JUDGMENT OF THE COURT (Grand Chamber)

18 October 2011 (*)

(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')

In Case C-34/10,

REFERENCE for a preliminary ruling under Article 267 TFEU from the Bundesgerichtshof (Germany), made by decision of 17 December 2009, received at the Court on 21 January 2010, in the proceedings

Oliver Brüstle

v

Greenpeace e.V.,

THE COURT (Grand Chamber),

composed of V. Skouris, President, A. Tizzano, J.N. Cunha Rodrigues, K. Lenaerts, J.-C. Bonichot, M. Safjan (Rapporteur) and A. Prechal, Presidents of Chambers, A. Rosas, R. Silva de Lapuerta, K. Schiemann, D. Šváby, M. Berger and E. Jarašiūnas, Judges,

Advocate General: Y. Bot,

Registrar: B. Fülöp, Administrator,

having regard to the written procedure and further to the hearing on 12 January 2011,

after considering the observations submitted on behalf of:

– Oliver Brüstle, by F.-W. Engel, Rechtsanwalt, M. Grund and C. Sattler de Sousa e Brito, Patentanwälte,

– Greenpeace e.V., by V. Vorwerk, Rechtsanwalt, R. Schnekenbühl, Patentanwalt, and C. Then, Expert,

– Ireland, by G. Durcan, acting as Agent,

– the Portuguese Government, by L. Inez Fernandes, acting as Agent,

– the Swedish Government, by A. Falk and A. Engman, acting as Agents,

– the United Kingdom Government, by F. Penlington and C. Murrell, acting as Agents, and C. May, Barrister,

– the European Commission, by F.W. Bulst and H. Krämer, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 10 March 2011,

gives the following

Judgment

1 This reference for a preliminary ruling 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 (OJ 1998 L 213, p. 13; 'the Directive').

2 The reference has been made in proceedings brought by Greenpeace e.V. ('Greenpeace') seeking annulment of the German patent held by Mr Brüstle, which relates to neural precursor cells and the processes for their production from embryonic stem cells and their use for therapeutic purposes.

Legal context

Agreements binding the European Union and/or the Member States

3 Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, which constitutes Annex 1 C to the Agreement establishing the World Trade Organisation (WTO), signed in Marrakech on 15 April 1994, approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ 1994 L 336, p. 1), states that:

'1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* (public policy) or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.'

4 Article 52(1) of the Convention on the Grant of European Patents, signed at Munich on 5 October 1973 ('the CGEP'), to which the European Union is not party, but of which the Member States are signatories, reads as follows:

'European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.'

5 Article 53 of the CGEP states:

‘European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.’

European Union legislation

6 The preamble to the Directive states as follows:

‘…

(2) Whereas, in particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable;

(3) Whereas effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology;

…

(5) Whereas differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the different Member States; whereas such differences could create barriers to trade and hence impede the proper functioning of the internal market;

(6) Whereas such differences could well become greater as Member States adopt new and different legislation and administrative practices, or whereas national case-law interpreting such legislation develops differently;

(7) Whereas uncoordinated development of national laws on the legal protection of biotechnological inventions in the Community could lead to further disincentives to trade, to the detriment of the industrial development of such inventions and of the smooth operation of the internal market;

…

(14) Whereas a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes; whereas, consequently, substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards;

…

(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;

(17) Whereas significant progress in the treatment of diseases has already been made thanks to the existence of medicinal products derived from elements isolated from the human body and/or otherwise produced, such medicinal products resulting from technical processes aimed at obtaining elements similar in structure to those existing naturally in the human body and whereas, consequently, research aimed at obtaining and isolating such elements valuable to medicinal production should be encouraged by means of the patent system;

…

(20) Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment;

(21) Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself;

…

(37) Whereas the principle whereby inventions must be excluded from patentability where their commercial exploitation offends against *ordre public* or morality must also be stressed in this Directive;

(38) Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide referring courts and patent offices with a general guide to interpreting the reference to *ordre public* and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability;

(39) Whereas *ordre public* and morality correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter; whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention;

…

(42) Whereas, moreover, uses of human embryos for industrial or commercial purposes must also be excluded from patentability; whereas in any case such exclusion does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it;

(43) Whereas pursuant to Article F(2) of the Treaty on European Union, the Union is to respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from

the constitutional traditions common to the Member States, as general principles of Community law;

…'

7 The Directive provides:

'Article 1

1. Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive.

