

Interlocutory Decision of Technical Board of Appeal 3.3.08 dated 7 April 2006**T 1374/04 - 3.3.08**

(Language of the proceedings)

Composition of the board:

Chairman: L. Galligani
Members: T. J. H. Mennessier
M. B. Günzel

Applicant: Wisconsin Alumni Research Foundation

Headword: Stem cells/WARF

Article: 53(a), 83, 112(1)(a) EPC

Rule: 23d EPC

Keyword: "Human embryonic stem cell culture - sufficiency of disclosure (yes)" - "Exclusion from patentability under Rule 23d(c) in conjunction with Article 53(a) EPC - important point of law - referral of questions to the Enlarged Board of Appeal"

Headnote

The following questions are referred to the Enlarged Board of Appeal for decision:

- 1. Does Rule 23d(c) EPC apply to an application filed before the entry into force of the rule?*
- 2. If the answer to question 1 is yes, does Rule 23d(c) EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which - as described in the application — at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?*
- 3. If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims?*
- 4. In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: eg derivation from available human embryonic cell lines)?*

Summary of facts and submissions

I. With decision of 13 July 2004 the Examining Division refused European patent application No. 96 903 521.1 published as WO 96/22362 (EP No. 0 770 125) with the title "Primate embryonic stem cells".

II. Basis for the refusal was the set of claims 1 to 10 filed with a letter dated 18 June 2003.

Claim 1 read:

"1. A cell culture comprising **primate embryonic stem cells** which (i) are capable of proliferation in vitro culture for over one year, (ii) maintain a karyotype in which all chromosomes normally characteristic of the primate species are present and are not noticeably altered through culture for over one year, (iii) maintain the potential to differentiate to derivatives of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (iv) are prevented from differentiating when cultured on a fibroblast feeder layer."

(emphasis added by the Board)

Claims 2 to 8 were directed to further embodiments of the subject-matter of claim 1, the cell culture according to claim 8 being directed to **non-human** primate cells.

Claims 9 and 10 read as follows:

"9. A method of maintaining a cell culture according to any one of the preceding claims comprising culturing the primate embryonic stem cells on a fibroblast feeder layer so that the **primate embryonic stem cells** proliferate in culture in an undifferentiated state."

(emphasis added by the Board)

"10. A method of obtaining differentiated **primate cells** in culture comprising the step of permitting primate embryonic stem cells of a cell culture according to any one of claims 1 to 8 to differentiate."

(emphasis added by the Board)

III. The Examining Division recognised that the application enabled also the generation of human embryonic stem cell cultures which were covered by the claims, notwithstanding the absence of specific examples, because human embryonic stem cell lines according to the application had been deposited with the NIH Human Embryonic Stem Cell Registry (cf document D3). However, it refused the application under Article 97(1) EPC for the reason that claims 1 to 7, 9 and 10 did not comply with the requirements of Article 53(a) in conjunction with Rule 23d(c) EPC, because, as regards the generation of human embryonic stem cell cultures, the use of human embryos as starting material was described in the application as originally filed as being indispensable. The use of a human embryo as starting material for the generation of a product of industrial application (ie the claimed embryonic stem cell cultures) meant a use thereof for industrial purposes within the meaning of Rule 23d(c) EPC and was thus prohibited under the said provision in conjunction with Article 53(a) EPC. The provisions of Rule 23d(c) in conjunction with Article 53(a) EPC were not directed exclusively to the claimed subject-matter but rather concerned inventions, thus including all aspects that made the claimed subject-matter available to the public. The description provided only one source of starting cells, namely a pre-implantation embryo. It was therefore irrelevant that the claimed subject-matter related to cell cultures and not to a method of production of said cultures. The exception to the exclusion from patentability with regard to the use of human embryos derivable from Recital 42 of the Directive 98/44/EC (document D5) did not apply to the present case because the generated cell cultures did not serve any therapeutic or diagnostic purpose useful to the embryo that gave rise to the said cultures, even if the availability of the said cell cultures would potentially benefit the development of substances for treating conditions relating to human infertility.

IV. On 6 September 2004 the appellant lodged an appeal against this decision. The appeal fee was paid on the same day. On 19 November 2004 the appellant submitted the statement setting out the grounds of appeal in which, in addition to the documents already on file, the appellant referred to additional documents D11 to D28 in support of the request to set the appealed decision aside.

V. The Examining Division did not rectify its decision and referred the appeal to the Board of Appeal (Article 109 EPC).

VI. The Board issued with the summons to oral proceedings a communication dated 27 May 2005 in which the appellant was informed *inter alia* that, under the provisions of Article 112(1)(a) EPC, the Board was entitled of its own motion to refer questions to the Enlarged Board of Appeal.

VII. In a letter dated 17 October 2005, the appellant made the request on an auxiliary basis that the matter be referred to the Enlarged Board of Appeal and formulated the four following questions:

"1. Does Rule 23d(c) EPC extend to patent applications whose claimed subject-matter comprises a product derived from human embryos?"

"2. If the answer to question 1 is no, are such applications nevertheless capable of being refused under Article 53(a) EPC and if so, what criteria are to be applied?"

"3. If the answer to question 1 is yes, does Rule 23d(c) EPC extend to patent applications whose claimed subject matter comprises a product which can in any way be traced back to the use of a human embryo?"

"4. If the answer to question 3 is no, what criteria are to be applied in determining whether a product can be traced back to the use of a human embryo so as to invoke Rule 23d(c)?"

A further document D29 was filed.

