VII. CJEU's Brüstle Judgment

A. Background

Dr. Oliver Brüstle, from University of Bonn, applied for a patent on Feb. 19, 1997. The German Patent Office issued the patent on Apr. 29, 1999. The application covered a product claim and a method claim, respectively, neural precursor cells and a method of obtaining them and the use of these neural precursor cells for therapy of neural defects.[158]

After the grant of the patent, Greenpeace, a NGO, commenced an action for nullification by asserting the violation of *ordre public* and morality. The BPatG revoked the patent to the extent that claim 1 of the patent application concerning precursor cells and claims 12 and 16 concerning the manufacture

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158 Claim 1: *Isolated, purified precursor cells with neuronal or glial properties from embryonic stem cells*, containing at most about 15% primitive embryonic and non-neutral cells obtainable by the following steps:
cultivate of E Cells into embryoid bodies,
cultivate of the neutral precursor cells to embryoid bodies,
……
Claim 5: Cells according to any one of claims 1 to 4, wherein *the embryonic stem cells were obtained from oocytes after nuclear transfer*
Claim 6: Cells according to any one of claims 1 to 4, wherein *the embryonic stem cells obtained from embryonic germ cells*
Claim 7: Cells according to any one of claim 1 to 6, wherein said cells are *mammalian cells*.
Claim 8: Cells according to claim 7, wherein the cells from the group *comprising mouse, rat, hamster, pig, are bovine, primate or human* been isolated.
….
Claim 12: *A method* for preparing *purified precursor cells with neuronal or glial properties*, comprising the steps of
cultivate of ES cells into embryoid bodies,
cultivate of the embryoid bodies to neural precursor cells,
……
Claim 22: *Use of the precursor cells* according to any one of claims 1 to 11 *for the therapy of neural defects.*
The translation of these claims are generated by using the Patent Translate tool powered by the EPO and Google. For more information about the patent DE 19756864 C1 http://worldwide.espacenet.com(follow out with the patent number above) (last visited Aug 07, 2012).

of precursor cells that are obtained from hESCs.[159] The BPatG based its decision on the Sec.2(2) first sentence No.3 of GPA which were implemented due to the Biotech Directive Art. 6(2)(c).[160] This decision was appealed by Dr. Brüstle in the BGH. The BGH has made a referral to the CJEU under Art. 234 of TFEU for a preliminary ruling related to the interpretation of the Biotech Directive.[161] The BGH asked three questions: The first question was dealing with the definition of the concept of the human embryo, whether its scope covered certain organism and whether stem cells obtained from human embryos at the blastocyst stage could be considered as a 'human embryo' under Article 6(2)(c) of the Biotech Directive. The second question was related to the meaning of 'use of human embryos for industrial or commercial purposes'. The last question was whether the invention would be patentable under Art. 6(2)(c) even if the use of human embryos is not part of the patented teaching but the claimed product requires the destruction of human embryos or such claimed product is needed as a starting material for the performance of the claimed method. The BGH made a gradual reasoning on the possible conditions for an invention which requires the use of 'human embryo'. The first step is to determine the scope of the definition of 'human embryo' and the second one is to decide whether hESCs used for precursor cells are 'human embryos'.[162] If the answer is negative to the first question then the categorization as 'human embryos' of blastocysts from which hESCs are derived should be analysed.[163] As the last step, in case the use of alternative methods such as SCNT and the development of an ovum stimulated by parthenogenesis are claimed, the question whether the cells derived therefrom would be classified as 'human embryos' needed a clarification.[164]

As it is seen, a comprehensive task was expected by the BGH from the CJEU who had to interpret the Art. 6(2)(c) of the Biotech Directive for the first time.

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159 Reference made by German Federal Supreme Court to the decision of Federal Patent Court in supra note 97, Bundesgerichtshof [BGH] [Federal Court of Justice] Dec. 17, 2009, Case No: X ZR 58/07, (Christopher Heath (trans.), 7 IIC at 853 (2010).
160 *Id.,* ¶12, at 853.
161 *Id.*.
162 *Id.,* ¶36, at 854.
163 *Id.,* ¶40, at 854.
164 *Id.,* ¶42, at 855.

B. The Rationale

The CJEU made its preliminary ruling regarding the questions referred by the BGH.[165] CJEU has followed substantially the legal solution offered by the AG Bot who delivered his opinion in that case.[166] In this section while revealing the rationale of the CJEU's judgment, we will also analyze the opinion of the AG.

