VI. EPO's Web of Precedents

A. University of Edinburgh Case

The University of Edinburgh filed a patent application on Apr.21, 1994 before the EPO. The patent claims refer to a method involving the *"use of a selectable marker to isolate and/or enrich and/or selectively propagate animal stem cells."*[127] The patent was granted by the EPO on Dec. 06, 1999. Thereafter,the patent was challenged several times. The main concern of the opponents was whether the term 'animal' could be considered in a manner including humans in regard to the source of selection of ESCs. Because even though the research subject to the patent was established by using the mice, claims of the patent were drafted in a way to cover also hESCs. As we learn from Porter, this was the first case of the patent eligibility of hESC-related inventions before the EPO.[128] The OD decided[129] to maintain the patent with amended claims, including claims to stem cells *per se*, but with a disclaimer to human or animal ESCs.[130]

In this case, the OD made an assumption about the possible situation of the patent without disclaimer. In that task, the OD opted for the broad interpretation of the Rule 23d(c) (now 28(c)). Because, according to the OD, the broad interpretation of the said rule would justify the rationale of the Rule 23e(1) (now Rule 29(1)). This reasoning of the OD could be rephrased as follows: inventions involving the use of human embryos for commercial and industrial purposes are not patentable. Therefore, the hESC-related inventions should not be patent eligible when they involve the destruction of human embryos. Since the rationale of Rule 23e(1) is to protect human embryos against commodification, then the elements extracted from human embryos for commercial and industrial purposes should not be patented.[131]

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127 For claims of the EP 0695351 B1 see EPO Patent Database Espacenet, *available at* http://worldwide.espacenet.com (last visited Aug. 05,.2012).

128 Porter, *supra* note 64, at 25.

129 EP 0695351 B1 Opposition Division Decision, Mar.21, 2003.

130 Porter, *supra* note 64, at 25.

131 Paul Torremans, *The Construction of The Directive's Moral Exclusions under the EPC*, Embryonic Stem Cell Patents *in supra* note 64, at 151.

Torremans does not agree with the reasoning of the OD stated above, because each of these provisions implemented from the Biotech Directive has specific and different purposes. According to him, Rule 23e(1) does not allow the patentability of human embryos *per se*, whereas the Rule 23d(c) prohibits inventions claiming *"the direct use of the embryo as a raw material in a repetitive (technical) process…"*[132] In other words, as long as the use of human embryos is not claimed in the application, it is not possible to make a broad interpretation which covers also the clause on the prohibition of the patentability of human embryos as such.

Before this decision was handed down, the 16th Opinion of the European Group on Ethics in Science and New Technologies to the European Commission (hereinafter, EGE) was published in May 2002 by virtue of Art. 7 of the Biotech Directive.[133] According to the 16th Opinion, *"…the patentability of processes involving human stem cells,* ***whatever their source****, there is no specific ethical obstacle, in so far as they fulfill the requirements of patentability."*[134] Therefore the statement of the OD decision does not go along with the 16th Opinion. In spite of its inconsistency with the EGE's opinion, the said decision got support from other instances of European institutions: European Parliament made reference to the decision of the OD accepting in its resolution that the patenting of hESCs is not possible.[135] Besides, the Parliament in the same Resolution stated: *"...for creation of embryonic stem cells embryos have to be destroyed and the patenting of technologies where human embryos are destroyed or used for commercial or industrial purposes is excluded according to Article 6(2)(c) of the Directive*". Nevertheless, these statements do not have any binding force for decisions of the EPO, however, it evidences the diversity of ideas and a lack of consensus on this issue.

It seems that the OD decision regarding *Edinburgh* patent had also some implication for future cases of the EPO. In the next subsection we will an-

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132 *Id.*.

133 Article 7:
The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology.

134 Opinion of the European Group on Ethics in Science and New Technologies to the European Commission 16, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells*, § 2.3, May 7, 2002 *available at* http://ec.europa.eu/bepa/european-group-ethics/docs/avis16_complet_en.pdf (last visited Aug. 05, 2012).