VIII. At the oral proceedings which took place on 18 November 2005, the appellant submitted a further question 1, with consequent renumbering of those already on file, for referral to the Enlarged Board of Appeal, said question reading:

"1. Does Chapter VI of the Implementing Regulations apply to EPC applications pending as at 1st September 1999, that being the date on which these Implementing Regulations entered into force?"

IX. A list of the documents D1 to D29 cited in the present appeal proceedings is provided in Annex 1 to this decision.

X. Insofar as relevant in the context of the referral, the submissions of the appellant in the written and in the oral proceedings can be summarised as follows:

In relation with the issue of patentability of the claimed subject-matter under Rule 23d(c) in conjunction with Article 53(a) EPC a two step examination had to be performed (cf T 315/03 of 6 July 2004, published in an abridged form in OJ EPO 2006, 15). The first question to be asked was whether the claimed subject-matter contravened Rule 23d(c) EPC. If this was not the case, compliance of the claimed subject-matter with Article 53(a) EPC had then still to be examined.

Interpretation of Rule 23d(c) EPC

The main issue in this respect involved a question of construction of a provision of the law, namely *whether Rule 23d(c) EPC should be construed narrowly* (thereby excluding from patentability only applications whose claims were directed to the use of human embryos) *or broadly* (thereby extending the exclusion to products whose isolation necessitated the direct and unavoidable use of human embryos).

The purpose and effect of Rule 23d EPC was to exclude from patentability the specific activities and products listed in sub-paragraphs (a) to (d). Whether or not a patent application contravened Rule 23d EPC was to be judged solely by reference to the matter for which protection was sought, ie as set out in the claims.

Although the application disclosed that human embryonic stem cells might be derived from pre-implantation embryos (and to that extent disclosed the use of human embryos) the claimed subject-matter was confined to cultures of embryonic stem cells. Thus, the application did not contravene Rule 23d(c) EPC.

Patent applications whose claimed subject-matter comprised a product which derived from a human embryo did not contravene Rule 23d(c) EPC, even in circumstances where the isolation of the product necessitated the direct and unavoidable use of a human embryo.

Merits of the narrow construction of Rule 23d(c) EPC as compared with the difficulties which were inherent in the broad construction

- The primacy of the claims

It was a basic principle of the law of European patents that the claims defined the invention for which protection was sought. Accordingly the reference to particular "inventions" in Rule 23d EPC was a reference to the subject-matter of the claims.

The fact that the English language version of Rule 23d EPC referred to inventions which "concern" the subject-matter of paragraphs (a) to (d) did not broaden the exclusion to all aspects that made the claimed subject-matter available to the public. On the contrary, the word "concern" was used in this context in precisely the opposite sense, namely to limit the exclusion to inventions which had as their subject-matter or were directed to the activities and products listed in paragraphs (a) to (d). This proposition was amply supported by the German and French versions of Rule 23d EPC, the provisions of Rule 23b(2) EPC and the Directive 98/44/EC (document D5).

- Construction of Rule 23d(c) EPC in the light of Rule 23d(d) EPC

Whereas the subject-matter of Rule 23d(d) EPC comprised the following "processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, *and also animals resulting from such processes*" (emphasis added), in contrast, the subject-matter of Rule 23d(c) EPC was confined to "uses of human embryos ...". In the light of Rule 23d(d) EPC, the clear implication was that the omission of any reference to the products resulting from the use of human embryos was deliberate and that Rule 23d(c) EPC should be construed narrowly.

- Construction of Rule 23d(c) EPC in the light of the Directive 98/44/EC

Rule 23d EPC originated from Article 6.2. of Directive 98/44/EC (document D5) which listed exactly the same exceptions to patentability, including uses of human embryos for industrial or commercial purposes.

A review of the history of the Directive showed that the exclusion of "Methods in which human embryos are used" as introduced into the draft Directive by the Committee on Legal Affairs and Citizen's Rights on 25 June 1997 (document D21) had been amended by the Council in the Common Position on 8 April 1998 (document D4) by limiting the exclusion in two respects. The first of these was to include the words "for industrial or commercial purposes", the reason being that the Council wanted to ensure that inventions for therapeutic or diagnostic purposes which were applied to the human embryo and were useful to it were not excluded from patentability. The second amendment made by the Council was to replace "methods in which human embryos are used" with "uses of human embryos". Thus "methods in which human embryos are used" arguably covered procedures which made use of products derived from embryos, albeit without using embryos *per se*. However, "uses of human embryos" could only relate to procedures which used embryos directly as distinct from downstream products or processes.

It ought to be noticed that as Article 6(2)(c) was introduced at a time when the technology relating to embryonic stem cells was already available, the use of human embryonic stem cells could readily have been excluded, for example in one of the recitals of the Directive 98/44/EC (document D5).

The "redundancy argument" as used in "the Edinburgh case", EP 0 695 351 (document D9)

In "the Edinburgh case" (cf document D9), the then competent Opposition Division had argued (cf page 22 of its decision of 21 July 2003) that a narrow interpretation of Rule 23d(c) EPC (ie exclusion only of *per se* claimed uses of embryos) could not have been intended by the legislator because that would have meant that Rule 23d(c) EPC was redundant over Rule 23e(1) EPC, the latter rule already excluding the patenting of human embryos (as being an early stage of formation of the human body) and thereby also the patenting of uses of human embryos. This view was, however, incorrect, as could be derived from the corresponding Articles 5 and 6 of the Directive. The purpose and the subject-matter of both provisions overlapped: a) Article 5, besides distinguishing between an invention and a discovery, also guaranteed respect for human dignity as did Article 6; b) both provisions shared the same subject-matter since both rules related to or included human embryos *per se*. Moreover, the Opposition Division's

argument that "if the patenting of a product is ethically unacceptable, it is hardly conceivable that the patenting of 'uses' can be judged differently" did not justify the conclusion that Rule 23d(c) EPC prohibited the patenting of claimed subject-matter other than the direct use of human embryos.

