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**Datasheet for the decision  
of 25 June 2015**

**Case Number:** T 1354/11 - 3.3.02

**Application Number:** 99913967.8

**Publication Number:** 1064353

**IPC:** C12M3/04, C12M1/34

**Language of the proceedings:** EN

**Title of invention:**

VASCULARIZED PERFUSED MICROTISSUE/MICRO-ORGAN ARRAYS

**Patent Proprietor:**

Massachusetts Institute of Technology

**Opponent:**

Karlsruher Institut für Technologie

**Headword:**

Perfused Microtissue/MIT

**Relevant legal provisions:**

EPC Art. 56, 123(2)  
RPBA Art. 12(4), 13, 13(1)

**Keyword:**

Late-filed evidence - admitted (no)  
Late-filed request - submitted during oral proceedings  
Inventive step - (no)  
Amendments - added subject-matter (yes)

**Decisions cited:**

T 0329/06, G 0002/88, G 0009/91, T 0189/09, T 1990/07

**Catchword:**



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Case Number: T 1354/11 - 3.3.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.02**  
**of 25 June 2015**

**Appellant:** Karlsruhe Institut für Technologie  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
19 April 2011 concerning maintenance of the  
European Patent No. 1064353 in amended form.**

**Composition of the Board:**

**Chairman** U. Oswald  
**Members:** T. Sommerfeld  
L. Bühler

## **Summary of Facts and Submissions**

- I. European patent No. 1064353, based on European patent application No. 99913967.8, which was filed as an international patent application published as WO99/047922, was granted with 29 claims.
- II. Opposition was filed against the granted patent, the opponent requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Articles 54(2) and 56 EPC and Article 100(a) EPC).
- III. A first decision of the opposition division was issued, revoking the patent for non-compliance with Article 53(a) EPC 1973 (in conjunction with Rule 23d(c) EPC 1973), Article 54 EPC and Article 123(3) EPC. The patent proprietor appealed against this first decision of the opposition division. By decision T 329/06 of 4 September 2009, technical board of appeal 3.3.04 ordered that the appealed decision be set aside and that the case be remitted to the department of first instance for further prosecution on the basis of the new main request filed on 4 September 2009 during oral proceedings before the board.

In decision T 329/06, the board decided that the claims of the main request complied with the requirements of Articles 123(2) and (3) EPC, 84 EPC, 53(a) EPC with Rule 28(c) EPC, and Article 54 EPC.

- IV. During the second round of proceedings before the opposition division, the patent proprietor requested that the patent be maintained as amended, on the basis of the main request filed on 4 September 2009, or alternatively according to auxiliary requests 1 to 9,

which had all been filed during appeal proceedings. The opponent requested that the patent be revoked in its entirety for lack of inventive step.

- V. By an interlocutory decision, the opposition division decided that the patent was to be maintained in amended form on the basis of the main request filed on 4 September 2009 (Articles 101(3)(a) and 106(2) EPC).
- VI. The opponent - hereinafter, the appellant - lodged an appeal against that decision. With the statement of the grounds of appeal, the appellant requested that the decision be set aside and the patent revoked in its entirety. New documents D18 and D19 were submitted.
- VII. With its reply to the appellant's grounds of appeal, the patent proprietor - hereinafter, the respondent - requested that the appeal be rejected and that the patent be maintained in the form as allowed by the opposition division (main request) or alternatively according to auxiliary requests 2, 4, 5 and 7 to 9, all filed with the grounds of appeal. The respondent also requested that documents D18 and D19 not be admitted into the proceedings.
- VIII. Summons for oral proceedings before the board on 25 June 2015 were issued on 27 October 2014.

In the communication accompanying the summons for oral proceedings, the board summarised the case and provided its preliminary opinion as regards the admissibility of late-filed documents D18 and D19 and Articles 123(2) and 84 EPC (in relation to the auxiliary requests).

IX. Both parties submitted replies to the communication of the board. The respondent submitted a further reply to the letter of the appellant.

