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**Datasheet for the decision
of 20 April 2023**

Case Number: T 1566/19 - 3.3.08

Application Number: 11158157.5

Publication Number: 2336293

IPC: C12M1/12, C12M1/24, C12M1/04,
C12N1/00

Language of the proceedings: EN

Title of invention:

Cell culture methods and devices utilizing gas permeable materials

Patent Proprietor:

Wilson Wolf Manufacturing Corporation

Opponent:

Corning Incorporated

Headword:

Cell culture methods/WILSON WOLF MANUFACTURING CORPORATION

Relevant legal provisions:

EPC Art. 76(1), 123(2)
EPC R. 80
RPBA 2020 Art. 13(2)

Keyword:

Divisional application - added subject-matter (yes)
Amendment occasioned by ground for opposition - (no)
Amendment after summons - exceptional circumstances (no)

Decisions cited:

G 0001/05, G 0002/10



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Case Number: T 1566/19 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 20 April 2023

Appellant: Wilson Wolf Manufacturing Corporation
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 25 March 2019
revoking European patent No. 2336293 pursuant to
Article 101(3) (b) EPC**

Composition of the Board:

Chair T. Sommerfeld
Members: R. Morawetz
R. Winkelhofer

Summary of Facts and Submissions

I. European patent No. 2 336 293 ("the patent") is based on European patent application No. 11 158 157.5 ("the application"), which was filed as a divisional application of earlier European patent application No. 04 794 599.3, filed as an international application published as WO 2005/035728 ("the earlier application"). The patent is entitled "Cell culture methods and devices utilizing gas permeable materials" and was granted with 15 claims.

Independent claim 1 as granted reads as follows:

"1. A method of culturing cells in a cell culture device comprised at least in part of a gas permeable material and including at least one access port and including more than one scaffold, with each scaffold being positioned at a discrete location within the cell culture device, the method comprising:

- a) inoculating cells and a volume of liquid medium into said cell culture device;
- b) orienting said cell culture device into an inoculation position such that said scaffolds reside one above the other within said cell culture device;
- c) allowing cells to gravitate upon said scaffolds so that cells reside at varying elevations within said cell culture device, said cell culture device being filled with medium such that a gas-liquid interface is not present above said scaffolds;
- d) said cell culture device residing in a cell culture location that includes ambient gas at a composition suitable for cell culture, said ambient gas making contact with said gas permeable material; and

e) maintaining said liquid medium in a static state."

Dependent claims 2 to 15 further define the method of claim 1.

- II. One opposition to the granted patent was filed. The patent was opposed under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) and under Article 100(b) and 100(c) EPC.
- III. The opposition division revoked the patent. It held that claim 1 of each of the main request and the first and second auxiliary requests, all submitted on 9 November 2018, did not meet the requirements of Articles 123(2) and 76(1) EPC; that claim 1 of the third auxiliary request, submitted on 9 November 2018, met the requirements of Articles 123(2) and 84 EPC but infringed Article 123(3) EPC; that claim 1 of the amended third auxiliary request, submitted during oral proceedings on 10 January 2019, infringed Article 123(3) EPC; that claim 1 of a further, "final" third auxiliary request ("third auxiliary request"), submitted during oral proceedings on 10 January 2019, contravened Rule 80 EPC; and that the fourth and the fifth auxiliary requests, both submitted on 9 November 2018, did not meet the requirements of Article 123(3) EPC.
- IV. The patent proprietor (appellant) appealed this decision.
- V. With the statement setting out the grounds of appeal, the appellant re-submitted sets of claims of the main request and the first, second and third auxiliary requests as submitted before the opposition division,

and submitted further sets of claims of a new fourth, fifth and sixth auxiliary request.

Claim 1 of the main request reads as follows:

"1. A method of culturing cells in a cell culture device comprised at least in part of a gas permeable material and including a medium access port and including more than one scaffold, with each scaffold being positioned at a discrete location within the cell culture device, the device comprising a gas permeable sidewall, the method comprising:

- a) inoculating cells and a volume of liquid medium into said cell culture device;
- b) orienting said cell culture device into an inoculation position such that said scaffolds reside one above the other within said cell culture device;
- c) allowing cells to gravitate upon said scaffolds so that cells reside at varying elevations within said cell culture device, said cell culture device being filled with medium such that a gas-liquid interface is not present above said scaffolds;
- d) said cell culture device residing in a cell culture location that includes ambient gas at a composition suitable for cell culture, said ambient gas making contact with said gas permeable material; and
- e) maintaining said liquid medium in a static state."