The broad construction is ethically artificial

Human embryonic stem cells in practice could now be obtained readily without handling or disposition of an embryo. The ethical issues relating to such cell lines were clearly not the same as those relating to human embryonic stem cell cultures established *de novo* from an embryo. However, the broad interpretation of Rule 23d(c) EPC treated existing human embryonic stem cell lines and human embryonic stem cells obtained by other means as equally objectionable.

The EPO should not be an arbiter in respect of ethical issues

The EPO was not and should not act as a moral censor of controversial technologies. The EPO's expertise was in the field of patents, not in resolving controversial moral and ethic issues. The regulation of controversial technologies was a matter for legislators rather than the EPO.

The correct approach in relation to ethical issues, application of Article 53(a) EPC

It was important to distinguish between inventions which unarguably contravened Article 53(a) EPC and those in which patentability involved a genuine exercise of interpretation of the provisions of the EPC.

In cases where a provision of the EPC was capable of bearing two alternative meanings, one of which resulted in refusal of the application on ethical grounds (ie the broad interpretation) and one of which permitted grant (ie the narrow interpretation), the correct approach was to construe the provision narrowly, the reasons being that (i) the narrow interpretation avoided the EPO acting as a moral censor, (ii) Article 53(a) EPC was an exception to the general principles of patentability under Article 52(1) EPC and consequently was to be interpreted narrowly in accordance with the jurisprudence of the Boards of Appeal, and (iii) the Guidelines also plainly adopted a narrow interpretation of "ordre public" and morality.

In relation to inventions directed to human embryonic stem cells, one should consider that there was no consensus amongst Contracting States as to the ethical acceptability of using human embryonic stem cells. The development of human embryonic stem cells from supernumerary embryos was permitted in several EPC states and there was an ongoing debate as to the ethics of using human embryonic stem cells, it being clear that moral attitudes were changing as was eg shown by the fact that in November 2003 the European Parliament voted to permit public funding for human embryonic stem cell research.

Where matters relevant to morality arose, any decision based on them should be based on facts as substantiated at the date of the decision.

Inventions relating to human embryonic stem cells were clearly not of the type that was so abhorrent that the grant of patent rights would be inconceivable.

The correct approach in this respect was to undertake the balancing exercise advocated by decision T 19/90 (OJ EPO 1990, 476), ie a careful weighing up of the moral objections on the one hand and the invention's usefulness to mankind on the other.

XI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 10 of 18 June 2003. As auxiliary request, the appellant requested that the matter be referred to the Enlarged Board of Appeal on the basis of question 1 submitted during oral proceedings and questions 1 to 4 (to be renumbered accordingly) filed on 17 October 2005.

Reasons for the decision

1. In the decision under appeal, essentially two aspects of the present application have been treated both of which are in relation to **human** embryonic stem cell cultures, these being embodiments of the invention falling within the scope of the claims (cf the wording "**primate**" in the claims as well as pages 13 and 17 of the description). These aspects are: (a) the sufficiency of the disclosure of said embodiments (Article 83 EPC), and (b) their exclusion from patentability according to Rule 23d(c) in conjunction with Article 53(a) EPC. While (a) was decided in favour of the applicant, (b) led to the refusal of the application.

2. As regards the issue of sufficiency, the Board is, as a result, in agreement with the positive finding of the Examining Division, as will be set out below (cf points 7 to 14 below).

3. Thus, the decision under appeal could be set aside in accordance with the main request of the appellant **only if** the appellant's position in respect of the interpretation of Rule 23d(c) and Article 53(a) EPC were to be adopted. In other words, the decision on the issue dealt with by the Examining Division under (b) is decisive for the outcome of the present appeal.

4. The Board considers the question of the patentability of human embryonic stem cells and of the conditions therefor as being an outstandingly important point of law within the meaning of Article 112(a) EPC for which a decision by the Enlarged Board of Appeal is required. The patentability of human embryonic stem cells is a highly critical matter which is passionately debated.

5. Following the introduction at the European Community level of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (document D5, also published in OJ EPO 1999, 101), Chapter VI was introduced into the Implementing Regulations to the EPC, and therein also Rule 23d(c) EPC, as a supplementary means of interpretation of Article 53(a) EPC as regards the exclusion from patentability of inventions using human embryos for industrial or commercial purposes.

6. A decision on the matter by the Enlarged Board of Appeal will lay basic and reliable ground to the treatment of other cases concerning the patenting of human embryonic stem cells which are or will become pending before the present Board as well as before other Boards, in particular before Board 3.3.04. It is also in view of this latter fact that this Board would have considered it inappropriate to decide itself on that fundamental issue. Although not a reason for a referral in itself, the Board also considers that a decision by the Enlarged Board of Appeal on the matter will greatly enhance acceptance of future practice of the EPO based on the principles developed by such a decision. To refer the matter to the Enlarged Board of Appeal is, moreover, in accordance with the auxiliary request of the appellant which proposed a number of questions.

Sufficiency of disclosure (Article 83 EPC)

7. The Examining Division came to the conclusion that, in spite of the absence in the description of specific examples on how to prepare **human** embryonic stem cell cultures, the disclosure in the application enables them, because (i) it indicates that the same methods and growth conditions exemplified for two other primates (rhesus monkey and common marmoset) can be used, (ii) it points to a source for said cells, namely human spare embryos of *in vitro* fertilisation (IVF) procedures, and (iii) **human** embryonic stem cell lines had been "deposited" with the NIH Human Embryonic Stem Cell Registry, as referred to in document D3.

