community authorisation procedures applying to this type of therapy would of necessity have to be observed before any use of this therapy 224.

5. Use of human embryo's (article 6 (2) (c))

The EU Biotechnology Directive further excludes uses of human embryos for industrial or commercial purposes from patent protection (article 6 (2) (c)). With regard to this exclusion, some questions have being raised as well. First, the question has been put forward whether the Directive envisages the exclusion of the use of 'spare' embryos 225 or rather the use of created 'research' embryos 226.

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222 In the case of somatic gene cell therapy an attempt is made to repair the sick body cells of the patient by replacing the defective genes in these cells by normal genes. The genetically altered cells are not being transferred to the progeny. In the case of embryo therapy (also called germ line gene therapy) an attempt is made to replace the sick gene by a normal one in the fertilised egg-cell, so that the gene ends up in all the cells of an individual and also into the cells responsible for reproduction (See VAN OVERWALLE, G., The Legal Protection of Biotechnological Inventions in Europe and in the United States. Current Framework and Future Developments, Leuven, Universitaire Pers, 1997,16).


225 Spare embryos (i.e. supernumerary embryos) are created for infertility treatment to enhance the success rate of IVF, but no longer needed for this purpose. They are intended to be discarded but, instead may be donated for research by the couples concerned. See EOE, 2000, 10.

226 Research embryos are created for the sole purpose of research. These may either be produced with donated gametes, i.e. they are derived from the fertilisation in vitro of a human oocyte by a human sperm, or they may be produced by embryo splitting or nuclear transfer. In the latter case they would be derived by introducing the nucleus from an adult somatic cell into an enucleated human
Second, the question has been raised what the faith is of the use of human embryos for research purposes.

With regard to both these questions, Recital 42 stipulates that the exclusion of human embryos for industrial or commercial purposes in any case does not affect "inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it", which are not excluded from patentability. This addition does not offer much guidance, since one can easily imagine inventions with a combined commercial and therapeutic purpose, and the recital does not make clear what the faith should be of such inventions.\textsuperscript{227}

6. Processes to produce chimeras, (processes to produce) totipotent human or animal cells (recital 38)

Examination of the articles 3, 5 and 6 and the related recitals of the EU Biotechnology Directive offered some guidance with regard to the patentability of human stem cells.

It appears, that some supplementary guidance can be found in recital 38 as well. This recital emphasises that the operative part of the Directive the list of inventions excluded from patentability is an illustrative list aiming at providing national courts and patent offices with a general guide to interpreting the reference to ‘ordre public’ and morality. The recital underlines that “processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells, or totipotent cells of humans and animals, are obviously excluded from patentability.”\textsuperscript{228}

Careful reading, however, raises serious questions with regard to the exact scope of the exclusion envisaged in recital 38. Does recital 38 aim at excluding processes to produce human totipotent cells, at processes to produce chimeras from human totipotent cells, or at human totipotent cells as such? It seems to be generally understood that the exclusion relates to processes to produce chimeras from human totipotent cells.\textsuperscript{229}

It has to be underlined that the exclusion seems to be limited to processes to produce chimeras from totipotent human or animal cells\textsuperscript{230} and not to processes to produce chimeras from pluripotent (e.g. embryonic) human or animal stem cells.

\textsuperscript{227} The Common Position of the Council of 26 February 1998 does not offer any additional guidance either (See Official Journal EC – C - 8 April 1998, 110(17), 30, point 37.

\textsuperscript{228} My Italic.

\textsuperscript{229} This was the opinion of various members of the EGE in reply to a question on this issue of the author of the present study, at the Round Table Conference, which was held at Brussels on 20 November 2001 (Within the preparatory work on its opinion on patents relating to human stem cell research, the EGE organised on 20 November 2001 in Brussels, a round-table debate on the ethical aspects of patenting inventions involving human stem cells in order to discuss the topic with scientific experts, lawyers, philosophers, as well as representatives from the European Parliament, international organisations, representatives of patients, industry, religions, and other interested parties.)

\textsuperscript{230} Embryonic stem cells are pluripotent, not totipotent. At the blastocyst stage, embryonic stem cells can no longer develop into an embryo of their own. Evidence is emerging that these cells do not behave in the laboratory as they would in the developing embryo. If they are transferred to the uterus, they would neither implant nor develop into an embryo. Supra.
C. Substantive patentability requirements

Besides the major question to which extent inventions relating to human stem cell research can enjoy patent protection, some issues of seemingly minor importance have to be assessed as well. More in particular, it has to be examined whether the rules governing patentability criteria and the rules regarding patent scope have any implications on patents for human stem cell research.

The EU Biotechnology Directive does not introduce a new set of substantive patentability requirements, neither does it change the existing conditions. Biotechnological patents have to meet the same substantive patentability requirements as other inventions, which requirements are governed by national patent law (cf. article 1(1)). The EU Biotechnology Directive underlines in this respect that on no account the harmonisation depart from the basis principles of patent law. In order to qualify for patent protection, the conditions governing patent law - notably novelty, inventive step and industrial applicability - have to be satisfied.

