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**Datasheet for the decision
of 4 February 2014**

Case Number: T 2221/10 - 3.3.08
Application Number: 03751238.1
Publication Number: 1554373
IPC: C12N5/00, C12N15/00
Language of the proceedings: EN
Title of invention:
HUMAN FORESKIN CELLS SUITABLE FOR CULTURING STEM CELLS
Applicant:
TECHNION RESEARCH AND DEVELOPMENT FOUNDATION, LTD.
Headword:
Culturing stem cells/TECHNION
Relevant legal provisions:
EPC Art. 53(a)
EPC R. 28(c)
Keyword:
"Main request - unallowable"
Decisions cited:
G 0005/83, G 0002/02, G 0002/06, T 0197/10

Headnote:

Inventions which make use of publicly available human embryonic stem cell lines which were initially derived by a process resulting in the destruction of the human embryos are excluded from patentability under the provisions of Article 53(a) EPC in combination with Rule 28(c) EPC (points (10) to (29)).



**Beschwerdekammern
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Chambres de recours**

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Case Number: T 2221/10 - 3.3.08

**D E C I S I O N
of Technical Board of Appeal 3.3.08
of 4 February 2014**

Appellant: TECHNION RESEARCH AND DEVELOPMENT FOUNDATION,
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted on 13 April 2010
refusing European patent application No.
03751238.1 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: M. Wieser
Members: B. Stolz
J. Geschwind

Summary of Facts and Submissions

- I. The appeal lies against the decision of the examining division to refuse European patent application No. 03751238.1. The examining division decided that the main and sole request before it, filed at the oral proceedings on 26 November 2009, met the requirements of Articles 123(2), 83 and 84 EPC but that it was unallowable in view of Article 53(a) EPC in combination with Rule 28(c) EPC.
- II. With the grounds of appeal, the applicant (appellant) submitted a new document, D23, and in a further submission, new documents D24 to D26.
- III. The board issued a summons to oral proceedings. In a communication annexed to the summons, the board informed the appellant of its preliminary, non-binding opinion on some of the issues in particular in relation to Article 53(a) EPC and Rule 28(c) EPC.
- IV. In a letter dated 28 October 2013, the appellant informed the board that it would not attend the oral proceedings and requested a decision according to the state of the file.
- V. In a letter dated 11 November 2013, the appellant was informed that the oral proceedings were cancelled.
- VI. Independent claims 1, 2, and 5 of the main and sole request read as follows:

"1. A method of maintaining human embryonic stem cells in an undifferentiated state comprising co-culturing the human embryonic stem cells with a human foreskin feeder cell line, wherein cells of said human foreskin

feeder cell line are growth suppressed by irradiation or treatment with an anti-mitotic agent and wherein said co-culturing is effected in the presence of serum or serum replacement, wherein said human foreskin feeder cell line is obtainable by:

- (a) isolating foreskin cells from foreskin tissue from an 8-30 day old male individual; wherein step (a) is effected by:
 - (i) mincing said foreskin tissue; and
 - (ii) dissociating said foreskin tissue resultant from step (i) into single cells via treatment with trypsin;
- (b) culturing said foreskin cells in a culture medium including serum and/or serum replacement at a concentration range of 10% to 30%.

2. A method of maintaining human embryonic stem cells in an undifferentiated state comprising culturing the human embryonic stem cells on a synthetic matrix supplemented with a human foreskin cell conditioned medium, wherein said human foreskin cell conditioned medium is enriched with foreskin secreted factors present in the foreskin culture following a certain culturing period, which factors are sufficient to maintain stem cells in culture and wherein said human foreskin cell conditioned medium is obtainable by culturing human foreskin cells from a human foreskin tissue from an 8-30 day old male individual in a growth medium containing serum or serum replacement, wherein said human foreskin feeder cell line is obtainable by:

- (a) isolating foreskin cells from foreskin tissue from an 8-30 day old male individual:
 - wherein step (a) is effected by:

- (i) mincing said foreskin tissue; and
 - (ii) dissociating said foreskin tissue resultant from step (i) into single cells via treatment with trypsin;
- (b) culturing said foreskin cells in a culture medium including serum and/or serum replacement at a concentration range of 10% to 30%, and wherein the medium is conditioned for 4 hours.