2. This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.

…

Article 3

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

…

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

…

Article 6

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;

…'

National law

8 Paragraph 2 of the Patentgesetz (Law on patents), as amended for the purposes of transposition of Article 6 of the Directive (BGBl. 2005 I, p. 2521; 'the PatG'), is worded as follows:

'1. Patents may not be granted for inventions whose 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. In particular, patents shall not be awarded for:

...

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

…

The application of points (1) to (3) shall be governed by the appropriate provisions of the Embryonenschutzgesetz [(Law on the protection of embryos; "the ESchG")].'

9 Paragraph 21 of the PatG provides:

'1. A patent shall be revoked (Paragraph 61) if it appears that:

(1) the object of the patent is not patentable pursuant to Paragraphs 1 to 5.'

10 Under Paragraph 22(1) of the PatG:

'A patent shall be declared void on application (Paragraph 81) if it appears that one of the grounds set out in Paragraph 21(1) applies, or that the scope of the protection conferred by the patent has been extended.'

11 Paragraphs 1(1), point 2, and 2(1) and (2) of the ESchG of 13 December 1990 define as a criminal offence the artificial fertilisation of ova for a purpose other than inducing pregnancy in the woman from whom they originate, the sale of human embryos conceived *in vitro* or removed from a woman before the end of the nidation process in the uterus, or their transfer, acquisition or use for a purpose other than their preservation, and the *in vitro* development of human embryos for a purpose other than inducing pregnancy.

12 Under Paragraph 8(1) of the ESchG, an embryo is a fertilised human ovum capable of development, from the time of karyogamy, and any cell removed from an embryo which is 'totipotent', that is to say, able to divide and develop into an individual provided that the other conditions necessary are satisfied. A distinction must be made between those cells and pluripotent cells, which are stem cells which, although capable of developing into any type of cell, cannot develop into a complete individual.

13 Under Paragraph 4 of the Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen (Law to ensure the protection of embryos in connection with the importation and use of human embryonic stem cells) (BGBl. 2002 I, p.

2277) of 28 May 2002:

‘(1) The importation and use of embryonic stem cells are prohibited.

(2) By derogation from subparagraph 1 above, the importation and use of embryonic stem cells shall be authorised for purposes of research on the conditions set out in Paragraph (6) if:

1. the authorising authority is satisfied that

(a) the embryonic stem cells were obtained before 1 May 2007 in accordance with the legislation in force in the State of origin and have been preserved in culture or stored thereafter in cryopreserved form (lineage of embryonic stem cells);

(b) the embryos from which they originate were produced by *in vitro* fertilisation with a view to inducing pregnancy and became definitively superfluous to that purpose and there is no evidence that this was for reasons connected with the embryos themselves;

(c) no remuneration or other valuable benefit has been granted or promised in consideration of the donation of the embryos for the purpose of obtaining stem cells, and,

2. the importation and use of the embryonic stem cells does not infringe any other provisions of law, in particular those of the ESchG.

(3) Authorisation shall be refused if the embryonic stem cells were manifestly obtained in contravention of the founding principles of the German legal order. It shall not be refused on the ground that the stem cells were obtained from human embryos.’

14 Under Paragraph 5(1) of that Law:

‘Research work on embryonic stem cells may be carried out only if it is scientifically established that

1. that work pursues high-level research aims for the increase of scientific knowledge in the area of basic research or serves to extend medical knowledge in connection with the development of diagnostic, preventive or therapeutic procedures for human use …’

The dispute in the main proceedings and the questions referred for a preliminary ruling

15 Mr Brüstle is the holder of a German patent, filed on 19 December 1997, which concerns isolated and purified neural precursor cells, processes for their production from embryonic stem cells and the use of neural precursor cells for the treatment of neural defects.