8. The Board agrees with the finding of the Examining Division that the provisions of Article 83 EPC are satisfied in respect to the area of the claims covering **human** embryonic stem cell cultures. However, the Board's conclusion is based on a partly different reasoning, as outlined hereinafter.

9. For the assessment of whether the disclosure of an invention is sufficient within the meaning of Article 83 EPC, it should be kept in mind that the only relevant information is that provided in the application as read by the skilled person with the background of common general knowledge. In cases like the present one concerned with cell lines, the disclosure may be complemented by references to a deposit of a sample of the biological material made in accordance with the provisions of Rule 28 EPC, if said cell lines cannot be reproduced otherwise.

10. However, in the present case no deposit of any **human** cell line is referred to in the application. Thus, the fact alluded to by the Examining Division that **human** embryonic stem cell lines had been later "deposited" with the NIH Human Embryonic Stem Cell Registry (cf reason (iii) referred to in point 7 supra) is *per se* immaterial for the issue of sufficiency, as such a deposit cannot be part of the disclosure of the application as filed. Relevant to the sufficiency issue is here therefore the question whether, in the absence of a reference to a deposit and of specific examples, the description contains sufficient information to enable the skilled person to prepare without undue burden or excessive experimentation **human** embryonic stem cell cultures.

11. The application describes in detail (see the examples on pages 26 to 36) how to derive embryonic stem cell lines from blastocysts of two non-human primates, namely the rhesus macaque and the common marmoset, and how to culture such cell lines. In particular, the preparation of one rhesus macaque embryonic stem cell line, namely the cell line R278.5, is described which when put into culture has been proved to have the technical features recited in claim 1. Additionally, a method for creating a macaque embryonic stem cell line is described (see pages 33 to 36) which permitted to prepare seven putative embryonic stem cell lines, each of which has been cultured for over six months. Thus, in this respect, the disclosure is clear and complete.

12. As regards **human** embryonic stem cell lines, for which indeed no examples are given, it is explicitly stated in the application (see page 13, lines 8 to 25) that, given the close evolutionary distance between rhesus macaques and humans, the techniques described therein for the isolation of embryonic stem cell lines from the rhesus macaque (cf point 11 supra) may be used successfully for deriving embryonic stem cell lines in other higher primates, including humans. As a source for the derivation of human cells, spare human IVF-produced embryos of high quality are indicated (see page 17, line 24 to page 18, line 6). It is also indicated that the same procedures described for non-human primates can be used for the preparation of human cells (*loc.cit.*, *ibidem*).

13. The Board is not in a position, based on any available evidence, to raise doubts about these statements. As a matter of fact, later evidence in the form of a scientific publication in November 1998 *inter alia* by the present inventor (cf document D16) shows that human embryonic stem cell lines were indeed derived from human blastocysts and that this was achieved "*essentially as described for nonhuman primate ES cells*" (see the column on the middle of page 1145, where reference is made both to citation 5 - a scientific publication by the inventor disclosing in similar terms the invention as described in the present application, and to note 6 on page 1147, which outlines a method which essentially corresponds to the one described in the present application).

14. Thus, it has to be accepted by the Board that at the relevant filing date the skilled person would have been in a position to prepare and grow human embryonic cell lines without undue burden or excessive experimentation. Under these circumstances, specific examples and/or a deposit of a cell line are not considered to be indispensable for enablement.

The compliance with Rule 23d(c) and Article 53(a) EPC

Technical background

15. A human embryonic stem cell culture consists of cells resulting from the multiplication of cells of a chosen cell line which have been put into a culture medium and grown.

16. According to the techniques described in the application (and as later illustrated in document D16 - see point 13 supra), human embryonic cell lines are to be derived from spare human embryos at the stage of pre-implantation blastocysts. These consist of two parts, the trophoblast (an hollow sphere of cells which in the pregnant woman will go on to implant in the uterus and develop into the extra-embryonic membranes) and the inner cell mass (ICM) which in the pregnant woman will develop into the baby.

17. As in the case of non-human primates, human embryonic stem cell lines are derived from the inner cell mass of embryos according to a multi-step operating procedure. As shown in document D16, in particular note 6 on page 1147, used as expert opinion, in brief: (i) blastocysts are selected (the patent application emphasises the importance of using only high quality embryos; cf page 17, lines 32-33), (ii) the inner cell masses are isolated by immunosurgery (to remove the trophoblast cells from the blastocysts) and then plated on irradiated mouse embryonic fibroblasts in a culture medium, (iii) after 9 to 15 days inner cell mass-derivative outgrowths are dissociated into clumps replated on irradiated mouse embryonic fibroblasts in fresh culture medium, (iv) individual colonies with a uniform undifferentiated morphology are individually selected by micropipette, mechanically dissociated into clumps, and replated, and (v) once established and expanded, cultures are passaged by exposure to type IV collagenase or by selection of individual colonies by micropipette.

18. The present application (cf page 17 line 24 onwards) indicates that human embryonic stem cells which are derived from pre-implantation embryos will be derived from in vitro fertilized embryos because ethical considerations in the USA do not allow the recovery of human in vivo fertilised pre-implantation embryos from the uterus. The authors of later document D16, who were able to report the establishment of **human** embryonic stem cell lines, indicate to have used spare human embryos in the form of pre-implantation blastocysts produced by in vitro fertilization and then donated for research purposes with informed consent of the donors (supranumerary embryos which would otherwise be discarded). Pre-implantation embryos created for the specific purpose of being submitted to research could also have been used. All these techniques necessarily imply the destruction of the embryos.