5. A cell culture comprising:

- (i) human embryonic stem cells; and
- (ii) human foreskin cells wherein the human foreskin cells are growth suppressed by irradiation or treatment with an anti-mitotic agent, wherein said human foreskin feeder cells are obtainable by:
 - (a) isolating foreskin cells from foreskin tissue from an 8-30 day old male individual; wherein step (a) is effected by:
 - (i) mincing said foreskin tissue; and
 - (ii) dissociating said foreskin tissue resultant from step (i) into single cells via treatment with trypsin;
 - (b) culturing said foreskin cells in a culture medium including serum and/or serum replacement at a concentration range of 10% to 30%, wherein the culture includes a culture medium including serum or serum replacement and wherein said human foreskin cells form a monolayer in the cell culture."

Dependent claims 3 and 4 refer to specific embodiments of the method of claim 1. Dependent claims 6 and 7 (incorrectly numbered as claims 7 and 8, respectively) refer to specific embodiments of the cell culture of claim 5.

VII. The following documents are cited in this decision:

D9: Richards M. et al, 2002, Nature Biotechnology,
20(9): 933-936,

D10: Richards M. et al., 2003, Stem Cells,
21(5): 546-556,

D17: Amit M. et al., 2000, Dev. Biol.,
227(2): 271-278

D19: Amit M. and Itskovitz-Eldor J., 2002,
J. Anat., 200: 225-232

D22: Thomson J.A. et al., 1998, Science 282: 1145-1147

D24: Copy of the home page of
ES Cell International as of April 14, 2002

D25: News report from the University of Wisconsin-
Madison, website dated February 1, 2000

D26: News report from the University of Wisconsin-
Madison, website dated January 9, 2002

VIII. Appellant's arguments as far as relevant for the present decision, can be summarized as follows:

Article 53(a) EPC

The decision of the examining division was based on the finding that human embryonic stem cell (HES cell) lines referred to in the application and employed to carry out the invention were not publicly available at the date of filing. As a consequence, the only possibility to put the claimed method into practice was considered to be based on destroying human embryos.

One question for the present appeal case was therefore whether the cell lines disclosed in the patent application were in fact publicly available. The decisive question was however whether any human embryonic stem cell line including cell lines not disclosed in the application were publicly available.

The claimed methods did not refer to any specific deposited cell line. Several cell lines were indeed publicly available, as for instance shown in documents D17, D18, D19, D21 and D22. The only relevant question was thus, whether a third party, such as for instance a university researcher, could obtain these cells. As shown by document D23, the authors of document D22, upon publication, had to make the cell lines available. The same applied also to the authors of document D17. Thus, cell lines such as H9, H9.1 and H9.2 were publicly available before the priority date.

This was also the case for HES cell lines from "ES Cell International" and the "WiCell Research Institute" as evidenced by documents D24 to D26.

In view of the public availability of HES cells that did not require the destruction of an embryo as of November 6, 1998, the claims on file did not violate Article 53(a) EPC.

- IX. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of claims 1 to 7 of the main request.

Reasons for the Decision

1. Claims 1 and 2 of appellant's sole request refer to methods of maintaining HES cells in culture in an undifferentiated state. Claim 5 refers to a cell culture comprising HES cells (see section VI above).
2. HES cells are derived from the inner cell mass of human embryos at the blastocyst stage and can be proliferated in vitro in an undifferentiated state. They are capable of developing into any organ or tissue of the human body (cf. page 1, lines 6 to 14 of the patent application published as WO 2004/031343 hereinafter referred to as "the application").
3. According to Article 53(a) EPC in conjunction with Rule 28(c) EPC European patents shall not be granted in respect of biotechnological inventions which concern uses of human embryos for industrial or commercial purposes.
4. It has therefore to be examined whether the subject-matter of appellant's request falls under the exceptions to patentability of Article 53(a) EPC in conjunction with Rule 28(c) EPC.

