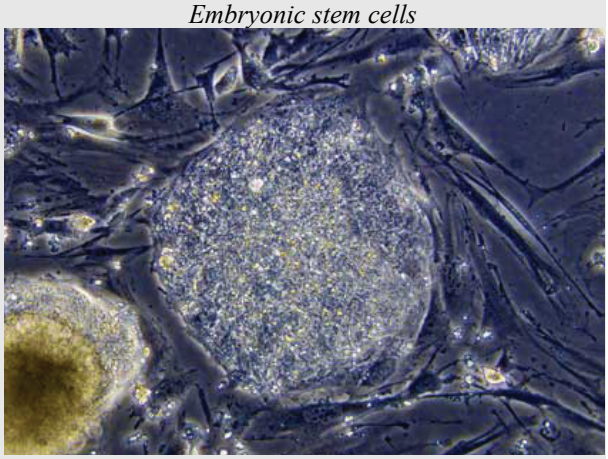
Enlarged Board of Appeal, 25 November 2008, Stem cells

Embryonic stem cells



PATENT LAW

Request for preliminary ruling by ECJ inadmissable

- **The request for a preliminary ruling by the European Court of Justice on the questions suggested is rejected as inadmissible.**

Application Rule 28(c) EPC to all pending applications

- **Rule 28(c) EPC (formerly Rule 23d(c) EPC) applies to all pending applications, including those filed before the entry into force of the rule.**

Products derived from destruction of human embryos excluded from patentability

- **No patenting of products prepared exclusively by method involving destruction of human embryos, even if method is not claimed**

Rule 28(c) EPC (formerly Rule 23d(c) EPC) forbids the patenting of claims directed to products 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, even if the said method is not part of the claims.

- **not 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.**

For the reasons given above, the Enlarged Board of Appeal comes to the conclusion that the legislators (both the legislator of the Implementing Regulations to the EPC and of the Directive) wanted to exclude inventions such as the one underlying this referral from patentability and that in doing so, they have remained within the scope of Article 53(a) EPC and of the TRIPS Agreement. In view of this result, it is not necessary nor indeed appropriate to discuss further arguments and points of view put forward in these proceedings such as whether the standard of ordre public or morality should be a European one or not, whether it matters if research in certain European countries involving the destruction of human embryos to obtain stem cells is permitted, whether the benefits of the invention for humanity should be balanced against the prejudice to the embryo, or what the point in time is to assess ordre public or morality under Article 53a EPC. The legislators have decided, remaining within the ambit of Article 53(a) EPC, and there is no room for manoeuvre.