16 It is claimed in the patent specification filed by Mr Brüstle that the transplantation of brain cells into the nervous system is a promising method of treatment of numerous neurological diseases. The first clinical applications have already been developed, in particular for patients suffering from Parkinson’s disease.

17 In order to remedy such neural defects, it is necessary to transplant immature precursor cells, still capable of developing. In essence, that type of cell exists only during the brain’s development phase. The use of cerebral tissue from human embryos raises significant ethical questions and means that it is not possible to meet the need for the precursor cells which are required to provide publicly available cell treatment.

18 However, according to the specification, embryonic stem cells offer new prospects for the production of cells for transplantation. Being pluripotent, they can develop into all types of cells and tissues and can be conserved during many passages in the state of pluripotentiality and can multiply. The patent at issue seeks, in those circumstances, to make it possible to resolve the technical problem of producing an almost unlimited quantity of isolated and purified precursor cells having neural or glial properties, obtained from embryonic stem cells.

19 On application by Greenpeace, the Bundespatentgericht (Federal Patent Court) ruled, on the basis of Paragraph 22(1) of the PatG, that the patent at issue was invalid in so far as it covers precursor cells obtained from human embryonic stem cells and processes for the production of those precursor cells. The defendant appealed against that judgment to the Bundesgerichtshof (Federal Court of Justice).

20 In the view of the referring court, the outcome of the application for annulment depends on whether the technical teaching of the patent at issue, in so far as it concerns precursor cells obtained from human embryonic stem cells, is excluded from patentability under Paragraph 2(2), first sentence, point 3, of the PatG. The answer to that question depends in turn on the interpretation which should be given in particular to Article 6(2)(c) of the Directive.

21 According to the referring court, having regard to the fact that Article 6(2) of the Directive does not allow the Member States any discretion as regards the fact that the processes and uses listed therein are not patentable (see Case C-377/98 *Netherlands* v *Parliament and Council* [2001] ECR I-7079, paragraph 39, and Case C-456/03 *Commission* v *Italy* [2005] ECR I-5335, paragraph 78 et seq.), the reference made in the second sentence of Paragraph 2(2) of the PatG to the ESchG, particularly to the definition of an embryo which Paragraph 8(1) of that Law gives, cannot be regarded as the fruit of the task left to Member States to put Article 6(2)(c) of the Directive into concrete terms in that regard, even though the Directive did not expressly define the concept of embryo. The only possible interpretation of that concept is European and unified. In other words, the second sentence of Paragraph 2(2) of the PatG and, in particular, the concept of embryo which it uses cannot be interpreted differently from that of the corresponding concept in Article 6(2)(c) of the Directive.

22 With that in mind, the referring court seeks, inter alia, to ascertain whether the human embryonic stem cells which serve as base material for the patented processes constitute 'embryos' within the meaning of Article 6(2)(c) of the Directive and whether the organisms from which those human embryonic stem cells can be obtained constitute 'human embryos' within the meaning of that article. In that regard, it notes that the human embryonic stem cells which serve as base material for the patented processes are not all totipotent cells, some being only pluripotent cells obtained from embryos at the blastocyst stage. It is also uncertain as to the classification, in the light of the concept of embryo, of blastocysts from which human embryonic stem cells can also be obtained.

23 In those circumstances, the Bundesgerichtshof decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling:

'1. What is meant by the term "human embryos" in Article 6(2)(c) of [the Directive]?

(a) Does it include all stages of the development of human life, beginning with the fertilisation of the ovum, or must further requirements, such as the attainment of a certain stage of development, be satisfied?

(b) Are the following organisms also included:

– unfertilised human ova into which a cell nucleus from a mature human cell has been transplanted;

– unfertilised human ova whose division and further development have been stimulated by parthenogenesis?

(c) Are stem cells obtained from human embryos at the blastocyst stage also included?

2. What is meant by the expression "uses of human embryos for industrial or commercial purposes"? Does it include any commercial exploitation within the meaning of Article 6(1) of [the Directive], especially use for the purposes of scientific research?

3. Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching:

– because the patent concerns a product whose production necessitates the prior destruction of human embryos,

– or because the patent concerns a process for which such a product is needed as base material?'