5. In decision G 2/06 of 25 November 2008 (OJ EPO 2009, 306), the Enlarged Board of Appeal addressed questions of law relating to the patentability of HES cells which at the date of filing could be prepared exclusively by a method which necessarily involved the destruction of human embryos. Regarding the interpretation of Rule 28(c) EPC, the Enlarged Board of Appeal stated the following:

"22. However, this Rule [28(c) EPC] (as well as the corresponding provision of the Directive) does not mention claims, but refers to "invention" in the context of its exploitation. **What needs to be looked at is** not just the explicit wording of the claims but **the technical teaching of the application as a whole** as to how the invention is to be performed. Before human embryonic stem cell cultures can be used they have to be made. Since in the case referred to the Enlarged Board the only teaching of how to perform the invention to make human embryonic stem cell cultures is the use (involving their destruction) of human embryos, this invention falls under the prohibition of Rule 28(c) (formerly 23d(c)) EPC (compare also the decision of the BPatG of 5 December 2006, loc.cit., points IV 2.1 to 2.3). To restrict the application of Rule 28(c) (formerly 23d(c)) EPC to what an applicant chooses explicitly to put in his claim would have the undesirable consequence of making avoidance of the patenting prohibition merely a matter of clever and skilful drafting of such claim." (emphasis added by the board)

6. In the light of this decision of the Enlarged Board of Appeal the technical teaching of the patent application has to be looked at as a whole and not just the explicit wording of the claims, which themselves do not

- explicitly specify a step of obtaining HES cells by the use, involving their destruction, of human embryos.
7. The patent application discloses several ways of obtaining HES cells.
 8. According to a first embodiment, disclosed on page 13, line 29 to page 14, line 13 of the application, HES cells can be isolated from human blastocysts. Human blastocysts are typically obtained from human in vivo preimplantation embryos or from in vitro fertilized embryos. For the isolation of HES cells the zona pellucida is removed from the blastocyst and the inner cell mass (ICM) is isolated by immunosurgery, in which the trophectoderm cells are lysed and removed from the intact ICM by gentle pipetting. The ICM is then plated in a tissue culture flask containing the appropriate medium which enables its outgrowth. Following 9 to 15 days, the ICM derived outgrowth is dissociated into clumps either by a mechanical dissociation or by an enzymatic degradation and the cells are then re-plated on a fresh tissue culture medium. Colonies demonstrating undifferentiated morphology are individually selected by micropipette, mechanically dissociated into clumps, and re-plated. Resulting HES cells are then routinely split every 1-2 weeks.
 9. This method of obtaining HES cells includes the destruction of the human embryo and corresponds exactly to the method which yielded the HES cells which were held unpatentable in the case underlying decision G 2/06.
 10. According to a second embodiment, disclosed on page 14, lines 14 to 18, of the patent application,

commercially available HES cells lines can also be used for putting the invention into practice.

11. The applicant/appellant argued that methods using commercially or otherwise publicly available HES cell lines were not excluded from patentability because no *de novo* destruction of human embryos was necessary to perform them. The point of contention at the oral proceedings before the examining division and the major issue in appellant's statement setting out the grounds of appeal was whether established HES cell lines were publicly available at the date of filing or not.
12. The examining division decided that the evidence on file to establish public availability of HES cell lines at the date of filing was insufficient, and that, in order to put the claimed invention into practice, *de novo* destruction of human embryos was necessary. Therefore it refused the main and sole request then pending before it under Article 53(a) in connection with Rule 28(c) EPC by referring to the decision of the Enlarged Board of Appeal G 2/06.
13. To further substantiate its view that HES cell lines were available at the relevant date, the appellant submitted additional documents D24 to D26 with the statement setting out its grounds of appeal.
14. This evidence, however, is not more conclusive than the evidence that was already on file. The first part of document D24, carrying a web archive date of 14/04/2002, discloses the business model of "ES Cell International" and a page on stem cell products and conditions of use. The more important list of available stem cell lines carries however a web archive date of 11/10/2002 which is after the first priority date of

the application. Documents D25 and D26 only describe that the Wisconsin Alumni Research Foundation established a private subsidiary whose primary purpose was to distribute the cells at a future date, and that an agreement with Geron was reached. Both documents are completely silent as to what cells were to be distributed and as to when in the future this was to take place.

