V. The Panorama in Europe

There is no place for speculation in the law and one should defend her argument based on strong justification. The previous chapter represented the blurred situation constituted of a wide array of views regarding the patentability of hESC-related inventions based on different philosophical and scientific arguments. Under this chapter, we intend to be more concrete and specific in regard to the positive law. We start by examining the Biotech Directive to find out the right application for hESC-related inventions in the first part of this section. The Biotech Directive constitutes the basis of the applicable law in the territory of EU member states. Moreover, the interpretation of its provisions is important because of its essentiality for the application of the EPC rules to the same issues that would be subsequently dealt.

A. Determining the Right Interpretation of the Biotech Directive

1. The Patent Eligibility of the Human Embryo

Before we deal with the hESC-related inventions, Art. 5(1) of the Biotech Directive should be mentioned to clarify the difference among subject matters of the patent protection. The said article precludes the patentability of human body at various stages of its formation and development. According to that, the human embryo could refer to an early stage of the human body formation. This literary interpretation does not conflict with the intent of the legislator. As we learn from Porter about the preparatory works of the Directive, the legislator's intent was to avoid the availability of patent protection for human embryos *per se*.[88] One drawback of this provision is that the Biotech Directive does not provide for the definition of human embryo.Nevertheless, especially the definition of a scientific term should not be made in a legal text because of the possible inconsistency that might appear with the actual state of the science when the said rule is applied.

88 Porter, *supra* note 64, at 18.

Therefore there is a concern about the existence of a variety of the human embryo definition in national laws. In the German Embryo Protection Act the human embryo is defined as "*the human egg cell, fertilised and capable of developing from the time of fusion of the nuclei, and further, each totipotent cell removed from an embryo that is assured to be able to divide and to develop into an individual under the appropriate conditions for that.*"[89] In the law of the U.K., the embryo is "*a live human embryo and does not include a human admixed embryo (as defined by section 4A(6)), and references to an embryo include an egg that is the process of fertilisation or is undergoing any other process capable of resulting in an embryo*."[90] The German law has a broader definition of human embryo than the law of the U.K. in a sense that totipotent cells removed from an embryo are covered by the definition as well. As it might be seen, this difference between legal definitions of the human embryo is also important to make a decision whether the definition covers the hESCs and, thus, the hESC-related inventions are patent eligible.

2. The Patent Eligibility of hESC-related Inventions

The patent eligibility of hESC-related inventions is the most controversial issue. Since hESCs do not have the potential to develop into the human body, it is not possible to consider them within the framework related to embryos.[91] Nevertheless, there are two aspects of morality concerns related to the patent eligibility of hESCs. The first ethical aspect is related to the destruction of human embryos irrespective of the source of the human blastocyst for the collection of hESCs. Second perspective of ethical concern is related to the source of human embryos, especially when blastocysts are created specifically for the purpose to collect hESCs.

---

89 Gesetz zum Schutz von Embryonen [ESchG] [Embryo Protection Act], Feb. 13, 1990, Sec.8 (F.R.G)*available at* http://www.auswaertiges-amt.de/cae/servlet/contentblob/480804/publicationFile/5162/EmbryoProtectionAct.pdf (last visited Aug. 01, 2012).

90 Human Fertilisation and Embryology Act, 2008, c.22, Part 1, (U.K.) http://www.legislation.gov.uk/ukpga/2008/22/pdfs/ukpga_20080022_en.pdf (last visited Aug, 01.2012).

91 *See supra* Part II. B.2.

a) The Destruction of Human Embryos for hESCs

The most relevant provision related to the patentability of hESCs obtained by the destruction of human embryos is possibly Art. 6(2)(c) of the Biotech Directive. This is an example of a provision that EU Member States have no discretion to interpret it in light of their national rules.[92] Therefore, it is important to identify cases which could fall within the scope of this Article. If one considers the patent eligibility of hESCs within this provision, the moral rationale for the exclusion from the patent protection would be the industrial and commercial use of human embryos for the extraction of hESCs. One could reach the result that the invention is immoral by looking at commercial and industrial purposes of the use of human embryos. So this is mostly related to the use of the embryo which results with its destruction. In this approach, there are two crucial points that should be considered. One problem is to determine the scope of the invention excluded from the patent protection: The question is whether the immoral element of the invention lies within the scope of the claims, or in the whole specification, or even beyond. One could say by reference to Art. 69 of the EPC that only claims matter to construe the scope of the patent protection and thus the same rule is valid for the exclusion. As a counter-argument, it is possible to say that the 'invention' covers the whole content including its teaching and other acts accomplished to reach the invention.[93] Therefore, even though the destruction of human embryos to generate hESCs is not claimed, it could be considered as an element of the patent teaching constituting immorality and, thus, precluding the patent eligibility.

