Margit Piirman

Adviser to the Civil Chamber
Supreme Court of Estonia

Patentability of Inventions Related to Human Embryonic Stem Cells

1. Introduction

Imagine the case where it is possible to treat patients who have suffered a spinal cord injury by using human embryonic stem cell[*1] (hereinafter referred to as the hESC) therapy. At first glance, this might seem impossible, but Geron Corporation has already initiated a clinical trial of hESC-derived oligodendrocyte progenitor cells. At that time, in 2010, Geron's president, Thomas B. Okarma, considered this clinical trial a milestone for the field of hESC-based therapies.[*2] Embryonic stem cells are stem cells derived from the blastocyst stage of the embryo (5–7-day embryo).[*3] These stem cells are pluripotent; that is, they have the capacity to develop into any of the 200 cell types that make up the human body[*4] and can proliferate in the laboratory (*in vitro*) indefinitely.[*5] It is hoped that, because of the properties stem cells possess, it will become possible to use them in therapy for degenerative diseases or injuries[*6], to use them to replace whole cells, and to manipulate them to regenerate defective tissues or organs and cause them to grow back.[*7] Clearly, the potential benefit for mankind from hESCs cannot be underestimated. Still, hESC research, especially the patentability of inventions pertaining to hESCs, has created heated debate in Europe. One reason for this is that, for obtaining the hESCs from the blastocyst stage of the embryo, the embryo is usually destroyed.[*8]

---

1 A stem cell is a precursor cell that gives rise to specialised cells of various types as well as to more stem cells. It is an undifferentiated cell that can divide without limit and whose progeny includes both further stem cells or cells destined to differentiate. See D. P. Clark, N. J. Pazdernik. Biotechnology: Applying the Genetic Revolution. Amsterdam etc.: Elsevier/Academic Press 2009, p. 733; G. Van Overwalle. European Commission, European Group on Ethics in Science and New Technologies to the European Commission. Study on the patenting of inventions related to human stem cell research, 30.12.2001. Luxembourg 2002, p. 8.

2 Geron Initiates Clinical Trial of Human Embryonic Stem Cell-Based Therapy. Available at http://www.geron.com/media/pressview.aspx?id=1235 (2.4.2011).

3 D. P. Clark, N. J. Pazdernik (Note 1), p. 709.

4 G. Laurie. Patenting Stem Cells of Human Origin. – European Intellectual Property Review 2004 (26) 2, p. 60.

5 G. Van Overwalle (Note 1), p. 8.

6 European Group on Ethics in sciences and new technologies to the European Commission. Opinion on ethical aspects of patenting inventions involving human stem cells. Opinion No. 16, 7 May 2002. Luxembourg 2002, p. 5.

7 D. P. Clark, N. J. Pazdernik (Note 1), p. 488.

8 M. Eder-Rieder. Aspekte der Stammzellentechnologie im Besonderen in Großbritannien, Deutschland, Österreich und der Schweiz. – ZfEV 2007/4, p. 18; J. A. Johnson *et al*. Stemm Cell Research – CRS Report for Congress. – Practicing Law Institute. Patents, Copyrights, Trademarks, and Literary Property Course Handbook Series, September 2005, p. 359. (840 PLI/Pat 351).

The purpose of this article is to analyse the problems related to the patentability of inventions related to hESCs, especially the questions raised in the case *Oliver Brüstle vs. Greenpeace eV*[*9], which was brought before the European Court of Justice (hereinafter referred to as the ECJ) for a preliminary ruling. The main questions raised in the *Brüstle* case that the author will consider in this article are the following: What is meant by the term 'human embryos' in Article 6 (2) (c) of Directive 98/44/EC? What is meant by the expression 'uses of human embryos for industrial or commercial purposes'? The author analyses these questions in light of Estonian laws, including the Estonian Patents Act[*10] (hereinafter referred to as the EstPA), and attempts to interpret the relevant paragraphs of the EstPA, considering also Community law and Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Invention[*11] (hereinafter referred to as 'the Biotech Directive'). It is important to note that, as of the time of writing, no judgement has been issued by the ECJ in the *Brüstle* case yet; it is hoped that a ruling will resolve the relevant questions raised. In the meantime, however, as there is already the opinion of the Advocate General[*12] available in this case, it has been possible to analyse the solutions offered by the Advocate General. The author also briefly points to the problems arising in evaluation of the patentability of inventions related to pluripotent stem cells under a general *ordre public* or morality clause. The aim of this article is also to offer a possible new wording for the EstPA (and the Biotech Directive) concerning the patentability of hESC-related inventions. An accompanying aim is to create discussion among Estonian lawyers about the patentability of inventions related to hESCs. So far, there has been no public discussion of this in Estonia. There also has been no official statement of the Estonian Patent Office about the patentability of hESC-related inventions. Because the ethics questions surrounding the patentability of inventions related to hESCs have been raised mainly in the European Union, this article does not give great attention to regulations and practice outside the European Union.