15. The Board intended to further examine this issue at the oral proceedings scheduled for 27 November 2013. However, with letter of 28 October 2013 the appellant informed the Board that it would not attend the oral hearing and that it requested a decision according to the state of the file. Thus, as already pointed out in the Board's communication dated 4 September 2013, annexed to the summons to oral proceedings, there remain serious doubts with regard to the public availability of HES cell lines at the claimed priority date.

16. As also pointed out in the Board's communication, apart from the question of availability of established HES cell lines, there is a more fundamental issue which has to be considered when examining the requirements of Article 53(a) EPC in conjunction with Rule 28(c) EPC. This is whether or not the accomplishment of the invention by relying on the use of an established HES cell line, thus without *de novo* production of HES cells by destroying a human embryo, would nevertheless be in conflict with the requirements of Article 53(a) EPC if said HES cell line has been originally produced by a method involving the destruction of an human embryo (see points 8 and 9 of the Board's communication).

17. The documents on file, submitted by the appellant to demonstrate public availability of HES cell lines at the date of filing, provide technical information concerning the establishment of HES cell lines.
18. The first cell line, designated H9, referred to by the appellant as having been available to the public, was described by J.A. Thomson and colleagues in the November 6, 1998 issue of Science (document D22). The cell line was obtained from the inner cell mass of a human blastocyst after isolation of said inner cell mass by immunosurgery (cf. footnote 6 of document D22). In this process, the trophoblast layer of the blastocyst is selectively removed, and the inner cell mass, is further cultured. The human embryo at the blastocyst stage, used as the source for the inner cell mass, is destroyed.
19. Although the derivation of HES cell lines HES-3 and HES-4 is not explicitly disclosed in documents D9 and D10, document D9 discloses the development of new HES cell lines by isolation of the inner cell mass from a human embryo at the blastocyst stage by immunosurgery, involving the destruction of the human embryo. The board therefore sees no reason to assume that cell lines HES-3 and HES-4 were not derived from the isolated inner cell mass of blastocysts and by destruction of embryos.
20. Likewise, cell lines I-3, I-4, and I-6, disclosed in document D19, were derived from the isolated inner cell mass by destruction of human blastocysts (cf. page 226, right column of document D19).
21. Cell lines H9.1 and H9.2, respectively, described in document D17, were derived from the parental cell line

H9 disclosed in document D22 by clonal derivation (cf. page 272, left column of document D17).

22. All cell lines mentioned by the appellant in the appeal proceedings as being publicly available at the relevant date of the application were thus initially derived from the inner cell mass of blastocyst stage human embryos resulting in the destruction of the human embryos. Regarding any of the further cell lines mentioned by the appellant which were allegedly available from the US NIH (e.g. cell lines BG01, CY12, TE03 or others, mentioned in point 20 of the decision under appeal), there is no evidence on file that these cell lines were obtained by methods not involving the destruction of a human embryo.
23. Decision G 2/06 is concerned with the exclusion from patentability of inventions concerning products, i.e. human stem cell cultures, which can only be obtained by the use, involving their destruction, of human embryos (cf. point 35 of the Reasons for the decision).

The claims in the case referred to the Enlarged Board of Appeal concerned cell cultures comprising primate (including human) embryonic stem cells but did not encompass a method of obtaining them by way of destruction of a human embryo. Nevertheless, as stated in point 22 of its decision (cf. point 6 above) the EBoA considered it necessary to take the entire technical teaching of the case into account when assessing the exclusion from patentability.

24. As the relevant filing date of the patent application underlying said decision lies in 1997, a date at which no established HES cell lines were available (cf. e.g.

Document D20, page 4), the Enlarged Board of Appeal of course did not address the use of HES cell lines.

25. Regarding the appellant's argument that it would go too far if one were to take into account all the steps preceding an invention, the Enlarged Board of Appeal added the following considerations in point 23 of decision of G 2/06:

"23. In a case like the present one, **where the teaching to obtain the embryonic human stem cells claimed is confined to the use (involving their destruction) of human embryos, the argument raised by the Appellant,** namely that the exclusion from patentability would go much too far if one would consider all the steps preceding an invention for the purposes of Rule 28(c) (formerly 23d(c)) EPC, **is not relevant.**"
(emphasis added by the Board)

26. The Board interprets this statement of the Enlarged Board of Appeal as meaning that for the purpose of Rule 28(c) EPC, all steps preceding the claimed use of HES cells which are a necessary precondition for carrying out the claimed invention, have to be considered. In this respect the Enlarged Board of Appeal has neither made a distinction between steps which have been carried out by the inventor or by any other person, nor between steps which took place in direct preparation of the experiments leading to an invention and steps having taken place at a point in time further remote from these experiments.

