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**Datasheet for the decision
of 14 February 2023**

Case Number: T 1703/19 - 3.3.10

Application Number: 09805294.7

Publication Number: 2326335

IPC: A61L27/36, A61L27/56

Language of the proceedings: EN

Title of invention:

COMPOSITION FOR A TISSUE REPAIR IMPLANT AND METHODS OF MAKING
THE SAME

Applicant:

Lifenet Health

Headword:

Relevant legal provisions:

Keyword:

Decisions cited:

Catchword:



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Case Number: T 1703/19 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 14 February 2023

Appellant: Lifenet Health
(Applicant) 1864 Concert Drive
Virginia Beach, VA 22453 (US)

Representative: SJW Patentanwälte
Goethestraße 21
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 2 January 2019
refusing European patent application No.
09805294.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair P. Gryczka
Members: R. Pérez Carlón
F. Blumer

Summary of Facts and Submissions

I. The appellant lodged an appeal against the decision of the examining division refusing European patent application No. 09805294.7 for lack of inventive step.

II. The documents cited included the following:

D1 US 2007/0254041 A1

D3 US 2008/0147197 A1

III. The sole request before the examining division corresponds to the third auxiliary request in the current appeal proceedings. Claim 1 reads as follows:

"A process for preparing an osteoinductive tissue repair implant having a porous sponge-like structure comprising

a homogenizing a connective tissue from 15°C to 100°C for a period of time from 0.5 minutes to 30 minutes to produce a connective tissue homogenate, wherein the connective tissue homogenate contains connective tissue particles;

b mixing said connective tissue homogenate with a carrier solution to produce a connective tissue carrier;

c mixing one or more natural or synthetic bone fragments with said connective tissue carrier to produce a tissue repair mixture;

d freezing or freeze-drying said tissue repair mixture to produce a porous sponge-like structure and

create a three-dimensional framework to entrap said natural or synthetic bone fragments; and

e treating said frozen or freeze-dried porous sponge-like structure with one or more treatment solutions to produce a stabilized porous sponge-like structure,

wherein step (e) is carried out with a treatment solution comprising ionic, enzymatic, chemical, or photoactive crosslinking agents, or a combination comprising at least one of the foregoing agents."

- IV. The examining division concluded that claim 1 had the required basis in the application as originally filed, and that its subject-matter was novel. Document D1 was the closest prior art. The problem underlying the claimed invention was to provide an alternative process for preparing an osteoinductive tissue repair implant. The claimed solution, which was characterised by freeze-drying first (step (d)) and then crosslinking (step (e)), was obvious to a skilled person in view of D3 and therefore lacked inventive step (Article 56 EPC).
- V. With the statement setting out the grounds of appeal, the appellant filed a main request and first to third auxiliary requests. The main request and the first and second auxiliary requests have claims directed to an osteoinductive tissue repair implant. The third auxiliary request corresponds to the sole request forming the basis of the appealed decision.
- VI. The appellant's arguments were as follows.

The product of claim 1 of the main request and the first and second auxiliary requests was novel. The

examining division's conclusion on the issue of novelty (point 3. of the minutes, last sentence) was thus not correct. The appellant provided no arguments regarding the admissibility of these requests.

Document D1 was the closest prior art for the method of claim 1 of the third auxiliary request. The method of D1 did not lead to a three-dimensional porous sponge-like structure. In addition, D1 disclosed neither homogenisation step (a) nor the order of steps (d) and (e) required by claim 1. The problem underlying the claimed invention was to provide a simple and economical process for the preparation of an osteoinductive tissue repair implant having a porous sponge-like structure comprising a uniform composition containing a connective tissue homogenate with connective tissue particles, carrier and naturally or synthetic bone fragments that were evenly distributed within a three-dimensional framework. The claimed solution was characterised by including a homogenisation step and by freeze-drying before crosslinking. The prior art did not teach that these features could solve the problem of obtaining a sponge-like structure and thus the claimed solution was inventive.

VII. The board informed the appellant in a communication dated 12 August 2020 that it was likely to consider the main request and the first and second auxiliary requests not admissible, as the appealed decision had not dealt with claims directed to an implant. The board saw not only D1 but also D3 as a suitable starting point for examining inventive step. Regardless of which of them came closest to the process of claim 1 of the third auxiliary request, the board was likely to

consider it not inventive.

VIII. The appellant did not file any response addressing any of the issues mentioned by the board. On the eve of the scheduled oral proceedings the appellant informed the board that it would not be attending. The oral proceedings were cancelled.