The CJEU made an attempt to determine a common definition of 'human embryo' throughout the EU. According to the CJEU, a single definition of the term would be in line with the harmonization aim of the Biotech Directive.[167] It was admitted both by the CJEU and the AG that an ethical approach would not be followed in this exercise, mainly, because of the lack of consensus on this issue based on different moral, social and religious beliefs: so they both avoided the question of "medical and ethical nature".[168] The AG expressly determined that the single 'legal categorisation' of 'human embryo' should be based on "scientific objective information".[169] According to the CJEU, the lack of the definition of 'human embryo' would cause inconsistency among different results as to the patent eligibility of the same invention in different Member States. As a result, a situation against the purpose to create an internal market would appear.[170] Moreover, according to the AG in the same line with the CJEU, there is not any specific intent of the legislator revealed from the legislative history to leave the concept undefined. At this point we might think that some details of *travaux preparatoires* of the Biotech Directive are undermined by the CJEU. An evidence for the background of the diverse situation in different Member States guiding legislative intent related to the Art. 6(2)(c) is reported by Porter who

165 C-34/10, Oliver Brüstle v. Greenpeace e.V., Court of Justice of the European Union, [CJEU], 2011 CURIA (Oct. 18, 2011) (*hereinafter* C -34/10).

166 Op. of Adv. Gen. Bot, Case 34/10 Oliver Brüstle v. Greenpeace eV. CJEU Mar. 10, 2011 (*hereinafter* AG Opinion).

167 C-34/10, *supra* note 165, ¶26-27. Contrary to that argument it is stated that the Biotech Directive does not provide a suitable environment for such definition based on Recital 8 of the Biotech Directive setting forth "legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law". For this argument *see* Aurora Plomer, *After Brüstle: EU Accession to the ECHR and the Future of European Patent Law*, 2 Queen Mary Journal of Intellectual Property 110, 125 (2012).

168 *Id.,*¶ 30., AG Opinion, *supra* note 166, ¶39.

169 *Id.,* ¶47.

170 C-34/10, *supra* note 165, ¶ 28.

makes a reference to the report of the rapporteur Rothley.[171] Nonetheless, in the CJEU's judgment we see the implication of the AG's view considering the diversity of the meaning given to 'human embryo' in different Member States' legislations. Hence, the CJEU came up with a very broad definition of 'human embryo' covering the range starting from "the fertilisation stage to the initial totipotent cells and to the entire ensuing process of the development and formation of the human body".[172] The breadth of the definition is evidenced in the way that different points of biological development are included.

Contrary to the CJEU's findings and the AG's opinion, there is not a consensus on the meaning of 'human embryo' in the scientific environment.[173] The scope of the concept 'human embryo'is also construed by considering different technologies where traditional fertilisation does not take place, namely, in the SCNT and induced parthenogenesis. In that "unfertilised ova into which a cell nucleus from a mature cell has been transplanted and unfertilised ova whose division has been stimulated by parthenogenesis" are considered within the scope of the human embryo definition.[174] But this addition to the definition by the CJEU could be problematic, especially, in the context of the SCNT. Because the potential of a live birth of an entity which is created as a result of the SCNT is considered as a factor to define that the human embryo could not be analyzed in a clear-cut manner by the scientific community.[175] Nevertheless, in its definition, the CJEU focused on a cell's capacity of "commencing the process of development of a human being".[176] This yardstick could be insufficient, because the determination of the hESCs capability to differentiate into an individual would require *in vit-*

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171 Committee on Legal Affairs and Citizens' Rights, Report on the Proposal for the Directive, referred by Porter, *supra* note 60, at 20 n.61.

172 C-34/10, *supra* note 165, ¶35.

173 *"There has been a consensus within the scientific litterature that a human embryo is an entity in its earliest stages of development that is less than eight weeks gestation…However, there is a difference of opinion as to which points of biological development should be covered by the term 'embryo'."* Australian Government National Health and Medical Research Council*, Human Embryo, – A Biological Definition* (Discussion Paper) *available at* http://www.nhmrc.gov.au/_files_nhmrc/file/research/embryos/reports/humanembryo.pdf (last visited Aug. 08, 2012).