X. Oral proceedings before the board took place on 25 June 2015.

During the oral proceedings, the appellant filed amended auxiliary requests 4 and 5 and new auxiliary requests 10 and 11.

The **main request** is identical to the request which was maintained by the opposition division. It comprises 29 claims, claim 1 reading as follows:

"1. An apparatus comprising  
a) a matrix formed of a solid support made from an inert material comprising one or more channels,  
b) cells within the channels of the matrix provided that the cells are not human embryonic stem cells,  
c) means for perfusing the cells within the channels using cross-flow, and  
d) means for detecting changes in the cells or in compounds exposed to the cells,  
wherein the channels are open at both ends and run through the matrix wherein the size and orientation of the channels in the matrix allow perfusion of the cells with nutrients and oxygen sufficient to maintain the viability of the cells."

Claim 1 of **auxiliary request 2** differs from claim 1 of the main request by the addition, at the end of the claim, of the feature "..., and wherein the cells within the channels of the matrix are perfused by cross-flow."

Claim 1 of **auxiliary request 4** differs from claim 1 of the main request in that it is directed to a use rather than to the apparatus itself, as follows:

"1. Use, for perfusing cells within channels using cross-flow, of an An apparatus comprising..."  
[apparatus defined as in claim 1 of the main request]

Claim 1 of **auxiliary request 5** differs from claim 1 of the main request in that it is directed to a method rather than to the apparatus itself, as follows:

"1. A method of culturing cells within an An apparatus comprising..."  
[apparatus defined as in claim 1 of the main request]

Claim 1 of **auxiliary request 7** differs from claim 1 of the main request in feature c) and in the last characterising part as follows:

"1. An apparatus comprising  
...  
c) means ~~for~~ perfusing the cells within the channels using cross-flow, and  
...  
wherein the channels are open at both ends and run through the matrix wherein the size and orientation of the channels in the matrix allow perfusion of the cells with nutrients and oxygen sufficient to maintain the viability of the cells, wherein the matrix comprises perfused microvascular networks and wherein the nutrients are provided by culture medium which perfuses through the microvascular networks."

Claim 1 of **auxiliary request 8** also comprises the further feature of the last characterising part as in

auxiliary request 7; it further differs from claim 1 of the main request in feature b) which reads as follows: "b) cells within the channels of the matrix ~~provided that the cells are not human embryonic stem cells~~ the cells being endothelial cells that form lumens equivalent to blood vessels,".

Claim 1 of **auxiliary request 9** differs from claim 1 of the main request in feature c) which reads as follows: c) means for perfusing the cells within the channels using cross-flow, the said means being arranged in a manner that allows for control of the rate of culture medium perfusion through the channels of the matrix, and".

**Auxiliary request 10** consists of 8 claims which are identical to claims 1 and 22 to 28 of auxiliary request 7.

**Auxiliary request 11** consists of 3 claims which are identical to claims 1, 20 and 21 of auxiliary request 8.

XI. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

- D1 Weibezahn K.F. et al. (1994), KFK-Nachrichten, 26, 1/94, pp. 10-14
- D15 Knedlitschek et al. (1999), J. Biomechanical Engineering 121, pp. 35-39
- D18 Storhas W. (1994), Bioreaktoren und periphere Einrichtungen, Vieweg Lehrbuch Biotechnologie, pp. 116-123 et 335-341
- D19 Bier W. et al. (1993), KFK-Bericht 5238 zum 1. Statuskolloquium ..., pp. 134-139