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Enlarged Board of Appeal, 25 November 2008
(P. Messerli, S. Perryman, P. Alting van Geusau, U. Kinkeldey, M. Scuffi, J.-P Seitz, O. Spineaunu-Metai)
Decision of the Enlarged Board of Appeal dated 25 November 2008
G 2/06
(Language of the proceedings)
Composition of the Board:
Chairman: P. Messerli
Members: S. Perryman, P. Alting Van Geusau, U. Kinkeldey, M. Scuffi, J.-P. Seitz, O. Spineanu-Metai
Appellant/Applicant: WISCONSIN ALUMNI RESEARCH FOUNDATION
Headword: Use of embryos/WARF
"Admissibility of referral (yes)" – "Referral for preliminary ruling by European Court of justice (no) – request not admissible, as no power to make such referral under EPC" – "Rule 28(c) (formerly 23d(c)) EPC applicable to pending applications filed before it came into force (yes)" – "Rule 28(c) (formerly 23d(c)) EPC intra vires Article 53(a) EPC and in conformity with TRIPS Article 27 (yes)" – "Exception to patentability of Rule 28(c) (formerly 23d(c)) EPC applicable where claimed product could be prepared exclusively by method necessarily involving the destruction of embryos even if method is not explicitly part of claims (yes)" – "In assessing the exception to patentability of Rule 28(c) (formerly 23d(c)) EPC technical developments after date of filing not of relevance"
Headnote
1.
Summary of facts and submissions
I. In its decision T 1374/04 (OJ EPO 2007, 313) Stem cells/WARF, Technical Board of Appeal 3.3.08 referred the following points of law to the Enlarged Board of Appeal:
1. Does Rule 23d(c) [now 28(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) [now 28(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: e.g. derivation from available human embryonic cell lines)?
(To facilitate understanding, hereinafter the Rules of the Implementing Regulations to the European Patent Convention are cited as numbered according to the amended Implementing Regulations to the European Patent Convention which entered into force on 13 December 2007, with the old numbering given in brackets, except when quoting decisions, legislation or the referral questions.)
II. The appeal pending before the referring Board 3.3.08 is against the decision of 13 July 2004 of the Examining Division, refusing European patent application No. 96 903 521.1. This decision related to a set of claims 1 to 10 of which Claim 1 reads:
"1. A cell culture comprising primate embryonic stem cells which (i) are capable of proliferation in vitro [sic] 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."
III. The Examining Division refused the application under Article 97(1) EPC 1973 for the reason that claims 1 to 7, 9 and 10 did not comply with the requirements of Article 53(a) EPC 1973 in conjunction with Rule 23d(c) [now 28(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 (i.e. the claimed embryonic stem cell cultures) meant a use thereof for industrial purposes within the meaning of Rule 23d(c) [now 28(c)] EPC and was thus prohibited under the said provision in conjunction with Article 53(a) EPC 1973. The provisions of Rule 23d(c) [now 28(c)] EPC in conjunction with Article 53(a) EPC 1973 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.
IV. Board of Appeal 3.3.08 considered 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(1)(a) EPC for which a decision by the Enlarged Board of Appeal is required.
V. The Enlarged Board of Appeal asked the President of the European Patent Office (hereinafter "EPO") to comment on the case, and also issued an invitation for third parties to file comments. On 20 March 2008 the Enlarged Board of Appeal sent a summons to attend oral proceedings accompanied by a communication drawing attention to some legal issues that seemed of potential significance.
VI. The main points submitted by the Appellant in written submissions of 31 October 2006 and 22 May 2008, and at the oral proceedings on 24 June 2008 can be summarized as follows: Introductory comment:
– In 1998 the named inventor using the methods suggested in the application was the first to successfully isolate and culture human embryonic stem cells that can grow in vitro. The provision of these is a major scientific breakthrough and pioneering invention opening up a new and very exciting field of research having great potential for promising medical therapies and other applications, and worthy of patent protection. Relating to a reference to the European Court of Justice (hereinafter ECJ):
– Since Rule 28(c) (formerly 23d(c)) EPC repeats the wording of Article 6(2) (c) of the Directive 98/44/EC of 6 July 1998 (hereinafter "the Directive"), the Enlarged Board of Appeal in interpreting Rule 28(c) (formerly 23d(c)) EPC is interpreting the law of the European Union (hereinafter "EU") and is required by Article 234 of the Consolidated Version of the Treaty establishing the European Community in force since 1 February 2003 under the Treaty of Nice signed 26 February 2001 (hereinafter "EC Treaty"), as a court or tribunal of a member state against whose decision there is no judicial remedy to ask for a ruling by the ECJ, in the present situation where the interpretation of Article 6(2)(c) of the Directive is not free of doubt (i.e. not acte clair).
– The Enlarged Board of Appeal meets the ECJ criteria of being a court or tribunal, and ECJ Case C-337/95 ("Dior v. Evora") is a precedent for a court under an international treaty and having jurisdiction for more than a single EU member state asking for a ruling. Further the vast majority of EPC states are Member States of the EU and the Enlarged Board of Appeal sits in such a state.
– Not asking the ECJ for a ruling now, bears the risk that national courts will subsequently apply (and be obliged to apply) an interpretation of Article 6 of the Directive which does not accord with that applied by the EPO.
Relating to question 1:
– Rule 28(c) (formerly 23d(c)) EPC applies to pending European patent applications filed before its entry into force. It does not change the law, nor render immoral that which formerly was not, nor seek to define new classes of acts which are contrary to ordre public.
Relating to questions 2 and 3:
– The prohibition of Rule 28(c) (formerly 23d(c)) EPC must be interpreted in the context of Article 53(a) EPC and Article 27(2) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter "TRIPS Agreement") as only applicable where the commercial exploitation of the invention is contrary to ordre public or morality. The forbidden exploitation