2. Legal framework

In Estonia, in order for us to consider whether hESC-related inventions are patentable, it is important to look at §7 of the EstPA, which gives a list of inventions that are considered unpatentable. According to §7 (1) 1) of the EstPA, inventions that are contrary to public order and morality shall not be protected by a patent. Further, §7 (2) 3) of the EstPA stipulates that uses of human embryos for commercial purposes, including processes prohibited by the Artificial Insemination and Embryo Protection Act, are biotechnological inventions, which shall not be protected by a patent.

As Estonia is a Member State of the European Union, it is important to look at Directive 98/44/EC also. According to Article 6 (1) of the Biotech Directive, 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 53 (a) of the European Patent Convention[*13] (hereinafter referred to as the EPC) and Article 27 (2) of the Agreement

9 Reference for a preliminary ruling from the Bundesgerichtshof (Germany) lodged on 21 January 2010. See Prof. Dr. Oliver Brüstle v. Greenpeace e.V (Case C-34/10). Available at http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&alljur=alljur&jurcdj=jurcdj&jurtpi=jurtpi&jurtfp=jurtfp&numaff=&nomusuel=BrĆ¼stle&docnodecision=docnodecision&allcommjo=allcommjo&affint=affint&affclose=affclose&alldocrec=alldocrec&docor=docor&docav=docav&docsom=docsom&docinf=docinf&alldocnorec=alldocnorec&docnoor=docnoor&docppoag=docppoag&radtypeord=on&newform=newform&docj=docj&docop=docop&docnoj=docnoj&typeord=ALL&domaine=&mots=&resmax=100&Submit=Rechercher (3.4.2011).

10 Patendiseadus. – RT I 1994, 25, 406; 2010, 22, 108 (in Estonian). English text available at http://www.legaltext.ee/ (2.4.2011).

11 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. Available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML (2.4.2011).

12 Opinion of Advocate General Bot, delivered on 10 March 2011. See Case C-34/10, Oliver Brüstle v. Greenpeace eV. Available at http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&alljur=alljur&jurcdj=jurcdj&jurtpi=jurtpi&jurtfp=jurtfp&numaff=&nomusuel=BrĆ¼stle&docnodecision=docnodecision&allcommjo=allcommjo&affint=affint&affclose=affclose&alldocrec=alldocrec&docor=docor&docav=docav&docsom=docsom&docinf=docinf&alldocnorec=alldocnorec&docnoor=docnoor&docppoag=docppoag&radtypeord=on&newform=newform&docj=docj&docop=docop&docnoj=docnoj&typeord=ALL&domaine=&mots=&resmax=100&Submit=Rechercher (11.4.2011).

13 European Patent Convention, 5 October 1973. Available at http://www.epo.org/law-practice/legal-texts/html/epc/1973/e/ma1.html (5.4.2011).

on Trade-Related Aspects of Intellectual Property Rights[*14] (hereinafter referred to as the TRIPS) contain a similar *ordre public* and morality clause. Article 6 (2) (c) of the Biotech Directive stipulates that, on the basis of paragraph 1, the following, in particular, shall be considered unpatentable: 'uses of human embryos for industrial or commercial purposes'.[*15]

The author examines first whether hESC-related inventions could be unpatentable under §7 (2) 3) of the EstPA and Article 6 (2) (c) of the Biotech Directive, what might be the definition of 'embryo', and what is meant by use of human embryos for 'industrial or commercial purposes'. Then, the work briefly points to the problems arising when one evaluates the patentability of inventions related to pluripotent stem cells under a general *ordre public* or morality clause.

3. The definition of 'embryo'

For us to reach a conclusion as to whether hESC-related inventions are patentable or fall within the exception laid down in §7 (2) 3) of the EstPA, it is important to examine first what an 'embryo' is within the meaning of that paragraph. The question of what is meant by the term 'human embryos' in Article 6 (2) (c) of the Biotech Directive was raised also by the German courts (the *Bundesgerichtshof*), before the ECJ for a preliminary ruling in case C-34/10, the *Brüstle* case.[*16] This case involves a German patent, filed on 19 December 1997, the holder of which is Mr. Brüstle and which concerns isolated and purified neural precursor cells, processes for their production from embryonic stem cells, and the use of neural precursor cells for the treatment of neural defects. Greenpeace eV brought an action for the annulment of the patent filed by Brüstle insofar as certain claims under that patent pertain to precursor cells obtained from hESCs. The Federal Patent Court allowed the application made by Greenpeace in part and declared the patent filed by Brüstle invalid insofar as the first claim is related to precursor cells obtained from hESCs and the twelfth and sixteenth claims pertain to processes for the production of precursor cells. Brüstle appealed against that judgement with the *Bundesgerichtshof*, who considered the outcome of the case to depend on the interpretation of certain provisions of Directive 98/44.[*17]