XII. The appellant's submissions, in so far as relevant to the present decision, may be summarised as follows:

Main request - inventive step

Document D1, which provided a system for three-dimensional cell culture and also disclosed a fixed-bed reactor, could be considered the closest prior art. D1's system avoided the disadvantages of the prior art (page 10, right column) and succeeded in providing cell cultures wherein the cells survived for several weeks (page 13, left column). D1 moreover disclosed that the tissue layers were perfused, and not only superficially (page 11, left column). The only difference to claim 1 was feature c) "means for perfusing the cells within the channels using cross-flow", which was not explicitly disclosed. The skilled person would however make use of his common general knowledge in physics and would realise that in Figure 2b of D1 some kind of pressure had to be present in order to allow for cell perfusion. Since the apparatus of claim 1 was structurally identical to the apparatus of D1, the technical problem could be formulated as the provision of cell culture using cross-flow with the same apparatus. Since, as confirmed by the patent (Example 7, column 54, line 4 ff.), it was known that hydrostatic pressure was sufficient to drive flow through the channels of the scaffold, D1 together with common general knowledge rendered the solution obvious. In fact D1 disclosed computer-controlled in- and outlets, i.e. the means by which a differential pressure, and thus a perfusion in cross-flow, could be created without difficulty (D1, page 11, left column, lines 25 to 33).

XIII. The respondent's arguments, in so far as relevant to the present decision, may be summarised as follows:

Inventive step - Main request and auxiliary request 2

The difference of D1 to the claimed subject-matter, namely the means for perfusion using cross-flow, was not disclosed in any prior art documents. Figure 2b of D1 showed that the cells were closely packed: with such a structure it would be impossible to operate the apparatus with cross-flow, since the resistance would be much higher for cross-flow than for unidirectional flow. In D1 the cells completely filled the channels (page 12, right column, second paragraph; Figure 3 and its legend; page 13, left column, middle of first complete paragraph; page 13, paragraph bridging left and middle columns; Figure 4, legend; end of section 4): this was also disclosed in D2, D3 and D15. Moreover, D1 stated that the upper and lower flows were isolated, and the skilled person would understand that this isolation was achieved by the cell layers. The skilled person would thus not arrive at the claimed solution from D1 (or from any other document on file). The technical problem could be formulated as how to modify D1 in order to provide alternative means of cultivating cells. The appellant relied on D1's statement concerning cell longevity to conclude that there had to be cross-flow, but cross-flow would not be possible since the cells completely filled the channels. Indeed, other possible ways of retaining cell longevity were shown e.g. in D15 (Figure 3), wherein cell culture using the apparatus of D1 was made with simple mountings and not cross-flow.

In auxiliary request 2 the apparatus was claimed in its condition of use and the skilled person would be taught

away from using the apparatus of D1 with cross-flow, in view of the very high resistance.

Auxiliary requests 4, 5, 7, 8 and 9 - Article 123(2)  
EPC

As regards the use (auxiliary request 4), there were in the application as filed extensive references to uses of the apparatus, illustrated by multiple examples. By way of example, page 37, line 15 was a very broad statement of use.

Concerning the method (auxiliary request 5), the basis was to be found on page 8, line 9, page 15, lines 4 to 5, page 40, line 7, in originally filed claim 3, and also on page 37, line 15. These passages disclosed the apparatus, and the amendment merely encompassed the apparatus limited to the condition of use. G 2/88 confirmed that a change of claim category was permissible.

As regards auxiliary requests 7 and 8, the basis for the dependent claims was found in the following passages: page 15, lines 2 to 7 (claim 2); page 15, lines 24 to 25, figure 1 (claim 3); page 4, line 23 (claim 4); original claim 6 (claim 5); original claim 7 (claim 6); page 21, line 5 (claim 7); page 21, line 17, page 29, lines 5 to 6 (claim 8); page 29, line 25 (claim 9); page 32, lines 28 to 29 (claim 10); page 31, lines 12 to 16 (claim 11); page 31, lines 16 to 17 (claim 12); page 31, lines 17 to 18 (claim 13); page 39, lines 5 to 12, original claim 15, figure 3 (claim 14); page 17, line 2 (claim 15); general introduction (claim 16); figures 2b and 2c (claim 17); page 15, line 13 (claims 18 and 19); page 9, lines 26 to 27 (claims 20 and 21).

As regards auxiliary request 9, perfusion of cells was disclosed *inter alia* in the following passages of the application as filed: page 3, line 27 to page 4, line 3; page 5, lines 3 to 8; page 6, line 32 to page 7, line 2; page 8, lines 11 to 17, 26 to 27 and 31 to 33; page 9, lines 1 to 2 and 12 to 17; page 14, lines 28 to 30; page 15, lines 10 to 14; page 40, line 13; page 40, line 33 to page 42, line 13; page 64, line 19 et seq.; page 68, line 11 et seq.; claim 2. In view of a variety of references in the application as filed to control of rates of perfusion, the skilled person would be persuaded that each and every combination in auxiliary request 9 was supported by the originally filed application.