If we assume that human stem cells constitute eligible subject matter, patents can subsequently only be granted when the related technology satisfies the requirements of novelty and inventive step and is susceptible of industrial application (article 52 (1) EPC).

The invention claimed in the patent application must be new. The invention shall be considered to be new if it does not form part of the state of the art. The definition of the state of the art in the EPC amounts to absolute novelty, i.e. the state of the art is held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing (article 54 EPC).

In light of the novelty condition, there arises the question of whether a product patent can be obtained for a substance that is to be found openly in the natural world as part of a living organism. As far as the EU Biotechnology Directive is concerned, this question, together with the question of whether one can speak of there being an invention at all, is answered in the affirmative. The novelty requirement thus does not constitute any particular hurdle for the patenting of human stem cell technology in comparison with other biotechnological inventions.

The invention shall be considered to be involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art (article 56 EPC). The inventive step requirement is intended to prevent exclusive rights forming barriers to normal and routine development.

The condition that the invention bear witness to inventiveness would not appear in practice in the granting of patents for human stem cell research to pose any greater obstacle than in the case of other biotechnological inventions.

The invention shall be considered to be susceptible to industrial application if it can be made or used in any kind of industry, including agriculture (article 57 EPC).

The requirement that the invention has to be capable of industrial application is no greater hindrance in the case of human stem cell techniques than in the case of other biotechnological inventions.

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D. Scope of protection

Another issue, which has to be assessed, is the question of patent scope.

1. Product patents

Living material’s ability to self-replicate throws up the particular question of the generation to which patent protection extends. An example to illustrate this problem: in principle, patent protection can be obtained for a gene containing information on resistance to illness; if this patented gene is then incorporated into a plant cell, the question arises as to whether the patent protection over the gene also extends to the transgenic plant cell.\textsuperscript{232}

The EU Directive stipulates in this respect that “the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics” (article 8 (1)). This means that in order to obtain patent protection on further generations, it is essential that the propagated or multiplied material has the same features as the originally patented product. Assuming this condition has been met, protection stretches out to an almost unlimited amount of generations.

Applying the principle embedded in article 8 (1) on the above example, leads to the conclusion that patent protection extends to the transformed plant cell in question: from the point of view of the Directive, establishing a satisfactory protection of biotechnological inventions, the contrary is unacceptable, because endless new plant cells, and even whole plants, can be regenerated from the plant cell in question. So, the scope of biotech patents can become rather broad.

The Directive further specifies that “the protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in article 5 (1), in which the product is incorporated and in which the genetic information is contained and performs its function (article 9)”. This provision emphasises that patent protection on a product extends to other products which contain the genetic information, on the condition that the inserted genetic information “performs its function” in that product, which is generally understood to mean that the genetic information is “expressed” in that product.

This regime probably equally applies to human cells. However, some uncertainty remains with regard to the exact interpretation of article 8 in this field.

2. Product by process patents

With regard to the scope of protection for processes, the common rule laid down in article 64 (2) EPC, implies that “if the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process”.

On this issue the Directive stipulates that "the protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics" (article 8 (2)).

It appears that the scope of protection for processes offered by the Directive is much wider than the scope provided by the EPC. The Directive does not only offer protection for the products directly obtained through the process, but also for any product derived from the directly obtained product, on the condition that the product still possesses the same features. Here again, we witness the extension of patent protection to future generations.

CHAPTER 3. THE RELATIONSHIP BETWEEN PATENT LAW, RESEARCH REGULATIONS, COMMERCIALISATION AND BIO-ETHICS

A. The relationship between patent law and research regulations

1. Key question

Chapter 1 and 2 examined how past and present patent law deal with the results of human stem cell research. The major question in this respect was how patent law has adapted itself to this new type of technology, biotechnology, and how it handles questions relating to the patentability of inventions using elements from human origin. It can be concluded that, over the years, patent law has developed a series of international and European instruments to accommodate patent law to the advent of biotechnology and the use of elements of human origin.

The focus of Chapter 1 and 2 was not to investigate how the legislation with regard to biomedical research has developed over the years, and how national, European and transnational laws have treated questions relating to research in the field of human stem cells.

Patent law and biomedical research regulations largely legislate the same issues, but from a different angle. Biomedical research regulations try to outline the type of research which is considered legitimate, taking into account certain ethical values. In the case of human stem cell research it has been pointed out by the EGE that the ethical acceptability of human stem cell research depends on the objectives which are aimed at and on the source of the stem cells. Is it necessary to carry out research on embryonic stem cells? Is it legitimate to carry out research on embryonic stem cells in view of the fact that the scientific community discovered that adult stem cells have to a large extent the same properties? Should a distinction be made between cells derived from embryos, foetuses and adult human bodies? Assuming that

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research on embryos is accepted, questions are raised with regard to the type of embryos used for carrying out stem cell research: Up to what stage can of development can embryos be used? Under what conditions? Is it possible, in ethical terms, to create embryos only for the purpose of research? Can we be satisfied with using supernumerary embryos, which would never be implanted and would be destroyed anyway?

