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Datasheet for the decision of 26 June 2019

Case Number: T 1781/16 - 3.3.08

Application Number: 01903136.8

Publication Number: 1252293

IPC: C12N5/071, C12N5/074

Language of the proceedings: EN

Title of invention:
Liver tissue source

Patent Proprietor:
University of North Carolina at Chapel Hill

Opponent:
Grund, Dr., Martin

Headword:
Liver tissue/UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL

Relevant legal provisions:
EPC Art. 111(1), 113(1), 123(2)
EPC R. 103(1)(a), 115(2)
RPBA Art. 13(1), 15(3)

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It can be changed at any time and without notice.

Keyword:
Right to be heard - violation (no)
Remittal to the department of first instance (no)
Main request and auxiliary requests 1 to 5 - added subject matter (yes)

Decisions cited:
G 0002/10

Catchword:

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1781/16 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 26 June 2019

Appellant: (Patent Proprietor)	University of North Carolina at Chapel Hill 308 Bynum Hall, Campus Box 4105 Chapel Hill, NC 27599-4105 (US)
Representative:	Swinkels, Bart Willem Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Respondent: (Opponent)	Grund, Dr., Martin Nikolaistr. 15 80802 Munich (DE)
Representative:	Grund, Martin Mester, Gabor Grund Intellectual Property Group Patentanwalt und Solicitor PartG mbB Postfach 44 05 16 80754 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 24 May 2016 revoking European patent No. 1252293 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	B. Stolz
Members:	M. Montrone
	D. Rogers

Summary of Facts and Submissions

I. An appeal was lodged by the patent proprietor (hereinafter the "appellant") against the decision of an opposition division to revoke the European patent No. 1 252 293, having the title "Liver tissue source". The patent was filed under the PCT and published as international patent application WO 01/53462 (hereinafter the "patent application").

II. With its statement of grounds of appeal, the appellant submitted a main request (corresponding to auxiliary request 2 dealt with in the decision under appeal), and three new auxiliary requests (auxiliary requests 1 to 3).

III. In reply, the opponent (hereafter the "respondent") submitted arguments *inter alia* as to why the new auxiliary requests should not be admitted into the appeal proceedings, and that all claim requests contravened Article 123(2) EPC.

IV. In reply, the appellant submitted amended versions of auxiliary requests 1 to 3, and new auxiliary requests 4 and 5.

V. In reply, the respondent provided *inter alia* additional arguments against the admission of auxiliary requests 1 to 5 into the proceedings.

VI. The parties were summoned to oral proceedings. In a communication pursuant to Article 15(1) RPBA, the parties were informed of the board's provisional, non-binding opinion on some of the legal and substantive matters of the case. In reply thereto, the appellant announced that it would not be attending the oral

proceedings without submitting substantive arguments in response to any of the issues raised in the board's communication.

VII. Oral proceedings before the board were held on 26 June 2019, in the absence of the appellant.

VIII. Claim 1 of the main request reads:

"1. A method of processing non-fetal donor liver tissue to obtain an enriched population of liver progenitor cells comprising:

(a) providing non-fetal donor tissue obtained from a donor whose heartbeat has ceased, within 30 hours postmortem but not during the period within three hours after the heartbeat ceased; and

(b) processing said non-fetal donor tissue to obtain an enriched population of liver progenitor cells".

IX. The subject-matter of claim 1 of auxiliary request 1 differs from that of the main request in that the feature "*donor*" in step a) has been replaced by "*a human donor of up to 45 years of age*".

X. The subject-matter of claim 1 of auxiliary request 2 differs from that of the main request in that the feature "*donor*" in step a) has been replaced by "*a human neonate, infant, child or juvenile donor*".

XI. The subject-matter of claim 1 of auxiliary request 3 differs from that of the main request in that the feature "*donor*" in step a) has been replaced by "*a human neonate, infant or child donor*".

XII. The subject-matter of claim 1 of auxiliary request 4 differs from that of the main request in that in step a) the feature "*donor*" has been replaced by "*a human neonate, infant or child donor*", and in that the feature "*the period within three hours*" has been replaced by "*the period within six hours*".

XIII. The subject-matter of claim 1 of auxiliary request 5 differs from claim 1 of the main request in that in step a) the feature "*donor*" has been replaced by "*a human donor of up to 45 years of age*", and in that the feature "*the period within three hours after the heartbeat ceased*" has been replaced by "*the period within two hours postmortem*".