#### Auxiliary requests 10 and 11 - Admissibility

These requests were a straightforward reaction to the objections under Article 123(2) EPC raised by the board and by the appellant. The intention to file them had been announced in the latest letter and their admission would simplify the proceedings, as it avoided discussion of the Article 123(2) EPC objection.

- XIV. The appellant (opponent) requested that the decision under appeal be set aside and that European patent No. 1 064 353 be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed (main request) or, alternatively, that the patent be maintained in amended form on the basis of one of the following auxiliary requests:  
- auxiliary request 2, filed with the reply to the statement of grounds of appeal of 16 December 2011, or

- auxiliary requests 4 and 5, as amended during the oral proceedings of 25 June 2015, or
- auxiliary requests 7, 8 and 9, all filed with the reply to the statement of grounds of appeal of 16 December 2011, or
- auxiliary requests 10 and 11, filed during the oral proceedings of 25 June 2015.

### **Reasons for the Decision**

1. The appeal is admissible.
2. Admissibility of documents D18 and D19
  - 2.1 Pursuant to Article 12(4) RPBA, the boards of appeal may hold inadmissible facts, evidence or requests which could have been presented or were not admitted in the first-instance proceedings.
  - 2.2 Documents D18 and D19 were filed by the appellant with its statement of the grounds of appeal. In its reply to the grounds of appeal, the appellant objected to their admission into the proceedings. In the communication accompanying the summons to oral proceedings, the board also questioned their admissibility. The appellant however did not provide any written arguments - neither in its grounds of appeal nor with its reply to the summons to oral proceedings - as to why these documents should be admitted. At oral proceedings, the appellant stated that it relied on its written submissions as regarded documents D18 and D19, and that it did not intend to refer to them in its oral presentation.
  - 2.3 The board considers that neither D18 nor D19 adds anything to the documents already on file, and the

appellant did not in fact use them in its main inventive-step argumentation. Hence the board made use of its discretionary power under Rule 12(4) RPBA and decided not to admit them into the proceedings.

3. Admissibility of evidence filed at oral proceedings

3.1 At oral proceedings, the respondent submitted a one-page handout comprising a calculation of the resistance to flow through tissue.

3.2 Admission of evidence filed at such a late stage of the appeal proceedings is at the discretion of the boards of appeal, pursuant to Article 13 RPBA. That 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.

3.3 While the respondent argued that the calculations presented in the handout simply relied on the well-known Hagen-Poiseuille law for fluid dynamics, they nevertheless involved a number of assumptions as regards parameters of D1's apparatus. Moreover, two publication sources were given as references, but said documents were not on file and hence their content could not be verified. Further, it is noted that the argument underlying these calculations - namely that resistance to cross-flow is much higher than to unidirectional flow - was not even disputed.

3.4 The board thus decided not to admit this evidence into the proceedings (Article 13 RPBA).

4. Main request

4.1 The present main request is identical to the request which was filed at oral proceedings before the technical board 3.3.04 on 4 September 2009 and decided upon in decision T 329/06 of 4 September 2009. In view of the conclusions of this decision, the only outstanding issue as regards this request is inventive step, as all other issues - within the framework of the opposition - have already been decided by said board and are thus *res judicata*.

4.2 Inventive step

4.2.1 Claim 1 is directed to an apparatus as defined by a number of structural features. According to the patent (see e.g. paragraphs [0011] to [0013]), said apparatus is part of a system which allows to produce arrays of synthetically fabricated microscale tissues or organs, made from cells of one or more types. The system can be used in screening methods e.g. to screen materials, such as compounds, for an effect on the cells or to test the effect of the cells on the materials or compounds. The embodiment claimed in claim 1 is represented in Figure 2 of the patent, wherein the functioning of the apparatus in cross-flow mode is shown.