must be something contravening the underlying legal principles of all contracting states.
– The correct approach to Rule 28(c) (formerly 23d(c)) EPC is to identify the claimed monopoly and ask whether that monopoly embraces the "use of an embryo for an industrial or commercial purpose". A claim to an embryonic stem cell is not a monopoly to "the use of an embryo" still less to "the use of an embryo for an industrial or commercial purpose". At most an embryonic stem cell is a product which ultimately was derived from an embryo. As there is no constitutional tradition common to member states that a pre-14 day embryo should not be used for stem cell research (which itself is not contrary to such unitary values, nor outlawed by international treaty) there is no reason to forbid patenting of a use involving extracting some cells from a pre-embryo (that is one less than 14 days old in accordance with usage in the medical field) as suggested in the application. The obtaining of a cell from the inner cell mass of an embryo to start a stem cell line with which to embark upon pioneering therapy is not in any real sense performing an industrial or commercial act.
– Had the Directive sought to exclude acts which fall outside the monopoly claimed but which may be preparatory to working an invention alternative words could and would have been used. In particular if the Directive was intended to exclude from patentability products derived from human embryos it would have explicitly said so. Thus some uses of embryos, for example in patents which were not directly aimed at industrial and commercial purposes but were directed at pioneering therapies, are not to be excluded from patentability. Such a construction of Rule 28(c) (formerly 23d(c)) EPC is consistent with the mischief to which objection is taken; being the commercialisation of embryos themselves, in distinction to tissues or cells derived from embryos.
– The question of the patentability of processes relating to embryos was first raised in the Opinion No 9 of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission (GAEIB) in a report of 28 May 1997 who expressed concern about human cloning, but no desire to hamper therapeutic stem cell research. In the light of this opinion it was proposed there should be a prohibition against the patenting of "methods in which human embryos are used". This provision was modified by the Council of Ministers to its present wording relating to prohibiting patenting of "uses of human embryos for industrial or commercial purposes". The change was influenced by UK government submissions based on UK legislative provision for licences to be granted for the use of pre-14 day embryos for research or the treatment of disease. The words "uses of human embryos for industrial and commercial purposes" in the Directive are, in the light of the UK's position, seeking to identify a class of unacceptable uses on the one hand which contrasts with a class of acceptable uses on the other. That negotiations at highest level within the EU were involved, means that the use of the words "industrial and commercial" in Article 6(2)(c) of the Directive cannot be treated merely as a reference to the pre-requisite for any patent of there being "industrial applicability".
Relating to question 4:
– That technical developments after the date of application might allow the claimed subject matter to be made by a method not involving the use of any embryos is irrelevant. The use of embryos in the present case is anyway outside the prohibition of Rule 28(c) (formerly 23d(c)) EPC.
VII. The main points made on behalf of the President of the European Patent Office in writing and at the oral proceed- ings can be summarized as follows: Relating to a reference to the ECJ:
– The Boards of Appeal of the EPO are not courts or tribunals of a member state of the EU, and there is no power under the EPC for a Board of Appeal to refer questions to the ECJ.
Relating to question 1:
– Rule 28(c) (formerly 23d(c)) EPC has immediate effect and applies to European patent applications filed before its entry into force. The principle of legitimate expectations and/or acquired rights cannot be extended to the point of preventing this rule from applying to the future effects of situations which arose under earlier rules.
Relating to question 2:
– The ratio legis of Rule 28(c) (formerly 23d(c)) EPC is the prohibition of misuses or the commodification of embryos.
– The relevant question for the patenting prohibition enshrined in Rule 28(c) (formerly 23d(c)) EPC is whether the technical contribution to the prior art, which is to be determined on the basis of the relevant disclosure, amounts to uses of human embryos for industrial or commercial purposes. The claim category per se is irrelevant. Hence, where the skilled person wishing to perform or reproduce the invention cannot succeed unless he follows the steps of some specific technical means or methods disclosed in the application which form an integral part of the technical contribution to the prior art, those technical means or methods are to be taken into consideration for the purposes of Rule 28(c) (formerly 23d(c)) EPC.
– The exception to Rule 28(c) (formerly 23d(c)) EPC stipulated in Recital 42 of the Directive should apply in any case where it can be established from the relevant invention that it serves a therapeutic or diagnostic purpose for the used embryo. Usefulness to the individual embryo presupposes that the used embryo is still in existence and is not irreversibly destroyed.
– That the legislator used the term "embryo" without giving any precise definition of it, was deliberate, and means that "embryo" should not be interpreted in any specially restricted sense.
Relating to question 3:
– In situations where Rule 28(c) (formerly 23d(c)) EPC is applicable, the legislator has predetermined a genuine European ordre public and morality, in substance and in time, falling under Article 53(a) EPC, which is binding on the relevant departments of the EPO.