27. As mentioned above, according to the second embodiment of the claimed invention, commercially available HES cell lines may be used in the methods of claims 1 and 2, and may be comprised in the cell culture of claim 5.

- These cell lines, which were established either by the inventor or by another person, were thus not created specifically for the claimed invention (*de novo*), but at a point in time preceding the actual experiments that eventually led to the invention.
28. However, as shown in points (18) to (22) (above) all the HES cell lines which allegedly were publicly available at the relevant date of the application were initially derived from the inner cell mass of blastocyst stage human embryos resulting in the destruction of the human embryos.
29. Applying the considerations of the Enlarged Board of appeal (points 22 and (23) of the Reasons for the decision) to this second embodiment of the present application, and taking into consideration all the steps that were necessary to establish the HES cell lines available at the relevant date, including, inevitably, the step of isolating cells by way of destruction of a human embryo, the Board concludes that the second embodiment is also excluded from patentability according to Article 53(a) EPC in conjunction with Rule 28(c) EPC.
30. Finally, according to page 14, lines 19 to 20 of the application, "Stem cells used by the present invention can also be derived from human embryonic germ (EG) cells".
31. Human EG cells are prepared from the primordial germ cells obtained from human fetuses of about 8 to 10 weeks gestation using known laboratory techniques. The genital ridges are dissociated and cut into small chunks which are thereafter disaggregated into cells by mechanical dissociation. The EG cells are then grown in

- tissue culture flasks with the appropriate medium. The cells are cultured with daily replacement of medium until a cell morphology consistent with EG cells is observed, typically after 7-30 days or 1-4 passages (cf. page 14 of the present description, lines 21-27).
32. The claims of the main request explicitly refer to the use of HES cells and not to the use of germ line derived EG cells.
33. According to established case law of the Boards of Appeal the description can be used as the patent's "dictionary" to assess the correct meaning of ambiguous terms used in claims. However, if a term used in a claim has a clear technical meaning, the description cannot be used to interpret such a term in a different way. In case of a discrepancy between the claims and the description, the unambiguous claim wording must be interpreted as it would be understood by the person skilled in the art without the help of the description (e.g. decision T 197/10 of 28 October 2011, and the Case law of the Boards of Appeal, 7th Edition 2013, II.A.6.3.1, page 268).
34. As stated in document D19, a review article provided by the appellant, HES cell lines are derived from a preimplantation embryo (page 226, left column, first criterion proposed by Thomson et al., 1998). A similar definition can be found on page 1 of the present description ("Embryonic stem (ES) cells are derived from the inner cell mass (ICM) of the mammalian blastocyst"). Document D17 makes it clear that pluripotent cell lines can be derived from two different sources. The first sentence of its introduction reads: "Human pluripotent cell lines have been derived from preimplantation embryos (embryonic

stem cell lines, ES cells; Reubinoff et al., 2000; Thomson et al., 1998) and from fetal germ cells (embryonic germ cell lines, EG cells; Shamblott et al., 1998) that for prolonged periods of culture maintain a stable developmental potential to form advanced derivatives of all three embryonic germ layers".

The term HES cells has a clear technical meaning in the art which is distinct from the meaning of the term EG cells. EG cells are derived from a postimplantation embryo (cf. point 30 above) and are, despite the fact that they may have similar developmental potency, not embraced by the term HES cells.

35. Therefore, the description on page 14 of the application is not considered as a basis for the provision of HES cells from human embryonic germ cells.
36. In consequence, the claimed invention depends entirely on the use of HES cells, either obtained by *de novo* destruction of human embryos (cf. points 8 and 9, above) or by using established HES cell lines which initially were obtained by methods involving the destruction of human embryos (cf. points 10 to 29, above), both of which are excluded from patentability under the provisions of Article 53(a) EPC in combination with Rule 28(c) EPC.

Therefore appellant's sole request is not allowable.

