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**Datasheet for the decision
of 18 June 2026**

Case Number: T 1378/24 - 3.3.02

Application Number: 14737491.2

Publication Number: 2943231

IPC: A61L27/40

Language of the proceedings: EN

Title of invention:
SYNTHETIC SCAFFOLDS

Applicant:
Harvard Apparatus Regenerative Technology, Inc.

Headword:

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Amendments - allowable (no) - added subject-matter (yes)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1378/24 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 18 June 2026

Appellant: Harvard Apparatus Regenerative Technology, Inc.
(Applicant) 84 October Hill Road
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Representative: Graham Watt & Co
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted/electronically
transmitted on 28 May 2024 refusing European
patent application No. 14737491.2 pursuant to
Article 97(2) EPC.**

Composition of the Board:

Chairman M. O. Müller
Members: M. Kollmannsberger
M. Blasi

Summary of Facts and Submissions

- I. The applicant appealed against the examining division's decision to refuse European patent application No. 14 737 491.2 under Article 97(2) EPC.
- II. The patent application concerns methods for producing synthetic scaffolds useful for the engineering of artificial tissues or organs.
- III. During examination proceedings, the appellant requested that a patent be granted on the basis of one of several sets of amended claims. The decision under appeal was based on the claims of the appellant's final main request and two auxiliary requests.
- IV. Independent claims 1 and 4 of the appellant's main request underlying the decision under appeal read as follows:

Claim 1:

"A method of producing a synthetic scaffold, the method comprising assembling a synthetic scaffold using a first material for a first structural component and a second material for a second structural component, wherein the first material of the first structural component is a synthetic electrospun nanofiber material configured as a tube and the second material is either a synthetic material or a natural material wherein the second material is configured as a perfusion pathway, the first material configured as a tube, wherein the

synthetic electrospun material has a surface that is modified or coated to promote at least one of cellularization, cell growth, cell viability, wherein the scaffold has a size and shape similar to gastrointestinal tissue, and wherein the perfusion pathway has a first end and a second end and a plurality of branches that extend from the perfusion pathway and are disposed between the first and second ends; and introducing one or more cell types onto the first structural component, wherein the first end of the perfusion pathway is connectable with a bioreactor and wherein the second end of the perfusion pathway is proximate to the one or more cell types coated on the surface of the tubular member and where the perfusion pathway is configured to deliver the perfusion fluid to the cells to support cellularization, the cell viability, or the cell growth."

Claim 4:

"A synthetic scaffold comprising a first structural component produced from a first material, wherein the first material is a perfusion pathway and a second structural component produced from a second material, wherein the second component is a tubular body containing the first component therein composed of a synthetic electrospun nanofiber polymeric material forming a porous body, and one or more cell lines coated on the second component and supported by the porous body, the perfusion pathway connectable to a bioreactor and configured to promote cell growth and differentiation."

Claim 1 of auxiliary requests 1 and 2 is identical to claim 4 of the main request.

- V. In its decision, the examining division concluded that independent claim 1 of the appellant's main request contained subject-matter extending beyond the content of the application as filed, and thus contravened Article 123(2) EPC. The same held for independent claim 4, which contained some of the features objected to in claim 1. Since this claim appeared as claim 1 in auxiliary requests 1 and 2, those requests were also found not to be allowable.
- VI. Here, the application as filed refers to the application as published under the PCT, WO 2014/110300 A1.
- VII. In the statement setting out the grounds of appeal, the appellant submitted arguments as to why the subject-matter of claim 1 of the main request did not extend beyond the content of the application as filed. No specific arguments were filed concerning claim 4 of the main request or claim 1 of auxiliary requests 1 and 2, which is identical to it.
- VIII. On 7 August 2025, the appellant was summoned to oral proceedings before the board, scheduled to take place on 9 June 2026.
- IX. In its letter dated 30 September 2025, the appellant informed the board that it would not be attending oral

proceedings and would not be represented at the hearing.

- X. On 9 October 2025 the board informed the appellant that oral proceedings had been cancelled and that the procedure would be continued in writing.
- XI. As understood by the board, the appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of the main request or, alternatively, of auxiliary request 1 or 2, all of which underlie the decision under appeal.

Reasons for the Decision

- 1. Decision taken in written proceedings
 - 1.1 The appellant's statement that it would not be attending the oral proceedings means that it did not wish to make any oral submissions before the board. The appellant's statement was therefore understood to imply a withdrawal of the request for oral proceedings, which had initially been made in the statement setting out the grounds of appeal. The board did not consider oral proceedings to be expedient in the present case either, and so no oral proceedings needed to be held, cf. Article 116(1) EPC.
 - 1.2 This decision is based on the appellant's written submissions and on the grounds and evidence as set out in the decision under appeal. The appellant had an

opportunity to comment, so its right to be heard has been respected, Article 113(1) EPC.

2. Main request, non-allowable amendments
(Article 123(2) EPC) in claim 1

Claim 1 relates to a method of producing a synthetic scaffold in which a scaffold is assembled from first and second structural components made of a first and a second material.

