

***Human dignity and research programmes using embryonic stem cells:
An Analysis of Brüstle/Greenpeace-jugment of the the European Court of Justice***

The following brief report analyzes the judgement in the case of *Brüstle/Greenpeace*, passed by the European Court of Justice on 18 October 2011, and its legal repercussions regarding European research policy, in particular the further promotion of stem cell research under Title XIX of the Treaty on the Functioning of the European Union (TFEU).

1 The Judgement

On 18 October 2011, the European Court of Justice in the case of *Brüstle/Greenpeace* (C-34/10) decided on a reference for a preliminary ruling under Article 267 TFEU from the German Federal Supreme Court of Justice (*Bundesgerichtshof*) with respect to the patentability of technical processes using human embryonic stem cells. Greenpeace filed proceedings seeking annulment of a patent, which relates to neural precursor cells, the processes for their production from embryonic stem cells, and their use for therapeutic purposes. The preliminary ruling given by the Court concerns the interpretation of Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (Official Journal 1998 L 213, p. 13).

The Court of Justice decided on the merits as follows:

1. 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' regarding to the directive and are, thus, excluded from patentability.

2. The exclusion from patentability concerning the use of human embryos for industrial or commercial purposes according to the directive covers the use of human embryos for purposes of scientific research.
3. The directive also 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.

2 Analysis of the judgement

Corresponding to the request for preliminary rulings, the Court of Justice interprets the key provision of Article 6 of the Directive 98/44/EC that deals with bioethical restrictions to patentability. Article 6(1) of the Directive 98/44/EC bans inventions that are contrary to ethical minimum-standards: Inventions shall be considered un-patentable where their commercial exploitation would be contrary to public order or morality. Art. 6(2) of the Directive 98/44/EC defines examples where granting a patent would violate the European *ordre public*. In particular, use of human embryos for industrial or commercial purposes shall be considered un-patentable.

The Court of Justice strongly refers to *human dignity* as the fundamental reason for the ethical concerns that resulted in the restrictions to bio-patents inherent in the Directive 98/44/EC. Although the directive "seeks to promote investment in the field of biotechnology, use of biological material originating from humans must be consistent with regard for fundamental rights and, in particular, the dignity of the person" (paragraph 32). The Court identifies dignity as the very reason for the integration of the disputed Article 6: "The context and aim of the Directive thus show that the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected." Considering this, the Court consequently concludes that the concept of 'human embryo' within the meaning of Article 6(2)(c) of the Directive 98/44/EC must be understood in a wide sense (paragraph 34; corresponding the opinion of Advocate General Bot, paragraph 96).

The Court of Justice applies, in a first step, the widely interpreted prohibition clause in Article 6(2)(c) of the Directive 98/44/EC in a sense that any human ovum must, as soon as fertilised, be regarded as a 'human embryo', "since that fertilisation is such as to commence the process of development of a human being" (paragraph 35).

Furthermore, in a second step the Court draws the conclusion that the classification of an embryo must also apply to a non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis. The Court refers to common scientific knowledge that such an ovum is capable of commencing the process of development of a human being just

as an embryo created by fertilisation of an ovum (paragraph 36). The Court stresses that this also applies to processes using embryonic stem cells primarily to promote scientific research. Although the aim of scientific research is to be distinguished from industrial or commercial purposes, the use of human embryos for the purposes of research which constitutes the subject-matter of a patent application can not be separated from the patent itself and the rights attaching to it (paragraph 43).

The Court of Justice reaches the conclusion that Article 6(2)(c) of the Directive 98/44/EC declares any invention un-patentable that is based on processes destroying embryonic human life, even if the claims of the relevant patent do not concern the use of human embryos. The Court argues that the removal of a stem cell from a human embryo at the blastocyst stage entails the destruction of that embryo (paragraph 48). “The fact that destruction may occur at a stage long before the implementation of the invention, as in the case of the production of embryonic stem cells from a lineage of stem cells the mere production of which implied the destruction of human embryos is, in that regard, irrelevant” (paragraph 49). This means, that Article 6(2)(c) of the Directive 98/44/EC, regarding the respect to human dignity as a general principle of European Union law substantiated by the Directive 98/44/EC, has to be interpreted as a *precautionary clause* protecting embryonic human life against any substantial danger of violation throughout the scientific or technological process preconditioning the invention. In an earlier decision the Court of Justice already spelled out that with regard to “living matter of human origin, the Directive frames the law on patents in a manner sufficiently rigorous to ensure that the human body effectively remains unavailable and inalienable and that human dignity is thus safeguarded” (Court of Justice, Case C-377/98, *Netherlands v. European Parliament*, [2001] ECR I- 7149, para 77).