XIV. The appellant's submissions in writing, insofar as relevant to the present decision, may be summarised as follows:

Reimbursement of the appeal fee due to a substantial procedural violation and remittal of the case to the opposition division

The respondent (opponent) presented during the oral proceedings before the opposition division for the first time an entirely new objection under Article 83 EPC. This objection took the appellant's representative by surprise, and since the patent proprietor/inventors were all residing in the US, i.e. in a different time zone, the issue could not be discussed. Furthermore, this new objection became the key issue on the basis of which the opposition division rejected all auxiliary requests under consideration, which as a consequence, led to the revocation of the patent. Moreover, the opposition division expressed an unwillingness to admit further claim requests. This situation prevented the

appellant from adequately defending its case, amounting to a substantial procedural violation justifying the reimbursement of the appeal fee, and a remittal of the case to the opposition division.

Admission of auxiliary requests 1 to 5 all filed by the appellant with its letter of 18 December 2017

Auxiliary requests 1 to 5 should be admitted into the proceedings, since they could not have been submitted earlier. Auxiliary requests 1 to 3 addressed an issue under Article 83 EPC that came up only during the oral proceedings before the opposition division. Auxiliary requests 4 and 5 addressed an issue under Article 123(3) EPC that was raised by the respondent for the first time in it's reply to the statement of grounds of appeal.

Main request and auxiliary requests 1 to 5

Article 123(2) EPC - claim 1

The subject-matter of claim 1 of the main request met the requirements of Article 123(2) EPC for the reasons set out in the decision under appeal.

The feature "*human donor of up to 45 years of age*" in claim 1 of auxiliary request 1 found a basis in the passages on page 5, line 23 and page 27, line 8 of the patent application.

The features "*human neonate, infant, child or juvenile donor*" and "*human neonate, infant, or child donor*" in claims 1 of auxiliary requests 2 to 4 respectively, had a basis in page 5, line 23 and claim 8 of the patent application.

Furthermore, the feature "*the period within six hours*" in claim 1 of auxiliary request 4 was based on page 4, lines 31 and 32 and page 5, last paragraph of the patent application, in line with the criteria established in the decision G 2/10, published in OJ 2012, 376.

Lastly, the feature "*but not during the period within three hours after the heartbeat ceased*" in claim 1 of auxiliary request 5 had a basis on page 4, lines 33 and 34, page 2, lines 26 to 31, and page 3, lines 1 to 4 and 25 to 34 of the patent application, in line with the criteria established in the decision G 2/10.

XV. The respondent's submissions, insofar as relevant to the present decision, may be summarised as follows:

Reimbursement of the appeal fee due to a substantial procedural violation and remittal of the case to the opposition division

Although the argument under Article 83 EPC that the claimed method could not be carried out with donors of every age was raised during the oral proceedings only, the argument was based on evidence disclosed in the patent in suit itself, i.e. on facts known to the appellant since it drafted the patent application. During the oral proceedings, the appellant refrained from submitting auxiliary requests addressing this issue under Article 83 EPC. The appellant did not request a postponement of the oral proceedings to adequately address this issue after consultation with the inventors. Thus, the appellant was neither surprised by the argument, nor was it deprived of any right to defend its case in an adequate manner.

Admission of auxiliary requests 1 to 5 all filed by the appellant with its letter of 18 December 2017

Auxiliary requests 1 to 5 should not be admitted into the proceedings. The appellant already submitted a substantial number of auxiliary requests during the first instance proceedings. Further as set out above, despite the appellant having had the opportunity to address the key issue under Article 83 EPC during the oral proceedings by, for example, submitting a further claim request or requesting a postponement, it refrained from doing so.

Main request and auxiliary requests 1 to 5

Article 123(2) EPC - claim 1

The feature "*providing non-fetal donor tissue obtained from a donor whose heartbeat has ceased, within 30 hours postmortem but not during the period within three hours after the heartbeat ceased*" in step a) of claim 1 of the main request had no basis in the patent application, because the upper and the lower limit defining the time window for obtaining the donor tissue were derived from different parameter ranges in the patent application, namely time after death and time after cardiac arrest.

The same objection applied to the subject-matter of claims 1 of auxiliary requests 1 to 5. Furthermore, the features "*two hours postmortem*" and "*a human donor of less than 45 years of age*" in step (a) of claim 1 of auxiliary request 5 were not disclosed in the patent application, which instead mentioned "*two hours after the heartbeat ceased*" (see page 4, lines 33 to 35), and

the age of 45 years only in the context of organ harvesting (see page 27, lines 7 to 9).