The second problem is that according to the Biotech Directive, the existence of either commercial or industrial purpose would suffice for the exclusion and this requires a cautious approach when this legal provision is

92 C-456/03, Commission v. Italy, 2005 ECJ CURIA, ¶78 (June 16, 2005).

93 This argument is accepted by the Stem Cells Patent Report prepared for the European Commission that the scope of the invention must be determined with regard to the claim. To strengthen this argument the reference is made to the para.79 of ECJ's Netherlands v. Parliament and Council judgment of the date 9.10.2001 stating that "[T]he Directive concerns only the grant of patents and whose scope does not therefore extend to activities before and after that grant, whether they involve research or the use of the patented products." *See* A.Plomer et al., *Stem Cell Patents: European Patent Law and Ethics Report,* 78 (European Commission, 2006), *available* at http://www.nottingham.ac.uk/~llzwww/StemCellProject/project.report.pdf (last visited Aug. 01, 2012).

applied. The distinction between commercial and research purposes should be clearly made. It is also important to specify the point of time when the use of the invention could be closely attributed to the commercial purpose of the use of human embryo. Additionally, whether concepts 'commercial' and 'industrial' refer to the repetitive and multiple use of the embryo is an issue that should be clarified in order to make a decision under the Art. 6(2) (c).[94]

So far in light of explanations made above, one might reach to the argument that the patentability of hESCs would not be immoral under Art. 6(2) (c) as long as the invention is not related to the direct use of human embryos *per se* for commercial or industrial purposes. Nevertheless, it could be still argued that the invention is unpatentable based on Art. 6(1) of the Biotech Directive. This article, as mentioned earlier in this research, constitutes the general morality provision and therefore EU Member States have a right of manoeuvre based on their specific understanding of *ordre public* and morality.[95] At this point there is a possibility for applicants to establish the compliance of hESCs with the *ordre public* or morality by taking into account the Recital 39.[96] In that, the said recital makes clear that *ordre public* and morality principles would be derived from "principles recognised in a Member State." The plenitude of different approaches that we tried to show earlier in this research find their reflection in rules of different Member States. Unlike the consensus among Member States regarding the immorality of interventions into the human germ line and the cloning of human beings as stated in Recital 40 of the Biotech Directive, no similar common ground has been reached on the status of human embryo and on the issue when the life

94 Paul Torremans, *Legal Problems Raised by Patents on Human Stem Cell-Based Inventions,* in Translational Stem Cell Research, Stem Cell Biology and Regenerative Medicine 287, 305 (K.Hug&G. Hermerén, eds.,Humana Press, 2011).

95 C-377/98, Netherlands v. Parliament and Council 2001 ECJ CURIA, ¶38 (Oct. 10, 2001).

96 As a side remark, we must state that in the EU law, recitals of the Directive do not form the operative part of the rules. Hovewer, they are useful in providing the background of the legislative intent and, thus, contributing to a viable interpretation of the law.

begins.[97] Therefore the application throughout the EU Member States on the patent eligibility of hESCs could be diverse.

b) The Creation of Human Embryos for hESCs

As mentioned previously[98], the morality concern is tried to be overcome usually by the use of frozen blastocysts from the IVF treatment. These embryos are no more capable to develop into a human body. Here, the moral rationale for the exclusion of hESC related inventions from the patent protection could be the 'creation of embryos for destruction'. Some embryos could be created for the sole purpose to destroy them in order to obtain hESCs. In that perspective, we must especially analyze the status of hESCs derived from the SCNT according to the current legislation. The creation of an embryo by SCNT should be considered immoral if the reproduction of a human being from a cloned embryo is aimed. This method could be also called as reproductive cloning. If someone uses this method to extract hESCs from the embryo created, called as therapeutic cloning, there is also a possibility that this method falls within the scope of the Art. 6(2)(a), regardless whether the purpose of the cloning is reproductive or therapeutic, because in any case, the production of embryos is the unavoidable result. However, one should consider that this method is allowed in the U.K. under very strict conditions, e.g. the disease targeted with the stem cell research using supernumerary or cloned embryos should have particular seriousness and gravity.[99]

The assessment of *ordre public* or morality according to the rules briefly discussed of the Biotech Directive implemented in the national level, would not create a problem since this test of patent eligibility would be effectuated by national courts and patent offices of EU Member States based on different

97 *See also* the Report on the Protection of the Human Embryo in vitro, Steering Committee on Bioethics, CDBI-CO-GT3 (Council of Europe, June 19, 2003) at 37 *available at* http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/CDBI-CO-GT3(2003)13E.pdf (Last visited Aug. 08, 2012).