VIII. Numerous submissions were made by third parties, of which some were made in identical form by hundreds of individuals. Points made therein included the following:
Relating to question 1:
– The large majority considered that Rule 28(c) (formerly 23d(c)) EPC was applicable also to applications pending at the date of its introduction, but the opinion was also expressed that it amounted to a change in law which should only be applicable to applications filed after its introduction.
Relating to question 2:
In favour of patenting it was submitted:
– that there should be no prohibition of patenting if the use of a human embryo was not mentioned in the claims.
– that the potential benefit to humanity should lead to a restrictive interpretation of Rule 28(c) (formerly 23d(c)) EPC, so that patenting should be possible in this case.
Against patenting it was submitted
– that it was not relevant that the use of a human embryo was not explicitly in the claim: if the use of human embryos was necessary to put into practice a claimed invention such a claim fell within the prohibition, otherwise a circumvention of the prohibition would be easy.
– that the clear intention of the legislator was to prevent the commercialization of embryos. Both the clear intention of the legislator and general moral and ethical considerations prohibited patenting of uses of embryos which would lead to their commercial exploitation.
IX. Oral proceedings took place on 24 June 2008. For the Appellant the representatives requested to answer question 1 of the referral with: yes; question 2 of the referral with: no; question 3 of the referral with: no; question 4 of the referral with: no. It was also requested that the Enlarged Board refer to the European Court of Justice the following questions:
1. Under Article 6(2)(c) of Directive 98/ 44/EC of 6th July 1998 is a Member State permitted to 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?
2. If the answer to question 1 is no, does Article 6(1) of the Directive mean a Member State is permitted to forbid patenting such claims?
X. At the end of the oral proceedings, the Chairman closed the debate and announced that the decision would be given in writing.

Reasons for the decision

Admissibility

1. The Enlarged Board of Appeal is satisfied that answers to at least referred Questions 1 and 2 are necessary for the referring Board to dispose of the appeal before it on the correct legal basis. The referral is thus admissible. Referral for a preliminary ruling by the European Court of Justice
2. Since the Appellant is seeking referral of questions to the ECJ on the argument that since Rule 28(c) (formerly 23d(c)) EPC repeats the wording of Article 6(2)(c) of the Directive, the Enlarged Board of Appeal in interpreting Rule 28(c) (formerly 23d(c)) EPC is interpreting European Union law and should refer the question of interpretation to the ECJ, it is convenient to deal with this as a preliminary point.
3. Neither the EPC nor the Implementing Regulations thereto make any provision for a referral by any instance of the EPO of questions of law to the ECJ. The Boards of Appeal are a creation of the EPC, and their powers are limited to those given in the EPC. Prima facie the conclusion must be that the absence of any provision enabling such a referral makes such referral impossible.
4. Nor does Article 234 of the EC Treaty giving the ECJ jurisdiction to give preliminary rulings concerning inter alia the validity and interpretation of acts of the institutions of the European Community, such as the Directive, appear to provide any basis for a Board of Appeal of the EPO to request the ECJ to give a ruling on any questions before such Board of Appeal. Article 234 of the EC Treaty requires the question to be raised in a case pending before a court or tribunal of an EU member state. Whereas EPO Boards of Appeal have been recognized as being courts or tribunals, they are not courts or tribunals of an EU member state but of an international organization whose contracting states are not all members of the EU.
5. The Administrative Council of the EPO as legislator responsible for the Implementing Regulations found it necessary to introduce what are now Rules 26 to 29 (formerly 23b to 23e) EPC so that the provisions of the EPC correspond to those of the Directive. Thereby all Contracting States to the EPC, even those not members of the EU, have indi- cated their will that these rules be used to interpret the EPC when considering whether or not a European patent should be granted. But this cannot be taken as conferring some new power or imposing some new obligation on the Boards of Appeal to ask for an interpretation by the ECJ of the EPC or its Implementing Regulations. Certainly the Contracting States to the EPC which are not member states of the EU cannot be presumed to have conferred jurisdiction on the ECJ.
6. The mere identity of the wording of Rule 28(c) (formerly 23d(c)) EPC and of Article 6(2)(c) of the Directive cannot lead to the conclusion that the ECJ now has jurisdiction to decide matters for the EPO under the EPC. The Boards of Appeal apply the provision because it is law under a specific Rule of the Implementing Regulations to the EPC, and not because the Directive is a source of law to be applied directly. This is corroborated by the fact that Rule 26(1) (formerly 23b(1)) EPC only states that the Direc- tive shall be used as a supplementary means of interpretation of Rules 26 to 29 (formerly 23b to 23e) EPC.