Patent law deals with the same subject matter, but mainly focuses on the research applications and the ethical implications the exploitation thereof might entail. In doing so, patent law first and foremost addresses the invention quality of the applications, which arise from research. Can human stem cell lines be qualified as inventions? Can human stem cell lines be regarded as new? Do they give evidence of creativity, from inventiveness, which goes beyond the usual routine? Are the results industrially applicable? Only in the rare case an invention meets the general patentability criteria of invention, novelty, inventive step and industrial applicability but the exploitation appears to run counter to ‘ordre public’ and morality, patent law will take action and put a limit to the patentability.

The relationship between patent law and biomedical research regulations, and the different role and scope they both fulfil, is being manifestly put to test in the field of embryonic stem cell research.

As the EGE pointed out, no specific stem cell research regulations exist at the national level, so it is necessary to turn to the general legislation on embryo research. The EGE makes a distinction between three different situations. First, there is the case in which no clear and/or enforceable legislation on embryo research exists, and embryo research is variably carried out or not performed. Second, there is the situation in which embryo research is legislated, and variably authorises or prohibits embryo research. Third, there is the situation in which bioethical laws and conventions are in place, which clearly admit or prohibit commercialisation of embryo research.

Looking at this multitude of situations, various questions arise with regard to possible patenting. In the case embryo research is not legislated, can patents be considered admissible? In the case embryo research is authorised, can we conclude patents are justified? In the case embryo research is excluded, what is the effect of the ban on embryo research on the issuance of patents? In case the research is authorised and the commercialisation of derived products is not excluded, are patents then legitimate? In the case commercialisation is banned, what is the effect is of that ban on the grant of patents?

These pertinent questions illustrate an underlying problem, which raises even greater concern. Especially in the case where research legislation on embryos is lacking, public opinion might turn to patent law for guidance. Experience has shown, that in cases where appropriate research legislation is missing, high expectations are raised and many claims are laid on the patent authorities and on the patent legislator to address controversial issues and offer guidance in ethically delicate matters, which have not effectively been treated by bio-ethical research laws.

The decisions of patent authorities and legislators can have an indirect effect on research. A situation might arise where patent law determines the limits of stem cell research. Is it the role of patent authorities and patent legislators to determine the shape of stem cell research? Should patent law decide on the legitimacy of stem cell

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234 See EGE, 2000, p. 11, paragraph 1.13.
research? Should patent law have authority over the bioethical borders to be observed in stem cell research?

2. Guiding elements

a. EPO case law

The Boards of Appeal of the EPO explained that the assessment of whether or not a particular subject matter is to be considered contrary to either ‘ordre public’ or morality is not dependent upon any national laws or regulations. Conversely and by the same token, the Board is of the opinion that a particular subject-matter shall not automatically be regarded as complying with the requirements of article 53 (a) EPC merely because its exploitation is permitted in some or all of the Contracting States. Thus, approval or disapproval of the exploitation by national law(s) or regulation(s) does not constitute per se a sufficient criterion for the purposes of examination under article 53 (a) EPC.

b. Opinion of the GAEIB

The GAEIB took the view that there might be certain types of genetic manipulation which should be strictly prohibited, but was of the opinion that this matter should be dealt with under the competent branches of public law dealing with the use and commercialisation of research results in respect to public safety, health, environment and animal welfare. In this line of reasoning the GAEIB acknowledged the need to reaffirm the ban on genetic engineering for non-therapeutic purposes contrary to the dignity of man, but felt that the Directive was not the right place to deal with the very complex issue of the legitimacy of germinal therapy. The GAEIB equally felt that if patent law cannot substitute laws in the respective fields, it is useful to mention the ethical concerns raised by genetic engineering in the Directive. The GAEIB underlined, however, that the appropriate place to address and resolve the ethical considerations are the recitals of the Directive, and not as a part of the Directive’s body.

c. Opinion of the EGE. The pluralism principle.

The EGE takes the view that in the field of ethics and human stem cell research, pluralism should prevail. The EGE states that “Pluralism is characteristic of the European Union, mirroring the richness of its tradition and adding a need for mutual respect and tolerance. Respect for different philosophical, moral and legal approaches and for diverse cultures is implicit in the ethical dimension of building a democratic European society.” The Convention of Human Rights and Biomedicine equally

235 Board of Appeal EPO, Decision 21 February 1995, Case T 356/93, Official Journal EPO, 1995, (545), 558, more in particular, see point 8 of the decision (Also see http://www.european-patent-office.org/dg3/biblio/930356ex1.htm). This case has already been discussed supra.
238 Opinion n° 3, 2.2.1.
239 Opinion n° 3, 2.2.2.
240 EBE, 2000, p. 14, paragraph 2.3.
241 Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and
reflects this pluralist approach and starts from the idea that it is up to each country to decide whether to authorise embryo research or not. The Convention restricts itself to imposing two conditions: "Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo" and "The creation of human embryos for research purposes is prohibited".

The derivation of embryonic human stem cells raises the issue of the moral status of the human embryo. According to the EGE "in the context of European pluralism, it is up to each member state to forbid or authorise embryo research". This basic principle laid down by the EGE raises a fundamental question with regard to possible patenting.