XVI. The appellant requested in writing that the decision under appeal be set aside and that the case be remitted to the opposition division for assessing Article 83 EPC of the main request, filed under cover of a letter dated 3 October 2016, or of any of auxiliary requests 1 to 5, all filed under cover of a letter dated 18 December 2017. Further, the appellant requested a reimbursement of the appeal fee due to a substantial procedural violation. If the board intended to decide on compliance with Article 83 EPC of the main request, the appellant requested the remittal of the case to the opposition division for assessing inventive step on the basis of said main request, or upon the basis of any of auxiliary requests 1 to 5.

XVII. The respondent requested that the appeal be dismissed, and that auxiliary requests 1 to 5 not be admitted into the appeal proceedings.

Reasons for the Decision

1. The duly summoned appellant did not attend the oral proceedings, which in accordance with Rule 115(2) EPC and Article 15(3) RPBA took place in its absence.

Reimbursement of the appeal fee due to a substantial procedural violation and remittal of the case to the opposition division

2. In its communication in preparation of the oral proceedings, the board addressed the issue of an

alleged substantial procedural violation in the present case. In this context it was observed that (i) both parties brought up relevant issues only during the oral proceedings before the opposition division and, hence, at a very late stage of the proceedings. The issues concerned were the submission of auxiliary request 2 (corresponding to the main request in the present proceedings), and the argument that "*All ages of donor are possible while the application contains clear statements that certain areas claimed with respect to the age of the donor are not working*" (see points 11 and 12 of the board's communication). The board further observed (ii) that from the evidence on file (the minutes and the decision under appeal) no information was derivable that the appellant objected to the respondent's late submission of the argument set out above, for example, by requesting its non-admission and/or a postponement of the oral proceedings to discuss the matter with the inventors, nor (iii) that the appellant asked for a break to cope with the new situation and to adapt its defence strategy accordingly.

3. In other words, the evidence on file provides no indications that during the oral proceedings before the opposition division the appellant considered a discussion of the matter with the inventors necessary, or that it was taken by surprise by the respondent's late submission of the argument. In any case, the board is of the view that the appellant had enough opportunities to object to the argument's admission into the first instance proceedings.

4. Thus, the appellant was aware of the likely failure of its requests for reimbursement of the appeal fee and remittal of the case to the first instance.

5. The appellant did not provide any substantive comments or arguments in reply to the board's negative provisional opinion on the occurrence of an alleged substantial procedural violation, including the non-allowance of its requests for reimbursement of the appeal fee and remittal to the first instance. Nor did the appellant attend the oral proceedings (see point VII supra).

6. In these circumstances the board decides that no substantial procedural violation has occurred during the first instance proceedings (Article 113(1) EPC), and that, accordingly the requests for a reimbursement of the appeal fee pursuant to Rule 103(1)(a) EPC and a remittal of the case to the opposition division (Article 111(1) EPC) are not warranted.

Admission of auxiliary requests 1 to 5

7. Auxiliary requests 1 to 5 were submitted under cover of a letter dated 18 December 2017. New auxiliary requests 1 to 3 replaced previous auxiliary requests 1 to 3 submitted with the appellant's statement of grounds of appeal, while auxiliary requests 4 and 5 were completely new to the proceedings.

8. According to Article 13(1) RPBA, any amendment to a party's case after it has filed its grounds of appeal or reply (in case there is more than one appellant) may be admitted and considered at the board's discretion. The discretion shall be exercised in view of *inter alia* the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy. Other aspects to be considered

relate to the question whether or not facts, evidence or requests could have been presented in the first instance proceedings.

9. As set out above, the opponent's/respondent's key argument in relation to the age of donors under insufficiency of disclosure was first raised during the oral proceedings before the opposition division, and hence, at a very late stage in the opposition proceedings. In view of these circumstances, the appellant could not address the issue under Article 83 EPC earlier than with the submission of auxiliary requests 1 to 3 in its statement of grounds of appeal.

10. However, as set out above, these auxiliary requests were later amended and replaced by new auxiliary requests 1 to 3. As regards new auxiliary request 1, the amendments reside in the deletion of dependent claim 6, and in respective adaptations of back references of the remaining claims; and for new auxiliary requests 2 and 3 in the deletion of dependent claims 5 and 6, and in respective adaptations of back references. Thus, the amendments in new auxiliary requests 1 to 3 are straightforward in that they remove inconsistencies between independent claim 1 and the claims dependent thereon without raising any new complex issues.