4.2.2 Document D1 is the closest prior art. It discloses three-dimensional cell cultures in a so-called tissue model, which consists of cells contained in a specific microstructure. Said tissue models reproduce many of the properties of natural cell tissues (page 14, last sentence), which is particularly important for their use in studies of toxic effects (page 10, left column,

second paragraph). Thus the system disclosed in D1 also serves the same purpose as the system of the patent. The microstructures of D1 consist of a multitude of micro-containers with a porous bottom which act as a support for the cells to be cultured. These microstructures, comprising the cell tissue layers, are introduced into a supply vessel, wherein they are in contact with two isolated medium reservoirs, one above and one below the microstructure (Figure 2 on page 11).

4.2.3 As concluded by the board in T 329/06, the device disclosed in document D1 differs from the apparatus as claimed in claim 1 in that a means for perfusing the cells within the channels using cross-flow - feature c) of claim 1 - is not described. According to the respondent, this allows the production of microtissues wherein the cells retain their longevity and physiological characteristics. It is however undisputed that in D1 the cells are also shown to maintain their longevity and physiological activity (page 13, left column, line 9 of the last paragraph to middle column, line 5). Moreover, there is no evidence in the patent or elsewhere on file that there is an improvement over the device disclosed in the closest prior art D1. Hence, the problem to be solved has to be seen as the provision of alternative means to produce cell tissue model microstructures. The solution is the apparatus as claimed in claim 1 and, in view of the data of the patent (Example 7), the board is convinced that the problem has been plausibly solved.

4.2.4 While D1 does not specify how the cells are perfused, it is nevertheless readily apparent to the skilled person that the cells have to be somehow perfused in order to be able to survive and produce the tissue models of D1. In view of Figure 2 of D1, which shows



that the microtissues are made of several layers of cells and that medium is flowing in reservoirs both above and below said microtissues, the skilled person would certainly realise that not only the cell layers at the surface (both on top and at the bottom) but also the inner cell layers had to be efficiently perfused with nutrient media and oxygen, in order to avoid central necrosis - which was acknowledged in D1 as one of the disadvantages of the prior-art multicellular spheroids (D1, page 10, right column, first full paragraph). The skilled person would thus consider that means were necessary to make the medium flow not only parallel to the cell layer surface but also to the interior of the cell layers, i.e. in cross-flow. The skilled person would thus arrive at the solution to the problem without the need for inventive skill.

4.2.5 The respondent essentially argued that the skilled person would not consider it possible to have cross-flow in D1, because the resistance would be too high, the cells being so closely packed together. The board however notes that it is not conceivable that the cells are so tightly packed as to form an impermeable untransposable layer. If that were the case, it would not be apparent how these cells - in particular those lying inside the structure - could be perfused, and thus maintained at all. Although D1 discloses that the cells indeed form a dense tissue that fills the microcontainers, it cannot be inferred from the passages cited by the respondent (page 12, right column, second paragraph; Figure 3 and its legend; page 13, left column, middle of first complete paragraph; page 13, paragraph bridging left and middle columns; Figure 4, legend; end of section 4) that they form impermeable layers, since this would contradict the disclosed longevity and physiological activity of

the tissues (page 13, left column, line 9 of the last paragraph to middle column, line 5). Even if a very high resistance caused by the compacted structure is to be expected, the skilled person would have routine methods to overcome it by applying sufficient hydrostatic pressure, e.g. by means of a pump (see in this context also D1, page 11, left column, second paragraph, stating that perfusion of the tissues is controlled by a computer). Moreover it is noted that claim 1 does not provide any information concerning the degree of packing of the cells and indeed it is apparent from Figure 4 of the patent (in particular 4B) that cells are also tightly packed in the channels of the invention's apparatus.