At first glance, it seems that defining the term 'embryo' is the simplest task. In Estonia, the EstPA does not define 'embryo'. However, in Estonia, §3 of the Artificial Insemination and Embryo Protection Act[*18] (hereinafter referred to as the AIEPA) stipulates that an 'embryo' is the embryo/foetus in its early stage of development from the time of fertilisation of the ovum. Also, for the purposes of said act, 'embryo' refers to a human embryo unless otherwise provided therein. This is clearly a very general definition. It also raises the question of whether the aim of the legislator has also been that this definition should be used in interpretation of §7 (2) 3) of the EstPA. As §7 (2) 3) of the EstPA makes clear reference to the processes prohibited by the AIEPA as unpatentable inventions, it can be assumed that in interpretation of the term 'embryo' within the meaning of §7 (2) 3), it is also necessary to consider paragraphs in the AIEPA, including §3. Although it might seem that §3 of the AIEPA resolves the question of what an embryo is, the questions raised in the *Brüstle* case show that the task is much more complicated than one might think. The ECJ has the task of answering the following questions concerning the term 'human embryos': Does the term 'human embryos' in Article 6 (2) (c) of Directive 98/44 include all stages of the development of human life, beginning with the fertilisation of the ovum, or must further requirements, such as the attainment of a certain stage of development, be satisfied? Are the following organisms also included: unfertilised human ova into which a cell nucleus from a mature human cell has been transplanted and unfertilised human ova whose division and further development have been stimulated by parthenogenesis? Are stem cells obtained from human embryos at the blastocyst stage also included?[*19]

14 The Trade Related Aspects of Intellectual Property Rights Agreement – Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, 15.4.1994. Available at http://www.wto.org/english/tratop_e/trips_e/t_agmo_e.htm (8.4.2011).

15 The similar rule is also included into the Implementing Regulations to the Convention on the Grant of European Patent of 5 October 1973. Available at http://www.epo.org/law-practice/legal-texts/html/epc/1973/e/ma2.html (8.4.2011).

16 Reference for a preliminary ruling from the *Bundesgerichtshof* (Note 9).

17 Opinion of Advocate General (Note 12), paragraphs 26, 32–34.

18 Kunstliku viljastamise ja embrüokaitse seadus. – RT I 1997, 51, 824; RT I, 3.3.2011, 1 (in Estonian). English text available at http://www.legaltext.ee/ (2.4.2011).

19 Reference for a preliminary ruling (Note 9).

Looking at the 'embryo' definition in the AIEPA, one can see that the criterion for status as an embryo is the fertilisation of the ovum. No further requirements (for example, the transplantation of the fertilised ovum into the uterus) are needed before the fertilised ovum is termed an embryo, at least according to §3. Does this mean that all the other possibilities listed in the questions above are patentable? Of course not, but the term 'embryo' seems to be defined restrictively in §3 in comparison to, for example, the German *Embryonenschutzgesetz*[*20] (hereinafter referred to as the ESchG) (Embryo Protection Act). According to §8 (1) of the ESchG, an embryo is a fertilised human ovum capable of development, from the time of karyogamy, and any totipotent cell removed from an embryo that is able to divide and develop into an individual, provided that the other necessary conditions are satisfied. Therefore, in Germany, not only a fertilised human ovum is considered an embryo, but also totipotent cells removed from an embryo are. Totipotent cells are stem cells with the capacity to become a complete and separate embryo.[*21]

As expected, the Biotech Directive itself does not define the concept of a human embryo. The Advocate General notes in the *Brüstle* case that the drafting history of this directive does not give any indication of the intended substance of the concept. Also, as one might expect, there is no unanimous conception among Member States of the European Union.[*22] This raises the question of why there are no special articles in the directive concerning patentability of hESCs. One obvious reason for this is that the possibility of deriving human stem cells from embryos only arose in the year in which the Biotech Directive was adopted.[*23]

Before the *Brüstle* case, the Enlarged Board of Appeal (hereinafter referred to as the EBA) of the European Patent Office (hereinafter referred to as the EPO) too faced the problem of defining 'embryo', in the *WARF* case[*24], which also dealt with hESC-related inventions. The EBA presumed that 'embryo' was not to be given any restrictive meaning and that what is an embryo is a question of fact in the context of any particular patent application.[*25] This is a slightly different view than that seen in the opinion of the Advocate General in the *Brüstle* case: the Advocate General finds that the concept of the human embryo must be subject to common understanding in all Member States of the EU.[*26] The handling of the *WARF* case is greatly criticised, and it has been argued (by P.L.C. Torremans, for example) that the EBA did not define the term 'embryo' in the case at all. The Board simply refused to adopt the one restrictive definition that was put to it and proceeded to leave the term undefined.[*27]

When looking at the *Brüstle* case, the Advocate General took the view that the concept of a human embryo applies from the fertilisation stage to the initial totipotent cells and to the entire ensuing process of development and formation of the human body. As totipotent cells represent the first stage of the human body that they will become, they must be legally categorised as embryos.[*28] Although, in Estonia, §3 of the AIEPA does not literally classify totipotent cells with the concept of an embryo, the author finds it reasonable to interpret §7 (2) 3) of the EstPA in a similar way, such that the term 'embryo' also includes totipotent stem cells, which are able to develop into a human being. The author is of the opinion that, as one of the main objectives of the exception to patentability of an 'embryo' is to preclude the commoditisation of human life, the criterion under which the term 'embryo' within the meaning of §7 (2) 3) of the EstPA (and also within the meaning of Article 6 (2) (c) of the Biotech Directive) could be evaluated could be the following: Is it capable of developing into a human being? When the answer to this question is 'yes', it can be considered an 'embryo' within the sense of §7 (2) 3) of the EstPA (and also within that of Article 6 (2) (c) of the Biotech Directive).

