



Synthetic analysis of the ECJ Case C-34/10 *Oliver Brüstle v Greenpeace e.V.* and its ethical consequences

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January 10th 2013

October 18th 2011, the Court of Justice of the European Union delivered an important judgment in the area of the protection of the human embryo in the case C-34/10 ***Oliver Brüstle v Greenpeace e.V.*** In this case the judges in Luxembourg précised the legal definition of the human embryo, and relying on the respect due to human dignity, excluded from patentability all processes which would imply the destruction of human embryo, such as a processes using embryonic stem cells.

In this case, a German citizen, Oliver Brüstle, submitted a patent concerning the production of neural precursor cells used for the treatment of neurological diseases made from human embryonic stem cells. At the request of Greenpeace, the federal tribunal of patents (*Bundespatentgericht*), ruled that Mr. Brüstle's patent was invalid since it concerned processes which allow precursor cells to be obtained from human embryonic stem cells.

The Federal Court of Justice, (*Bundesgerichtshof*), ruling in an appeal taken by Mr. Brüstle, decided to request a preliminary ruling from the European Court of Justice on the interpretation of the Parliament and the Council's Directive 98/44/CE, from July 6th 1998, regarding the legal protection of biotechnological inventions, since, according to the Germany's highest Court, if this Directive excluded from patentability the "use of human embryos for industrial or commercial purposes", it did not define what it meant by "human embryos", nor did it specify what the legislator had intended by the term "the use" of those embryos.

Article 6, of the Directive says:

"1. 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.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

...

(c) uses of human embryos for industrial or commercial purposes;

For the judges of the *Bundesgerichtshof* the question was specifically whether the exclusion from patentability of the human embryo concerned all stages of life starting from the fertilisation of the ovule or whether it was possible to allow

patentability in certain circumstances, for example, before a certain stage of development or if it involved a cloned embryo.

I. The CJEU delivered the following responses to the three questions asked

1. *Firstly*, in light of the context and the aim of the Directive, the CJEU considered that the term “human embryo” used in Article 6, paragraph 2, section c, of the Directive, must be widely interpreted. It considered in particular that all human ovules, must be considered as “human embryos” from the moment of their fertilisation for the meaning and the application of this article, since fertilisation initiates the development process of a human being: “*any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a ‘human embryo’ within the meaning of Article 6(2)(c) of the Directive*” (§38) The CJEU ruled that human embryos created by cloning and parthenogenesis should also come under this term, in other words, an unfertilised human ovule in which the nucleus of a mature human cell has been implanted and an unfertilised human ovule intended to split and to develop by parthenogenesis. Indeed, for the CJEU, even those organisms have not been fertilised, as a result of the technique used to obtain them, they are capable of initiating the development process of a human, just as an embryo created by the fertilisation of an ovule.

2. *Secondly*, the CJEU considered that the ban on the patentability of “human embryos for industrial and commercial purposes” also covers the use of embryos for scientific research, since the granting of a patent for an invention involves, in principle, industrial and commercial uses. Therefore, the use of human embryos for scientific research which would be the object of a patent request cannot be distinguished from an industrial and commercial use, and thus excluded from the ban of patentability. The Court précised that “*only use for therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it being patentable*” (§ 46), for example to correct a genetic disease or to improve the chances of living.

3. *Thirdly*, the CJEU ruled that “*Article 6(2)(c) of the Directive excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos*” (§ 53). Therefore, it is not possible to isolate the subject-matter of the patent from the prior destruction of the embryo, even if the link between both is not immediate

II. The definition of the embryo and the principle of human dignity

The Brüstle decision clarifies the definition of the human embryo and it limits the use of the human embryo.

Concerning the definition of the embryo, the debated issue was clearly put by the *Bundesgerichtshof* Court, since this Court asked the CJEU if the meaning of embryo covered “all stages of development of human life from the fertilisation of the ovule” or if “a certain stage of development must have been reached”.

However, the CJEU refused to have a materialist and arbitrary comprehension of the embryo, according to which the fertilised ovule would not have the status of an embryo until it reached a certain stage of development, for example, after its implantation in the fallopian tube. The CJEU chose to adopt a teleological interpretation of the embryo and recognized that an embryo “initiates the human development process”; therefore, the human ovule must be regarded as a human embryo from the moment it initiates the human development process, whether it is initiated by fertilization or by any artificial technique.

The Brüstle decision is also essential for the issue of the use of embryos. Indeed, being delivered in the aftermath of the Grand Chamber decision from November 25th 2008, in a case submitted by the European Office of patents, (Wisconsin Alumni Research Foundation WARF, G 2/06 JO OEB, 5/2009) and having strong similarities with the present case, the CJEU expressly excluded from patentability all scientific processes which implies the destruction of the embryo.