- 4.2.6 Regarding D15, the board agrees that Figure 3 indeed teaches that simple mountings are used in order "to make sure that both sides of the culture system are sufficiently supplied with medium and oxygen" (last sentence of the legend to figure 3). However, this teaching is not in contradiction with D1's disclosure, but rather is another alternative for producing cell cultures in microstructures. The cells in the microstructures of both D1 and D15 need to be supplied with nutrients and oxygen, and D15 solves this problem by keeping the cells in simple mountings in order to guarantee an efficient supply; D1 on the other hand does not explicitly explain how the problem is solved but it is immediately apparent that the solution cannot be the one of D15, because the tissue models according to D1 consist of several cell layers. In view of the structure of D1's tissue models, the solution of D15 would not be an option.

4.2.7 The board thus considers that the subject-matter of claim 1 does not involve an inventive step (Article 56 EPC).

5. Auxiliary request 2

5.1 Articles 84 and 123(2) EPC

5.1.1 Objections had been raised by the board and taken up by the appellant regarding both Article 84 EPC and Article 123(2) EPC. The specific issues raised did not however have an impact in the assessment of inventive step. Accordingly, no decision was taken regarding Articles 84 and 123(2) EPC.

5.2 Article 56 EPC

5.2.1 Claim 1 of this request differs from claim 1 of the main request only in that the apparatus is further defined by the functional feature that the cells in the channels are perfused by cross-flow. The board notes that the same conclusions as discussed above in relation to claim 1 of the main request also apply to claim 1 of this request.

5.2.2 In this respect, the board cannot follow the respondent's argument that the added feature is limiting. This feature relates to the apparatus in its functioning state; however what is covered by the claim is still the apparatus independently of any use, because the claim conveys absolute product protection. This functional feature does not have any structural implications that were not already present in claim 1 of the main request, since means for perfusing by cross-flow was already a feature of the claim.

5.2.3 Auxiliary request 2 is thus considered to lack inventive step (Article 56 EPC).

6. Auxiliary request 4

6.1 Admissibility

6.1.1 The respondent asked at oral proceedings to be allowed to amend this request, the amendment consisting solely of the insertion of "the" before "size and orientation". The respondent had no objections to this amendment and the board, noting that said amendment merely served to bring the language of claim 1 into line with that of the other requests on file, used its discretionary power to admit this request into the proceedings (Article 13 RPBA).

6.2 Article 123(2) EPC

6.2.1 Article 100(c) EPC was not invoked as a ground of opposition in the present case, neither by the opponent nor by the opposition division of its own motion. According to G 9/91 (OJ 1993, 408), fresh grounds for opposition may in principle not be introduced at the appeal stage, unless the patentee agrees to their introduction (loc. cit., point 18 of the Reasons). However, as also made clear by decision G 9/91 (point 19 of the Reasons), in case of amendments of the claims or other parts of a patent in the course of opposition or appeal proceedings, such amendments are to be fully examined as to their compatibility with the requirements of the EPC, including the provisions of Article 123(2) and (3) EPC.

6.2.2 No basis is apparent in the application as originally filed for the use of an apparatus for perfusing cells,

in particular with the apparatus which is defined in the claim. The passage on page 37, lines 14 to 17, indicated by the respondent as a basis for this amendment, reads "The unique aspect of the approach described herein is the focus on formation of *perfused* capillary structures within the tissue of interest, to induce stable differentiation of the cells and enable long-term culture." A use of the apparatus for perfusing cells is not disclosed in this passage, which refers to "perfused capillary structures" and not to perfused cells and does not even refer to the use of an apparatus defined as in claim 1. In fact, the "approach" which is described immediately prior to the passage cited refers to "mixtures of the various cell types from a mature tissue" and to "cultures of embryonic stem cells", all features which are not part of the present claim. Thus also the respondent's arguments that this passage is a general statement which can therefore be combined with the other features of the claim are not convincing: rather than being part of a general disclosure, this passage refers to specific embodiments, at least as regards the cells to be used.

6.2.3 Moreover, the respondent's arguments that, in view of the many references to uses of the apparatus, the skilled person would be provided with a broad variety of use examples is not convincing: even if, taking the whole disclosure of the patent application, such a use might have been obvious for the skilled person, the standard for Article 123(2) EPC is not obviousness but rather a direct and unambiguous disclosure.