7. Article 23(3) EPC provides that in their decisions the members of the Boards shall not be bound by any instructions and shall comply only with the provisions of this Convention. While Article 23(3) EPC is in its present form, the Enlarged Board concludes 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) (formerly 23d(c)) EPC.
8. The Enlarged Board has not been made aware of any precedent for asking the ECJ for a consultative opinion and it must be questionable whether the ECJ would entertain such a request in a situation where it would be unclear as to who would be entitled to make submissions to the ECJ on any questions submitted.
9. The Appellant seeks to rely on **ECJ Case C-337/95 ("Dior v. Evora")** on the basis that the situation of the Benelux Court being allowed to make references to the ECJ in relation to matters referred to it by the highest courts of Belgium, the Netherlands and Luxembourg suggested a precedent for a referral by the Enlarged Board to the ECJ. Closer consideration destroys this as a suitable precedent. If the Enlarged Board can make a referral under Article 234 of the EC Treaty to the ECJ, then this possibility would also have to apply to each of the EPO Boards of Appeal, because against their decisions too there is no appeal, and a referral to the Enlarged Board by them is optional. The position of a Board of Appeal cannot be compared to that of one of the highest courts of Belgium, the Netherlands and Luxembourg, each of which is clearly a national court of an EU member state entitled to make a referral to the ECJ. The referral in Dior v. Evora was by the Netherlands Hoge Raad, which took it as a premise that either it or the Benelux Court could make a refer- ence to the ECJ but wished to know whether it was obliged itself to make a reference or could leave it to the Benelux Court as the highest court for matters governed by the Benelux treaty. Further the latter is a special treaty set up with permission of the European Community authorities as a regional treaty. The Benelux Court is composed of three judges from each of the highest courts of Belgium, the Netherlands and Luxembourg, and this position as a national judge is a requirement for being a member of the Benelux Court. The Benelux Court can thus be considered in relation to matters for which it has jurisdiction under the Benelux treaty as the highest national court of each of these three EU states. In contrast to this, some or possibly even all the members of a Board of Appeal might not even be nationals of an EU state. The Enlarged Board of Appeal is unable to deduce from Dior v. Evora anything suggesting that the ECJ would regard a reference by an EPO Board of Appeal as permissible under Article 234 of the EC Treaty.
10. That the seat of the EPO Boards of Appeal is in a member state of the EU, Germany, cannot alter their status as part of an international organisation with jurisdiction conferred under the EPC. The EPO Boards of Appeal are not and have never been treated as courts or tribunals of their host country.
11. For the above reasons the Enlarged Board concludes that it has no power to ask the ECJ for a preliminary ruling under the existing provisions of the EPC, so that the request for referral of the questions for a preliminary ruling by the European Court of Justice must be refused as inadmissible.

Q1. Does Rule 23d(c) [now 28(c)] EPC apply to an application filed before the entry into force of the rule?