Claim 1 of the first auxiliary request differs from claim 1 of the main request in that step c) has been amended (indicated by underlining or strikethrough) and reads "allowing cells to gravitate upon said scaffolds so that cells reside at varying elevations within said cell culture device, said cell culture device being completely filled with medium; ~~such that a gas-liquid~~

~~interface is not present above said scaffolds".~~

Claim 1 of the second auxiliary request differs from claim 1 of the main request in that step c) has been amended (indicated by underlining or strikethrough) and reads "allowing cells to gravitate upon said scaffolds so that cells reside at varying elevations within said cell culture device, said cell culture device being completely filled with medium such that a gas-liquid interface is not present above said scaffolds".

Claim 3 of the third auxiliary request reads as follows:

"3. The device of claim 2 wherein the silicone is pleated to allow movement of the scaffold that is the furthest from the cap to be moved into a position for microscopic evaluation."

Claims 1, 2 and 3 of the fourth auxiliary request read as follows:

"1. A method of culturing cells on both sides of scaffolds located within a cell culture device comprising a gas permeable sidewall and including one medium access port and a cap that is sealed to the access port by an o-ring, and including more than one scaffold, with each scaffold being parallel to each other and separated from its adjacent scaffold by spacers to form a space for medium to fill, and each scaffold being positioned at a discrete location within the cell culture device, the method comprising:

- a) inoculating adherent cells and a volume of liquid medium into said cell culture device;
- b) orienting said cell culture device into an inoculation position such that said scaffolds reside

one above the other within said cell culture device and said access port is located on the top of the device;

c) allowing cells to gravitate onto the upper surface of each of said scaffolds so that cells reside at varying elevations within said cell culture device, and the space between each adjacent scaffold is filled with medium, the cell culture device being filled with medium such that a gas-liquid interface is not present above the scaffolds;

d) said cell culture device residing in a cell culture location that includes ambient gas at a composition suitable for cell culture, said ambient gas making contact with said gas permeable material;

e) maintaining said liquid medium in a static state;

f) inoculating adherent cells into said cell culture device and adjusting the media volume so that the device is filled with medium;

g) reorienting said cell culture device into a position such that said access port is located on the bottom of the device and allowing cells to gravitate onto the upper surface of each of said scaffolds, medium thereby in contact with said cap; and

h) maintaining said liquid medium in a static state.

2. The method of claim 1 wherein the gas permeable material of said cell culture device is silicone.

3. The device of claim 2 wherein the silicone is pleated to allow movement of the scaffold that is the furthest from the cap to be moved into a position for microscopic evaluation."

Claim 1 of the fifth auxiliary request reads as follows:

"1. A method of culturing cells on scaffolds located within a collapsible cell culture device comprising a pleated gas permeable side-wall made of silicone, an access port and a cap that is sealed to the access port by an o-ring, more than one scaffold, with each scaffold being parallel to each other and separated from its adjacent scaffold by spring arms that exert force on a neighboring scaffold, a buoyant shoulder, the method comprising:

a) inoculating adherent cells and a volume of liquid medium into said cell culture device when said cell culture device is in a collapsed state, whereby the volume of medium exerts force on said buoyant shoulder causing the device to increase in height to accommodate the volume of medium which fills the space between each of said scaffolds;

b) orienting said cell culture device into an inoculation position such that said scaffolds reside one above the other within said cell culture device, and said access port is located on the top of the device;

c) allowing cells to gravitate onto the upper surface of each of said scaffolds whereby cells reside at varying elevations within said cell culture device, the cell culture device being filled with medium such that a gas-liquid interface is not present above the scaffolds;

d) placing cell culture device residing in a cell culture location that includes ambient gas at a composition suitable for cell culture, said ambient gas making contact with said gas permeable material;

e) maintaining said liquid medium in a static state."