---

20 Gesetz zum Schutz von Embryonen (Embryonenschutzgesetz – ESchG). – 13. Dezember 1990 BGBl. I p. 2746; 23. Oktober 2001 BGBl. I p. 2702. Available at http://www.gesetze-im-internet.de/eschg/BJNR027460990.html (3.4.2011).

21 G. Laurie (Note 4), p. 60.

22 Opinion of Advocate General (Note 12), paragraphs 64, 66.

23 G. Laurie (Note 4), p. 59; J. A. Thompson *et al*. Embryonic Stem Cell Lines Derived from Human Blastocyst. – Science, 6 November 1998, Vol. 282, No. 5391, pp. 1145–1147. Available at http://www.sciencemag.org/content/282/5391/1145.full (3.4.2011).

24 G 2/06 (WARF) (25 November 2008). Available at http://archive.epo.org/epo/pubs/oj009/05_09/05_3069.pdf (6.4.2011).

25 *Ibid*., paragraph 20.

26 Opinion of Advocate General (Note 12), paragraph 7.

27 P. L. C. Torremans. The Construction of the Directive's Moral Exclusions under the EPC. – A. Plomer, P. Torremans (eds.). Embryonic Stem Cell Patents: European Law and Ethics. New York: Oxford University Press 2009, p. 165.

28 Opinion of Advocate General (Note 12), paragraph 85.

Looking at the *Brüstle* case, the Advocate General also finds that every totipotent cell, whatever the means by which it has been obtained, is an embryo and that any patentability must be excluded. This definition, therefore, covers unfertilised ova into which a cell nucleus from a mature cell has been transplanted and unfertilised ova whose division has been stimulated by parthenogenesis insofar as totipotent cells would be obtained in that way. The Advocate General also includes a blastocyst within the 'embryo' concept, as it is one of the stages of development of the human body.*[29] The author finds no objection to including blastocysts under the concept, within the meaning of §7 (2) 3) of the EstPA (and also within that of Article 6 (2) (c) of the Biotech Directive). This kind of interpretation is also in accordance with §3 of the AIEPA, as it refers to the 'embryo in the early stage of development'. A 5–7-day-old organism (blastocyst) is, without a doubt, in the early stage of development, and it also meets the criterion of being capable of developing into a human being.

Although 'embryo' is not defined in the EstPA and it can be difficult to understand what is meant by it in §7 (2) 3) of the EstPA (or Article 6 (2) (c) of the Biotech Directive), the author does not think that this definition should be included in the EstPA or the Biotech Directive itself. Defining the term in the EstPA would not resolve the question of whether inventions related to pluripotent stem cells are patentable or not. As the author reasons below, it would be wiser to stipulate concrete inventions (related to hESCs) that are unpatentable. This could prevent differing interpretations of the term.

4. Pluripotent stem cells

As noted above, the next question to analyse is whether stem cells obtained from human embryos at the blastocyst stage are also included in the definition of 'embryo'. In *Brüstle*, the Advocate General takes the view that a pluripotent stem cell in isolation cannot be regarded as constituting an embryo itself, because, although it can develop into all kinds of cells, it cannot develop separately into a complete human being.*[30] The author finds that this view is in accordance with §8 (1) of the German ESchG and definitely with §3 of Estonia's AIEPA. As the Advocate General refers also to the fact that a pluripotent stem cell cannot develop into a complete human being, this would be in accordance also with the criteria offered by the author for evaluating whether something is considered an 'embryo' or not. Given the conclusion that pluripotent stem cells are not considered embryos, it could be assumed that inventions related to pluripotent stem cells should not fall within the scope of Article 6 (2) (c) of the Biotech Directive, since it prohibits patenting of uses of 'human embryos' for industrial or commercial purposes. However, this does not mean that those inventions should not be precluded from patentability under Article 6 (1) of the Biotech Directive (the general clause on *ordre public* or morality).

The Advocate General nonetheless goes further and finds that it is not possible to ignore the origin of these pluripotent cells. He explains that the pluripotent stem cell in the present case is removed from the blastocyst, which itself constitutes an embryo—one of the stages in the formation and development of the human body, which the removal will destroy. The Advocate General does not support the view that the way in which the cell has been removed and the consequences of such removal do not have to be taken into account, for reasons connected with *ordre public* and morality. The Advocate General concludes that it must be agreed, if only for the sake of consistency, that inventions related to pluripotent stem cells can be patentable only if they are not obtained to the detriment of an embryo, whether its destruction or its modification.*[31]

The reference to *ordre public* and morality leads the author to wonder whether it is meant also that Article 6 (1) of the Biotech Directive should be applied in this case. As the questions referred to the ECJ pertain only to Article 6 (2) (c), this is questionable, although Article 6 (2) also refers to Article 6 (1) as a basis.