12. By its decision of 16 June 1999, the Administrative Council of the EPO inserted a new Chapter VI (now V) entitled "Biotechnological inventions" into Part II of the EPC Implementing Regulations. These new provisions entered into force on 1 September 1999, thus transposing the Directive on the legal protection of biotechnological inventions into the European Patent law. Rule 26(1) (formerly 23b(1)) EPC expressly provides that the relevant provisions of the Convention shall be applied to European patent applications and patents concerning biotechnological inventions in accordance with the provision of this new chapter, and that the Directive shall be used as a supplementary means of interpretation. No transitional provisions for pending cases were adopted. Rule 28 (formerly 23d) EPC on "Exceptions to patentability" expressly refers to Article 53(a) EPC.
13. The introduction of this new chapter without any transitional provisions, can only be taken as meaning that this detailed guidance on what was patentable and unpatentable was to be applied as a whole to all then pending applications. It has not been argued that Rule 28 (formerly 23d) EPC took away the possibility to patent anything which had previously been regarded as patentable under Article 53(a) EPC, nor that the Directive did so (see in this respect the reference in Art. 6(1) to what is contained in Article 53(a) EPC as well as the reference to the TRIPS Agreement in Article 1(2)). Already by 1984 (see Dolder, Mitteilungen der Deutschen Patentanwälte, 1984, 1, "Barriers to patentability of biotechnological inventions under the EPC"), instrumentalization of the human body (as opposed to parts of it), thus degrading it to an object of technology, had been considered as a barrier to patentability. There is no indication that the commercial exploitation of human embryos was ever regarded as patentable.
14. In view of the above, the answer to referred Question 1 must be that Rule 28(c) (formerly 23d(c)) EPC applies to all pending applications, even those filed before the entry into force of the rule. As the Appellant itself agrees with this answer, as does the Presid ent of the EPO and the vast majority of the amicus curiae briefs, nothing more need be said.

Q2. If the answer to question 1 is yes,does Rule 23d(c) [now 28(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?

15. The present invention concerns inter alia human embryonic stem cell cultures which at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which they are derived, said method not being part of the claims. Rule 28 (formerly 23d) EPC provides, inter alia: "Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern ... (c) uses of human embryos for industrial or commercial purposes". The question thus is whether the present invention falls under the prohibition of this provision.

16. When looking at the travaux prépara- toires relating to the introduction of Rules 26 to 29 (formerly 23b to e) EPC, it becomes apparent that the aim was to align the EPC to the Directive. This follows from the Notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the European Patent Convention (OJ 1999, 575) and is also evidenced by the fact that, according to Rule 26(1) (formerly 23b(1)) EPC, the Directive shall be used as a supplementary means of interpretation. Therefore, the Enlarged Board of Appeal turns to the interpretation of Article 6(2) of the Directive, which corresponds to Rule 28 (formerly 23d) EPC. Although the Directive is not a treaty, the Enlarged Board of Appeal will, in view of the reference in Rule 26(1) EPC just mentioned and in line with the established case law (see eg G 5/83, OJ EPO 1985, 064, G 1/84, OJ 1985, 299, J 16/96, OJ 1998, 347) apply mutatis mutandis the general rules laid down in the Vienna Convention on the Law of Treaties. It will thus look at the ordinary meaning to be given to the terms of a provision in its context and in the light of its object and purpose, including the preparatory documents.

17. The first drafts of the Directive did not contain any specific prohibition relating to the use of human embryos. In the Opinion by the Economic and Social Committee of the European Parliament adopted on 11 July 1996 (Official Journal of the EC of 7.10.96, pages C 295/11-18) proposals were made to specifically exclude the human embryo from patentability (see section 4.3.2) and to indicate the committee's total opposition to practices involving the misuse of human embryos (see section 4.7.2). In the amended proposal for the Directive submitted by the Commission in 1997 (Official Journal of the EC of 11.10.97 pages C 311/12-30) there appears the following text:

Article 6

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to public policy or morality; however, exploitation shall not be deemed contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following shall be considered unpatentable:

(a) ...

(b) ...

(c) methods in which human embryos
are used;

(d) ...

Finally in the Common Position EC No 19/98 adopted by the Council on 26 February 1998 (Official Journal of the EC 8.4.98 C 110/17), the text of Article 6(2)c was amended to read "uses of human embryos for industrial or commercial purposes". This is also the text of Article 6(2)(c) of the final version of the Directive that was adopted on 6 July 1998.