174 C-34/10, *supra* note 165, ¶36.

175 *"… With the current state of the art it appears that a SCNT blastocyst is likely to have a significantly lower probability of successful development than one created by gamete fertilisation."* Australian Gov. Discussion Paper, *supra* note 173, at 21.

176 C-34/10, *supra* note 165, ¶35-37.

ro experiments or *in vivo* animal models. In some of these experiments hESCs have to be placed in primate blastocysts. This is a scientific exercise prohibited by guidelines at national and international levels.[177]

As regards the categorization of stem cells obtained from a human embryo at the blastocyst stage, the CJEU left this task to the BGH or, generally speaking to national courts. At this point, it seems that the Court was reluctant to make a distinction between totipotent and pluripotent hESCs depending on their capacity to develop into a human being. On the contrary, the AG concluded more precisely that the hESCs disclosed in the present case could not be considered as 'human embryo' because pluripotent hESCs do not have the capability to develop into a complete individual.[178] It would not be wrong to say that this is the only point where the CJEU's and the AG's opinion diverge.

The CJEU's answer to the second question should be analyzed as well. According to the CJEU, the use of human embryos for scientific research is also covered by their use for industrial and commercial purposes provided for by the Article 6(2)(c) of the Biotech Directive.[179] The CJEU held that if the use of human embryos for scientific research is a part of the subject-matter of the patent, then there is no possibility to distinguish between scientific research and industrial or commercial purposes.[180] To better understand this reasoning, one should refer again to the *travaux préparatoires* of the Art. 6(2)(c). The first version of this article was 'Methods in which human embryos are used…' but then it gained its actual state with amendments proposed.[181] The CJEU makes reference to the Recital 14 of the Biotech Directive to indicate that, in principle, a patent application implies the industrial or commercial use of an invention. This reasoning shows that the CJEU does not make a distinction between the 'industrial or commercial purposes' which indicates the rationale of moral exclusion and the 'industrial application' which is a patentability requirement. It is true that an invention should be 'susceptible to industrial application' according to the EPC

177 Katja Triller Vrtovec & Christopher Thomas Scott, *The European Court of Justice Ruling in Brüstle v. Greenpeace: The Impacts on Patenting of Human Induced Pluripotent Stem Cells in Europe*, 9 Cell Stem Cell 502, 503 (2011.).

178 AG Opinion, *supra* note 166, ¶100.

179 C-34/10, *supra* note 165, ¶.46.

180 *Id.,* ¶ 43.

181 *See* for the details of *travaux preparatoires*, Aurora Plomer et al. *supra* note 93, at 20-21.

Art. 51(1), but the aim of the Art. 6(2)(c) is to preclude a certain way of use of human embryos, namely, the use with industrial or commercial purpose.[182] In the case at issue, the mere fact that the patented invention (neural precursor cells) is used, for example, as an element of a disease treatment device, thus, proving its susceptibility for industrial application, should not be equivalent to the case where the patented invention still needs to be improved for a future use in the medicine. Scientific purpose could be pursued even if the inventor holds a patent. The important factor here should be whether human embryos *per se* are directly used each time the treatment device in our example is produced.[183] Otherwise, the same result of the Court could have been reached without the latter part of the sentence in Art. 6(2)(c), namely, 'industrial or commercial' purposes, because the Biotech Directive itself targets the patents related to the biotechnological inventions.

The most seminal part of the CJEU's judgment is related to the third question. Its focus is oriented to the process of hESCs' generation. The fact that hESCs are removed from the inner cell mass of a blastcosyst, which is defined as a human embryo by the AG,[184] deserves a closer look for the assessment made in light of '*ordre public*' and morality. The CJEU held that the invention should be excluded from patentability although the extraction of pluripotent hESCs from human embryos are neither claimed, nor described. The rationale behind this argument is the possible intention of the patent applicant to make an attempt to circumvent the exclusion under the Art. 6(2)(c) of the Biotech Directive.[185] Before commenting on this, we must underline the analogy made by the AG to reach the same result as the CJEU. AG made an assumption on the patent eligibility of some inventions based on the research on the organs of victims murdered in Yugoslavia. The choice of example is quite untenable by creating a link between the patent eligibility and an act which is described as 'humanity crime'. Probably, according to the CJEU with the same idea in mind, when a human embryo is a source for the biological material, regardless, whether it is claimed or described, the very end product is excluded from the patent protection, even though the

182 *Id.,* at 74.