Indeed, the CJEU refused to enter into moral debates, opting to base its reasoning on the test of the context and the objectives of the Directive 98/44/CE. There is no doubt that an ethical worry, based on the principle of respect for human dignity, is embedded in the reasoning of the CJEU. The principle appears not only in the law of the European Union (Articles 2 and 21 of the TFUE, first title in the Charter of Fundamental Rights of the European Union), but also in other international instruments (Universal Declaration of Human Rights, International Pact on Civil and Political Rights, the Convention against torture). Moreover, the principle of respect for human dignity, is embedded in the preamble of the Directive, and serves as a basis to interpret article 6:

The preamble states: “(16) *Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented;*”

The CJEU ruled, essentially, that the patentability of all inventions resulting in the destruction of the human embryo, at the various stages of its formation and development, including germ cells, should not be allowed so as to respect the fundamental principles safeguarding the dignity and integrity of the person. On this point, the Advocate General Yves Bot asserted in its opinion delivered on 10 March 2011 on that case that “*This shows that human dignity is a principle which must be applied not only to an existing human person, to a child who has been born, but also to the human body from the first stage in its development, i.e. from fertilisation*” (§ 96).

The CJEU refused to allow itself to be influenced neither by arguments based on the advantages that such techniques could bring to medicine and to the treatment of certain diseases nor by the possible economic and commercial benefits. In this way, the Advocate General Yves Bot had recourse to a striking comparison between these techniques and those used during the Civil War in the former Yugoslavia to assassinate prisoners of war in order to extract their organs. For the CJEU, the end does not justify the means.

III. The consequences of the Brüstle judgment

The CJEU reiterated that “*the purpose of the Directive is not to regulate the use of human embryos in the context of scientific research. It is limited to the patentability of biotechnological inventions*” (§ 40). Indeed, the inventions implying the destruction of embryos are not prohibited by the Directive, but their patentability. A researcher can, provided that the national legislation permits it (which is the case of several European countries), put in place a process which aims to produce cells from human embryos and implying the prior destruction of human embryos.

The practical and legal consequences of the Brüstle case are of no less importance.

Firstly, a practical consequence of the Brüstle case is that it prohibits the patentability of all techniques which aim to produce precursor cells from stem cells, as was the case for Mr. Brüstle. As the judges in Luxembourg highlighted, the collection of a stem cell from a human embryo in the blastocyst stage leads *ipso facto* (in the actual state of science) to the destruction of the embryo. On the other hand, if these techniques are not themselves prohibited, the prohibition of their patentability is of a nature which noticeably stops their development, since research today relies largely on the obtaining of patents, and on the promise, thanks to these, of economic benefits.

Next, the Brüstle case can strongly influence the status of the embryo under both national and European law, in particular through the case-law of the European Court of Human Rights and the legislation of the European Union.

Regarding the case-law of the European Court of Human Rights, the Brüstle decision ends the confusion which the ECHR usually creates in the subject of the protection of life. Indeed, the judges in Strasbourg, under the pretext that there is no consensus among the member States on this point, refuse to answer the question whether the embryo/foetus/unborn child is “a person” under the meaning of Article 2 of the European Convention of Human Rights (*Vo. v France*, case no. 53924/00, July 4th 2004). In the pending and future cases at the ECHR, the Brüstle case could be a weighty argument allowing the Court to grant legal protection to the human prenatal life.

With regard to the implications of the Brüstle case on the legislation of the European Union, the consequences could be significant.

For a number of years, each negotiation of the budget for the Multiannual Financial Framework for research, innovations and development of technologies creates long debates and opposition to the European public financing of research on embryos. This funding implies for the countries which criminally prohibit this research to contribute to its funding via the European budget.

In this way, it must be pointed out that the European Union has put in place a new programme for the period of 2014-2020, called “Horizon 2020”, which has a budget of 90 billion euros and aims at supporting the increase and the innovation in the European Union. However, this program does not mention the commitment that the European Commission took on July 24 2006, for the seventh research program

(2007-2013)¹, to “*continue with the same ethical framework for deciding on the EU funding of human embryonic stem cell research as in the 6th Framework Programme*”, and, in particular that it “*will continue with the current practice and will not submit to the Regulatory Committee proposals for projects which include research activities which destroy human embryos, including for the procurement of stem cells. The exclusion of funding of this step of research will not prevent Community funding of subsequent steps involving human embryonic stem cells*”². This commitment interprets the Article 6 on the “Ethical principles” of the EU Decision of 18 December 2006 concerning the Seventh Framework Programme. According to its article 6, which defines the ethical principles of the framework, “*research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member State(s) involved.*”

If, on the base of Horizon 2020 program, the European Union decides to fund research of stem cells, which necessarily implies the destruction of embryos, such a decision could be the subject of a judicial review before the CJEU, under Article 263 TFEU, and the CJEU could ban it on the basis of the principle of respect for human dignity.

¹ Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013).

² Official Journal of the European Union, L 412/42, 30.12.2006. Statements by the Commission Re Article 6, § 12.