19. Once established cell lines have been obtained from human pre-implantation embryos (some of them are listed in document D3), these can be repeatedly used for the preparation of a human embryonic stem cell culture without having to rely on the destruction of embryos. The latter is, however, necessary if further human embryonic stem cell lines in accordance to the claims have to be established.

Preliminary remarks

Elements acknowledged by the appellant

20. In respect to the legal and technical situation of the present case, the appellant, in answer to questions from the Board at oral proceedings, has explicitly acknowledged the following elements:

- (a) The term "primate embryonic stem cells" as used in the claims covers **human** embryonic stem cells;
- (b) At the filing date, the skilled person willing to repeat the invention, ie to prepare a cell culture of **human** embryonic stem cells, had necessarily to start from spare pre-implantation embryos, as indicated in the application, and thus destroy them in the process;
- (c) The said pre-implantation embryos from which human embryonic stem cells are to be derived are "embryos" within the meaning of Rule 23d(c) EPC;
- (d) Rule 23d EPC applies when assessing whether the present claimed invention meets the requirements of the EPC, although it entered into force after the filing date of the application;
- (e) The legal situation as regards the interpretation of Rule 23d(c) EPC is not yet clear;
- (f) The patentability of human embryonic stem cells is a highly debated matter.

Questions referred to the Enlarged Board of Appeal

21. The four questions referred herewith to the Enlarged Board of Appeal are set out hereinafter with an outline of the considerations which have brought to their formulation.

First question to the Enlarged Board of Appeal

22. The question reads:

"Does Rule 23d(c) EPC apply to an application filed before the entry into force of the rule?"

23. To this date, two decisions of the Boards of Appeal have dealt with the applicability of particular provisions of Chapter VI of Part II of the Implementing Regulations, ie of Rules 23b-e EPC, and of the said chapter as a whole to

patent applications filed before the entry into force of that chapter, namely decisions T 272/95 of 23 October 2002 and T 315/03 of 6 July 2004 (supra X).

24. In decision T 272/95 (cf point 4 of the reasons), the competent Board concluded from the absence of any transitional provisions in respect of the applicability of Rules 23b-e EPC that the Administrative Council must have seen them as just giving a more detailed interpretation of Article 53 EPC as intended from its inception, and, hence, as being applicable as from their entry into force on 1 September 1999 to applications pending before that day. In point 5 of the reasons, the Board examined also whether, having regard to Article 164(2) EPC, the provisions of said rules, insofar as they relate to Article 53(a) EPC, are in conformity with that article. The Board then observed that in decision G 1/98 (OJ EPO 2000, 111, points 3.10, 5 and 6) the Enlarged Board of Appeal, when dealing with the interpretation of Article 53(b) EPC, had stated that Article 4,1.(b) and 4,3. of the Directive 98/44/EC (document D5) was intended to be interpreted in the same sense as the Enlarged Board of Appeal interpreted the scope of Article 53(b) EPC. This latter interpretation corresponded entirely to the new Rule 23(c) EPC which in turn was based on the said Directive. The Enlarged Board of Appeal had found the said rule, which related to Article 53(b) EPC, to be only interpretative. From this, the Board in decision T 272/95 concluded the same to hold true also for the new rules as far as they related to the interpretation of Article 53(a) EPC, and thus applied them to the case pending before it.

25. In decision T 315/03 (supra X), the competent Board held that Rules 23b-e EPC applied to a case which was pending on the date when the said rules took effect. In its view, Rules 23b-e EPC had to be regarded as a "package" with the only function to supply provisions for the application and interpretation of pre-existing provisions of the EPC. With regard to "animal patents", the Board was of the view that the new rules did not mark an entire change of regime and did not create retrospective bars to patentability (cf Headnote I, point 5.1 and 5.12 of the reasons). The argument of the respondent (patent proprietor) that the introduction in Rule 23d(d) EPC of the concept of "substantial medical benefit" had caused a previously unpredictable change to the interpretation of Article 53(a) EPC as determined by decision T 19/90 in that it introduced a more restrictive test, and that thus Rule 23d EPC was "ultra vires", was refuted by the Board. Although the reasoning by the Board is essentially directed to the legal situation as regards animal patenting and takes comprehensive account of the specificities of the arguments as they were actually formulated by the parties, the overall conclusion to be drawn from this decision is nevertheless that Rules 23b-e EPC apply to cases pending on the date of their entry into force without any further condition having to be met by the rule under consideration.

26. This Board sees a slight difference between the two quoted decisions in the reasoning for deciding that the rules in question applied to cases filed before their entry into force: while decision T 272/95 seems to set the condition that the rule under consideration be merely of interpretative nature, decision T 315/03 found that the "package" of the rules was applicable without any further conditions.

27. The issue raised by question 1 has not yet been decided by the Enlarged Board of Appeal. In its decision G 1/98 concerning the patentability under Article 53(b) EPC of genetically modified plants, the Enlarged Board of Appeal referred to Article 4(1)(b) and 4(3) of the Directive 98/44/EC (document D5) but only to say that with respect to question 4 of the referral the Enlarged Board's interpretation of Article 53(b) EPC corresponded to the meaning which according to Recital 32 of the Directive was to be given to Article 4(1)(b) and 4(3), said article using language corresponding to Article 53(b) EPC (loc. cit., 5.3 at the end). So, the reference to the provisions of the Directive was used in that decision only as an argument which corroborated the interpretation given to Article 53(b) EPC by the Enlarged Board of Appeal. No conclusion can be drawn from that decision as regards the answer to be given to question 1.