183 AG does not bring a clear answer to the question but underlines that the 'industrial and commercial purposes' refer to a repetitive (each and every time) use of human embryos in the example he gave, namely the manufacture of medicines. AG Opinion, *supra* note 158, ¶114.

184 AG Opinion, *supra* note 166, ¶95.

185 *Id.,* ¶108.

inventor is unaware of the said act and does not perform it to come up with the invention.

In addition to our previous critics to the highly similar approach of the EBA in the WARF decision,[186] we must make further comments related to the CJEU's judgment. In the European patent system, the focus should be on the invention's claims to decide on its patentability and to determine its scope of protection. The specification should be used to understand and interpret the claim. Moreover, Art. 83 EPC requires the disclosure of the invention in a manner that makes the person skilled in the art capable to perform the invention. So to fulfill the sufficiency of disclosure requirement, the information how an invention is produced is not necessarily to be included in the claim.[187] If we come back to the case at issue, the generation of hESC used to obtain neural precursor cells does not have to be included in the claim as far as the person skilled in the art can produce the same invention by using hESCs in the stem cell banks.[188] Also according to the Rule 43(1) EPC, all technical features of the invention should be included in the claim. Therefore, there is no need to go beyond the claims when we make the patent eligibility assessment.

In my opinion, the origin of the flawed result belies under the one sided construction of the subject-matter related to the invention. We can try to find the source of this argument in AG's opinion in its discussion of the term 'industrial and commercial purposes'. He pointed out that for the performance of the invention many embryos would be destroyed.[189] That alone is a good evidence of the misconstruction of the invention. The inventor could perform this invention with already generated hESC lines, in other words without being involved in the destruction of human embryos. In my view, it is not a fair solution to preclude one invention for the reason that its base material has been obtained in immoral manner regardless the time it has occurred, the person who made it, its existence in the claim of the invention and even its procurement is in compliance with the regulatory provi-

186 *See supra* text accompanying note 143.

187 Rudolf Teschemacher, *in supra* note 105, ¶13, at 379.

188 W.Cornish et al., Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights ¶21-24 at 946 (Sweet&Maxvell,7.ed, 2010) (1981.).

189 AG Opinion, *supra* note 166, ¶ 114-115.

sions.[190] Also, there is no possibility for patent examiners to make this investigation throughout the whole life cycle of the invention. Contrary to the view of the CJEU, there could not be any intent to circumvent the law if there is no necessity for the inventor to put in the claim an act that he does not need to come up with the invention. This statement of the CJEU is not in line with general patent law principles and with the previous case of the ECJ we referred earlier in this research.[191]

C. Comparison of WARF and Brüstle Cases

Since the EU is not a contracting party to the EPC, the EBA and the CJEU are not bound with the decision of each other, but it is possible that one inspire the other. Although the CJEU has reached similar conclusion with the EBA, there are some points in which they differ.

In the *WARF* case, the patent application was made for hESCs, whereas in the *Brüstle* case, the neural precursor cells were claimed. When it comes directly to the patentability of hESCs *per se*, the WARF would struggle more before the CJEU. Because there is a possibility that national courts could categorize these hESCs as human embryos and non patent eligible.

Another point is related to acts, which occurred before the invention but not claimed in the application. In the WARF decision, if the invention is exclusively prepared by a method which necessarily involved the destruction of human embryos at the filing date and even if it is not in the claim, the invention could not be patentable.[192] Due to the use of the word 'exclusively', one could interpret this ruling that the EBA allows the patentability of inventions which could be performed with existing hESC lines from cell

190 Stammzellgesetz [StZG] [Stem Cell Act], Bundesgesetzblatt Jahrgang [BGBL] I, Jun. 29, 2002, Teil I, at.2277, last amended by Gesetz zur Änderung des Stammzellgesetzes (StZGAndG), Aug. 14, 2008, BGBL. I at 1708, *translated* in Oduncu, *supra* note 76, at 8.

191 *See* the case cited *supra* note 95.