98 *See supra* Part B.1.b.(2.).

99 Porter, *supra* note 64, at 24; Isasi&Knoppers, *supra* note 87, at 46. Even in the UK, some development within the method of SCNT for making ESCs is recently reported, *See* Human 'Cloning' makes embryonic stem cells, Oct. 5, 2011*, BBC News Health, available at* http://www.bbc.co.uk/news/health-15181015 (last visited Aug. 28, 2012).

ethical conceptions on the patent eligibility of hESCs. The lack of consensus on the concept of morality would create a more difficult situation when the EPO applies the EPC in a centralized patent grant procedure which will be discussed below in detail.

B. Application of the EPC

1. Lack of Uniform Moral Standard

The diversity and the relativity of the morality conception among different States are previously mentioned.[100] But when it comes to the EPC, the legislator's intent could possibly be the creation of a uniform European morality standard in light of some approaches we referred above.[101] The Rule 28(c) of the EPC is not different from Art. 6(2)(c) of the Biotech Directive and its application could create similar results like those encountered within the scope of the Biotech Directive. As stated before when the Art. 6(2)(c) of the Biotech Directive was analyzed, some hESCs-related inventions could not fall within the scope of the EPC Rule 28(c) depending on the interpretation of the said legal provision. In that situation, the problem might occur in the next step, where the assessment is done by the EPO according to the general morality clause under Art. 53(a) EPC. Additionally, the question which morality norm would be applicable for the patentability of hESCs-related inventions, arises at this point.

Alternative solutions have been developed in the literature, labeled by Torremans as 'extreme approaches'.[102] The first approach is that the finding of immorality for an invention in one EPC Contracting State should be taken into account by the EPO and this would suffice to refuse the grant of the patent protection. This, so called, 'maximalist test' requires the compliance of the invention to the morality in all Contracting States. The other, so called, 'minimum approach' underscores that the EPO would make a mistake by refusing the patent on moral grounds, once the patent eligibility of the invention is in line with morality norms of a single Contracting State. The second approach is more suitable while considering the complexity of morality issues of hESCs-related inventions in different Contracting

100 See supra Part IV.A.1) a.).
101 *Id.*.
102 Torremans, *supra* note 94, 298.

States.[103] In that context, the suitable approach to be taken by the EPO should be that inventions in conformity with the morality of, at least, one Contracting State get the patent protection.[104] It ia also possible to bring some variation of these extreme approaches. One variation is expressed by Schatz after having accepted that there could be an exception in regard to morality rules among Contracting States. He justifies his standing by stating that once the EPO is aware of contrariety of the invention to the morality in one Contracting State it should warn the applicant about the situation. In this case, the applicant could choose the path to withdraw its application for the designated states where there are morality concerns about the invention and get patent protection in the remaining designated States.[105]

All of these proposed approaches are not far from applicability. In my view, if the applicant does not comply with the warning of the EPO's Examining Division to withdraw the application for designated states where there could be morality concerns, the EPO must in any case, grant the patent as requested by the applicant. By doing so, the applicant takes a risk after the grant due to the buffer of Art. 138 of the EPC which provides for the start of national revocation proceedings where the patent eligibility of the subject matter on the morality ground could be the issue of discussion. As a result, the function of the EPO to assess an invention based on *ordre public* or morality could be pushed to the second plan. Nevertheless, there are attempts on the side of the EPO to create a uniform standard for the assessment of morality. This cannot be described as a morality rule setting initiative, but, rather the determination of a threshold to come up with viable consequences for all Contracting States. In the following subsection we would like to explain these two standards.

---

103 This case is similar to the situation depicted in the EU. UK is one example having not restrictive provisions based on the morality of hESCs-related inventions.

104 Torremans, *supra note* 94, refers to Straus who defends this approach in his article, Joseph Straus, *Ethische, rechtliche und wirtschaftliche Probleme des Patent – und Sortenschutztes für die biotechnologische Tierschützung und Tierproduktion*, Gewerblicher Rechtsschutz und Urheberrecht [GRUR],913 (1990).