IX. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted with the claims of the main request or with the claims of the first to third auxiliary requests, all requests being as filed with the statement of grounds of appeal.

Reasons for the Decision

1. The appeal is admissible.

2. Main request, first and second auxiliary requests.
Admissibility

2.1 Claim 3 of the main request is directed to an osteoinductive tissue repair implant.

2.2 The sole request pending before the examining division at the end of the oral proceedings, annexed both to the decision and to the minutes, did not contain any claim directed to an implant.

During the oral proceedings before the examining division a number of requests were filed. Most of them are not annexed to the minutes of the oral proceedings. The text of the minutes shows nevertheless the following sequence of events.

The examining division dealt with a number of requests containing claims directed to an implant at the oral proceedings: the main request filed with a letter of 30 October 2018, a new main request replacing it, which was filed during the oral proceedings at 9:15 a.m. (point 2. of the minutes, last sentence), and a new main request filed at 9:35 a.m. (point 3. of the minutes, lines 11 and 12).

The examining division concluded that the product which was the subject-matter of claim 3 of the main request filed at 9:35 a.m. was not novel (last sentence of point 3. of the minutes). That request was then replaced by the sole request, annexed to the minutes, which had no claim directed to a product (point 4. of the minutes). Only that request was pending at the end of the oral proceedings (point 6. of the minutes). It corresponds to the appellant's third auxiliary request.

- 2.3 Article 12(4) RPBA 2007 stipulates that a board has the discretion not to admit requests which could have been presented before the opposition division. According to the case law that the Boards of Appeal do not admit into examination appeal proceedings requests that have been withdrawn before the examining division (Case Law of the Boards of Appeal, 10th edition, 2022, V.A. 5.11.4.c).

By withdrawing every request having claims directed to an implant, the appellant prevented the examining division from issuing a reasoned decision on its merits. Admitting the main request into the proceedings would have involved either the board having to give a first ruling on the claimed implant, which is contrary to the revising purpose of appeal proceedings, or the case being remitted to the examining division, which

would be contrary to procedural economy. For these reasons, the board did not admit the appellant's main request into the proceedings.

2.4 Claim 3 of the first and second auxiliary requests is directed to a tissue repair implant too. These requests are not admitted into the proceedings for the same reasons as the main request.

3. Third auxiliary request. Inventive step

Claim 1 of the third auxiliary request relates to a process for preparing an osteoinductive tissue repair implant having a porous sponge-like structure.

3.1 Closest prior art

3.1.1 The appellant agreed with the examining division that document D1 was the closest prior art. The board also sees D1 as a suitable starting point.

3.1.2 D1 relates to the preparation of osteoinductive demineralised bone matrix devices. Example 1 of D1 [0052] discloses blending a milled, crosslinked collagen sponge with a carrier solution containing sodium alginate. Bone matrix is added, the slurry is poured into moulds, crosslinked with calcium chloride and lyophilised.

3.1.3 The process of D1 carries out steps (d) and (e) in the reverse order. Claim 1 requires freeze-drying first and then treatment with a crosslinking agent. The implant of D1 is crosslinked first and then freeze-dried.

3.1.4 The appellant argued that homogenising step (a) further distinguished the claimed process from that of D1.

Although D1 discloses the use of milled collagen sponge and a milling step is arguably a homogenising step, the board will examine the issue of inventive step considering the homogenising step (a) of claim 1 to be a feature distinguishing the claimed process from that of D1 too.

- 3.1.5 The appellant argued that D1 did not disclose the preparation of an implant having a porous sponge-like structure. This was also a feature differentiating the claimed invention from the method of D1.

However, the wording of claim 1 requiring the product of the claimed process to be an implant "having a porous sponge-like structure" does not limit the process of claim 1 to the preparation of a entirely spongeous implant. The implant of D1 contains milled collagen sponge and thus has a porous sponge-like structure, as required by claim 1.

Document D3 also shows that a skilled person would not consider claim 1 to be limited to the preparation of an implant having sponge-like structure only. Despite including a solid impervious membrane in addition to a collagen sponge, the implant of D3 is disclosed as a sponge-type biomedical implant (see lines 17 to 20 of paragraph [0033]).

- 3.2 Technical problem underlying the invention

The appellant defined the problem underlying the claimed invention as being to provide a simple and economical process for the preparation of an osteoinductive tissue repair implant having a porous sponge-like structure comprising a uniform composition containing a connective tissue homogenate with

connective tissue particles, carrier and naturally or synthetic bone fragments that are evenly distributed within a three-dimensional framework (page 6 of the grounds of appeal, first paragraph).