192 G 2/06, *supra* note 136, ¶15.

banks.[193] In the same vein, one could find the CJEU's judgment as more restrictive, whereby a broad retrospective look encompasses the activities prior to the invention which could involve the destruction of human embryos. Judging solely based on this parameter, it could be possible to say that Dr. Brüstle's patent could be patentable under the EBA's approach because in this invention legally deposited hESC lines from stem cell banks in Israel were used. Nevertheless, our arguments could be criticised since they do not consider that the EBA sees also the definition of human embryo as decisive in each particular patent application.[194] It is true that unlike the CJEU, the EBA did not make any attempt to define the human embryo, however this was mainly because that the Board found it reasonable that the EU and EPC's legislators had chosen to not define the term but added that it would be against any restrictive interpretation of the term 'human embryo'.

D. The Devil is in Details, Unpatentable but Exploitable?

The expression in English 'the last but not least' is literally confirmed by the BGH. In the last paragraph of the referral judgment of the BGH, the attention is drawn to the controversial situation, in which hESCs-related inventions are excluded from patent protection but still can be commercially exploited in terms of sale, import, export, etc.[195] This last point made by the BGH deserves a closer look especially, in a legal environment, where there is a tendency to exclude the hESC-related inventions from patentability.

TRIPs does not force WTO member states to implement exclusion from patent protection based on *ordre public* and morality reasons. But the EU Member States and EPO Contracting States has bought this option. Hence, the Art. 1(2) of the Biotech Directive implies that any result generated by the application of the Biotech Directive rules should not contradict Member States obligations under TRIPs.

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193 This situation is called as 'deposit loophole' in the article written by Sigrid Sterckx& Julian Cockbain, *Assessing the Morality of the Commercial Exploitation of Inventions Concerning Uses of Human Embryos and The Relevance of Moral Complicity: Comments on the EPO's WARF Decision*, 7 SCRIPTed 83, 94 (2010) *available at* http://www.law.ed.ac.uk/ahrc/script-ed/vol7-1/sterckx.pdf (last visited Aug. 09, 2012).

194 G 2/06, *supra* note 136, ¶20, at 325.

195 *See* ¶ 62)cc) of the original version of the case cited *in supra* note 159 in GRUR Int 2010, at 243.

Nowadays, neither in Germany, nor in Europe, there is a prohibition of similar human treatments involving hESCs. As we learn from Plomer, an analysis of the EU legislation shows that there is no prohibition for the commercial and industrial exploitation of products derived from human embryonic tissues and cells derived products in the application of advanced therapy method.[196] As a result, there is no legal barrier to commercial exploitation of an invention whose patentability is precluded on moral grounds.

At this point, we should look whether this situation reflects the rationale of Art. 27(2). As a first step, the motivation of the legislator as reported by Bonadio could be found in the history.[197] Industrialized states were in favour for the implementation of this rule in order to avoid developing countries from freeriding on inventions which are not granted patents by these countries but commercialised in their territory. Bearing this in mind we should take a look at some commentators' approaches to the provision of TRIPs. Straus points out that a country could exclude one invention from patentability if that country prohibits the commercial exploitation of this invention.[198] Accordingly, a WTO Member State must bring a prohibition to the commercial exploitation of an invention, then it could preclude the patentability of an invention. In the same vein, Pires de Carvalho indicates that exclusion from patentability must follow the exclusion from commercial exploitation.[199] This argument is also stated in the Explanatory Statement to

196 Specific examples of legal provisions creating a free environment for the commercial explotation of hESC related inventions are: *EU Directive 2004/23 on Human Tissue and Cells* "setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells" and *EU Regulation 1394/2007 on Advanced Therapies for Medicinal Products* covering "advanced therapy medicinal products which are intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process" Plomer&Torremans, *Towards Systemic Legal Conflict: Article 6(2)(c) of the EU Directive on Biotechnological Inventions*, *in* Embryonic Stem Cell Patents, *supra* note 64, at 180, 183, 186.

197 Enrico Bonadio, *Biotech Patents Morality After Brüstle*, 7 European Intellectual Property Review [E.I.P.R] 441 (2012).