105 Ulrich Schatz, *Article 53*, *in* European Patent Convention- A Commentary, 91(Margarate Singer&Dieter Stauder, eds.,3rd edition, Carl Heymanns 2003).

2. Attempts to Create a Uniform Morality Standard

The EPO's Examining Division's practice to grant patent protection for inventions is mainly based on some internal rules without binding force. These instructions called 'Guidelines for Examination in the European Patent Office' are prepared to help EPO practitioners during the patent granting proceedings.[106] As regards the explanation of exceptions to patent eligibility, it is stated in the Examination Guidelines that the Art. 53(a) would be referred to in "rare and extreme cases."[107] This is followed by the depiction of the test to apply: "*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.*"[108] This is so called 'abhorrence test' or 'rebuttable presumption approach'.[109] In this approach, the patent eligibility of an invention would be only refused if there is no single evidence that the invention has the opportunity to comply with legal and ethical values. In other words, it should be highly unlikely that any counter-argument would be asserted.[110] In this approach, very strong evidence is required showing that the invention is against the *ordre public* and morality. Because this approach intends to assure that this invention has not a single chance to be granted patent protection in the future. The contrary result could create an unfair situation among competitors when one invention, which is deemed immoral today, could find a way around to get the patent protection in the future.[111]

Another test is the unacceptability test which suggests a lower threshold than the abhorrence test. According to this test, it is possible to discuss the patent eligibility of the invention in both ways. In other terms, arguments about the incompatibility of an invention with the *ordre public* and morality are not situated on the extreme points that there exist ways to balance them. Therefore it contains the balancing approach.[112]

We would like to develop our explanation about the balancing approach based on a concrete example although the subject-matter of the invention

106 Guidelines for Examination, General Part ¶ 3.2, the European Patent Office (June 20, 2012) *available at* http://www.epo.org/law-practice/legal-texts/guidelines.html (last visited 20.8.2012) (hereinafter Examination Guidelines).
107 Examination Guidelines, *supra* note 99, Part G, Ch.II ¶.4.1.
108 *Id.*.
109 Warren-Jones, *supra* note 63, at 835.
110 *Id.,* at 835.
111 Warren-Jones, *supra* note 55, at 652.
112 Warren-Jones, *supra* note 63, at 835.

does not relate to stem cells. We had shortly mentioned the *Harvard Oncomouse* patent to explain Art. 6(2)(d) of the Biotech Directive.[113] In its judgment, the TBA required the Examining Division to use the balancing exercise of different interests, namely, suffering of animals and possible risks to the environment on the one hand and the benefit to the human health on the other hand, in order to make its assessment of patent eligibility.[114] Hence, the Examining Division decides by using this test that the invention is patent eligible.[115] After the grant, the opposition based on different grounds was raised against the patent application and the OD mainly focused on Article 53(a). At the time of the decision of the OD,[116] Article 6(2)(d) had already been transposed in the Implementing Rules, namely, Rule 23d(d) (which is now 28(d)). In the view of the OD, this Article reflects the balancing test postulated in the TBA decision *T 19/90*.[117] After having applied the balancing exercise the OD decided in the following way:

> *In the present case, it cannot be denied that the animals of the invention were made for a good cause, namely progress in cancer research. In view of the new approach the inventor took vis-à-vis the problem of medical cancer testing at the time, there were* ***bona fide reasons at the effective date to expect a substantial medical benefit****. Rule 23d(d) EPC is therefore no bar to patentability of those animals covered by the patent which were found to be allowable under Article 53(a) EPC above.*[118]

This decision was appealed again and it came before the TBA,[119] whichaffirmed the result of the balancing test.[120] However, it also made an important addition stating that the Implementing Rule 23d(d) reflects the balancing exercise only in regard to the suffering of animals *vis-à-vis* the medical benefit to man or animal. From this decision it could be understood that the scope of the balancing test scope might not be limited to the interests determined in the Rule 23d(d).

---

113 *See supra* note 68.
114 T 19/90, Onco-mouse/HARVARD, O.J EPO 12/1990, Reasons of the Decision ¶5, at 490.
115 European Patent No: EP 0169672, May 13,1992.
116 Onco-mouse/HARVARD, Decision of the Opposition Division, Nov. 07, 2001, the O.J EPO, 10/2003, at 473.
117 *Id*. Reasons of the Decision, ¶9.3 at 502.
118 *Id.,* ¶9.5 at 504.
119 T 315/03, Decision of the Technical Board of Appeal, July 06, 2004, O.J EPO 1/2006, at 15.
120 *Id.,* ¶10.5, at 53.