[29] *Ibid*., paragraphs 91, 94–95.

[30] *Ibid*., paragraphs 93, 98, 100.

[31] *Ibid*., paragraphs 103–105, 109.

More problematic is the reference to *ordre public* and morality made by the Advocate General in light of the case *Commission v. Italy*[*32] (hereinafter referred to as the *Italy* case), where the ECJ stated:

> Unlike Article 6(1) of the Directive, which allows the administrative authorities and courts of the Member States a wide discretion in applying the exclusion from patentability of inventions whose commercial exploitation would be contrary to ordre public (public policy) and morality, Article 6(2) allows the Member States no discretion with regard to the unpatentability of the processes and uses which it sets out, since the very purpose of this provision is to give definition to the exclusion laid down in Article 6(1) (see, to this effect, Netherlands v Parliament and Council, paragraphs 37 to 39). [...] It follows that, by expressly excluding from patentability the processes and uses to which it refers, Article 6(2) of the Directive seeks to grant specific rights in this regard.[*33]

This decision has been criticised by A. Plomer for the ECJ's insistence that the test to be applied in the interpretation of the list of specific exclusions is definitional, not moral. The implication is that, when reading and interpreting the specific exclusion in Article 6 (2) of the Biotech Directive, one must give the words their natural meaning. Plomer also suggests that, in view of the *Italy* case, additional words should not be imported to vary, broaden, or narrow the exclusion in order to instantiate the alleged underlying moral consensus, since, as stated by the ECJ, the specific exclusions are already illustrative of the principle. The analysis shows that there is no consensus in Europe to the effect that destructive uses of human embryos are morally impermissible. Neither is there consensus to the effect that uses of hESCs and related inventions or products is immoral when obtained by destruction of human embryos. Plomer finds that, in consideration of the *Italy* case, Article 6 (2) (c) cannot be read as excluding patents for hESC-based inventions and related industrial products whose derivation necessarily involved destruction of human embryos. Instead, the *Italy* case indicates that the exclusion is restricted to inventions involving commercial uses of human 'embryos'.[*34] The author agrees with Plomer's opinion that, in view of the *Italy* case, it is problematic to conclude that the uses of pluripotent stem cells (or patenting of pluripotent-stem-cell-related inventions) that are obtained by destruction of human embryos are considered immoral or contrary to *ordre public* in every Member State of the EU. As scientific research concerning hESCs is allowed in, for example, Estonia, there is no certainty that those inventions (or their commercial exploitation) that involve pluripotent stem cells obtained by destruction of human embryos would be considered immoral or contrary to *ordre public* in Estonia.

Therefore, if the ECJ follows the opinion of the Advocate General that pluripotent stem cells do not constitute embryos, the author finds that inventions related to pluripotent stem cells cannot be excluded from patentability under Article 6 (2) (c) of the Biotech Directive. As noted above, this does not mean that those inventions should not be precluded from patentability under Article 6 (1) (the general clause on *ordre public* or morality). Considering the *Italy* case, the author finds that the decision as to whether pluripotent stem cells are excluded from patentability under the *ordre public* and morality clause is at the discretion of each Member State.

So what could explain the conclusion that inventions that are related to pluripotent stem cells derived from embryos are not patentable under Article 6 (2) (c) of the Biotech Directive, when it has been found that pluripotent stem cells are not considered 'embryos'? The reason for this might be to resolve the long debate over the patentability of inventions related to hESCs in the EU conclusively. By agreeing with the opinion of the Advocate General, the ECJ could provide clarity for all parties concerned—Member States, biotechnology companies, scientists, courts, etc. With the question open for the Member States to resolve, the outcome in different Member States could be very different. Outcomes differing by state in relation to this important issue would definitely confuse the biotechnology companies and could also lead to a situa-

32 Case C-456/03, *Commission v. Italy*. Available at http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&alljur=alljur&jurcdj=jurcdj&jurtpi=jurtpi&jurtfp=jurtfp&numaff=C-456/03&nomusuel=&docnodecision=docnodecision&allcommjo=allcommjo&affint=affint&affclose=affclose&alldocrec=alldocrec&docor=docor&docav=docav&docsom=docsom&docinf=docinf&alldocnorec=alldocnorec&docnoor=docnoor&docppoag=docppoag&radtypeord=on&newform=newform&docj=docj&docop=docop&docnoj=docnoj&typeord=ALL&domaine=&mots=&resmax=100&Submit=Rechercher (3.4.2011).

33 *Ibid*., paragraphs 78–79.