For the time being, it is possible to obtain patent protection in Europe by separate application to each of the national Patent Offices within Europe (the so-called National Route) or by opting for a patent at the European Patent Office (the so-called European Route). The establishment of an opinion on the patenting of human stem cell research will probably be welcomed, both at the national and the European level. But taking into account that in most cases it is a European patent that is opted for and assuming that the EPO will follow the future opinion of the EGE, will that not lead to the (undesired) effect that one view will govern the various member states? Do we not run the risk that the so cherished plurality of opinions in Europe on embryo research - and subsequent patenting - will be lost? That only one monolithic view will prevail, notably the EPO opinion? Does it, therefore, not appear extremely dubious that patent law would have a considerable say in stem cell research?

**B. The relationship between patents and commercialisation**

**1. Key questions**

However much the insertion of article 6 and the introduction of a non-limitative list were welcomed, some issues remain unclear. Three elements in the wording of article 6 of the EU Biotechnology Directive lead to some uncertainty as to the exact scope of the exclusion envisaged.

The first element is the wording of article 6 (1) of the Directive. The EU Biotechnology Directive underlines in article 6 (1) that inventions shall be considered unpatentable where their commercial exploitation would be contrary to 'ordre public' or morality. A similar approach can be found in Recital 37 of the Directive, which stresses the principle whereby inventions must be excluded from patentability where their commercial exploitation offends against 'ordre public' or morality. In doing so, the Directive puts itself on the same line as the TRIPS where it emphasises 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 domestic law (article 27 (2)) 245.

Different from this wording, however, is the EPC which stipulates that European patents shall not be granted in respect of inventions the publication or exploitation of which would be contrary to 'ordre public' or morality (article 53 (a) EPC). Differing also is the wording used by the EU Council, which adopted the view that it was advisable to include in the body of the Directive a reference to public policy 246 and morality in order to highlight the fact that some applications of biotechnological inventions, by dint of some of their consequences or effects, are capable of offending against public policy and morality 247. Various national patent laws equally stipulate that patents shall not be granted for inventions of which the application runs counter to 'ordre public' and morality 248. It is rather unclear to which extent this different redactions lead to a different scope in exclusion.

The second element lies within the wording of article 6 (2). Article 6 enumerates various inventions which shall be considered unpatentable: processes for cloning human beings or processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial purposes. The memorandum preceding the Directive 249, as well as various recitals confirm the impression that the Directive aims at excluding the invention itself, rather than the exploitation of the invention 250.

245 Cf. Common Position (EC) n° 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 (98/110/EC), Official Journal EC - C - 8 April 1998, 110(17), 29, point 29: "As regards paragraph 1 of this article [6], the Commission did not include in its amended proposal the words 'exploitation or publication' proposed by the Parliament, preferring the words 'commercial exploitation' on the lines of Article 27(2) of the TRIPs Agreement. The Council concurred with the Commission".

246 Notice that the term 'public policy' which is used in the Common Position, is replaced by the notion 'ordre public' in the final text of the Directive of 8 July 1998. The - unjust - equalisation of the terms public policy and 'ordre public' was adopted in the Amended proposal for a Council Directive on the legal protection of biotechnological inventions, presented by the Commission pursuant to Article 149 (3) of the EEC-Treaty, (COM(92)589 final - SYN 159), Brussels, 16 December 1992.


248 Cf. article 4 § 2 Belgian Patent Act, 28 March 1984 (French version: "Les brevets ne sont pas délivrés pour les inventions dont la mise en œuvre serait contraire à l'ordre public ou aux bonnes mœurs, y compris pour protéger la santé et la vie des personnes et des animaux ou préserver les végétaux, ou pour éviter de graves atteintes à l'environnement, la mise en œuvre d'une invention ne pouvant être considérée comme telle du seul fait qu'elle est interdite par une disposition légale ou réglementaire"; Dutch version: "§ 2 De uitvindingssocroozen worden niet verleend voor uitvindingen waarvan de toepassing strijdig zou zijn met de openbare orde of met de goede zeden, met inbegrip van bescherming van het leven of de gezondheid van mensen, diereen of planten of ter vermindering van ernstige schade voor het milieu, met dien verstande dat niet als strijdig in deze zin zal worden beschouwd het enkele feit dat de toepassing van de uitvinding door een wetelijke of reglementaire bepaling is verboden".

249 Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions (96/C 296/03, COM (95) 661 final, 95/0350 (COD), p. 18, n° 67: "... To that end, it is proposed to exclude directly from patentability 'methods of germ line gene therapy on humans'"). (My Italic).

250 See e.g. Recital 40: "Whereas there is a consensus within the Community that intervention in the human germ line and the cloning of human beings offends against 'ordre public' and morality, whereas it is therefor important to exclude unequivocally processes for modifying the germ line
The third element equally lies within article 6 (2). According to the current understanding of the EPC and the current EPO patent practice, patent protection is granted for different "categories" of claims ("products, process, apparatus or use")\textsuperscript{251}. It appears from article 6 (2) EU Biotechnology Directive that various types of processes are excluded from patent protection, but it is unclear why the products used in or obtained by such processes are not explicitly considered to run counter to 'ordre public' and morality and therefore should be excluded from patentability as well.