Claim 1 of the sixth auxiliary request reads as follows:

"1. A method of culturing cells on scaffolds located within a cell culture device comprising a gas permeable side-wall made of silicone, an access port and a cap that is sealed to the access port by an o-ring, more than one scaffold, each scaffold being parallel to each other, each scaffold having three ramps that emanate from the top of the scaffold and each ramp is in contact with an elevation post, said elevation posts that are attached to a scaffold locator screw, the method comprising:

- a) inoculating adherent cells and a volume of liquid medium into said cell culture device wherein medium fills the space between each of said scaffolds;
- b) orienting said cell culture device into an inoculation position such that said scaffolds reside one above the other within said cell culture device, and said access port is located on the top of the device;
- c) allowing cells to gravitate onto the upper surface of each of said scaffolds whereby cells reside at varying elevations within said cell culture device, the cell culture device being filled with medium such that a gas-liquid interface is not present above the scaffolds;
- d) said culture device residing in a cell culture location that includes ambient gas at a composition suitable for cell culture, said ambient gas making contact with said gas permeable material;
and
- e) maintaining said liquid medium in a static state, the method comprising
increasing the distance between each scaffold by rotating the scaffold locator screw in the clockwise

direction as viewed by looking down from the top of the device, thereby moving each elevation post up the ramp it is in contact with."

VI. Oral proceedings before the board took place as scheduled. During the oral proceedings, the appellant submitted a set of claims of a seventh auxiliary request.

The seventh auxiliary request differs from the fourth auxiliary request submitted with the statement of grounds of appeal (see section V. above) in that claim 3 has been deleted.

VII. The appellant's arguments relevant to the decision are summarised below.

Main request - claim 1

Added subject-matter (Articles 123(2) and 76(1) EPC) - claim 1

Figs. 10A and 10B, Fig. 13, and Fig. 18 each disclosed a device having all the features of the device recited in claim 1. Furthermore, as for the device of Fig. 18, it was clearly stated in the application as filed that the device of Figs. 10A and 10B was filled completely so that there was no gas-liquid interface above the scaffolds (see page 42, lines 27 to 31 of the application as filed; page 41, lines 4 to 8 of the earlier application as filed). Figs. 10A and 10B and Fig. 13 were variations of the same device.

The invention behind the examples of Figs. 10A and 10B and Fig. 18, i.e. a device with multiple scaffolds with at least one gas permeable sidewall which allowed the device to be completely filled with medium and allowed

the passage of ambient gas into the device, was particularly preferred (see page 24, lines 14 to 16 of the application as filed and the earlier application as filed).

Further supporting statements were found in the application as filed and the earlier application as filed (see references in square brackets) in the description of Figs. 10A and 10B on page 29, lines 16 to 21 [page 27, lines 27 to 32]; Fig. 18 on page 57, lines 9 to 11 [page 55, lines 9 to 11] and page 58, lines 19 to 20 [page 56, lines 19 to 20]; and Fig. 13 on page 29, lines 27 to 31 [page 28, lines 6 to 10]. It was therefore clear that there was a strong indication in the application as filed and the earlier application as filed towards a device with one or more gas permeable walls being filled so that there was no gas liquid interface above the scaffolds.

The skilled person would use the devices of the application according to their common general knowledge for culturing cells and thus arrive directly and unambiguously at the recited method steps on the basis of their common general knowledge.

Claim 1 of the main request met the requirements of Articles 123(2) and 76(1) EPC.

First auxiliary request

Added subject-matter (Articles 123(2) and 76(1) EPC) - claim 1

The arguments presented for the main request also pertained to the first auxiliary request. The earlier application as filed provided many instances in which the device was described as being completely filled,

e.g. in relation to Figs. 10A and 10B (see page 41, lines 4 to 8).

Second auxiliary request

Added subject-matter (Articles 123(2) and 76(1) EPC) - claim 1

The arguments presented for the main request also pertained to the second auxiliary request.

Third and fourth auxiliary requests

Added subject-matter (Articles 123(2) and 76(1) EPC) - claim 1

The opposition division had held that the third auxiliary request had a basis in the application as filed. The reasoning applied also to the fourth auxiliary request.

Rule 80 EPC

The addition of new claim 3 had been a mistake made by the previous representative.

Fifth and sixth auxiliary requests

Added subject-matter (Articles 123(2) and 76(1) EPC) - claim 1

The arguments presented for the main request also pertained to the fifth and sixth auxiliary requests.