18. On its face, the provision of Article 6(2)(c) of the Directive and thus also of Rule 28(c) (formerly 23d(c)) EPC is straightforward and prohibits the patenting if a human embryo is used for industrial or commercial purposes. Such a reading is also in line with the concern of the legislator to prevent a misuse in the sense of a commodification of human embryos (see the decision of the German Bundespatentgericht (BPatG) of 5 December 2006, 3 Ni 42/04, point IV 2.2 i.f.) and with one of the essential objectives of the whole Directive to protect human dignity. This concern is also evidenced by the selective policy of the Community in funding stem cell research. The Appellant argues that the very fact that the Community funds such research shows that the legislator did not want to exclude activities such as those underlying the present invention and which include these (and destruction) of human embryos. However, Council press release 11554/ 06 (Presse 215) of 24 July 2006, states on page 7 that as regards Community Research "... the Commission confirmed that it will continue the current practice and will not submit to the Regulatory Committee proposals for projects which include research activities which destroy human embryos, including for the procurement of stem cells. The exclusion of funding for this step of research will not prevent the Community funding of subsequent steps involving human embryonic stem cells." This selective funding in no way supports the Appel- lant's position.

19. Against a reading of Rule 28(c) (formerly 23d(c)) EPC being applicable to the invention in this case, the Appellant has put forward several arguments. Firstly it argues for a very specific meaning of embryo, as being embryos of 14 days or older, in accordance with usage in the medical field.

20. Neither the EU legislator nor the EPC legislator have chosen to define the term "embryo", as used in the Directive or now in Rule 28 (formerly 23d) EPC. This contrasts with the German law (Gesetz zum Schutz von Embryonen of 13 December 1990, § 8) where embryo is defined as including a fertilized egg, or the UK law (Human Fertilisation and Embryology Act 1990, Section 1(1)) where embryo includes the two cell zygote and an egg in the process of fertilisation. The EU and the EPC legislators must presumably have been aware of the definitions used in national laws on regulating embryos, and yet chose to leave the term undefined. Given the purpose to protect human dignity and prevent the commercialization of embryos, the Enlarged Board can only presume that "embryo" was not to be given any restrictive meaning in Rule 28 (formerly 23d) EPC, as to do so would undermine the intention of the legislator, and that what is an embryo is a question of fact in the context of any particular patent application.

21. Secondly the Appellant contends that, in order to fall under the prohibition of Rule 28(c) (formerly 23d(c)) EPC, the use of human embryos must be claimed.
22. However, this Rule (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.
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.
24. The Appellant further argues that the use of human embryos to make the claimed human embryonic stem cell cultures is not a use "for industrial or commercial purposes", as required by Rule 28(c) (formerly 23d(c)) EPC, but some other form of use not prohibited by this Rule.
25. A claimed new and inventive product must first be made before it can be used. Such making is the ordinary way commercially to exploit the claimed invention and falls within the monopoly granted, as someone having a patent application with a claim directed to this product has on the grant of the patent the right to exclude others from making or using such product. Making the claimed product remains commercial or industrial exploitation of the invention even where there is an intention to use that product for further research. On the facts which this Board must assume in answering the referred question 2, making the claimed product involves the destruction of human embryos. This use involving destruction is thus an integral and essential part of the industrial or commercial exploitation of the claimed invention, and thus violates the prohibition of Rule 28(c) (formerly 23d(c)) EPC.
26. In the context of the terms "for industrial or commercial purposes" used in Rule 28 (formerly 23d) EPC and Article 6(2)c) of the Directive, the Appel-lant has also pointed to the legislative history of the Directive and argued that the replacement of the terms "methods in which human embryos are used" by "uses of human embryos for industrial or commercial purposes" meant a narrowing of the provision, excluding inventions such as the present one from its scope.
27. However, this Board cannot detect such a narrowing. The reason given in Point 37 of the Common Position for this amendment is that a distinction was wanted between the uses of human embryos for industrial or commercial purposes, which were excluded from patentability, and inventions for therapeutic or diagnostic purposes applied to the human embryo and useful to it, the latter not being excluded from patentability. To clarify this exception from the exception, a new Recital 42 was introduced into the Directive. Thus, if anything, these reasons point in the direction of the opinion of this Board that in the present case human embryos are used for industrial or commercial purposes, since patentability was only onsidered if the invention was to the benefit of the embryo itself (compare also decision of the BPatG of 5 December 2006, loc. cit., point IV 3). That this is not the case here is evident, since the embryos used to perform the invention are destroyed.
28. Addressing the relationship of Rule 28(c) (formerly 23d(c)) EPC to Article 53(a) EPC, the Appellant argues that, if the Rule is read to exclude inventions such as the one underlying this case, the Rule would go beyond Article 53(a) EPC and thus be ultra vires (Article 164(2) EPC). By the same token, it would also contravene Article 27 of the TRIPS Agreement, which in this area allows only an exception to patentability within the scope of Article 53(a) EPC.
29. The Enlarged Board of Appeal does not share the opinion that such a reading makes Rule 28(c) (formerly 23d(c)) EPC ultra vires. Article 53(a) EPC excludes inventions from patentability if their commercial exploitation is against ordre public or morality. Reference is made to points 25 to 27 where it has been explained why this Board considers the performing of this invention as commercial exploitation. In this context, it is important to point out that it is not the fact of the patenting itself that is considered to be against ordre public or morality, but it is the performing of the invention, which includes a step (the use involving its destruction of a human embryo) that has to be considered to contravene those concepts.
30. It should be noted that the wording of Article 53(a) EPC now differs slightly from the wording of Article 53(a) EPC 1973. Its text now reads "inventions the publication or commercial exploitation of which would be contrary to "ordre public" or morality , provided that the; such exploitation shall not to be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States" with deletions compared to the EPC 1973 shown struck through and additions in italics. The changes are not relevant to the issues considered in this decision.
31. For the reasons given above, the Enlarged Board of Appeal comes to the conclusion that the legislators (both the legislator of the Implementing Regulations to the EPC and of the Directive) wanted to exclude inventions such as the one underlying this referral from