In light of the foregoing case we come to the opinion that the high number of references to this test could not bring satisfactory results for the patent eligibility assessment. The balancing of different interests based on *ordre public* and morality concerns mentioned in the *T 315/03* decision could lead us to the following result: if arguments based on morality and *ordre public* concepts are subject to the balancing exercise, it could be implied that they are weak and might be refutable at the end of the balancing exercise, thus, the invention should not be precluded from the patent protection This strengthens the conviction that the patent law should not be used as a platform to assess inventions on the morality constituted of contentious and vanquishable arguments when they are 'weighed up' with other interests.[121] Additionally, if the examination of inventions were done by evaluating their possible benefits and risks based on different parameters, a high proportion of inventions for chemical, pharmaceutical and military purposes would not have got patent protection.[122] For that reason, the refusal of the patent application based on morality grounds should take into account strong principles which could be put in no way under a contentious situation with possibly other prevailing interests. So we defend the position for the abhorrence test which targets the refusal of patent eligibility based on uncontroversial results departing from *ordre public* and morality principles.

As regards the morality assessment for hESCs-related inventions, the general public perception and different existing interests of the parties should be taken into account.[123] If we try to apply the balancing exercise for a moment, on the one hand, there is interest in human healing, the development of drugs and scientific knowledge for patients suffering from serious diseases like Parkinson, Alzheimer, diabetes and cancer. On the other hand, there is the ethical concern related to the commodification of the human being, violation of the right to life, and other. The act of balancing of these two arguments would differ depending on the prevailing interests of the

---

121 "*The Opponent's first argument that the patenting of higher life forms in principle unethical is a philosophical argument that* WHICH CANNOT BE ACCEPTED IN THE ABSENCE OF ANY STANDARDS OF ABSOLUTE MORALITY.*"* Greenpeace UK v. Plant Genetic Systems N.V.,Opposition Division Decision EPO, (1992) 24 IIC 618, ¶3.16 at 624.

122 Straus, *supra* note 61, at 27.

123 Recitals of the Biotech Directive underscore these interests: In Recital 16, *"...fundemantal principles safeguarding the dignity and integrity of the person…" is mentioned followed by Recital 17 which states that the patent law system should incentivize the production of medicinal products "...derived from elements isolated from the human body...*".

person or group of persons involved and the result thereof would not be satisfactory for any of the parties.

Additionally, new developments in the stem cell research are reported on its unrevealed aspects. Moreover, the complexity of matters in the life sciences being subject to any judgment do not possess easy sides helping too much lay persons in the public to develop a convincing, reliable and uncontroversial position. Therefore, arguments which would be made by both parties would be neck and neck. Thereafter, the judgment to be made would not resolve discussions. For these reasons, opposing ideas in an emerging field should be strong and mature. Accordingly, for the hESCs-related inventions, if very convincing arguments are produced to justify the application of this technology, counter arguments should also come from the scientific environment. In the same vein, another implication could be made regarding the type of evidence that authorities in charge should devote their attention for the morality assessment. In *T 315/03* decision, the opinion polls were not seen as a reliable instrument to give evidence for the existence of morality principle.[124]

An example that would show the difficulty of the balancing test in regard to hESCs-related inventions is given by Annas in his article:[125] It is about the difficulty of making a choice between the rescue of seven embryos or one child from a fire in an IVF treatment laboratory. Even that difficulty shows the unsuitability of the balancing test for the patent eligibility assessment of hESCs-related inventions. Therefore, morality arguments should be very strong in this case in a way that leaves no justification for the healing purposes of the hESC technology and such arguments should be shared without any dissent by the Member States. This reflects especially the situation in the context of the EU, where a single European morality approach, particularly, for hESCs-related inventions is not easily achievable. So authorities should analyze each case in light of a diversity of evidence from legal rules to empirical data.[126] Hence, the test should be applied in a way that the decision to exclude hESCs-related inventions from the patent protection is reached when they are deemed abhorrent based on a wide array of evidence.

---

124 T 315/03, *supra* note 119, Reasons for Decision ¶10.4 at 53.

125 George J. Annas, *A French Homunculus in a Tennessee Court*, 19 The Hastings Center Rep. 20, 22 (1989) *available at* http://www.jstor.org/stable/3561982 (Last visited Aug.11,2012).

126 Warren-Jones, *supra* note 55, at 660.

After having structured the guiding principles existing in the legislative tools, we must have a look to the practice in Europe in the following sections.