It is clear that the EU Biotechnology Directive wants to take action in view of 'ordre public' and morality. It is not clear, however, what exactly is envisaged in article 6. Should only inventions of which the commercial exploitation (= commercialisation? = application?) is considered to be contrary to 'ordre public' and morality be excluded? Or should inventions which are believed to be contrary to 'ordre public' and morality be denied patent protection? And why are merely certain processes listed as unpatentable and are the derived products not expressly mentioned?

2. Guiding elements

a. Position of the EPO

The EPC Guidelines explain that exploitation is not to be deemed to be contrary to "ordre public" or morality merely because it is prohibited by law or regulation in some or all of the Contracting States. One reason for this is that a product could still be manufactured under a European patent for export to States in which its use is not prohibited \textsuperscript{252}.

b. Position of the EU Council

With regard to the exclusion of processes for modifying the germ line genetic identity of human beings from patent protection (article 6 (2) (b)), the 'Common Position' adopted by the Council on February 7 1994 suggested that not all processes for modifying the genetic identity of the human are to be excluded, but only those which are contrary to the dignity of man \textsuperscript{253}. Even in the case a process would enable a modification of the human genetic code to be controlled in connection with in vitro fertilisation intended to correct certain genetic deficiencies, such a process should be compatible with the dignity of man, taking into account the therapeutic aims which the process would enable to be achieved. Even if this condition were fulfilled, that would in no way imply automatic recognition of the patentability and legitimacy of what is known as germ gene therapy since, if such a patent were to be granted, the

\textsuperscript{251} Guidelines for substantive examination of the European Patent Office, Part C, Chapter III, 3.1. (Also see http://www.european-patent-office.org/legal/gui_lines/e/c_iii_3.htm). For more details, supra.

\textsuperscript{252} Guidelines for substantive examination of the European Patent Office, Part C, Chapter IV. 3, 3.1. (Also see http://www.european-patent-office.org/legal/gui_lines/e/c_iii_3.htm).

national or Community authorisation procedures applying to this type of therapy would of necessity have to be observed before any use of this therapy.\textsuperscript{254}

This explanation reminds us of one of the basic characteristics of patent law, which equally applies in the field of biotechnology and human stem cell research. A patent right does not confer the right to exploit the invention without restriction, but merely enables the holder to prohibit third parties from using his patent without his authorisation. In terms of competition rules, a patent confers a purely negative right of exclusion and not a positive right of exploitation. This basic feature of patent law was addressed in Recital 14 of the EU Biotechnology Directive, which emphasises that “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”.

Consequently, even after patent grant, national or Community legislation concerning health, safety, environmental protection, consumer protection, etc. have to be taken into account before the patented invention can be used and commercialised. Also this aspect is called in mind by the EU Directive where it is emphasised that “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” (Recital 14)\textsuperscript{255}.

However, when this explanation is read in connection with the questions raising from article 6 (1)\textsuperscript{256}, the whole issue on whether the Directive aims at excluding inventions which run counter to ‘ordre public’ and morality or to ban inventions of which the commercialisation is contrary to ‘ordre public’ and morality seems to become even more incoherent.

c. Opinions of the GAEIB

In its opinion on Ethical Questions Arising from the Commission Proposal for a Council Directive on Legal Protection for Biotechnological Inventions from September 30 1993 the GAEIB expressed the need to reaffirm the ban on genetic engineering for non-therapeutic purposes contrary to the dignity of man was acknowledged, but it was felt that the Directive was not the right place to deal with the very complex issue of the legitimacy of germinal therapy\textsuperscript{257}.

The GAEIB underlined in its opinion on the Ethical Aspects of Patenting Inventions Involving Elements of Human Origin of September 25 1996 that “the fact that a

\textsuperscript{254} Official Journal EC – C - April 9 1994, 101/65, Recital 13.
\textsuperscript{255} Similarly, Recital 38 of the ‘Common Position’ adopted by the Council on February 7 1994, where it is underlined that the Directive should be without prejudice to national and Community laws on the monitoring of the applications of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, the protection of the environment, the protection of animals, the preservation of genetic diversity and compliance with certain ethical standards (Official Journal EC – C - April 9 1994, 101/65).
\textsuperscript{256} Supra.
\textsuperscript{257} GAEIB, Opinion on Ethical Questions Arising from the Commission Proposal for a Council Directive on Legal Protection for Biotechnological Inventions, September 30 1993 (Opinion n° 3), point 2.2.3 (b).
patent allows monopoly of exploitation of an invention during a limited period of time, in general 20 years, in order to remunerate an inventor as compensation for his (her) intellectual and financial research efforts. A patent in itself does not give the authorisation to use or commercialise the patented invention.\textsuperscript{258}

The GAEIB further emphasised that “The questions of ethical acceptability and safety of the products, for health and the environment, need to be considered in the context of the European Union. Appropriate measures, independently of patent rights, have to be taken before the marketing authorisation of the considered products.”\textsuperscript{259}

d. Opinion of the EGE

In the field of human stem cell research, the EGE argues that measures should be taken to prevent the commercialisation of embryos as well as cadaveric foetal tissue: “The potential for coercive pressure should not be underestimated when there are financial incentives. Embryos as well as cadaveric foetal tissue must not be bought or sold not even offered for sale. Measures should be taken to prevent such commercialisation.”\textsuperscript{260}

Current patent legislation appears to reflect the trend towards the use of the human body as a source of diverse substances. Current patent law, in providing protection for parts of the human body, appears to encourage the commercialisation of the human body. Does the viewpoint of the EGE that commercialisation of embryos and foetal tissue is to be prevented not imply that patenting of some results of human stem cell research is discouraged? Should it not lead to the conclusion that patents for embryonic and foetal human stem cells and derived products are prohibited?