11. Auxiliary requests 4 and 5 were submitted in order to address objections under Article 123(3) EPC that were raised by the respondent for the first time in its reply to the appellant's statement of grounds of appeal.

12. Based on the evidence on file, the respondent has not raised objections under Article 123(3) EPC against any

of the auxiliary requests in the first instance proceedings, although several thereof comprised the now contested amendment (i.e. non-fetal donor liver tissue "*obtained between about 2 hours and about 30 hours postmortem*", see for example claim 1 of auxiliary request 1 filed with the letter of 19 December 2013 in reply to the notice of opposition, and claims 1 of auxiliary requests 2 and 4 filed with the letter of 26 February 2016). In other words, the contested amendment was present in claim 1 of various auxiliary requests since the beginning of the opposition proceedings.

13. Furthermore, no reasons were provided by the respondent why this objection under Article 123(3) EPC could not have been raised earlier.

14. Thus, auxiliary requests 4 and 5 could not have been submitted earlier than with the appellant's letter dated 18 December 2017.

15. In these circumstances the board exercised its discretion according to Article 13(1) RPBA and admitted auxiliary requests 1 to 5 into the appeal proceedings.

Main request

Article 123(2) EPC - claim 1

16. The issue to be assessed in the present case is whether or not the feature "*providing non-fetal donor tissue obtained from a donor whose heartbeat has ceased, within 30 hours postmortem but not during the period within three hours after the heartbeat ceased*" in step

(a) of claim 1 is directly and unambiguously disclosed in the patent application.

17. The contested feature relates to a time range specifying a window in which liver tissue is removed from donors having a cardiac arrest. The upper limit of the range is defined as being "*within 30 hours postmortem*", i.e. within a maximum period of 30 hours after the donor's death. The lower limit of the range is defined as "*not during the period within three hours after the heartbeat ceased*", i.e. the heart must have stopped beating for at least 3 hours before the tissue is removed from the donors.

18. The opposition division was of the opinion that the time range specified in claim 1 had a basis on page 40, lines 17 to 19, in conjunction with page 4, lines 31 to 34 of the patent application. The passage on page 40 relates to the processing of donor livers and reads: "*Cadaveric Livers: Livers obtained postmortem at different times but preferably within at least 24 hours, with a maximum of 30 hours*" (emphasis added). The passage on page 4 reads: "*The preferred tissues of the present invention are those which have been harvested within about six hours after the donor's heartbeat ceased, preferably, within about three hours after the heartbeat ceased, more preferably, within about two hours after the heartbeat ceased and, most preferably, within about one hour after the heartbeat ceased*" (emphasis added). The opposition division considered the feature "*but not during the period within three hours after the heartbeat ceased*" as a disclaimer of disclosed subject-matter according to the criteria set out in decision G 2/10 (published in OJ 2012, 376).

19. In this context it is considered relevant that the end points of the time ranges recited in step (a) of claim 1 are defined by different physiological conditions of the donor, namely by a cardiac arrest and death. Although a cardiac arrest will eventually result in death, both conditions do not describe the same physiological state, since patients affected by the former may be resuscitated, while the latter relates to an absolute condition. In other words they are not synonymous.

20. The board notes that the time ranges disclosed on pages 4 and 40 of the patent application start at time points defined by either cardiac arrest or death. As set out above, both states relate to different physiological conditions of the donor, and, hence, the time periods in relation to these conditions are necessarily different too. In particular, time "0" of when the heart stops beating and time "0" of death are different points in time.

21. Consequently, the range recited in step (a) of claim 1 is specified by end points that are derived from two different ranges disclosed in the patent application. Claim 1, as a result thereof, recites a new intermediate time range which cannot be directly and unambiguously derived by the skilled person from the patent application as a whole ("the gold standard"). Although the subject matter disclaimed ("*but not during the period within three hours after the heartbeat ceased*") in step (a) of claim 1 is directly and unambiguously disclosed, it follows from the above that the range specified as a whole does not meet the criteria defined in decision G 2/10. Thus, the main request contravenes Article 123(2) EPC.

Auxiliary request 1

Article 123(2) EPC - claim 1

22. The subject-matter of claim 1 of auxiliary request 1 differs from that of the main request in that the feature "*donor*" in step (a) has been replaced by "*a human donor of up to 45 years of age*".