Seventh auxiliary request

Admittance (Article 13(2) RPBA)

The appellant was represented by a new representative. Deletion of claim 3 from the fourth auxiliary request

was an amendment to correct an error made by the previous representative. The seventh auxiliary request differed from the third auxiliary request, which had been held by the opposition division to fulfil the requirements of Article 123(2) EPC, merely in that steps a) and b) had been reordered.

VIII. The respondent's arguments relevant to the decision are summarised below.

Main request - claim 1

Claim construction

The expression "*a gas-liquid interface is not present above said scaffolds*" was clear for the skilled person. The device could include a gas-liquid interface in other parts of the device.

Added subject-matter (Articles 123(2) and 76(1) EPC) - claim 1

Claim 1 step c) was an intermediate generalisation. Nowhere did the earlier application describe the gas-liquid interface relative to the scaffolds. All the passages cited by the appellant disclosed that there was no gas-liquid interface in the devices. This inevitably required that there be no gas-liquid interface in any part of the device. Since claim 1 allowed for gas-liquid interfaces in other parts of the device which were not above the scaffolds, it contravened Articles 123(2) and 76(1) EPC.

First auxiliary request

Added subject-matter (Articles 123(2) and 76(1) EPC) - claim 1

All arguments made for the main request applied equally to the first auxiliary request. The claim allowed for embodiments in which the device was completely filled but had a gas-liquid interface because the claim did not specify that this was a sealed device. This was contrary to Articles 123(2) and 76(1) EPC.

Second auxiliary request

Added subject-matter (Articles 123(2) and 76(1) EPC) - claim 1

All arguments made for the main request applied equally to the second auxiliary request.

Third auxiliary request - claim 3

Rule 80

The third auxiliary request comprised a new dependent claim.

Fourth auxiliary request

Added subject-matter (Articles 123(2) and 76(1) EPC) - claim 1

The arguments on "completely filled" (see first and second auxiliary requests) applied similarly to "filled" but to a greater extent as "filled" was broader. The claim also supported this by reciting that in step g) the device was reoriented such that "medium thereby [sic] in contact with said cap". This implied that, in other configurations, medium was not necessarily in contact with the cap - i.e. there was a

gas-liquid interface in the device. This went beyond the content of the earlier application as filed.

Fifth and sixth auxiliary requests

Added subject-matter (Articles 123(2) and 76(1) EPC) - claim 1

The arguments on the higher ranking requests applied equally to these requests.

Seventh auxiliary request

Admittance (Article 13(2) RPBA)

A change of representative did not qualify as an exceptional circumstance justifying the admission of a request in appeal proceedings. The change of representative had occurred months earlier, and there had been ample time to address the objection under Rule 80 EPC against claim 3 of the fourth auxiliary request earlier. Furthermore, the seventh auxiliary request did not *prima facie* overcome the Articles 123(2) and 76(1) EPC objections. There were no extraordinary circumstances or cogent reasons.

IX. The final requests of the parties relevant for the present decision were the following.

The appellant requested that the decision under appeal be set aside and amended such that the patent be maintained on the basis of the main request or, alternatively, on the basis of one of the first to seventh auxiliary requests.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

Main request - claim 1

Claim construction

1. Claim 1 of the main request is directed to a method of culturing cells in a cell culture device, the method comprising steps a) to e). The cell culture device includes a medium access port, more than one scaffold and a gas permeable sidewall (see section V. above for the exact wording of the claim).
2. With respect to step c) of the method, the opposition division held that the expression "*said culture device being filled with medium such that a gas-liquid interface is not present above said scaffolds*" was ambiguous and that, in light of the description, the only interpretation that made technical sense was that "the device must be completely filled with culture medium, leaving no empty space present" (see decision under appeal, page 3, point 2.2).
3. The board agrees with the respondent that the skilled person reading the expression at issue in the context of claim 1 understands what it means: the cell culture device comprises scaffolds and is filled with medium to the brim above these scaffolds such that there is no gas-liquid interface "*above said scaffolds*".
4. However, the skilled person has no reason to understand that the presence of a gas-liquid interface which is not "*above said scaffolds*", i.e. in other parts of the cell culture device, is excluded as well. Contrary to the decision under appeal, the expression at issue therefore does not imply that "the device must be

completely filled with culture medium, leaving no empty space present". An example of such a device filled with medium such that the main body is filled but there is a gas-liquid interface which is not "above said scaffolds" is the device of Fig. 13 of the application, with a gas-liquid interface in the medium access port in the neck located at the side of the device.