patentability and that in doing so, they have remained within the scope of Article 53(a) EPC and of the TRIPS Agreement. In view of this result, it is not necessary nor indeed appropriate to discuss further arguments and points of view put forward in these proceedings such as whether the standard of ordre public or morality should be a European one or not, whether it matters if research in certain European countries involving the destruction of human embryos to obtain stem cells is permitted, whether the benefits of the invention for humanity should be balanced against the prejudice to the embryo, or what the point in time is to assess ordre public or morality under Article 53a EPC. The legislators have decided, remaining within the ambit of Article 53(a) EPC, and there is no room for manoeuvre.

Q3. If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims?

32. Question 3 does not need answering, since the Enlarged Board has held that Rule 28(c) (formerly 23d(c)) EPC is applicable, that it is within the scope of Article 53(a) EPC, and that it forbids the patenting of products which at the filing date could be prepared exclusively by a method necessarily involving the destruction of human embryos from which said products are derived, so that the answers to questions 1 and 2 is yes.

Q4. 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)?

33. When assessing whether a claim contravenes Rule 28(c) (formerly 23d(c)) EPC, technical developments which became publicly available only after the filing date cannot be taken into consideration. It cannot be relevant whether later either the applicant himself or others made something further available that would then have allowed the product to be made in an innocuous manner. Similarly to the case of an invention which is insufficiently described in the application as filed to be carried out, lack of any disclosure in the application as filed putting the skilled person in possession of a way to carry out the invention complying with Rule 28(c) (formerly 23d(c)) EPC cannot be cured by the occurrence of subsequent technical developments. Any other conclusion would lead to legal uncertainty, and risk being to the detriment of any third party who later provided an innocuous way to carry out the invention.

34. Thus question 4 must be answered to the effect that it is not 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.

35. In view of the questions referred, this decision is not concerned with the patentability in general of inventions relating to human stem cells or human stem cell cultures. It holds unpatentable inventions concerning products (here: human stem cell cultures) which can only be obtained by the use involving their destruction of human embryos.

Order

For these reasons it is decided that:

1. The request for a preliminary ruling by the European Court of Justice on the questions suggested is rejected as inadmissible.

2. The questions referred to the Enlarged Board of Appeal are answered as follows:

Question 1: Rule 28(c) EPC (formerly Rule 23d(c) EPC) applies to all pending applications, including those filed before the entry into force of the rule.

Question 2: Rule 28(c) EPC (formerly Rule 23d(c) EPC) forbids the patenting of claims directed to products 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, even if the said method is not part of the claims.

Question 3: No answer is required since Questions 1 and 2 have been answered with yes.

Question 4: In the context of the answer to question 2 it is not 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.