23. The appellant indicated as a basis for this amendment page 5, line 23 and page 27, line 8 of the patent application.

24. The respective passages in the patent application relied on by the appellant read as follows: "*Preferably this invention comprises a method of providing a tissue source of liver diploid cells including progenitor cells, which comprises harvesting liver tissue from a donor, wherein the donor has a non-beating heart and processing the tissue to provide diploid cells and/or hepatic progenitor cells. Such cells are useful for example in repopulating damaged liver parenchyma or reconstituting liver in a host in need thereof. While any animal donor is equally suitable, the preferred donor is a human*" (see page 5, lines 18 to 23, emphasis added), and "*These results indicate that donor organs preferably useful for liver cell therapies as well as for organ transplantation include those from young donors up to 45 years of age and such livers are preferably isolated within the first 30 hours from heart arrest*" (see page 27, lines 7 to 9, emphasis added).

25. The board notes that the donor's age restriction in the passage on page 27 of the patent application relates to

"*donor organs*", while claim 1 recites "*donor tissue*". The terms organ and tissue do not have the same meaning, since tissue relates to an organisational level of cells that lies between that of a cell and a whole organ. Further, as set out above, the physiological states of cardiac arrest and death are not interchangeable since they relate to conditions starting at different time points. Thus, a time period for removing a liver organ from a human donor not being older than 45 years defined as "*within the first 30 hours from heart arrest*" in the passage indicated above (see point 24) is necessarily different from a time period specified as "*within 30 hours postmortem*" as referred to in claim 1.

26. In light of these considerations, the subject-matter of claim 1 of auxiliary request 1 extends beyond the content of the application as filed.

Auxiliary requests 2 and 3

Article 123(2) EPC - claim 1

27. The subject-matter of claims 1 of auxiliary requests 2 and 3 differs from that of the main request in that the feature "*donor*" in step (a) has been replaced by "*a human neonate, infant, child or juvenile donor*", or by "*a human neonate, infant or child donor*", respectively.

28. The appellant indicated as a basis for this amendment page 5, line 23 (see above), and claim 8 of the patent application which reads as follows: "*The method of claim 2 in which the donor is a neonate, an infant, a child, a juvenile, or an adult*".

29. Since step (a) of claims 1 of auxiliary requests 2 and 3 defines the same time range as claim 1 of the main request, the objections under added subject-matter set out above apply *mutatis mutandis*. Thus, auxiliary requests 2 and 3 do not comply with the requirements of Article 123(2) EPC either.

Auxiliary request 4

Article 123(2) EPC - claim 1

30. The subject-matter of claim 1 of auxiliary request 4 differs from that of the main request in that in step (a) the feature "*donor*" has been replaced by "*a human neonate, infant or child donor*", and in that the feature "*the period within three hours*" has been replaced by "*the period within six hours*".

31. The appellant indicated as a basis for the first amendment the same passages indicated above with regard to auxiliary requests 2 and 3, and for the second amendment page 4, lines 31 and 32, and page 5, last paragraph of the application as filed.

32. Although the lower limit in the time range recited in step (a) of claim 1 has been amended by specifying that the heart must have stopped beating for at least six hours, instead of three, before removing tissue from the donor, this amendment does not change the fact that a time period starting with death is different from a period starting from a cardiac arrest.

33. Thus, the objections raised above under Article 123(2) EPC against the subject-matter of claim 1 of the main request likewise apply to auxiliary request 4.

Auxiliary request 5

Article 123(2) EPC - claim 1

34. The subject-matter of claim 1 of auxiliary request 5 differs from claim 1 of the main request in that the feature "*donor*" has been replaced by "*a human donor of up to 45 years of age*" and in that the feature "*but not during the period within three hours after the heartbeat ceased*" has been replaced by "*but not during the period within two hours postmortem*".

35. As set out above with regard to auxiliary request 1, the patent application discloses a human donor of up to 45 years of age only in the context of a liver **organ** and a time period starting from a cardiac arrest, while step (a) of claim 1 specifies that non-fetal liver **tissue** is obtained from a donor in a time period starting with death. Furthermore, the feature "*within two hours postmortem*" as referred to in step (a) of claim 1 is not directly and unambiguously derivable from page 4, lines 33 to 34 of the patent application, which exclusively relates to a cardiac arrest (see point 19 above).

36. Consequently, also auxiliary request 5 contravenes Article 123(2) EPC.

37. In the absence of an allowable request, the appeal is to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

L. Malécot-Grob B. Stolz

Decision electronically authenticated