135 European Parliament Resolution on *Patents for Biotechnological Inventions*, P6_TA(2005)0407, ¶I, Oct. 26, 2005.

alyze a related and very important case of the EPO determining the course of affairs.

B. The WARF Case

1. Background

The EBA of the EPO gave its judgment[136] on questions referred to it by the TBA[137] concerning the patent eligibility of inventions involving hESCs under the EPC. The subject-matter of the patent application filed by WARF was a cell culture comprising hESCs which do not lose their characteristics even after keeping them *in vitro* for one year.[138] In the claims there was no method claim pointing out the source or the generation of hESCs.

The Examining Division rejected the application based on the Rule 23d(c) (now 28(c)) and Art. 53(a) of EPC on the grounds that it would be contrary to *ordre public* or morality to grant a patent for an invention relying on the destruction of human embryos. WARF appealed this decision and by virtue of Art. 112 EPC, the TBA referred four questions to the EBA. The first question was whether Rule 23d(c) of the EPC is applied to patent applications filed before the entry into force of the said rule. The second question inquires the patentability of human embryonic cell cultures even if methods involving the destruction of human embryos to derive hESCs are not mentioned in the claim. In the third question it is asked whether there is the possibility of the sole application of Art 53(a) EPC. The last question was about the relevance of the existence of new techniques allowing the pro-

136 G 2/06, Use of embryos/WARF, Nov. 25, 2008, EPO OJ 5/2009, at 306-332 (hereinafter G 2/06).

137 T 1374/04, Stem cells/ WARF, Apr. 07, 2006, EPO OJ 5/2007, at 313-343 (*hereinafter* T 1374/04).

138 Claim 1 of European Patent Application 96903 521.1, EP Nr. 0770125 is taken from Prof. Joseph Straus, Protection of Biotechnological Inventions (June 5-6, 2012), (unpusblished slides used in summer term class of the Munich Intellectual Property Law Center).: A cell culture comprising primate embryonic stem cells which (i) are CAPABLE OF PROLIFERATION IN VITRO CULTURE FOR OVER ONE YEAR, (ii) maintain a karyotype in which all chromosomes normally characteristic of the primate species are present and ARE NOT NOTICEABLY ALTERED THROUGH CULTURE FOR OVER ONE YEAR, (iii) maintain the potential to derivates of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (iv) are prevented from differentiating when cultured on fibroblast feeder layer.

duction of hESC cultures, which are generated without destroying human embryos after the filing date of the application at issue.

2. The Rationale

In regard to the first question, the EBA stated that the implementation of the new rule has not introduced a change as to the patentability criteria. Accordingly, EPC Rule 23d did not make unpatentable something which was considered as patentable before the entry into force of the Rule.[139] This was already the existing situation under Art. 53(a) EPC. Therefore the legal uncertainty as to the exceptions to the patentability is unlikely to arise for any potential inventor.

The core of the present discussion and which is more related to our research finds place in the second question. Claims of the patent application were not guiding the person skilled in the art to use human embryos. In that, WARF asserted that the subject-matter of claims was the cell culture comprising hESCs rather than a method necessarily involving the destruction of the human embryo to produce hESC cultures.[140] This argumentation is the result of a narrow interpretation of the Rule having the expression *"…inventions which, in particular, concern the use of embryos…"*. WARF based its argument on the Art. 84 EPC stating that the matter protected by the patent is in claims and claims are indicative of the invention. Then, as the invention does not have the use of human embryos as its object, the exception to the patentability should not apply here.[141]

The EBA had an opposite approach to WARF's opinion: It uses the method to find the object and purpose of legal provisions including preparatory documents according to the language of the Vienna Convention on the Law of Treaties.[142] By doing so, the EBA found that to remain undefined the term 'embryo' was the purpose of the legislator. The lack of the embryo's definition makes the situation more problematic.[143] Therefore, different approaches arise here again. According to WARF, an ovum could be called an embryo after being at least 14 days old. Hence, hESCs could be derived from