6.2.4 Hence, claim 1 of auxiliary request 4 does not comply with Article 123(2) EPC.

7. Auxiliary request 5

7.1 Admissibility

7.1.1 Claim 1 of this request was also amended at oral proceedings, the amendment consisting of the insertion of a disclaimer directed towards human embryonic stem cells. As argued by the respondent, said disclaimer was present in the preceding claim requests and was inadvertently omitted from the auxiliary request 5 as filed with the grounds of appeal. The appellant had no objections to admitting the amended request into the proceedings. The board thus made use of its discretionary power under Article 13 RPBA and decided to admit this request into the proceedings.

7.2 Article 123(2) EPC

7.2.1 No basis is present in the application as filed for a method for culturing cells using the apparatus as defined in the claim. The passages indicated by the respondent disclose some - but not necessarily all - of the apparatus features (e.g. page 8, line 9; page 15, lines 4 to 5; page 40, line 7; claim 3) but do not disclose a method for culturing cells; likewise the above-cited passage on page 37, lines 14 to 17, does not disclose the method either. Such a method is not apparent in the whole application as filed, which is directed to devices and methods to produce microtissue arrays and not to culture of cells - even if culture of cells may eventually be a step within the method to produce microtissue arrays.

7.2.2 While it is accepted that the patent application discloses not only apparatuses but also methods employing said apparatuses, the fact is that the

specifically claimed method for culturing cells with the specifically defined apparatus - as in the claim - is not disclosed. In this context, the respondent's arguments based on G 2/88 (OJ 1990, 83) are not convincing. This decision of the Enlarged Board deals solely with extension of protection (Article 123(3) EPC) and not with added subject-matter (Article 123(2) EPC); while it concludes that "[a]n amendment of granted claims directed to "a compound" and to "a composition including such compound", so that the amended claims are directed to "the use of that compound in a composition" for a particular purpose, is not open to objection under Article 123(3) EPC", it makes no statements concerning Article 123(2) EPC. As regards the requirements of Article 123(2) EPC, the same principles apply to an amendment consisting of a change of claim category from product to use as to any other amendment: the amendment is allowable only if there is a direct and unambiguous disclosure in the application as filed.

7.2.3 Claim 1 of auxiliary request 5 thus also fails to comply with Article 123(2) EPC.

8. Auxiliary request 7

8.1 Article 123(2) EPC

8.1.1 Claim 1 of auxiliary request 7 is based on a combination of granted claims 1 and 2. While granted claims 1 and 2 are not objected to under Article 123(2) EPC, there is no basis in the application as filed for all new combinations of features arising in the dependent claims, in view of the fact that the granted dependent claims were not dependent on granted claim 2. The many passages indicated by the respondent as

constituting a basis may indeed disclose each of the features of the dependent claims, but they do not disclose their combination with the other features of present claim 1. For example, for claims 5 and 6, the respondent indicated original claims 6 and 7, respectively, as the basis. These claims however provide no basis for the combination of features arising from dependency on claim 1 in suit (which comprises the features of original claims 1 and 2), as they were only dependent on claim 1. Also for present claim 4, for example, it is immediately apparent that the passage indicated as basis by the respondent (page 4, line 23) does not disclose channels with a depth of between 150 and 400 micrometers, as in present claim 4; instead, 50 to 500 micrometers is disclosed. This passage is hence not an adequate basis for present claim 4, which of course finds a basis in originally filed claim 5, but not in combination with the features of originally filed claim 2 which are also now encompassed by present claim 1: again originally filed claim 5 was only dependent on claim 3 which was in turn only dependent on claim 1.

- 8.1.2 These conclusions do not contradict the findings of the technical board in decision T 329/06, wherein it was decided that the claims of the main request (which was identical to the present main request) complied with Article 123(2) EPC. Indeed, in T 329/06 the board had to decide on combinations of claims which were already present in the granted patent. In view of the fact that Article 100(c) EPC was not a ground of opposition in the present case, nor was it raised by the opposition division of its own motion, the conclusions drawn by the previous board under Article 123(2) EPC only concerned the amendments made to granted claim 1, namely the added undisclosed disclaimer and some minor



linguistic corrections. These conclusions are obviously not challenged by the present board. The present objections do not concern combinations of features that were already present in the granted claims but rather those that were not: for such amendments, the board has the power and the duty to examine their compliance with all requirements of the EPC.

