

Case C-34/10

Oliver Brüstle

v

Greenpeace eV

(Reference for a preliminary
ruling from the Bundesgerichtshof)

(Directive 98/44/EC — Article 6(2)(c) — Legal protection of biotechnological inventions — Extraction of precursor cells from human embryonic stem cells — Patentability — Exclusion of ‘uses of human embryos for industrial or commercial purposes’ — Concepts of ‘human embryo’ and ‘use for industrial or commercial purposes’)

Opinion of Advocate General Bot delivered on 10 March 2011 I - 9825
Judgment of the Court (Grand Chamber), 18 October 2011 I - 9849

Summary of the Judgment

1. *Approximation of laws — Legal protection of biotechnological inventions — Directive 98/44 — Definition of ‘human embryo’ — Autonomous interpretation (European Parliament and Council Directive 98/44, Art. 6(2))*

2. *Approximation of laws — Legal protection of biotechnological inventions — Directive 98/44 — Exclusion from patentability on grounds of breach of public policy and morality — Use of human embryos for industrial or commercial purposes — Definition of ‘human embryo’*
(European Parliament and Council Directive 98/44, Art. 6(2)(c))
3. *Approximation of laws — Legal protection of biotechnological inventions — Directive 98/44 — Exclusion from patentability on grounds of breach of public policy and morality — Use of human embryos for industrial or commercial purposes — Meaning*
(European Parliament and Council Directive 98/44, Art. 6(2)(c))
4. *Approximation of laws — Legal protection of biotechnological inventions — Directive 98/44 — Exclusion from patentability on grounds of breach of public policy and morality — Use of human embryos for industrial or commercial purposes — Meaning*
(European Parliament and Council Directive 98/44, Art. 6(2)(c))

1. For the purposes of application of Directive 98/44 on the legal protection of biotechnological inventions, the term ‘human embryo’ in Article 6(2) of that directive, must be regarded as designating an autonomous concept of European Union law which must be interpreted in a uniform manner throughout the territory of the Union. That conclusion is supported by the object and the aim of the directive. The lack of a uniform definition of the concept of human embryo would create a risk of the authors of certain biotechnological inventions being tempted to seek their patentability in the Member

States which have the narrowest concept of human embryo and are accordingly the most liberal as regards possible patentability, because those inventions would not be patentable in the other Member States. Such a situation would adversely affect the smooth functioning of the internal market which is the aim of the directive.

(see paras 26, 28)

2. Although Directive 98/44 on the legal protection of biotechnological inventions states that it 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. 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. It follows that the concept of 'human embryo' within the meaning of Article 6(2)(c) of the directive must be understood in a wide sense.
3. The exclusion from patentability concerning the use of human embryos for industrial or commercial purposes set out in Article 6(2)(c) of Directive 98/44 on the legal protection of biotechnological inventions also covers the use of human embryos for purposes of scientific research, only use for therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it being patentable. The grant of a patent implies, in principle, its industrial or commercial application, even if the aim of scientific research must 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 cannot be separated from the patent itself and the rights attaching to it.

In that context, that provision must be interpreted as meaning that a human embryo is 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. It is for the referring court to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a 'human embryo' within the meaning of that provision.

(see paras 41, 43, 46, operative part 2)

(see paras 32, 34, 38, operative part 1)

4. In the context of a case concerning the patentability of an invention involving the production of neural precursor cells, which presupposes the use of stem cells obtained from a human embryo at the blastocyst stage, entailing the destruction of that embryo, an invention must be regarded as unpatentable, even if the claims of the patent do not concern the use of human embryos, where the

implementation of the invention requires the destruction of human embryos. In that case, the view must be taken that there is use of human embryos within the meaning of Article 6(2)(c) of Directive 98/44 on the legal protection of biotechnological inventions. 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.

In those circumstances, Article 6(2)(c) of that directive must be interpreted as excluding 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.

(see paras 48-49, 52, operative part 3)