37. The board has considered the judgement given by the European Court of Justice (ECJ) in case C-34/10 with regard to the reference for a preliminary ruling under Article 267 of the Treaty on the Functioning of the European Union (TFEU) made by the German

Bundesgerichtshof concerning German patent No. 197 56 864 related to the use of human embryonic stem cells for the preparation of neural precursor cells.

In its third question referred to the ECJ, the German court asked: "Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive (Article 6(2)(c) of Biotech Directive 98/44 EC is identical in wording to Rule 28(c) EPC; added by the Board) 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 a base material?" (see point 23(3) of the Judgment of the Court of 18 October 2011).

Considering this question, the ECJ ruled as follows:

"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 a 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."

With specific reference to HES cell lines the ECJ held in point (49) of its considerations that "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."

38. The EPO as an international organisation with its separate legal order is not a member of the EU. According to Article 23(3) EPC, in their decisions, the members of the Boards of Appeal shall not be bound by any instructions and shall comply only with the provisions of the EPC. In point (7) of the reasons for its decision G 2/06 the Enlarged Board of Appeal concluded that neither it nor any Board of Appeal of the EPO, has the power to bind itself to follow a ruling of the ECJ on the interpretation of Article 6(2)(c) of the Directive and apply this to Rule 28(c) EPC.
39. But, although judgements of the ECJ are not legally binding on the EPO or its boards of appeal, they should be considered as being persuasive.
40. The EPO (see Notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the European Patent Convention, OJ EPO 1999, page 573) and the Boards of Appeal (see decision of the Enlarged Board of Appeal G 5/83, OJ EPO 1985, 64) have acknowledged the need for uniformity in harmonised European patent law.

41. In decision G 5/83 (point 6 of the Reasons), the EBA stated):

"In the interpretation of international treaties which provide the legal basis for the rights and duties of individuals and corporate bodies it is, of course, necessary to pay attention to questions of harmonisation of national and international rules of law. This aspect of interpretation, not dealt with by the provisions of the Vienna Convention, is particularly important where, as is the case with European patent law, provisions of an international treaty have been taken over into national legislation. The establishment of harmonised patent legislation in the Contracting States must necessarily be accompanied by harmonised interpretation. For this reason, it is incumbent upon the European Patent Office, and particularly its Boards of Appeal, to take into consideration the decisions and expressions of opinion of courts and industrial property offices in the Contracting States."

42. The boards of appeal have applied provisions in international treaties even though acknowledging that they are not strictly bound by them. In decision G 2/02 (OJ EPO 2004, 483) the EBA stated:

(i) in point (5.2) of the Reasons, with regard to the interpretation of treaties:

"It is the established case law of the Enlarged Board of Appeal that the rules on interpretation of treaties incorporated in the VCLT 1969 may be relied on to provide guidance in matters pertaining to the interpretation of the EPC. As explained by the Enlarged Board of Appeal in decision G 5/83 (OJ EPO

1985, 64), the Vienna Convention is not directly applicable to the EPC but its principles can be referred to as they embody recognised international practice, applying to any treaty, which is the constituent instrument of an international organisation (Article 5 VCLT 1969).", and

(ii) in point (8.6), last sentence, of the Reasons, with regard to the applicability of further treaties:

"In summary, therefore, TRIPs provisions, like decisions of the European and International Courts of Justice and national decisions, are elements to be taken into consideration by the boards of appeal but are not binding on them".

43. The Contracting States to the EPC, including those not members of the EU, agreed to adopt the wording of Biotech Directive 98/44/EC in the Implementing Regulations of the EPC and, under Rule 26(1) EPC, accepted that the Directive shall be used as a supplementary means of interpretation.

44. The board observes that its decision in the present case, which is based on the decision G 2/06 of the Enlarged Board of Appeal, and which states that inventions which make use of HES cells obtained by *de novo* destruction of human embryos or of publicly available HES cell lines which were initially derived by a process resulting in the destruction of the human embryos are excluded from patentability under the provisions of Article 53(a) EPC in combination with Rule 28(c) EPC, is in line with decision C-34/10 of the ECJ.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar:

The Chairman:



A. Wolinski

M. Wieser

Decision electronically authenticated