Added subject-matter (Articles 123(2) and 76(1) EPC)

5. If a divisional application is amended, it must meet the requirements of both Article 123(2) EPC and Article 76(1) EPC. The same standard is used for assessing compliance with the requirements of Articles 123(2) and 76(1) EPC (see G 1/05, OJ EPO 2008, 271, Reasons 5.1) and is set out in G 2/10 (OJ EPO 2012, 376, Reasons 4.3). Amendments are only permitted within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the (earlier) application as filed. After the amendment, the skilled person may not be presented with new technical information (*ibid.*, Reasons 4.5.1).

6. Since in the case at hand the test for whether the claimed subject-matter extends beyond the content of the divisional application as filed (Article 123(2) EPC) and the test for whether the claimed subject-matter extends beyond the content of the earlier application as filed (Article 76(1) EPC) are based on the consideration of identical text passages and figures in both applications, they can be performed together. For ease of reference, the divisional application as filed and the earlier application as filed are referred to in the following

simply as "the application", and reference is made to the figures and the page and paragraph numbering of the PCT publication of the earlier application (WO 2005/035728).

7. The main argument of the appellant for the feature in claim 1 step c) "*said cell culture device being filled with medium such that a gas-liquid interface is not present above said scaffolds*" was that it found basis on page 41, lines 4 to 8 of the application.
8. That passage of the application relates to the cell culture device shown in Figs. 10A and 10B and discloses that "*[u]nlike traditional devices, the device can be filled completely with medium, as gas exchange occurs by way of the gas permeable walls and the need for a gas/liquid interface is not present. In this manner, the device is more efficient in its use of space than traditional devices since gas does not need to be present in the device for gas exchange of the culture*".
9. Contrary to the appellant's argument, the passage does not state that the device of Figs. 10A and 10B is filled completely so that there is no gas-liquid interface "above the scaffolds". Indeed, this passage of the application does not describe the gas-liquid interface relative to the scaffolds of the device at all. Instead, it discloses that the gas exchange occurs by way of the gas permeable walls of the device and that there is no need for a gas-liquid interface in the device. In line with the respondent's submissions, the skilled person reading page 41, lines 4 to 8 of the application understands that there is no gas-liquid interface in the device, i.e. anywhere in the device. The disclosure in page 41, lines 4 to 8 of the application therefore provides no basis for the feature

in step c) of claim 1 at issue.

10. The further passages of the application relied on by the appellant as providing a basis for the feature at issue disclose that: "*[t]he inventive apparatus and methods herein demonstrate that the gas/liquid interface is not necessary for adequate gas exchange when a wall of a device is gas permeable, scaffolds are present ...*" (see page 24, lines 14 to 16 of the application); that "*FIG. 10A and FIG. 10B show an embodiment of a gas permeable cell culture device configured with scaffolds for culturing adherent cells without need of a gas/liquid interface ...*" (see page 27, lines 27 to 29); that "*[g]as permeable test fixtures were constructed in a manner, as shown in FIG. 18, that eliminated the possibility of gas transfer by way of a gas/liquid interface*" (see page 55, lines 9 to 11); that "*[t]his demonstrates the ability to make much more efficient use of space by eliminating the need to maintain a gas headspace in a culture device*" (see page 56, lines 19 to 20) and that "*FIG. 13 is an embodiment of a gas permeable cell culture device with scaffolds and at least one sidewall comprised of gas permeable material. The need for a gas/liquid interface as a means of gas exchange is eliminated ...*" (see page 28, lines 6 to 8).
11. None of these further passages of the application describe the absence of a gas-liquid interface with reference to the scaffolds of the device. Furthermore, these passages likewise describe that the need for a gas-liquid interface as a means of gas exchange is eliminated as a consequence of the use of gas permeable side walls for gas exchange. This is understood by the skilled person to mean that there is no gas-liquid

interface in the device.

12. Since claim 1 is not limited to a device without a gas-liquid interface in any part of the device but allows for a gas-liquid interface in parts of the device which are not "above the scaffolds", it presents the skilled person with additional relevant technical information not included in the (earlier) application as filed. For this reason alone, claim 1 of the main request contravenes Articles 123(2) and 76(1) EPC. Accordingly, there is no need to assess whether the further features of claim 1 and their combination find a basis in the (earlier) application as filed.