139 G 2/06, *supra* note 136, ¶13.
140 T 1374/04, *supra* note 137, ¶37.
141 G 2/06, *supra* note 136, ¶21.
142 Vienna Convention on the Law of Treaties, May 23, 1969.
143 Torremans, *supra* note 94, 302.

these organisms younger than 14 days old. Nevertheless, the EBA draws our attention, as we discussed earlier, to the diversity of approach to the term under national legislations and gives concrete examples from German Law and law of the U.K. It does not prefer a single definition and construction. This attitude might prove that with the exclusion of human embryos from patent eligibility it is aimed to extend its scope to cover all possible embryo definitions.[144] As a result, the EBA suggests a case-by-case analysis to determine whether an entity is an embryo by taking into account the particular facts of any patent application.[145]

The choice of the EBA for the broad interpretation, like in the Edinburgh patent case, could also be indicated in its approach to the term 'invention' which is deemed to cover not only the explicit wording of claims but also the technical teaching of the application as a whole and of the technology involved. The EBA strengthened its argument by referring to the decision of the German Federal Patent Court (BPatG)[146] on the revocation proceedings of Oliver Brüstle's patent. Brüstle case is not discussed here, as it will be analysed in detail in the following chapter. According to the EBA, when the patent eligibility of an invention is discussed on moral grounds, it is not possible to refer only to the claims of an application. It has been acknowledged that at the filing date, the skilled person willing to repeat the invention had necessarily to start from the spare pre-implantation embryos as indicated in the application followed by their destruction in the process, so that human embryos are 'used'.[147]

As to the another issue whether the use of human embryos is for commercial and industrial purposes, the EBA's finding was affirmative. In that, the product must be made first before it can be used and commercially exploited, and such making falls within the monopoly granted. Consequently, to make the claimed product is equated to commercial or industrial exploitation of the invention, even if there is an intention to use the product for further research. Accordingly, the use involving destruction of human embryos is

144 Pierre Treichel, *G 2/06 and the Verdict of Immorality*, 4 IIC 450, 459 (2009).
145 G 2/06, *supra* note 136, ¶20.
146 Bundespatentgericht [BPatG] [Federal Court for Patent Matters], Dec.5, 2006, 3 Ni 42/04 Entscheidungen des Bundespatentgerichts, *available at* http://juris.bundespatentgericht.de (last visited Aug. 05, 2012).
147 G 2/06, *supra* note 136, ¶20.

an integral part of the industrial or commercial exploitation of the claimed invention.[148]

I would tend to disagree with the EBA because of the erroneous determination of the scope of patent protection. The process of hESC generation to form hESC cultures does not exist in claims of the patent application. Therefore, it is not possible to agree with the existence of the monopoly on the method involving the destruction of human embryos. In addition to that, to make the product would not necessarily have a commercial purpose where there is an intent for research with that product. Moreover, Torremans does not accept the existence of commodification or, in other terms, the commercial and industrial purpose in this case, because the human embryo is not repetitively used every time when the invention is performed.[149]

Another important aspect of the case is analyzed by the EBA in answering the fourth question. The science is a dynamic field, therefore even after the application's filing date, the technology used to reach the end-product could change. In the case at issue, the technique used for the isolation of hESC involved at the time of filing the step of destruction of human embryos. whereas today, as mentioned earlier, alternative methods to procure stem cells have emerged such as iPSCs which are not of embryonic origin.[150] However, according to the EBA, these developments creating possibility to perform the invention without the need to destroy embryos are irrelevant to the patentability of the invention at issue. Thus, if the extraction of hESCs is possible exclusively by the destruction of human embryos at the filing date and the inventor is not aware of an alternative method, the hESCs-related invention would not get patent protection. In my opinion, this argumentation urges applicants to disclose the method used to obtain the base material either in the specification or in the claims. Although this might create certainty for the applicant, its lack should not be a barrier to get a patent for the invention. On the contrary, EBA makes the statement that the application in case is insufficiently described and has a lack of disclosure that the invention could be carried out by the skilled person in the art.[151] Unlike the EBA, I think that the application does not have a lack of disclosure to enable the skilled person in the art to perform the invention. Because even though the destruction of human embryos is not disclosed in the specifica-