It is remarkable that the Court of Justice refers to “an autonomous concept of European Union law” to define a European *ordre public* that imposes restrictions to patentability (paragraph 26). The Court stresses the requirement that the terms of a provision of European Union law which makes no express reference to the law of the Member States for the purpose of determining its meaning and scope must be given an independent and uniform interpretation throughout the European Union (paragraph 25). In the *Omega* decision the Court of Justice for the first time had to deal with human dignity as a reason to justify restrictions on economic freedom rights. The Court was reluctant to develop an autonomous concept of dignity under European law, and instead referred to the competence of the Member States to protect human dignity, which is accepted as a common value within the European Union, in accordance with national law. The Court in *Omega* accepted differences in moral standards that can qualify as national *ordre public* exceptions pursuant to Articles 36, 45(3), 52(1) 62 TEU (Court of Justice, Case C-36/02, *Omega*, [2004] ECR I-9609, paragraphs 34-35). The Court made clear, that common legal or moral standards are a strong indication that the national *ordre public* is in conformity with European Union law. Thus, the European *ordre public* was rather decentralized (compare *Gärditz*, *Menschenwürde, Biomedizin und europäischer Ordre Public*, in: Dujmovits et al. (eds.), *Medizin und Recht*, 2006, p. 11 at 32-34). Now, the Court of Justice in the *Brüstle*-case found the resolution to develop autonomous human

dignity standards under European Union law. Certain processes are excluded from patentability without any discretion left to the Member States to define the ordre public in accordance to their national legal order and their national ethical values. In the result, the Court of Justice adopts a strong concept of human dignity that is applied uniformly. Thus, the Court implicitly accepts the responsibility of the European Union to fulfil their duty under Article 1 of the Charter to protect human dignity within the competences of European Union law. Comparing the judgements in *Omega* and in *Brüstle*, human dignity tacitly develops from a mere argument to justify national restrictions on market freedom rights to a general principle of European Union law.

3 The relevance for European research policy

Although the underlying patent dispute is at first glance based merely on secondary European Union law, namely the Directive 98/44/EC, the reasons given on the merits have further repercussions beyond patent law. As shown above, the relevant provision of Article 6 of the Directive 98/44/EC is an immediate consequence of the protection of the human dignity. But human dignity is also guaranteed as a fundamental right under *primary* European Union law:

- Human dignity is not explicitly mentioned by the European Convention on Human Rights (ECHR) but is an integral part of the concept of human rights inherent in the Convention (see e. g. *Feldmann*, Human Dignity as a Legal Value I, Public Law 1999, p. 682, 690 et seq.): „The very essence of the Convention is the respect for human dignity and human freedom“ (European Court of Human Right, judgement of 29 April 2002, Case 2346/02, *Pretty v. UK*, ECHR 2002-III, 155 at 194, para 65). According to Article 6(3) TEU, fundamental rights of the ECHR are, as general principles of law, also part of primary European Union law. Thus, Advocate General Bot in his opinion in the current case justly points out “that the Union is not only a market to be regulated, but also has values to be expressed. Before it was even enshrined as a fundamental value in Article 2 of the EU Treaty, the principle of human dignity had been recognised by the Court as a general legal principle” (paragraph 45).
- In accordance with Article 6(3) TEU, another supplementary source to identify fundamental rights consists in the constitutional traditions common to the member states. Constitutional traditions inevitably differ between the member states insofar as fundamental rights do not correspond closely with ECHR human rights. Nonetheless, an analysis of the constitutions of European states reveals that most constitutions refer to dignity, personal identity or personal integrity as fundamental aspects of dignity.
- Article 1 of the Charter of Fundamental Rights of the European Union guarantees the protection of human dignity: “Human dignity is inviolable. It must be respected and protected.” Pursuant to this provision human dignity is “inviolable”, that means, that every infringement of dignity is absolutely prohibited (Drafting Committee of the Convention, O. J. 2004 № C 310,

p. 424; *Schmidt*, Der Schutz der Menschenwürde als ‚Fundament‘ der EU-Grundrechtscharta unter besonderer Berücksichtigung der Rechte auf Leben und Unversehrtheit, *Zeitschrift für Europäische Studien* 2002, p. 631 at 642). Thus, there is no legal argument that can justify a violation of human dignity. Consequently Advocate General Bot in his opinion (11 March 2011) explicitly refers to the fundamental right of human dignity as provided by Article 1 of the Charta in order to interpret the Directive 98/44/EC with (paragraph 13).

In accordance with Article 1, human dignity demands the European Union to enact legislation that protects everyone against infringements of his or her rights, as far as the European Union has a sufficient competence to regulate the subject matter. That is exactly what the European Union did when it limited the patentability of biotechnological inventions by adding the prohibitive clause of Article 6 to the Directive 98/44/EC.