28. Having regard to the quoted previous decisions of Technical Boards of Appeal, this Board finds it pertinent to refer a specific question as to the applicability of Rule 23d(c) EPC, instead of referring the more general formulation of the question suggested by the appellant (applicability of Chapter VI of the Implementing Regulations as a whole) in order not to anticipate in any way the answer which will be given by the Enlarged Board of Appeal.

Second question to the Enlarged Board of Appeal

29. The question reads:

"If the answer to question 1 is yes, does Rule 23d(c) EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which - as described in the application - at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?"

30. The appellant has given a number of reasons why the answer to this question should be negative. As the present proceedings are *ex parte* proceedings, there are on file, apart from the reasons given by the examining division in its decision to refuse the application, only arguments raised by the appellant in support of its position.

31. It would be inappropriate for this Board to take any position on the matter by expressing any opinion on how this question should be answered. Therefore, the Board refrains from doing so. However, it is considered useful to set out some arguments in relation to the appellant's position, and to elucidate the reasons for referring question 2 in this form to the Enlarged Board of Appeal.

On how to interpret the rule

32. As a first argument, the appellant has submitted that, in accordance with repeated statements in decisions by the Boards of Appeal (cf eg T 320/87, OJ EPO 1990, 71; T 19/90, OJ EPO 1990, 476; T 356/93, OJ EPO 1995, 545), Rules 23d(c) and Article 53(a) EPC have to be interpreted **narrowly** as they are exceptions to patentability.

33. The Board is aware of only one decision of the Enlarged Board of Appeal in which this issue has been addressed directly. This is the recent decision G 1/04 of 16 December 2005 (to be published in the OJ EPO, cf point 6 of the reasons), wherein the Enlarged Board of Appeal held that the frequently cited principle according to which exclusion clauses from patentability laid down in the EPC were to be construed in a restrictive manner, **did not apply without exception**. The Board then considered that the principle of narrow interpretation applied to the exclusion from patentability under Article 52(4) EPC concerning diagnostic methods. However, when analysing the decision, it is apparent that this conclusion was not one drawn simply from the fact that Article 52(4) EPC is an exception to patentability. On the contrary, said conclusion was the result of having intensively analysed the said provision by all the usual methods of legal interpretation, ie after having considered the wording, the object and purpose of the provision, the interests involved, the consequences of a narrow or broad interpretation, respectively, and the aspect of legal certainty. In the earlier decision G 1/98 (*supra*), which concerned the scope of the exclusion of plant varieties from patentability under Article 53(b) EPC, there is not even a mention of the said principle but the Enlarged Board of Appeal arrived at its "narrow" construction of Article 53(b) EPC after having analysed the meaning of the terms used in it, its legislative context, in particular its historical background and the object and purpose of the provision.

34. The established jurisprudence of the Enlarged Board of Appeal has acknowledged that the rules on the interpretation of treaties incorporated in the Vienna Convention on the Law of Treaties may be relied on to provide guidance in matters pertaining to the interpretation of the EPC (G 5/83, OJ EPO 1985, 64 and more recently G 2/02 and G 3/02, OJ EPO 2004, 483, point 5.2 of the reasons). The Vienna Convention defines in Articles 31 and 32 the principles of interpretation to be applied.

35. Thus, it is to be expected that a similar analysis will have to be carried out in the present case before deciding how Rule 23d(c) EPC has to be interpreted.

The value of the word "use" in Rule 23d(c) EPC

36. The appellant has submitted several arguments in relation to the use of the word "use" in Rule 23d(c) EPC which, in its view, lead to the conclusion that only claims which directly claim uses of human embryos for industrial or commercial purposes fall under the exclusion.

37. With reference to Article 84 EPC, the appellant submitted that for the application of Rule 23d(c) EPC the subject-matter of the claim was to be considered as being the invention within the meaning of the said rule, this subject-matter having then to be examined as to its compliance with the rule. It was argued that in the present case the subject-matter of the claim and, consequently, the invention within the meaning of the said provision, was a cell culture comprising human embryonic stem cells, **not** a method for producing the human embryonic stem cell culture which admittedly and, as described in the application, at the filing date necessarily involved the destruction of the human embryo from which the embryonic stem cells were derived.

38. In its decision the Examining Division replied to this argument that according to its wording Rule 23d(c) EPC, just as Article 53(a) EPC, is not exclusively directed to the subject-matter of the claim, but rather concerns more generally the invention, which in the present case - as disclosed in the application - concerns the use of human

embryos as starting material and as an indispensable part of the invention for the generation of human embryonic stem cell cultures (point 10 of the decision).

39. In respect of this issue, the Board observes that even if the appellant was right in assuming that what has to be examined for its compliance with Rule 23d(c) EPC is the invention as claimed, and not something which, without being claimed, is described in the application, this does not mean that the term "use" in Rule 23d(c) EPC is to be construed as referring to the category of the claim in question.

40. The category of a claim (process/use or product/apparatus) has influence on the protective rights derivable from the patent (Article 64 EPC) and may also influence the evaluation of novelty and inventive step. Drawing up claims of different categories is, within the limits of Article 82 EPC, generally accepted with a view to securing best possible protection to the applicant in relation to competitors.

41. However, the category of a claim appears to the Board not to be something relevant *per se* where the law enshrines, in the prohibition of patenting, ethical objections against the exploitation of the technology involved in the claimed subject-matter. That is probably what the Examining Division intended to express.