Consideration of the questions referred

The first question

24 By its first question, the referring court asks the Court to interpret the concept of 'human embryo' within the meaning of and for the purposes of the application of Article 6(2)(c) of the Directive, that is to say, for the sole purpose of ascertaining the scope of the prohibition on patentability laid down in that provision.

25 It must be borne in mind that, according to settled case-law, the need for a uniform application of European Union law and the principle of equality require 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 normally be given an independent and uniform interpretation throughout the European Union (see, in particular, Case 327/82 *Ekro* [1984] ECR 107, paragraph 11; Case C-287/98 *Linster* [2000] ECR I-6917, paragraph 43; Case C-5/08 *Infopaq International* [2009] ECR I-6569, paragraph 27; and Case C-467/08 *Padawan* [2010] ECR I-0000, paragraph 32).

26 Although the text of the Directive does not define human embryo, nor does it contain any reference to national laws as regards the meaning to be applied to those terms. It therefore follows that it must be regarded, for the purposes of application of the Directive, as designating an autonomous concept of European Union law which must be interpreted in a uniform manner throughout the territory of the Union.

27 That conclusion is supported by the object and the aim of the Directive. It follows from recitals 3 and 5 to 7 in the preamble to the Directive that it seeks, by a harmonisation of the rules for the legal protection of biotechnological inventions, to remove obstacles to trade and to the smooth functioning of the internal market that are brought about by differences in national legislation and case-law between

the Member States, and thus, to encourage industrial research and development in the field of genetic engineering (see, to that effect, *Netherlands* v *Parliament and Council*, paragraphs 16 and 27).

28 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.

29 That conclusion is also supported by the scope of the listing, in Article 6(2) of the Directive, of the processes and uses excluded from patentability. It is apparent from the case-law of the Court that, unlike Article 6(1) of the Directive, which allows the administrative authorities and courts of the Member States a wide discretion in applying the exclusion from patentability of inventions whose commercial exploitation would be contrary to *ordre public* and morality, Article 6(2) allows the Member States no discretion with regard to the unpatentability of the processes and uses which it sets out, since the very purpose of this provision is to delimit the exclusion laid down in Article 6(1). It follows that, by expressly excluding from patentability the processes and uses to which it refers, Article 6(2) of the Directive seeks to grant specific rights in this regard (see *Commission* v *Italy*, paragraphs 78 and 79).

30 As regards the meaning to be given to the concept of 'human embryo' set out in Article 6(2)(c) of the Directive, it should be pointed out that, although, the definition of human embryo is a very sensitive social issue in many Member States, marked by their multiple traditions and value systems, the Court is not called upon, by the present order for reference, to broach questions of a medical or ethical nature, but must restrict itself to a legal interpretation of the relevant provisions of the Directive (see, to that effect, Case C-506/06 *Mayr* [2008] ECR I-1017, paragraph 38).

31 It must be borne in mind, further, that the meaning and scope of terms for which European Union law provides no definition must be determined by considering, inter alia, the context in which they occur and the purposes of the rules of which they form part (see to that effect, inter alia, Case C-336/03 *easyCar* [2005] ECR I-1947, paragraph 21; Case C-549/07 *Wallentin-Hermann* [2008] ECR I-11061, paragraph 17; and Case C-151/09 *UGT-FSP* [2010] ECR I-0000, paragraph 39).

32 In that regard, the preamble to the Directive states that although 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. Recital 16 in the preamble to the Directive, in particular, emphasises that 'patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person'.

33 To that effect, as the Court has already held, Article 5(1) of the Directive provides that the human body at the various stages of its formation and development cannot constitute a patentable invention. Additional security is offered by Article 6 of the Directive, which lists as contrary to *ordre public* or morality, and therefore excluded from patentability, processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial purposes. Recital 38 in the preamble to the Directive states that this list is not exhaustive and that all processes the use of which offends against human dignity are also excluded from patentability (see *Netherlands* v *Parliament and Council*, paragraphs 71 and 76).

34 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.

35 Accordingly, any human ovum must, as soon as fertilised, be regarded as a 'human embryo' within the meaning and for the purposes of the application of Article 6(2)(c) of the Directive, since that fertilisation is such as to commence the process of development of a human being.