34 A. Plomer. Towards Systematic Legal Conflict: Article 6 (2) (c) of the EU Directive on Biotechnological Inventions. – A. Plomer, P. Torremans (eds.). Embryonic Stem Cell Patents: European Law and Ethics. New York: Oxford University Press 2009, p. 189.

tion in which companies start to apply for the associated patents only in a Member State that supports the patenting of hESCs.

Would the outcome with §7 (2) 3) of the EstPA be different? As noted above, §7 (2) 3) of the EstPA also refers to the processes prohibited by the AIEPA. There is a list of prohibited acts with embryos in §35 of the AIEPA, which states that it is prohibited to perform the following acts in connection with artificial insemination of a woman: 1) artificial fertilisation of an ovum with a sperm that has been selected on the basis of the sex chromosome contained therein, except in cases where a gamete is selected for avoidance of a serious sex-linked inheritable disease being passed on to the child; 2) creation, by way of replacement of the nucleus of a fertilised ovum with a somatic cell of another embryo, a foetus, or a living or dead person, of an embryo with genetic information identical to that of said embryo, foetus, or living or dead person; 3) fusion of embryos with differing genetic information in order to create a cell fusion if at least one of the embryos is a human embryo, or fusion of a human embryo with a cell that contains genetic information different from that of the cells of the embryo and which may develop further together with the embryo; and 4) creation of an embryo capable of developing by fertilisation of a human ovum with animal sperm or an animal ovum with human sperm. As can be seen, although §35 of the AIEPA gives examples of prohibited acts involving embryos, it does not say anything about the pluripotent stem cells derived from the embryo. Therefore, it offers no more guidance on this issue than the Biotech Directive does. Also, the author finds that it has to be taken into consideration that §35 of the AIEPA refers to acts in connection with artificial insemination of a woman. The issue surrounding the patentability of pluripotent stem cells does not involve the insemination of a woman.

Considering that pluripotent stem cells are not able to develop into a complete human being and under this criterion cannot be considered 'embryos', the author finds that the patentability of inventions related to pluripotent stem cells should under Estonian law be evaluated also under §7 (1) 1) of the EstPA (under the general *ordre public* and morality clause). Interestingly, it has been argued that the altered wording of embryo exclusion and the direct reference to medical legislation makes it probable that patent applications for hESC inventions would be treated rather strictly in Estonia.[*35] The author calls this argument into question, since the reference in §7 (2) 3) of the EstPA to the processes stipulated in the AIEPA is only illustrative, not conclusive.

5. The uses of human embryos for industrial or commercial purposes

After analysing the concept of 'embryo', one who wishes to say that something is unpatentable according to Article 6 (2) (c) of the Biotech Directive (and §7 (2) 3) of the EstPA) must next examine what is meant by 'uses of human embryos for industrial or commercial purposes'. Questions of this sort have also been referred to the ECJ in the *Brüstle* case. Interestingly, §7 (2) 3) of the EstPA does not include uses of human embryos for 'industrial purposes' in the exclusion and refers only to 'uses of human embryos for commercial purposes'.

In the *WARF* case, the EBA took the view that, since the embryos used to perform the invention in question are destroyed, they are used for industrial or commercial purposes, because patentability is considered only if the invention is to the benefit of the embryo itself.[*36] The Advocate General takes the same view and argues that it is clear from the drafting history of the directive that, by introducing the concept 'for industrial or commercial purposes', the Council wished to draw a contrast between such uses and inventions for therapeutic or diagnostic purposes that are applied to the human embryo and are useful to it.[*37] It is true that Recital 42 of the Biotech Directive states that uses of human embryos for industrial or commercial purposes must also be excluded from patentability, although this exclusion on no account is intended to affect inventions for therapeutic or diagnostic purposes that are applied to the human embryo and are useful to it. However, the author agrees with Torremans that, while diagnosis and treatment as applied to an embryo

35 Å. Hellstadius. A Comparative Analysis of the National Implementation of the Directive's Morality Clause. – A. Plomer, P. Torremans (eds.). Embryonic Stem Cell Patents: European Law and Ethics. New York: Oxford University Press 2009, p. 124.

36 G 2/06 (Note 24), paragraph 27.

37 Opinion of Advocate General (Note 12), paragraph 111.

surely is not excluded from patentability, it is also hardly relevant in this context. A treatment (or diagnosis) that is beneficial to the embryo will hardly ever involve 'use' of the embryo; therefore, this cannot be the criterion for distinguishing industrial or commercial use from permitted use.*[38]