On the origin of Article 6(2)(c) of the Directive and the implications for Rule 23d(c) EPC

42. As regards the meaning of Article 6(2)(c) of the Directive from which Rule 23d(c) EPC is derived, the Board has doubts that the European legislator, when drafting that subparagraph of Article 6, and thereby excluding from patentability the "following" inventions: "(c) uses of human embryos for industrial or commercial purposes", was thinking in terms of claim categories. It appears more likely that what he was seeking to define was the essence of the inventions which should not be patentable.

43. In the view of the Board, the appellant's comparison with the wording of item (d) of the Directive is not valuable because each of the subparagraphs (a) to (d) of Article 6(2) of the Directive has its own legislative history and its own models in prior legislation or jurisprudence, if any, having served for drafting. Therefore the Board doubts that the correct interpretation to be given to Article 6(2)(c) of the Directive (and thereby to Rule 23d(c) EPC) can be derived from a comparison with the wording of item (d).

44. Said item (d) is concerned with a substantially different subject-matter as compared with the other subparagraphs of Article 6(2), ie with the patenting of genetically modified animals. The terminology of item (d) appears to be somewhat based on the wording of Article 53(b) EPC (although in a different context) and on the principles developed in decision T 19/90 (supra). Item (d) was present initially in a slightly different wording in Article 9(2)(b) of the proposal of the Commission which was submitted on 25 January 1996 (document D19) after the first proposal had failed, and it was thus based on considerations which had already been publicly debated by policy makers since long.

45. By contrast, item (c) was not contained in the second proposal of the Commission but was introduced so to say at the last minute by the European Parliament. Item (c) was proposed to be introduced in Article 6, initially in a slightly different wording, by the Committee on Legal Affairs and Citizens' Rights of the European Parliament in its report of 25 June 1997 (DOC_EN\RR\330\330382) (document D21), after the first reading of the Directive by the European Parliament. It was then proposed as an amendment by a legislative resolution of the European Parliament (COM(95)0661 C4-0063/96 95/0350(COD), OJ C286, 22 September 1997, page 87) and incorporated as proposed in the Commission's amended proposal (OJ C311, 11 October 1997, page 12), but was ultimately again amended to read as is presently the case in the Common Position politically agreed by the Council on 27 November 1997 (Bulletin EU 11-1997, Internal market(19/24)).

46. Thus, the wording of Article 6(2)(c) appears to have been essentially determined by the politically responsible legislative bodies which cannot be presumed to be thinking in terms of patent claim categories (see eg Recital 38 of the Directive: "processes, the use of which") but whose aim was to safeguard that technologies making use of human embryos for a purpose that was regarded as being ethically unacceptable (see in this context Recital 42 of the Directive) should be excluded from patentability as such.

47. Moreover, it appears from the above time schedule that the introduction of item (c) in Article 6 and its redaction were done in a very short period of time and, more importantly, at a point in time where there was an overwhelming interest in bringing the Directive to its adoption, said interest excluding further lengthy discussions on drafting.

48. The appellant also argued that at the point in time when item (c) was introduced in Article 6 the issue of the use of human embryos for the creation of human embryonic stem cells was already known. In its view, the fact that it was not expressly addressed in the directive, be it only in one of the recitals, indicated that the legislator did not want to exclude it from patentability.

49. In opinion No 9 of 28 May 1997 of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission (document D29), stem cells are vaguely referred to in the context of references to research involving human nuclear transfer (cloning techniques). Under the heading "Concerning human implications", it is said in paragraph 1.18: "However, research involving human nuclear transfer could have important therapeutic implications, for example the development of appropriate stem cell cultures for repairing human organs". This vague passage seems to indicate that the Advisers had not yet a clear view of whether and how such techniques could be exploited in practice.

50. Although the present patent application was published already in July 1996, according to the appellant's own submission, the first scientific report of the actual successful establishment of a human embryonic stem cell line (and this in a scientific journal, and not in the general press) was made in November 1998 by authors including the inventor of the application-in-suit (document D16), ie after the adoption of the Directive. Thus, the fact that the Directive does not expressly address the issue of the use of human embryos appears to be of no avail on the basis of the factual situation when the Directive was drafted.

51. Moreover, it appears to be a generally accepted principle that the meaning of a legal provision is not limited to the specific cases the legislator had in mind when drafting the provision (G 1/98, supra, point 5.3 of the reasons).

Third question to the Enlarged Board of Appeal

52. The question reads:

"If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims?"

53. The appellant has accepted that, if Rule 23d(c) EPC is not to be applied, this does not necessarily mean that patentability of the claimed subject-matter could not still be excluded under Article 53(a) EPC.

54. The interpretation to be given to this provision has been a subject of several decisions of the Boards of Appeal mostly in the field of biotechnology (T 19/90, T 315/03 (animals) T 356/93 (plants), T 272/95 (human genes), supra) but the Board is aware of only one decision of the Enlarged Board of Appeal in which the issue was addressed, ie decision G 1/98, loc.cit, point 3.3.3 of the reasons.

55. The appellant has submitted that the "balancing test" as applied in decision T 19/90 (supra) with respect to the issue of patenting of animals should also be applied in the present case. The Board has doubts whether, when it comes to human life, it would be ethically acceptable to make a decision by weighing the interests of human beings who could potentially benefit from the exploitation of the technology against a right, if any, of human embryos (whether or not they can already be qualified as human beings), to get to life and of not being destroyed for the benefit of others.

56. The Board will not add more on this matter than just voicing its doubts on the position advocated by the appellant.

Fourth question to the Enlarged Board of Appeal

57. The question reads:

"In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: eg derivation from available human embryonic cell lines)?"