At least some of the objections detailed in the decision under appeal are justified.

2.1 Claim 1 specifies that the first material of the first structural component is a "*synthetic electrospun nanofiber material configured as a tube*".

2.1.1 One of the possibilities defined in claims 2 and 4 of the application as filed is that the first material is synthetic and electrospun. However, the examining division held that there was no disclosure in the application as filed for the material of the first structural component to be an electrospun nanofiber material of tubular shape. The passage on page 20 (second and third full paragraphs) of the application as filed to which the appellant referred did not relate to the material of the first structural component, but to the synthetic organ structure as a whole.

2.1.2 In its statement setting out the grounds of appeal, the appellant submitted that the tubular shape of the first structural component was disclosed throughout the application as filed. The appellant referred to page 25 (third full paragraph), where the tubular shape of a

support is disclosed, or to the passage on page 20, where tubular shapes were likewise described.

2.1.3 However, while the passages referred to by the appellant may disclose tubular shapes, they do not disclose that the first component of the scaffold is made of an electrospun nanofiber material of tubular shape. As correctly held by the examining division, the passages on page 20 relate to the synthetic organ structure as a whole, not to the first component in the method defined in claim 1. The passage on page 25 does not relate to the first material either. It refers to a support as a part of the scaffold without reference to any material, let alone the material defined for the first component in claim 1.

2.2 Regarding the fact that the second material forms a perfusion pathway, the claim specifies that "*the perfusion pathway has a first end and a second end and a plurality of branches that extend from the perfusion pathway and are disposed between the first and second ends*". Further, regarding the method step of introducing cells onto the first structural component, the claim specifies that "*the first end of the perfusion pathway is connectable with a bioreactor and [...] the second end of the perfusion pathway is proximate to the one or more cell types coated on the surface of the tubular member and [...] the perfusion pathway is configured to deliver the perfusion fluid to the cells to support cellularization, the cell viability, or the cell growth.*"

2.2.1 With respect to these features, labelled features G and H in the decision under appeal, the examining division held that the appellant's reference to figure 1A and the corresponding description of this figure on pages

11 onwards was not sufficient as a basis for the features in the claim. The board agrees. The system depicted in figure 1A is complex and contains many features that are not part of the claim. Even if features G and H can be identified in figure 1A, they have been extracted from their context. Putting these features in the general context of claim 1 creates subject-matter which extends beyond the application as filed.

2.2.2 In its statement setting out the grounds of appeal, the appellant explained what features G and H were intended to define (page 3, second paragraph). However, no basis for these features is indicated in the application. The only references given relate to coating the scaffold and seeding it to promote cellularisation, but not to the above features G and H.

2.3 The appellant argued that the decision under appeal relied on simple literal wording rather than on the skilled person's reading with a view to understanding the invention. Moreover, when the application was read through the eyes of the skilled person, *"the claims as presented in the main request are fully disclosed but focused on particular embodiments"*.

The board disagrees. While it may be correct to state that the application as filed must be read through the eyes of the skilled person, Article 123(2) EPC nevertheless requires a direct and unambiguous disclosure of the claimed subject-matter, see the Enlarged Board of Appeal's decision G 2/10 (OJ EPO 2012, 376), point 4.3 of the Reasons. No such disclosure is apparent in the present case.

- 2.4 Claim 1 of the main request contains subject-matter that extends beyond the application as filed and thus contravenes Article 123(2) EPC.
- 3. Main request, non-allowable amendments (Article 123(2) EPC) in claim 4
 - 3.1 In claim 4 the first structural component is configured as a perfusion pathway and the second structural material is tubular, i. e. the opposite of what is defined in claim 1.
 - 3.2 The examining division stated that the same objections applied to claim 4 as to claim 1. The board agrees. At least the objection regarding the "*synthetic electrospun nanofiber material configured as a tube*" as set out above, here in relation to the second structural component, applies in the same way to claim 4 as to claim 1.
 - 3.3 The appellant did not present any arguments with respect to the examining division's findings on claim 4.
 - 3.4 Claim 4 of the main request contains subject-matter that extends beyond the application as filed and thus contravenes Article 123(2) EPC.
- 4. Auxiliary requests 1 and 2, non-allowable amendments (Article 123(2) EPC)
 - 4.1 The appellant did not submit any arguments rebutting the examining division's decision to hold claim 1 of auxiliary requests 1 and 2 not to be allowable. The

appellant's submission as regards the auxiliary requests reads as follows.

"The only objections to the Auxiliary Requests related to matters dealt with in the comments relating to the Main Request. It is believed that the Auxiliary Requests represent allowable subject matter regardless of the findings on the Main Request."

- 4.2 Claim 1 of auxiliary requests 1 and 2 is identical to claim 4 of the main request. This claim is the result of amendments which are not allowable under Article 123(2) EPC, see above. Thus, a patent cannot be granted on the basis of the claims of these requests.
5. The examining division's decision to refuse the patent application under Article 97(2) EPC is therefore upheld.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



U. Bultmann

M. O. Müller

Decision electronically authenticated