First auxiliary request - claim 1

Added subject-matter (Articles 123(2) and 76(1) EPC)

13. Claim 1 of the second auxiliary request corresponds to claim 1 of the main request, with step c) amended to refer to the device being "completely" filled with medium, the requirement that "*a gas-liquid interface is not present above said scaffolds*" having been omitted (see section V. above).
14. The passage relied on by the appellant as providing a basis for the amendment (page 41, lines 4 to 8 of the application) has been set out above (see point 8.). As noted in point 9. above, this passage discloses not only that the device is completely filled with medium but also that the gas exchange occurs by way of the gas permeable walls of the device and that there is no gas-liquid interface in the device.
15. The device of claim 1 of the first auxiliary request includes a medium access port (see section V. above).

A medium access port is open to the atmosphere unless it is sealed, e.g. by a cap. The respondent is correct in that there exists a gas-liquid interface in the completely filled device of claim 1 of the first auxiliary request as a consequence of the medium access port being open and hence in contact with ambient gas.

16. Accordingly, claim 1 of the first auxiliary request is not restricted to devices that have no gas-liquid interface, and it therefore presents the skilled person with additional relevant technical information not included in the (earlier) application as filed. Claim 1 of the first auxiliary request contravenes Articles 123(2) and 76(1) EPC.

Second auxiliary request - claim 1

Added subject-matter (Articles 123(2) and 76(1) EPC)

17. Claim 1 of the second auxiliary request corresponds to claim 1 of the main request, with step c) amended to refer to the device being "*completely*" filled with medium, the requirement that "*a gas-liquid interface is not present above said scaffolds*" having been re-inserted (see section V. above).
18. The passages of the application relied on by the appellant as providing basis for the amendment are the same as for claim 1 of the main request. As set out in points 7. to 11. above, these passages (i) do not describe the gas-liquid interface relative to the scaffolds of the device and (ii) disclose devices that have no gas-liquid interface in any part of the device. The requirement of being "*completely*" filled does not restrict the subject-matter of claim 1 to devices that have no gas-liquid interface in any part of the device

for the same reasons as set out above for claim 1 of the first auxiliary request (see point 15. above). Claim 1 of the second auxiliary request therefore contravenes Articles 123(2) EPC and 76(1) EPC for the same reasons as set out above for claim 1 of the main request, *mutatis mutandis*.

Third auxiliary request

Amendment of the European patent (Rule 80 EPC)

19. The third auxiliary request comprises a new claim 3, directed to a device, which has no counterpart in the granted set of claims (see sections I. and V. above). Claim 3 therefore constitutes an amendment of the granted patent not occasioned by a ground for opposition under Article 100 EPC, contrary to the requirements of Rule 80 EPC. This was not disputed by the appellant. The third auxiliary request is not allowable.

Fourth, fifth and sixth auxiliary requests

Admittance and consideration (Article 12(4) RPBA 2007)

20. The respondent submitted that the fourth, fifth and sixth auxiliary requests should not be considered pursuant to Article 12(4) RPBA 2007, applicable to the current appeal case pursuant to Articles 24 and 25(2) RPBA 2020.
21. In view of the board's conclusions on allowability under Rule 80 EPC (see point 22. below) and added subject-matter (see points 23. and 24. below), the question of whether these requests should be considered

in substance can be left open.

Fourth auxiliary request

Amendment of the European patent (Rule 80 EPC)

22. The fourth auxiliary request also comprises a new claim 3 directed to a device which has no counterpart in the granted set of claims (see sections I. and V. above) and therefore also constitutes an amendment of the granted patent not occasioned by a ground for opposition under Article 100 EPC, contrary to the requirements of Rule 80 EPC. Again, this was not disputed by the appellant. The fourth auxiliary request is not allowable either.

Fifth and sixth auxiliary requests

Added subject-matter (Articles 123(2) EPC and 76(1) EPC) - claim 1

23. Claim 1 step c) of the fifth and sixth auxiliary requests includes the feature "*the cell culture device being filled with medium such that a gas-liquid interface is not present above the scaffolds*" (see section V. above). The passages of the application relied on by the appellant as providing basis for claim 1 step c) are the same as for claim 1 of the main request, and the considerations set out above for claim 1 of the main request therefore apply, *mutatis mutandis*.
24. Claim 1 of the fifth and sixth auxiliary requests does not comply with Articles 123(2) and 76(1) EPC.