198 Straus, *supra* note 24,at 182.

199 Nuno Pires de Carvalho, The Trips Regime of Patent Rights, 298 (Kluwer Law International, 2010.).

the Report on the Proposal for the Biotech Directive.[200] This interpretation of Art. 27(2) is made in light of prevailing principles in the TRIPs such as those laid down in Art. 27(1) and Art. 30. Therefore, when the commercial exploitation of an invention is precluded in a country, only then the exclusion from patentability based on *ordre public* and morality would be 'reasonable', justifiable and 'non discriminatory'.[201] Pires de Carvalho suggests a method of application called two-step necessity test.[202] In the first step, the exclusion of an invention from commercial exploitation should be necessary to protect *ordre public* or morality. Thereafter, the necessity of the patent exclusion should be assessed to implement the ban of commercial exploitation. As a result, the first step of prohibition of the commercial exploitation of an invention should be followed by its exclusion from the patent protection. Accordingly, States would be able to provide guidelines to patent examiners by prohibiting the commercial exploitation of inventions which are contrary to *ordre public* or morality. One could make a counter-arguement based on the second part of the Art. 27(2) which states that the mere prohibition by law does not suffice for exclusion from patentability. Our answer would be that only prohibitions by law having the purpose of protection of *ordre public* and morality should be determinative for the patent examiner when deciding for the exclusion. This situation would also require a harmony between rules reflecting moral concerns in other branches of law and those in the patent law.[203] Hence, the possible implication of this debate could be a possible start of the Dispute Settlement Mechanism for EU Member States excluding hESC-related inventions from patentability while they are not reacting to their commercial exploitation, in other terms diverging from the rationale of TRIPs Art. 27(2).

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200 Member of European Parliament (Rothley), Report on the Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions, COM/95/0661, June 25,1997 *available at* www.europarl.europa.eu (follow out reports).

201 Gerard Porter*, Human Embryos, Patents, And Global Trade: Assessing the Scope and Contents of the TRIPS Morality Exception*, Embryonic Stem Cell Patents, *supra* note 64, at 359.

202 Pires de Carvalho, *supra* note 199, at 298.

203 Plomer, *supra* note 93, at 178.

E. Implications of the CJEU's Judgment to the Future of hESC-Related Inventions

The CJEU's interpretation of the Biotech Directive is binding for the EU Member States. Below, we refer to the situation in different jurisdictions with the latest developments in Germany, in the U.K. and at the EPO.

1. Germany

Approximately one year after the CJEU's decision, the referring court, namely the BGH rendered its final decision about the validity of the Brüstle patent.[204] The Court in its judgment stated that in case the technical teaching of the invention requires the destruction of human embryos, the invention cannot get patent protection.[205] However, the hESCs which are extracted without necessitating the destruction of human embryos can be patentable.[206] For that reason, there is a necessity of an amendment to the claim expressing the non-use of human embryos.[207] Additionally, methods to extract hESCs without the destruction of human embryos should be already in existence in the state of the art at the time of filing of the patent application and it is sufficient that the applicant points out to the method that does not require the destruction of human embryos to get hESCs.[208] The existence of that kind of method has been adressed by a reference to a publication dated of 2009 in the decision of the Court.[209] Moreover, the BGH determined that the patent specification at issue sufficiently disclosed the invention to be applied by the person skilled in the art.[210] In addition to that, according to the Court, the fact that the extraction of hESCs from the embryonic germ cells is mentioned in the patent specification, shows that the invention can be carried out without the destruction of human embryos.[211]

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204 Bundesgerichtshof [BGH] [Federal Court of Justice] Nov. 27, 2012, Case No: X ZR 58/07, *available at* http://juris.bundesgerichtshof.de (last visited Nov. 11, 2013.).
205 *Id.,* ¶ 13.
206 *Id.,* ¶ 15.
207 *Id.,* ¶ 32.
208 *Id.,* ¶ 33.
209 *Id.,* ¶ 34.
210 *Id.,* ¶ 25.
211 *Id.,* ¶ 26.

The BGH made also some statements about the definition of the 'embryo'. The criteria that the BGH pointed out was the "commenc[ing] the process of development of a human being."[212]. If this development process of embryos is not completed, the extraction of hESCs thereof is not considered as the use of embryos within the context of Art. 2(2) of the GPA.[213] The CJEU left to the BGH the task to determine whether hESCs derived from human embryos at the blastocyst stage are within the scope of the definition of the 'embryo.[214] Given their inability to start to the process of development of a human being, BGH came to the conclusion that hESCs derived from human embryos at the blastocyst stage are not considered as 'embryo'.[215] Overall, the BGH decides for the partial invalidity of the patent in suit by some insertions into claims pointing out the non-destruction of human embryos.[216]

The BGH decision followed the general rationale of the CJEU but with a more moderate result as to the validity of the patent in suit possibly taking into account some criticisms to the CJEU's judgment and its potential implications in the scientific environment.