- Article 3 of the Charter protects the right to the integrity of the person as an immediate expression of human dignity. This right can be violated, in particular, by certain biomedical practices, as Article 3(2) of the Charter makes explicitly clear. The provision of Article 3(2) of the Charter does not directly refer to *freedom rights* but outlaws aspects of biomedical science that are perceived as particularly threatening. As biomedical research and treatment are, at least in principle, not within the competences of the European Union’s organs, Article 3 primarily aims at the prohibition of relevant *private* activities (*Calliess*, in: *Calliess/Ruffert*, *EUV/AEUV*, 4th edition, 2011, Art. 3 GRCh RN 12). Article 3 develops no direct horizontal effect, but it constitutes a responsibility to protect (e. g. *Jarass*, *Charta der Grundrechte der Europäischen Union*, 2010, Art. 3 RN 3, 10). Thus, Article 3(2) of the Charter serves as justification to prohibit behaviour that otherwise would be part of the freedom of science and academia pursuant to Article 13 of the Charter (compare *Weiß*, *EU-Verfassungsvertrag und Biotechnologie*, *Medizinrecht* 2005, p. 458 at 462.). With regard to the dangers of unleashed biological sciences the founders of the Charter intentionally restricted science in favour of better protection of human dignity. The prohibitions in Article 3 of the Charter are therefore restrictions on the European Union’s policy on scientific research, too (*Weiß*, *supra*, at 462) and on secondary regulations.
- According to Article 6(1) TEU, the Charter is part of the European Union law in the rank of primary law. Therefore, the Charter is binding for all organs of the European Union, including the European Commission and the European Parliament as the European legislators (see Article 51(1) of the Charter: “The provisions of this Charter are addressed to the institutions and bodies of the Union”).

As the Court of Justice is interpreting Article 6 of the Directive 98/44/EC with regard to human dignity, the conclusions the Court has drawn must therefore be applied to the interpretation of human dignity guaranteed by primary law. Thus, there are strong indications that secondary law allowing practices prohibited under

Article 6(2)(c) of the Directive 98/44/EC would violate human dignity as part of primary European Union law.

The Court of Justice rightly accepts that human dignity has to be protected by European Union law as soon as the process of development of a human being is commenced. It is the embryonic human being in its dignity and integrity that is inviolable and, thus, must not be treated as a research tool or as an object of commercial exploitation. The embryo has an independent status with regard to human dignity. This status is violated, in particular, when the embryo is destroyed. In a “fruit of the poisonous tree”-approach the Court convincingly reaches the conclusion that the respect for the status of the embryo affords the exclusion of any invention from patentability that does not use human embryos itself but is derived from processes destroying embryonic life (paragraph 49). Thus, the Court seems to accept a responsibility of the European Union to protect human life because any human life, even in its earliest states of development, is bearer of human dignity. Regarding this protection-approach it makes no difference whether the European Union endangers the development of a human being by granting a title to a patent for an invention that furthers the destruction of human life or by promoting research in such processes. The direct promotion of the stem cell research by the European Union violates human dignity all the more. If the European Union adopts a relevant research programme, it would positively define scientific processes that further the destruction of embryonic human life as a desirable contribution to the scientific development within the European Union.

In my conclusion, it seems clear to me that the promotion of research with embryonic stem cells by the European Union under Chapter XIX of the TFEU consequently would violate human dignity that is guaranteed in the rank of primary law.

4 Conclusions

Considering the general principles of European Union law, the Court of Justice always felt obliged “to ensure that the fundamental right to human dignity and integrity is observed” (Court of Justice, Case C-377/98, *Netherlands v. European Parliament*, [2001] ECR I- 7149, para 77). If the European legislator promotes scientific research with human embryonic stem cells under programmes within Title XIX of the TFEU, the enacted programme would be legally contestable. In particular, if a member state files a claim under Article 263 TFEU the Court of Justice is competent to review the legality of the relevant legislative act regarding primary law. Considering the reasoning in the *Brüstle*-case it seems to be likely that the court will declare legal acts providing for the promotion of embryonic stem cell research to be void.

In contrast, if the European legislator relinquishes to promote scientific research with embryonic stem cells, from a legal point of view there would be no substantial risk. Neither the TFEU nor the Charta of Fundamental Rights nor any other legal act grants a claim to financial promotion of stem cell research.

Even if the *Brüstle*-judgement could not be interpreted to bar the European legislator from promoting stem cell research, the Court of Justice has legally blocked the way to patentable inventions. In the result, the European Union would finance research activities that will never enjoy the protection of intellectual property rights in accordance with European patent law. Inventions would therefore be free. Scientists outside the European Union could use the results of successful research projects financed by the Union and develop products that are suitable for commercial exploitation. Thus, it would be at least politically inappropriate to promote stem cell research projects.

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