Seventh auxiliary request

Admittance and consideration (Article 13(2) RPBA)

25. The appellant submitted the seventh auxiliary request at the oral proceedings before the board, after the board had announced its negative conclusion on added subject-matter for claim 1 of the main request. This claim request is based on the fourth auxiliary request submitted with the statement of grounds of appeal and differs from it in that claim 3 had been deleted. The respondent requested that this claim request not be admitted into the appeal proceedings.

26. Pursuant to Article 13(2) RPBA, which applies in the case at hand, any amendment to a party's appeal case after notification of a summons to oral proceedings is, as a rule, not to be taken into account unless there are exceptional circumstances justified with cogent reasons by the party concerned. Exceptional circumstances might be new or unforeseen developments in the appeal proceedings which lie outside the sphere of influence of the party affected by them, such as new objections raised by the board or another party (see Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2022 ("CLBA"), V.A.4.5.1).

27. The appellant submitted as justification for submitting the new claim request at the oral proceedings that the amendment served to correct a mistake made by the previous representative and that as a consequence of the opposition division's decision on the third auxiliary request, Articles 123(2) and 76(1) EPC were complied with.

28. Since a change of representation lies within the party's control, this circumstance cannot be relied upon to establish extraordinary circumstances or justify the submission of amendments only at the oral proceedings before the board (see CLBA, V.A.4.5.6n). Furthermore, the board agrees with the respondent that this line of reasoning does not explain why the amendment could not have been made at an earlier stage since the change of representative had occurred several months before the oral proceedings, and the objection under Rule 80 EPC had been on file and had been noted by the board in its communication pursuant to Article 15(1) RPBA.
29. Exceptional circumstances within the meaning of Article 13(2) RPBA have further been acknowledged in the case law of the boards if the admittance of amendments to a party's appeal case was not detrimental to the procedural economy of the appeal proceedings (see CLBA, V.A.4.5.1).
30. For the following reasons, the seventh auxiliary request would not *prima facie* overcome the added-matter problem, and its admittance would therefore also have been inconsistent with the requirement of procedural economy of the appeal proceedings.
31. Claim 1 step c) of the seventh auxiliary request includes the feature "... such that a gas-liquid interface is not present above the scaffolds" (see sections VI. and V. above). This feature contravenes Articles 123(2) and 76(1) EPC in the context of the main request, as laid out above (see points 8. to 12. above). The respondent is also correct in stating that claim 1 step g) of the seventh auxiliary request (absent in claim 1 of the main request) now

additionally implies a gas-liquid interface in the device as otherwise the medium would be in contact with the cap before re-orientation of the cell culture device.

32. On allowability under Articles 123(2) and 76(1) EPC, the appellant did not provide any arguments to address the objections that had been raised by the respondent against the fourth auxiliary request (see section VIII. above). Instead, it relied entirely on the decision under appeal (see section VII. above). In this decision, three versions of the third auxiliary request had been considered (see section III. above). The version of the third auxiliary request which the opposition division had held to fulfil the requirements of Articles 123(2) and 76(1) EPC was the third auxiliary request submitted on 9 November 2018 (see decision under appeal, page 5, point 1 to page 6, point 3). Contrary to the appellant's submissions, claim 1 of that version of the third auxiliary request differed from claim 1 of the seventh auxiliary request not only in that steps a) and b) have been reordered. The feature which adds matter in claim 1 of the main request, i.e. "*... a gas-liquid interface is not present above the scaffolds*", and which is still present in claim 1 of the seventh auxiliary request, had also been removed from claim 1 of the third auxiliary request submitted on 9 November 2018 (see decision under appeal, page 5, point 1). For this reason alone, the appellant's line of argument was unsuitable for showing that claim 1 of the seventh auxiliary request fulfilled the requirements of Articles 123(2) and 76(1) EPC.

33. Also in view of this, there are no exceptional circumstances within the meaning of Article 13(2) RPBA

which would have justified the admittance and consideration of the seventh auxiliary request at this stage of the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



L. Gabor

T. Sommerfeld

Decision electronically authenticated