In light of this latest judiciary activity, the legal status quo in Germany should be shortly adressed. Main guidelines of the research in the stem cell field are set by the German Stem Cells Act.[217] According to the law, any use and importation of hESCs is forbidden in principle. However, in some circumstances, the use of imported hESC lines are allowed for research purposes if the user gets a license for import from the official authority. The condition for these imported hESC lines is that they should be generated from supernumerary embryos of IVF treatment and be produced before May 1, 2007.[218] Especially after the BGH judgment, end products such as neural precursor cells are not patented just because at an earlier stage of its generation it involves the destruction of human embryos, even if they are produced with hESCs legally obtained in compliance with the StZG like in Brüstle case.

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212 C-34/10, *supra* note 165, ¶35.
213 The decision of the BGH, supra note 208, ¶ 35.
214 C-34/10, supra note 165, ¶ 38.
215 *Id.,* ¶ 37.
216 *Id.,* ¶ 30.
217 *See supra* note 190.
218 Art. 4, § 2(1)a. of StZG, *supra* note 190; A. Elstner et al*., The Changing Landscape of European and International Regulation on Embryonic Stem Cell Research*, 2 Stem Cell Research 101,104-105 (2009).

2. The U.K.

In the U.K, the research and technology development in the field of stem cell have enjoyed so far more freedom in comparison to other countries.[219] According to the UK IPO's Practice Notice, human totipotent cells could not be patentable due to their potential to develop into the entire human body, but hESCs lacking this potential are patentable.[220] However, this freedom is under attack of the case-law of different instances in Europe and as a result the change of practice for hESC-related inventions could be clearly seen. First of all, the U.K. had to react to the EBA's decision in the WARF case. In spite of the non-binding character of the EBA's decision for national patent offices, the UK IPO sets again its practice notice for the coherence with the EPO.[221] After the WARF decision, the UK IPO declared a new practice replacing the previous one. According to the new notice, the patentability of hESCs is conditioned to whether "at the filing or priority date, the invention could be obtained by means other than the destruction of human embryos."[222] At the very end, the UK IPO had to review its position after the CJEU has rendered its C-34/10 judgment. In its latest practice notice published on May 2012, the UK IPO affirms that the invention would be unpatentable if its implementation "requires the use of cells that originate from a process which requires the destruction of a human embryo."[223] Thus, only human stem cells not derived from human embryos for instance iPSCs and adult stem cells would be patentable. From the foregoing, we can see concretely the effect of the CJEU's judgment on the landscape of the patentability of hESC-related inventions: Therefore some patent applications are rejected by the UK IPO. These patent applications at issue were related to the extraction of hESCs by using parthenogenesis to activate

219 GB2415781B2: Genes that are up-or down-regualed during differentiation of human embryonic stem cells GB2412379B2: Hematopoietic cells from human embryonic stem cells
See for more examples, Plomer, *supra* note 93, 198.

220 UK IPO, *Practice Notice on Inventions Involving Human Embryonic Stem Cells*, *supra* note 152.

221 Plomer, *supra* note 93, at 196.

222 UK IPO, *Practice Notice, Inventions Involving Human Embryonic Stem Cells*, Feb. 3, 2009, *supra* note 152.

223 UK IPO, *Practive Notice, Inventions Involving Human Embryonic Stem Cells*, May 17 2012, www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20120517.htm (last visited Aug.10, 2012.).

oocytes.[224] Although the invention has fulfilled all the patentability requirements, the patent protection has not been granted because of "the use of embryos for industrial or commercial purposes".[225] This result is directly related to the findings of the CJEU in the Brüstle case. The opinion of the Comptroller of UK IPO has been appealed. The High Court of Justice Chancery Division Patents Court by its decision on 17.4.2013 has decided to refer some questions to the CJEU to clarify some issues that have already been discussed for the Brüstle case in order to reach a conclusion for the case at issue.[226] The reason for this referral is the fact that CJEU in its Brüstle decision while defining the scope of human embryo, included "any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis."[227] This classification of the CJEU generated the refusal of the patent application. According to the appellant, the observation done in the Brüstle case does not point out a consensus about the ability of parthenotes to develop into human body.[228] As mentioned above the meaning of CJEU's criteria of "commenc[ing] the process of development of a human being" is not clear as well. Therefore the need of a new referral to the CJEU has been arised. This referral's main point is related to the clarification of whether the process of developing into the human body should be completed or the start to this process is sufficient.