9. Auxiliary request 8

9.1 Article 123(2) EPC

9.1.1 The same conclusions as for auxiliary request 7 apply also to auxiliary request 8. Claim 1 of this request is a combination of granted claims 1, 2 and 12, and again no basis can be found for all new combinations arising in the dependent claims.

9.1.2 Auxiliary request 8 thus contravenes Article 123(2) EPC.

10. Auxiliary request 9

10.1 Article 123(2) EPC

10.1.1 No basis can be found for the feature added to claim 1 of this request: each of the many passages indicated by the respondent (see point XIII above) may relate to specific embodiments of means for control of culture medium perfusion but cannot provide a basis for the feature as generally disclosed in the claim and even less so in combination with the other features of the claim (or of the dependent claims).

10.1.2 Auxiliary request 9 thus contravenes Article 123(2) EPC.

11. Auxiliary requests 10 and 11

11.1 Admissibility

11.1.1 These requests, which were filed only at oral proceedings before the board, correspond respectively to auxiliary requests 7 and 8, wherein dependent claims have been deleted in order to overcome the objections under Article 123(2) EPC.

11.1.2 Under Article 13(1) RPBA, such late-filed requests are considered amendments to a party's case and admissible only at the board's discretion. Said discretion is to be exercised in view of *inter alia* the need for procedural economy, i.e. the need to conclude proceedings swiftly and so create legal certainty. As stated in decision T 183/09 of 9 September 2010 (point 4.1 of the Reasons), procedural economy "plays an increasingly dominant role as appeal proceedings progress to their end. In the final stages of an appeal procedure it may in fact come to outweigh all other factors in the balance of interests that the board must strike when deciding admissibility of new requests or of new facts and evidence. This shift in balance of interests towards legal certainty is a consequence of the judicial nature of an inter partes appeal procedure." As a consequence, an amendment by a party of its case at the final stage of appeal proceedings is seen as justifiable only if it is an appropriate and immediate reaction to unforeseeable developments which do not lie in the responsibility of the party submitting the amendment (T 1990/07 of 13 June 2012, point 7 of the Reasons).

11.1.3 The board notes that the objections that these requests attempt to overcome were raised by the board in its communication accompanying the summons to oral proceedings, which was issued already in October 2014. Thus, said requests could and should have been filed with the reply to the board's communication raising these objections for the first time. However, the respondent replied to this communication but chose not to submit amended claims. The same objections were picked up by the appellant in its reply to the communication by the board; the respondent replied to these submissions of the appellant but again did not submit any amended claims: it did, in fact, state that it would be prepared "to file a replacement Auxiliary Request 7 from which the dependent claims (...) are removed", but it did not submit such amended request until the oral proceedings. Hence, in spite of being aware of the objections with respect to the dependent claims of auxiliary requests 7 and 8 more than half a year before the oral proceedings, the respondent chose not to file requests limited to the subject-matter of respective independent claims 1 in order to set out its case and determine the framework for discussion at the oral proceedings in good time.

11.1.4 In this respect, it should be noted that, although indeed the main claim of these requests had been already on file since May 2006 as an element of auxiliary requests 7 and 8 (which were filed together with the statement of the grounds of appeal in the first appeal proceedings), it had never been discussed, because only the main request was examined - by either the previous board in T 329/06 or by the opposition division in the appealed decision. The filing at the oral proceedings of auxiliary requests 10 and 11 can

therefore not be accepted as an appropriate and immediate reaction to unforeseeable developments.

11.1.5 For the above reasons, the board thus made use of its discretionary power under Article 13 RPBA and decided not to admit auxiliary requests 10 and 11 into the proceedings.

## Order

### **For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



N. Maslin

U. Oswald

Decision electronically authenticated