How does the EGE viewpoint with regard to non-commercialisation of embryos and foetal tissue run parallel with the opinion that stem cell products can be imported and exported? The EGE lays down conditions for such products to be imported and exported, which presumes that embryo and foetal tissue research can lead to certain products, which can be imported and exported.\textsuperscript{261}

e. Judgement of the Court of Justice, October 9 2001

In its judgement of October 9 2001 the Court of Justice clarified the scope of the notion ‘ordre public’ and morality, but did not consider the scope of the term commercial exploitation in great depth.\textsuperscript{262}

The applicant submitted that, rather than helping to remove the legal ambiguities described in the recitals, the Directive tends to exacerbate them, thus breaching the principle of legal certainty. Amongst other things, the Directive gives the national

\textsuperscript{258} GAEIB, Opinion on the Ethical Aspects of Patenting Inventions Involving Elements of Human Origin, September 25 1996 (Opinion no 8), point 1.3.

\textsuperscript{259} GAEIB, Opinion on the Ethical Aspects of Patenting Inventions Involving Elements of Human Origin, September 25 1996 (Opinion no 8), point 1.4.

\textsuperscript{260} EGE, 2000, p. 18, paragraph 2.17.

\textsuperscript{261} EGE, 2000, p. 18, paragraph 2.18.

\textsuperscript{262} Judgement of the Court of Justice, 9 October 2001, Case C-377/98, Kingdom of the Netherlands, supported by Italian Republic and by Kingdom of Norway v. European Parliament and Council of the European Union, supported by Commission of the European Communities (See http://www.curia.eu.int).
authorities discretion in applying concepts expressed in general and ambiguous terms, such as 'ordre public' and morality, which appear in article 6.  

The Court stated that as regards article 6 it is common ground that this provision allows the administrative authorities and courts of the member states a wide scope for manoeuvre in applying this exclusion. In the view of the Court, that scope for manoeuvre is necessary 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, a context which the national legislative, administrative and court authorities are better placed to understand than are the Community authorities. That sort of provision, which allows patents to be refused where there is a threat to 'ordre public' or morality is, moreover, a well-known one in patent law and appears inter alia in the relevant international legal instruments, such as the EPC. The Court further underlined, that the scope for manoeuvre left to member states is not discretionary, since the Directive limits the concepts in question, both by stating that commercial exploitation is not to be deemed to be contrary to 'ordre public' or morality merely because it is prohibited by law or regulation, and by giving four examples of processes or uses which are not patentable. Thus, the Community legislature gives guidelines for applying the concepts at issue, which do not otherwise exist in the general law on patents. Finally, a directive cannot be considered contrary to the principle of legal certainty if it relies, as regards the conditions for its implementation, on concepts known to the laws of the member states, specifying, as here, their scope and limits and taking account, in order to do so, of the specific nature of the subject-matter. These arguments lead to the decision of the Court that article 6 of the Directive is not therefore such as to exacerbate the legal uncertainty which the Directive seeks to alleviate.

CHAPTER 4. CONCLUSIONS

A. Patentability of inventions relating to human stem cell research

1. Patentability of human stem cells. Criteria

As to the patentability of human material, the EU Biotechnology Directive stipulates that 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 (article 3 (1)). However, 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 (article 3 (2)).

In view of article 3, the question arises to which extent this provision applies to human stem cells. In an attempt to provide an answer to this question, various sources were carefully examined. First of all, the preparatory documents of the EU Biotechnology Directive were thoroughly screened. Next, the GAEIB Opinion on the

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263 Third plea in law. See Judgement of the Court of Justice, 9 October 2001, Case C-377/98, point 35.
264 Judgement of the Court of Justice, 9 October 2001, Case C-377/98, points 37 to 40.
Patenting of inventions related to human stem cell research

Ethical Aspects of Patenting Inventions Involving Elements of Human Origin of September 25 1996 was examined. Further, the recent judgement of the Court of Justice of October 9 2001 on the EU Biotechnology Directive was analysed. Last but not least, some academic scholars were consulted.

The examination of these sources reveals that various criteria are taken into account to decide on the patentability of elements from human origin. Below an overview of these criteria is offered, as well as some of the questions to which they give rise.

a. Technical intervention

In the great majority of EU documents, as well as in the judgement of the Court of Justice, it is stressed that the major test to decide whether an element from human origin is patentable or not is the technical intervention, the artificial process, the human intervention to isolate and reproduce the elements from human origin. It is repeatedly said that the touchstone to decide whether or not elements from human origin are patentable or not, whether they are to be considered as discoveries or not, lies in the technical intervention - the isolation, purification or reproduction of the element - techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself.