36 That classification 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. Although those organisms have not, strictly speaking, been the object of fertilisation, due to the effect of the technique used to obtain them they are, as is apparent from the written observations presented to the Court, capable of commencing the process of development of a human being just as an embryo created by fertilisation of an ovum can do so.

37 As regards stem cells obtained from a human embryo at the blastocyst stage, it is for the referring court to ascertain, in the light of scientific developments, whether they are capable of commencing the process of development of a human being and, therefore, are included within the concept of 'human embryo' within the meaning and for the purposes of the application of Article 6(2)(c) of the Directive.

38 In the light of the foregoing considerations, the answer to the first question is that:

– 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;

– 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 Article 6(2)(c) of the Directive.

The second question

39 By its second question, the referring court asks whether the concept of 'uses of human embryos for industrial or commercial purposes' within the meaning of Article 6(2)(c) of the Directive also covers the use of human embryos for purposes of scientific research.

40 In that regard, it must be pointed out 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.

41 With regard, therefore, solely to the determination of whether the exclusion from patentability concerning the use of human embryos for industrial or commercial purposes also covers the use of human embryos for purposes of scientific research or whether scientific research entailing the use of human embryos can access the protection of patent law, clearly the grant of a patent implies, in principle, its industrial or commercial application.

42 That interpretation is supported by recital 14 in the preamble to the Directive. By stating that a patent for invention 'entitles [its holder] to prohibit third parties from exploiting it for industrial and commercial purposes', it indicates that the rights attaching to a patent are, in principle, connected with acts of an

industrial or commercial nature.

43 Although 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.

44 The clarification in recital 42 in the preamble to the Directive, that the exclusion from patentability set out in Article 6(2)(c) of the Directive 'does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it' also confirms that the use of human embryos for purposes of scientific research which is the subject-matter of a patent application cannot be distinguished from industrial and commercial use and, thus, avoid exclusion from patentability.

45 That interpretation is, in any event, identical to that adopted by the Enlarged Board of Appeal of the European Patent Office regarding Rule 28(c) of the Implementing Regulations to the CGEP, which uses precisely the same wording as Article 6(2)(c) of the Directive (see decision of 25 November 2008, G 2/06, *Official Journal EPO*, May 2009, p. 306, paragraphs 25 to 27).

46 The answer to the second question is therefore that the exclusion from patentability concerning the use of human embryos for industrial or commercial purposes in Article 6(2)(c) of the Directive also covers use 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 third question

47 By its third question, the referring court asks the Court, in essence, whether an invention is unpatentable even though its purpose is not the use of human embryos, where it concerns a product whose production necessitates the prior destruction of human embryos or a process for which requires a base material obtained by destruction of human embryos.

48 It is raised in 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. It is apparent from the observations presented to the Court that the removal of a stem cell from a human embryo at the blastocyst stage entails the destruction of that embryo.

49 Accordingly, on the same grounds as those set out in paragraphs 32 to 35 above, 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 too, the view must be taken that there is use of human embryos within the meaning of Article 6(2)(c) of the Directive. 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.

50 Not to include in the scope of the exclusion from patentability set out in Article 6(2)(c) of the Directive technical teaching claimed, on the ground that it does not refer to the use, implying their prior destruction, of human embryos would make the provision concerned redundant by allowing a patent applicant to avoid its application by skilful drafting of the claim.

51 Again, the Enlarged Board of Appeal of the European Patent Office reached the same conclusion when asked about the interpretation of Rule 28(c) of the Implementing Regulations to the CGEP, the wording of which is identical to that of Article 6(2)(c) of the Directive (see decision of 25 November 2008, paragraph 22, referred to in paragraph 45 above).

52 The answer to the third question is therefore 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.

Costs

53 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the referring court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Grand Chamber) hereby rules:

1. **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 must be interpreted as meaning that:**

   – **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';**

   – **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 Article 6(2)(c) of Directive 98/44.**

2. **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 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.**

3. **Article 6(2)(c) of Directive 98/44 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.**

[Signatures]

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* Language of the case: German.