58. The appellant has submitted that the relevant point in time for determining whether or not the claimed products could be obtained without having to recur to the destruction of human embryos was the date on which the decision on the patentability of the subject-matter was taken. Moreover, the appellant regards as relevant that, as compared with the point in time when the Directive was drafted and came into force, the attitude towards human stem cell technology was changing into a more favourable direction.

59. The Board understands this submission to mean that unlike for the general requirements for patentability set out in Articles 83, 54 or 56 EPC, for the determination whether the claimed subject-matter concerns an invention falling under Rule 23d(c) EPC or the exploitation of which would be contrary to "ordre public" or morality within the meaning of Article 53(a) EPC the factual and legal situation subsisting when the decision is given is the relevant one.

60. In decision T 315/03 (supra), the contrary has been held as regards the application of both Rule 23d and Article 53(a) EPC (Headnotes IV and VI.4). In the said decision it was held that assessment of a "Rule 23d(d) type" or a "real" Article 53(a) EPC assessment is made as of the filing or priority date; evidence arising after that date may be taken into account provided it is directed to the position at that date.

61. It will be for the Enlarged Board of Appeal to decide whether or not this approach is correct should this issue turn out to be relevant in view of the Enlarged Board's answer to the preceding questions 1 to 3.

Order

For these reasons it is decided that:

The following questions are referred to the Enlarged Board of Appeal for decision:

1. Does Rule 23d(c) EPC apply to an application filed before the entry into force of the rule?
2. If the answer to question 1 is yes, does Rule 23d(c) EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which - as described in the application - at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?
3. If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims?
4. In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: eg derivation from available human embryonic cell lines)?

Annex 1

List of the documents in the present appeal proceedings

(D1) Ariff Bongso et al., Human Reproduction, Vol. 9, No. 11, 1994, Pages 2110 to 2117

(D2) Benjamin E. Reubinoff et al., Nature Biotechnology, Vol. 18, April 2000, Pages 399 to 404

(D3) Printout retrieved on 13 May 2005 from the internet site: <http://escr.nih.gov/>

(D4) Common Position (EC) N° 19/98, Official Journal of the European Communities, 8 April 1998, Pages C110/17 to C110/34

(D5) Directive 98/44/EC of the European Parliament and of the Council, Official Journal of the European Communities, 30 July 1998, Pages L213/13 to L213/21

(D6) Statement by the European Patent Office concerning the resolution of the European Parliament of 4 October 2001 on the patenting of BRCA1 and BRCA2 ("breast cancer") genes, document CA/145/01 e, 17 October 2001

(D7) Decision T 356/93, OJ EPO 1995, 545

(D8) Decision G 1/98, OJ EPO 2000, 111

(D9) Interlocutory decision of the opposition division dated 21 July 2003 concerning European patent 0 695 351

(D10) Interlocutory decision of the opposition division dated 16 January 2003 concerning European patent 0 169 672

(D11) Document of uncertain origin dated September 2002 with the title "Stem Cells: A Primer / National Institutes of Health"

(D12) Undated document of uncertain origin entitled "Executive summary"

(D13) Printout retrieved on 4 November 2003 from the internet site:
<http://europa.eu.int/comm/research/quality-of-life/stemcells/about.html>

(D14) Opinion No. 15 of the European Group on Ethics in Science and New Technologies to the European Commission, 14 November 2000, Pages 1 to 20

(D15) James A. Thomson et al., Proc. Natl. Acad. Sci. USA, Vol. 92, August 1995, Pages 7844 to 7848

(D16) James A. Thomson et al., Science, Vol. 282, 6 November 1998, Pages 1145 to 1147

(D17) Lori P. Knowles, Nature Biotechnology, Vol. 22, No. 2, February 2004, Pages 157 to 163

(D18) Report from the Commission to the European Parliament and the Council, document COM(2002) 545 final, 7 October 2002

(D19) Proposal for a European Parliament and Council Directive on the legal protection of biotechnical inventions, document 96/C 296/03, COM(95) 661 final - 95/0350(COD), Official Journal of the European Communities, 8 November 1996, Pages C 296/4 to C 296/10

(D20) Opinion of the Economic and Social Committee on the 'Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions', document 96/C 295/03, Official Journal of the European Communities, 7 October 1996, Pages C 295/11 to C 295/17

(D21) Report by the Committee on Legal Affairs and Citizen's Rights on the proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions, document DOC_EN\RR\330\330382, 25 June 1997, Pages 1 to 73

(D22) Interlocutory decision of the opposition division dated 16 August 2001 concerning European patent 0 322 240/88312222.8, as published in E.P.O.R., Issue 1, Sweet & Maxwell Limited, Pages 16 to 23

(D23) Printout dated 26 April 2004 retrieved from the internet site <http://www.eel.nl/cases/HvJEG/698j0377ag.htm>, concerning the opinion of Advocate General Jacobs delivered on 14 June 2001, Pages 1 to 37

(D24) Judgment of the European Court in Case C-377/98 on 9 October 2001, Pages 1 to 12

(D25) Survey on opinions from National Ethics Committees or similar bodies, public debate and national legislation in relation to human embryonic stem cell research and use, Vol. I, Edited by Line Matthiessen-Guyader, July 2004, Pages 1 to 87

(D26) Opinion No. 8 of the group of advisers on the ethical implications of biotechnology to the European Commission, 25 September 1996

(D27) Decision T 320/87, OJ EPO 1990, 71

(D28) Decision T 19/90, OJ EPO 1990, 476

(D29) Opinion No. 9 of the group of advisers on the ethical implications of biotechnology to the European Commission, 28 May 1997