The Advocate General finds in his opinion that use for industrial or commercial purposes requires large-scale production. Industrial and commercial exploitation would presuppose cell cultures intended for pharmaceutical laboratories with a view to the manufacture of medicines. The more the technique allows cases to be treated, the larger the production of cells, requiring recourse to a proportional number of embryos, which would, therefore, be created only to be destroyed a few days later. He further finds that a definition that in its essence authorises such a practice would not be consistent with the concept of *ordre public*, or with an ethical conception that could be shared by all Member States.*[39] The author holds the opinion that the argument about the production of more and more embryos to be destroyed is questionable, considering Estonian laws. According to §29 of the AIEPA, an ovum shall be fertilised *in vitro* only with the aim of transfer of said ovum to a woman. This means that the creation of embryos for research or some commercial purpose is banned. According to §32 (1) of the AIEPA, embryos that are not transferred to a woman and embryos that have remained unused may be utilised for scientific research. Accordingly, at least in Estonia, it would be forbidden to start creating embryos for industrial or commercial purposes. Furthermore, at the European level, creation of embryos for research purposes has been banned by the Additional Protocol to the Biomedicine Convention with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings.*[40] If the emphasis is on the fact that the embryos are destroyed, then, at least in Estonia, according to §30 (2) of the AIEPA, if an embryo is not transferred to a woman within a specified term, the embryo shall be used for scientific research or destroyed. Subsection 34 (1) of the AIEPA states that an embryo may be preserved or used on the grounds set forth in §31 or §32 of the act, within 14 days after fertilisation of the ovum. Preservation or use of embryos after expiry of the specified term is prohibited. Therefore, according to the laws of Estonia, the supernumerary embryos from *in vitro* fertilisation treatment are supposed to be destroyed when not used in research.

Torremans argues that the moral purpose of the provision in the Biotech Directive is to preclude instrumentalisation of the human embryo through direct use of the embryo as a raw material in a repetitive (technical) process or, alternatively, embryo commoditisation through uses of embryos that involve monetary exchanges and trade.*[41] Patents that directly claim repetitive use of the human embryo in a technical process would be excluded from patentability, and patents that claim products derived from a human embryo would not contravene the morality clause. This would have the effect of rendering processes for extracting hESCs from a human blastocyst non-patentable whilst pluripotent cells as products and methods related to their use would fall outside the scope of the special embryo exclusion and instead (as also suggested by the author) be evaluated under the general patent morality exception.*[42] The EBA in the *WARF* case and the Advocate General in the *Brüstle* case are clearly of differing opinions: The Advocate General stated in his opinion that, even though the claims under the patent did not specify that human embryos are used for the exploitation of the invention, they actually are and the patentability of such an invention must be excluded.*[43] The EBA concluded in the *WARF* case that it is important to look at not just the explicit wording of the claims but the technical teaching of the application as a whole as to how the invention is to be performed. Since in the case referred to the EBA the only teaching of how to perform the invention to create hESC cultures is the use of human embryos (involving their destruction), this invention falls under the prohibition of Rule 28 (c) (formerly 23d (c)) of the EPC.*[44] The EBA did not, however, consider the argument that the exclusion from patentability would go much too far if one were to consider all of the steps preceding an invention.*[45]

38 P. L. C. Torremans (Note 27), p. 167.

39 Opinion of Advocate General (Note 12), paragraphs 113–114.

40 R. M. Isasi, B. M. Knoppers. Towards Commonality?—Policy Approaches to Human Embryonic Stem Cell Research in Europe. – A. Plomer, P. Torremans (eds.). Embryonic Stem Cell Patents: European Law and Ethics. New York: Oxford University Press 2009, p. 39.

41 P. L. C. Torremans (Note 27), p. 151.

42 *Ibid*., p. 163.

43 Opinion of Advocate General (Note 12), paragraph 108.

44 G 2/06 (Note 24), paragraph 22.

45 *Ibid*., paragraph 23.

The author finds that if there is a common understanding in the EU that human pluripotent stem cells and other hESC-related inventions, which require at some stage the destruction of an embryo, should be beyond the scope of patentability in the EU, it would be better for there to be a clear paragraph stating the same. For example, §7 (2) 3) of the EstPA (and similarly Article 6 (2) (c) of the Biotech Directive) could be formulated in the following way: 'The following biotechnological inventions shall not be protected by a patent: (3) uses of human embryos for commercial purposes, including processes prohibited by the Artificial Insemination and Embryo Protection Act, and inventions that involve the destruction of a human embryo.'

6. *Ordre public* and morality exclusion

The task of evaluating the patentability of inventions related to pluripotent stem cells in light of the general *ordre public* and morality clause is not an easy one. The first problem arises when one considers Article 53 (a) of the EPC or Article 6 (1) of the Biotech Directive, or §7 (1) 1) of the EstPA, because there is no substantive definition addressing what morality is within the European context.[*46] The author argues that, although the EPO has made it clear in case law that *ordre public* and morality are two distinct concepts, it actually uses them as synonyms.[*47] According to a decision of the EPO Technical Board of Appeal (*Plant Genetic Systems v. Greenpeace*), 'the concept of "ordre public" covers the protection of public security and the physical integrity of individuals as part of society'. The Board continues as follows:

> This concept encompasses also the protection of the environment. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is likely to breach public peace or social order (for example, through acts of terrorism) or to seriously prejudice the environment are to be excluded from patentability as being contrary to "ordre public". 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, under Article 53(a) of the EPC, inventions the exploitation of which is not in conformity with the conventionally-accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality.[*48]

Although this is nicely worded, the author argues that it does not give a definition of morality or *ordre public*, which would allow the courts and patent offices to apply it with ease. There is no general framework or criteria concerning how to determine what would be contrary to morality in a non-arbitrary or non-biased fashion.[*49] The author agrees with T. Wasescha that we cannot ignore the fact that concepts such as that of *ordre public* or morality are fundamentally linked to national perceptions.[*50] That *ordre public* is connected to national perceptions is also referred to in private international law.[*51] This means that finding common criteria for determining which inventions (and commercial exploitation thereof) would be contrary to morality or *ordre public* in the context of the EU could be nearly impossible.