Contrary to several EU documents, which claim the distinction between discovery and invention is of a technical patent law nature, the GAEIB is of the opinion that 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. Nevertheless, the GAEIB takes the view that patents for inventions issued from the knowledge of a human gene or a partial human gene sequence are admissible in certain circumstances (The same would probably apply to human (stem) cells). Can such an approach be reconciled with the opinion expressed at the start? How is this line of reasoning to be understood?

b. Technical solution

It has also been suggested that the decisive element to turn material from the human body from a non patentable issue (discovery) into patentable subject matter (invention) is the way in which the biological material provides a technical solution for a technical problem.

This criterion appears to be superfluous, since it is incorporated in the current patentability criteria, more in particular the 'inventive step' assessment, which is conducted by a problem-solution test.

c. Essential change of the element

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265 GAEIB, Opinion on the Ethical Aspects of Patenting Inventions Involving Elements of Human Origin, September 25 1996 (Opinion n° 8), point 2.2.
The view has also been expressed that a patent can only be granted on an innovation capable of industrial application, which relates to an element of human origin - like an isolated gene - if this element has been essentially changed. It is not essentially changed if the structure of the element is identical to an element - gene - to be found in the human body or if the genetic information is identical to the information of a human element - gene - inside the human body. Patents on elements of human origin are not justified if the structure of that element is identical to that of a natural element, even if the element is isolated from the human body by means of a technical process.

Are human stem ‘cells’ essentially changed when cultured? Are human stem ‘cell lines’ essentially changed during the cultivation or differentiation process? From a scientific point of view, there appears to be difference between ‘cell’ and ‘cell line’. Is the difference between a ‘cell’ and a ‘cell line’ relevant in view of the patentability?

d. Anonymity of the individual

In the ‘Joint Text’ approved by the Conciliation Committee on 23 February 1995 emphasis has been put on the idea that a technical process should lead to the obtaining of human body parts which can no longer be linked with a specific individual.

Does this phrase aim at stressing that no physical link with a specific individual may be present anymore, or does it intend to underline that no association whatsoever with the particular individual may be present? Do human cells and human stem cells, not resemble human genes in this respect that cells, similar to genes, contain the entire genetic information of the person from whom the material is extracted? Can stem cells, similarly to genes, be qualified as ‘genetic information carriers’?

In the light of the fact that human genes and human cells contain valuable information with regard to the genetic make up of a specific individual, it is not clear whether physical separation through a technical method is envisaged or whether complete anonymity is claimed as a criterion to decide on the patentability of elements of human origin.

e. Return of the stem cells to the individual

The EPC Guidelines make clear that “treatment of body tissues or fluids after they have been removed from the human or animal body, or diagnostic methods applied thereon, are not excluded from patentability in so far as these tissues or fluids are not returned to the same body. Thus the treatment of blood for storage in a blood bank or diagnostic testing of blood samples is not excluded, whereas a treatment of blood by dialysis with the blood being returned to the same body would be excluded.”

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267 Mieth, D., in GABIB, Opinion on the Ethical Aspects of Patenting Inventions Involving Elements of Human Origin, September 25 1996 (Opinion n° 8), Addition to 2.5.
268 Supra.
269 Joint Text approved by the Conciliation Committee provided for in article 189 b (4) of the EC Treaty 0159 (COD), PE-CONS 3606/95.
270 Guidelines EPC, Part C, Chapter IV, 4.3.
In view of this guideline, what is the patentability status of human embryonic stem cells which have been extracted from a particular individual and then further cultured and propagated in view of tissue replacement in that same individual?

f. Source of the stem cells

In its opinion on Ethical Aspects of Human Stem Cell Research and Use from November 14 2000, the EGE addresses the principal requirements according to the diverse sources of stem cells. In this respect the EGE distinguishes between the retrieval from adult stem cells, the retrieval from the umbilical cord blood, the retrieval of foetal tissue and the derivation from embryonic blastocysts. In the first three cases, the EGE emphasises that the retrieval of those stem cells requires respect for the integrity of the human body and the free and informed consent of the donor. In the last case, however, the EGE expresses its deep concern about the use of those stem cells and explicitly underlines that the retrieval and use of embryonic stem cells is a very sensitive matter, “since this use may change our vision of the respect due to the human embryo”.

Generally speaking, the source of the stem cells appears not to have been a major issue in the various documents we examined. Except, maybe, for one opinion from the Council of February 7 1994, where the Council emphasised that in the light of the general principle that the ownership of human beings is excluded “the human body or parts of the human body as such, for example a gene, protein or cell in the natural state in the human body, including germ cells and products resulting directly from conception, must be excluded from patentability”.