148 *Id.,* ¶25.
149 Torremans, *supra* note 94, 301.
150 *See supra* Part II.B.3.
151 G 2/06, *supra* note 136, ¶33.

tion, there is always a certain possibility far from any uncertainty on the part of the skilled person to use derived hESCs found in cell banks as a research tool.[152] As a result, inventions, like the one at issue, concerning products obtained by techniques involving the destruction of human embryos are excluded from patentability according to the EBA.[153]

This decision of the EBA had important implications to the present debate. The findings in G 2/06 have played a role in the background of the revision made in the EPO's Guidelines for Examination which entered into force on June 20, 2012. In the section related to the patentability of the said Guidelines, there is an explicit reference to the G 2/06.[154] The Guidelines suggest that the examination should be targeted to 'the entire teaching' and 'the relevant disclosure in the description' to evaluate whether stem cell cultures are derived as a result of the destruction of human embryos. In the WARF's patent, the method of extracting hESCs by the destruction of embryos is not the invention. Rather, the gist of the invention is related to hESC cultures and how to keep the cell culture over one year in an undifferentiated state. Nevertheless, the assessment for patent eligibility is done in regard to the whole path leading to the invention. As stated by Torremans, the EPO should not look to the phase of gathering research tools and creation of other materials or methods pursued, for which the patent applicant does not require patent protection.[155] The reason for the inventor that one kind of technology is not expressed in the claims but in the description, might reflect his will to have flexibility towards the development in the technology. This is particularly the case for hESCs-related inventions: The first reason is that there is

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152 UK IPO, *Practice Notice, Inventions Involving Human Embryonic Stem Cells*, Feb. 3, 2009, http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20090203.htm.; Kathleen Liddell, *Immmorality and Patents: The Exclusion of Inventions Contrary to Ordre Public and Morality in* New Frontiers in the Philosophy of Intellectual Property 140, 168 (Annabelle Lever, ed., Cambridge University Press, 2012.).

153 G 2/06, *supra* note 136, ¶35.

154 *"*Uses of human embryos for industrial or commercial purposes
A claim directed to a product, which at the filing date of the application could be ***exclusively*** *obtained by a method which* necessarily *involved the destruction of human embryos from which the said product is derived is excluded from patentability under Rule 28(c),* even if said method is not part of the claim *(see G 2/06).* The point in time at which such destruction takes place is irrelevant.*"*, Examination Guidelines *supra* note 98, Part G Ch.II at 15.

155 Paul Torremans, *The Construction of The Directive's Moral Exclusions under the EPC*, Embryonic Stem Cell Patents *in supra* note 64, at 166.

a continuous race to create new sources for hESCs. A second more concrete reason is the possibility to create hESCs with already existing hESC lines in laboratories.

Consequently in my opinion, the investigation of the whole genealogy of the invention is beyond the task of the EPO. If the aim is to preclude the incentive to use existing hESC lines obtained by human embryo destruction, the patent law is not the instrument to avoid it. There are other alternative administrative and regulatory tools.[156] To make this argument crystal clear an analogy could be made to the situation depicted in the novel 'Perfume',[157] in which the inventor was killing women and isolating pheromones to create the perfect scent. So according to the G 2/06 decision the scent would not be patentable. Given that analogy, the patent law would take the place of the criminal law and other rules regulating approval for sale of perfumes which could already sanction the inventor. Therefore, the EPO is not in good position to assess the acts indirectly related to the claimed invention.

156 Straus, *supra* note 61, 27.

157 Patrick Süskind, Das Parfum [The Perfume], This example is taken from the class of Biotechnology and IP by Professor Margo Bagley at Munich Intellectual Property Law Center on June 22, 2012.