The problem of providing an implant with evenly distributed components is also solved by the process of D1. Example 1 of D1 discloses forming a uniform mixture of collagen and alginate [0052]. After adding demineralised bone matrix, additional mixing allows a uniform mixture to be obtained (last three lines of the left column on page 7). The implant obtained by the method of D1 is thus homogeneous, like that obtainable by the process of claim 1. In the absence of a direct comparison, the latter cannot be considered more homogenous than the former.

Claim 1 requires one step more than the process of Example 1 of D1, namely homogenisation step (a); steps (d) and (e) are merely carried out in the reverse order. No simplification is apparent with respect to the process of the closest prior art, D1.

The problem underlying the claimed invention is thus seen in providing an alternative process leading - like that of D1 - to a homogeneously distributed sponge-like implant in a simple and economical manner.

3.3 Solution

The solution to this technical problem is the claimed process, characterised in that freeze-drying (step (d)) precedes crosslinking (step (e)) and in that it includes a homogenising step (a) at a defined temperature and for a defined period of time.

3.4 Success

The claimed process credibly solves the problem of providing an alternative osteoinductive tissue repair implant in view of the examples in the application.

3.5 It thus remains to be decided whether the proposed solution to the objective problem defined above would have been obvious to a skilled person in view of the prior art.

3.5.1 The order of steps (d) and (e) required by claim 1 is known in the context of the production of osteogenic porous implants, as shown by D3. Like D1, document D3 relates to the preparation of sponge-like implants containing bone fragments and a collagen slurry. In the process of D3 (see paragraph [0033]), the mixture is freeze-dried and then exposed to formaldehyde vapour for crosslinking.

Seeking an alternative process, a skilled person would have turned to a document in the field of preparation of implants for osteogenesis such as D3 and would have considered freeze-drying before crosslinking. This part of the claimed solution would thus have been obvious to a skilled person.

3.5.2 Example 1 of D1 uses milled, crosslinked collagen sponge as starting material. D1 discloses uniformity as being essential after every mixing step (see paragraph [0052], lines 9 and 18). Seeking an alternative, the skilled person would have considered homogenising the starting material. The temperature required by step (a) of claim 1, which includes room temperature, would have been an obvious option for a skilled person. The appellant did not rely on any effect which could be

linked either to the temperature or to the required homogenising time. The specific conditions required by step (a) do not, therefore, go beyond an arbitrary selection of equally possible alternatives. The part of the claimed solution requiring a homogenising step would thus also have been obvious to a skilled person.

- 3.5.3 The appellant argued that the implant disclosed in D3 included a solid impervious membrane linked to the sponge-type part. The implant was thus not completely sponge-like. For this reason, the skilled person would not have combined the content of D3 with that of D1, as the two documents related to different types of implants.

However, the implant of D3 is explicitly disclosed as a sponge-type biomedical implant in paragraph [0033], lines 17 to 20, and claim 1 does not exclude the implant obtained by the claimed process also containing an impervious membrane. This argument is thus not convincing.

- 3.5.4 The appellant also argued that D3 disclosed that the freeze-drying step induced some crosslinking, including linking to the impervious membrane. Due to the membrane characteristics, further crosslinking could only be carried out in D3 by means of a gaseous reagent (formaldehyde). The skilled person would thus not have chosen a liquid crosslinking agent, as required by the claimed method.

However, claim 1 is not limited to liquid crosslinking agents. This argument is thus also not convincing.

- 3.5.5 The appellant also argued that the skilled person would not have considered the process of D3 to lead to an

implant having uniformly distributed components like the product of the claimed method, as the solid membrane was an integral part of the structure lacking connective tissue, carrier and bone particles. For this reason too, the skilled person would not have combined the teaching of documents D1 and D3.

The board agrees with the appellant that the distribution of connective tissue, carrier and bone particles of the implant of D3 is not homogeneous throughout the whole implant. However, having regard to paragraph [0033] of D3, the part of the implant with sponge-like structure is homogenous. This argument also fails to convince the board.

3.5.6 Therefore, the claimed solution would have been obvious to a skilled person and is thus not inventive (Article 56 EPC).

4. Conclusion

The main request and the first and second auxiliary requests are not admitted into the proceedings. The third auxiliary request is not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



L. Malécot-Grob

P. Gryczka

Decision electronically authenticated