It is also interesting that §7 (1) of the EstPA does not make any reference to commercial exploitation, as Article 27 (2) of the TRIPS, Article 6 (1) of the Biotech Directive and Article 53 (a) of the EPC do. Subsection 7 (1) of the EstPA states only that inventions contrary to public order and morality shall not be protected by a patent. This makes the author wonder whether the wording of §7 (1) of the EstPA was a conscious choice by the drafters and whether it is in compliance with the above-mentioned articles of regional and international instruments. The reasonable way to interpret §7 (1) of the EstPA is to interpret it such that it would be in accordance with the articles of the TRIPS, EPC, and Biotech Directive.

---

46 A. M. Viens. Morality Provisions in Law Concerning the Commercialization of Human Embryos and Stem Cells. – A. Plomer, P. Torremans (eds.). Embryonic Stem Cell Patents: European Law and Ethics. New York: Oxford University Press 2009, p. 87.

47 *Ibid*., p. 88.

48 T 356/93, *Plant Genetic Systems*. – OJ 8/1995, 545. Available at http://legal.european-patent-office.org/dg3/biblio/t930356ep1.htm (5.4.2011).

49 A. M. Viens (Note 46), p. 89.

50 European Group on Ethics (Note 6), p. 89.

51 I. Nurmela *et al.* Rahvusvaheline eraõigus (International Private Law). Tallinn: Kirjastus Juura 2008, p. 65 (in Estonian).

There is also a problem surrounding what is meant by the expression 'the commercial exploitation would be contrary to *ordre public* or morality'. Also questioned (by A. Plomer and Å. Hellstadius, for example) is whether patent examiners (qualified to assess the technical features of inventions) are also ready to make ethics evaluations.[*52] The author agrees that without special instructions and criteria available to patent examiners, the assessment could be very subjective and might express only the moral values of the specific patent examiner who assesses the invention. Therefore, when pluripotent stem cells are not considered an 'embryo', the difficulties in assessing their patentability under the general *ordre public* and morality clause are only beginning. Consequently, as the author has already suggested, when there is a policy that human pluripotent stem cells should lie outside the scope of patentability, it would be better that there be a clear paragraph stating this. This exception could be included in §7 (2) 3) of the EstPA (and, similarly, in Article 6 (2) (c) of the Biotech Directive).

Even if the ECJ finds that hESC-related inventions that include the destruction of an embryo are unpatentable, this does not affect the policy on the use of embryos for hESC research in Member States. And it is important to note that it is also already possible to create pluripotent stem cells without destroying the embryo (with the genetic reprogramming technology used to create induced pluripotent stem (iPS) cells[*53]). These kinds of inventions should not give rise to such ethical considerations as hESC-related inventions that involve the destruction of an embryo do.

7. Conclusions

In conclusion, it can be seen that the questions concerning patentability of hESC-related inventions are, even after years of discussions, still highly subject to debate. Defining an 'embryo' in patent law is harder than expected. If the ECJ agrees with the Advocate General in the *Brüstle* case and finds that hESC-related inventions are not patentable under Article 6 (2) (c) of the Biotech Directive when the process of making the invention involves destruction of human embryos or uses human embryos as a base material, this interpretation would be binding also in Estonia, even though the wording of §7 (2) 3) of the EstPA is slightly modified in comparison. If the ECJ finds that inventions pertaining to pluripotent stem cells should be evaluated under the general *ordre public* and morality clause, it might be possible for each Member State to decide whether patentability of inventions related to pluripotent stem cells would be contrary to *ordre public* or morality. This could end up problematic, as there are no clear frameworks or criteria for how patent offices and courts should assess this clause. It is also probable that in different Member States the outcome would be different. Where the policy direction is to preclude the patentability of pluripotent-stem-cell-related inventions the making of which requires the destruction of an embryo, this conclusion should be clearly stipulated in patent laws, including the EstPA. The author therefore has suggested formulating §7 (2) 3) of the EstPA (and similarly Article 6 (2) (c) of the Biotech Directive) in the following way: 'The following biotechnological inventions shall not be protected by a patent: (3) uses of human embryos for commercial purposes, including processes prohibited by the Artificial Insemination and Embryo Protection Act, and inventions that involve the destruction of a human embryo.'

52 Å. Hellstadius (Note 35), p. 129.

53 S. Russell. Britain grants patent for iPS cells. – Nature, 28 January 2010. Available at http://www.nature.com.ezproxy.utlib.ee/news/2010/100128/full/news.2010.43.html (5.4.2011).