The Position seems to suggest that the patent regime for human cells is not different from the one for human genes, which leads to conclude that human cells and human stem cells which are isolated from the human body are patentable. The Position raises some doubt, however, with regard to the patentability of human stem cells from embryonic or foetal origin (embryonic stem cells, embryonic germ cells, and foetal stem cells), since the Position indicates that “products resulting directly from conception” must be excluded from patentability. Is the Position to be understood in this way that embryos which are isolated as a whole from the human body are to be excluded from patent protection, whereas human (stem) cells originating from embryos are not to be excluded?

Contrary to the EU documental history, the source of stem cells was discussed in legal doctrine. STRAUS, an authority in the field of biotechnology patenting, takes the view that the EU Biotechnology Directive allows the patenting of biological material isolated from its natural environment or produced by means of a technical process e.g. cell lines, “whatever their source”. Other academic scholars express their doubts.

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271 EGE, 2000, p. 15, point 2.4.
272 EGE, 2000, p. 15, point 2.6.
about patent applications claiming embryonic cell lines \(^{275}\) or only find it acceptable under some strict conditions \(^{276}\).

With regard to the patentability of human stem cells some compelling and weighty reasons might justify a dissenting approach in comparison to human genes and cells, in particular in the case of research involving the use of human embryos. Probably the most delicate point in human stem cell technology relates to the use of embryos as the source of cells and the deliberate necessary destruction of an otherwise viable embryo in order to obtain embryo cells. In that case it is not inconceivable that the research involving the use of human embryos is considered to call for limits with regard to patenting.

2. Patentability of human cloning methods

To get around the problem of host rejection, human embryonic cells might have to be modified, or doctors might be able to clone an early embryo from a patient’s somatic cells and then generate his or her own embryonic cells. That explains why the patentability of the cloning phase was assessed in the present study.

The EU Biotechnology Directive underlines processes for cloning human beings shall be considered unpatentable (article 6 (2) (a)).

Various sources have been consulted to assess the question of the patentability of cloning methods. First, we found some guidance in the recitals preceding the EU Biotechnology Directive. Next, we thoroughly examined the Edinburgh case, which reveals the manner in which the EPO interprets the EU Biotechnology Directive at this point. Last but not least, we explored the position of the European Parliament on this issue.

At present, the exact scope of this exclusionary provision in relation to human stem cells research is not clear.

3. Patentability requirements

The governing substantive patentability requirements as laid down in the EPC – novelty, inventive step, industrial applicability – appear to be no greater hindrance in the case of human stem cell techniques than in the case of other biotechnological inventions.

4. Scope of protection

The EU Directive stipulates the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics (article 8 (1)).

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Assuming a patent has been granted for a human stem cell line and that human stem cells are then grown in vitro, caused to differentiate into the cell type required for transplantation to a patient, suffering from trauma. To which extent does the protection conferred by the patent stretch out to that individual?

**B. The relationship between patent law and research**

The relationship between patent law and biomedical research regulations, and the different role and scope they both fulfill, is being manifestly put to test in the field of embryonic stem cell research.

Various pertinent questions arise. In the case embryo research is not legislated, can patents be considered admissible? In the case embryo research is authorised, can we conclude patents are justified? In the case embryo research is excluded, what is the effect of the ban on embryo research on the issuance of patents? In case the research is authorised and the commercialisation of derived products is not excluded, are patents then legitimate? In the case commercialisation is banned, what is the effect is of that ban on the grant of patents?

These pertinent questions illustrate an underlying problem, which raises even greater concern. Especially in the case where research legislation on embryos is lacking, public opinion might turn to patent law for guidance. The decisions of patent authorities and legislators can have an *indirect* effect on research. Is it the role of patent authorities and patent legislators to determine the shape of stem cell research? Should patent law decide on the legitimacy of stem cell research? Should patent law have authority over the bioethical borders to be observed in stem cell research?

Over and above this, will a European policy on patenting embryo stem cell research, not lead to the (undesired) effect that one view will govern the various member states? Don't we run the risk that the so cherished plurality of opinions in Europe on embryo research - and subsequent patenting - will be lost? That only one monolithic view will prevail, notably the EPO opinion?

**C. The relationship between patent law and commercialisation**

It remains unclear what the exact ambit of the exclusionary provision laid down in article 6 of the EU Biotechnology Directive is. Paragraph 1 of article 6 appears to exclude the *commercial exploitation* of inventions, which run counter to 'ordre public' and morality, whereas the introductory phrase of paragraph 2 seems to exclude certain *inventions* as such. Moreover, no definition is given from the term 'commercial exploitation' itself, which is troublesome in view of the differing redactional phrasings used in other legislative texts ('exploitation' in the EPC, 'application' in various national patent acts).

Shall inventions related to human stem cell research be considered unpatentable where their commercial exploitation runs counter to 'ordre public' and morality (article 6 (1) approach)? Or shall certain types of human stem cell related inventions as such should be considered unpatentable as being contrary to 'ordre public' or morality (article 6 (2) approach)?
Even if these questions will have been addressed, the ambiguity in the EU Biotechnology Directive on the relationship between patent law and exploitation might remain. On the one hand, exploitation is a crucial concept in the ‘ordre public’ and morality test. On the other hand, the Directive (Recital 14) and the Court of Justice underline that exploitation is not an issue to be treated in patent law (see recital 14).