In the decision for a preliminary ruling, the Court made some important remarks. According to the Court, the purpose of the Biotech Directive is to incentivize with the patent protection the research in the biotechnology while the human dignity and integrity are not affected therefrom. As a result, a balance should be created between these interests. It is stated by the Court that this balance cannot be created when some processes are excluded from the patent protection with the reason that they are not able to develop into the human body, As stated further by the Court, the public health and the

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224 For detailed information about patent applications *see* GB0621068.6 *available at* http://www.ipo.gov.uk/p-ipsum/Case/ApplicationNumber/GB0621068.6 (Last visited: Apr 29, 2013), GB0621069.4 *available at* http://www.ipo.gov.uk/p-ipsum/Case/ApplicationNumber/GB0621069.4 (last visited: Apr. 29, 2013.).

225 Office Decision by Dr. L.Cullen, Aug. 16, 2012, ¶79 http://www.ipo.gov.uk/pipsum/Document/ApplicationNumber/GB0621068.6/G101394E0913B4P1%20-1/GB2431411-20120816-Office%20decision.pdf (Last visited Apr.19, 2013.).

226 International Stem Cell Corporation v. Comptroller General of Patents [2013] EWCH 807 (Ch). *available at* http://bailii.org (last visited Apr.25, 2013.).

227 *See supra* Text accompanying note 173.

228 International Stem Cell Corporation, see *supra* note 226, ¶ 39.

European industry would be negatively affected considering important potential treatment benefits of the stem cell technology.[229] It should be underlined that this language of the Court make us recall the balancing approach mentioned above in the context of EPO practice.[230]

3. The EPO

What the possible reaction of the EPO after this case would be more important. After its WARF decision, the attitude of the EPO was to grant patents for hESC-related inventions with a filing date after May 2003 if they fulfill also other patentability requirements. The rationale is that these hESC lines are deposited to institutions such as the U.S. National Institute of Health and there is not any damage to human embryos to implement this invention.[231] Now, according to the CJEU's decision, as stated earlier, even these inventions would not be patentable because there could be a stage that these deposited hESC lines are generated by the destruction of human embryos. After the CJEU rendered its judgment on Brüstle case, the EPO's President made a declaration expressing that the EPO will follow this decision.[232] But it must be underlined that the EPO and EU are two independent institutions which means that the EPO is not bound by judgments of the CJEU. At the same time, we must not forget that all EU Member States are also Contracting States of the EPO. Once these patents are granted by the EPO, it would be up to national courts of EU Member States to make judgments in possible revocation proceedings. Interestingly, in the same declaration, the President of the EPO draws attention to the EPO's counterpart of the Brüstle's patent.[233] This patent was granted by the EPO even before the EBA's decision on the WARF case. The national and European patent applications have

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229 *Id.,* ¶ 57-58.

230 *See supra* Part V.B.2.

231 Gurpreet Solanki, *Preliminary Ruling of the Court of Justice of the European Union in Oliver Brüstle v. Greenpeace e.V: Impacts on Patenting of Human Embryonic Stem Cells in Europe,* 2 BIOTECH. L. REP. 135, (2012.).

232 "*If the judges rule in favour of a restrictive interpretation of biotech patentability provisions, the EPO will immediately implement it.*" Posting of EPO's President's to http://blog.epo.org/uncategorized/patents-and-biotechnology (last visited: Nov. 03, 2011.).

233 European Patent No EP 1040185 B1, Feb. 22, 2006.

the same claim.[234] Following its grant, the patent was opposed by Geron Corporation on Jan. 01, 2007 but not on the morality ground.[235] This patent was revoked by the OD "on the ground that it covers subject-matter not disclosed in the original patent application."[236]

234 *See* for claims http://worldwide.espacenet.com.

235 Nick Bassil, *Developments in the Patentability of Inventions Relating to Human Embryonic Stem Cells*, 12 Bio-Science L. Rev., 6 (2011.).

236 As of today, the decision of the OD has not been published yet. *See* for the information for the revocation of this patent in EPO News dated Apr.11, 2013, *available at* http://www.epo.org/news-issues/news/2013/20130411a_de.html (last visited: Nov. 11, 2013.).