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**Datasheet for the decision
of 5 August 2013**

Case Number: T 2444/10 - 3.3.10

Application Number: 05250694.6

Publication Number: 1561480

IPC: A61L 27/24, A61L 27/56,
A61L 31/04, A61L 31/14

Language of the proceedings: EN

Title of invention:
Collagen device and method of preparing the same

Applicant:
CODMAN & SHURTLEFF INC.

Headword:
-

Relevant legal provisions:
EPC Art. 123(2), 84, 111(1)

Keyword:
"Main request: Amendments allowable (yes) - clarity (yes) -
remittal to the department of first instance"

Decisions cited:
-

Catchword:
-



Case Number: T 2444/10 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 5 August 2013

Appellant: CODMAN & SHURTLEFF INC.
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Representative: Mercer, Christopher Paul
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 15 June 2010
refusing European patent application No.
05250694.6 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: P. Gryczka
Members: C. Komenda
C. Schmidt

Summary of Facts and Submissions

- I. The appeal lies from the decision of the Examining Division posted on 15 June 2010 refusing European patent application No. 05 250 694.6 published with the publication No. 1 561 480.
- II. The Examining Division found that the subject-matter of claim 1 according to the then pending main request and auxiliary request did not fulfil the requirements of Article 84 EPC. In particular the Examining Division held that the feature that the collagen device has a plurality of pores "wherein a majority of the pores have a diameter of less than 10 micrometers" was considered as a result to be achieved. The physical steps characterizing the claimed method, namely
- mixing collagen with purified water,
 - lyophilizing the mixture into a collagen device
 - cross-linking the collagen device,
- were, however, insufficient for achieving the claimed result. The features, which were essential for the preparation of a collagen device having a plurality of pores wherein the majority of pores have a diameter of less than 10 micrometers, were indicated in the description on page 3, lines 10 to 17 and on page 6, lines 19 to 21 and related to the adjustment of the pH to solubilise the collagen and the indication of a particular ratio of collagen and water. Further, the description merely disclosed the lyophilisation of solubilised collagen, whereas the claimed method covered lyophilisation of any collagen source.
- III. With its letter dated 9 July 2013 the Appellant (Applicant) filed a new main request (claims 1 to 17)

and a first auxiliary request (claims 1 to 16).
Independent claim 1 of the new main request reads as follows:

"1. A method of preparing a collagen device having a plurality of pores wherein a majority of the pores have a diameter of less than 10 μm , said method comprising the steps of:

- i) mixing collagen with purified water for a period of time sufficient to form a mixture wherein the ratio of collagen to purified water is between 0.4% and 5.0% w/w;
- ii) adjusting the pH of the mixture to a predetermined pH level sufficient to substantially solubilise the collagen;
- iii) lyophilizing the mixture into a collagen device;
and
- iv) cross-linking the collagen device."

IV. The Appellant argued that claim 1 of the new main request fulfilled the requirements of Article 84, since the technical features, which according to the Examining Division were essential for characterizing the invention have been incorporated into claim 1.

V. The Appellant requested that the decision under appeal be set aside and that the case be remitted to the Examining Division for further prosecution on the basis of the main request, or, subsidiarily, on the basis of the first auxiliary request, all requests filed with letter dated 9 July 2013.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. *Amendments (Article 123(2) EPC)*

Claim 1 as amended is based on claim 1 as originally filed, wherein the collagen device has further been characterized as "having a plurality of pores wherein a majority of the pores have a diameter of less than 10 micrometers" derived from original claim 2. Further, in step i) of claim 1 the feature that "the ratio of collagen to purified water is between 0.4% and 5.0% w/w" from original claim 7 has been incorporated. As an additional step ii) it was inserted "adjusting the pH of the mixture to a predetermined pH level sufficient to substantially solubilise the collagen" derived from original claim 4. Steps ii) and iii) of original claim 1 have been renumbered as steps iii) and iv).

Claims 2 to 17 were based on original claims 5, 6, 8 to 13, 23 to 29 and 31. In particular, claim 2 corresponds to original claim 5; claim 3 corresponds to original claim 6; claim 4 corresponds to original claim 8; claim 5 corresponds to original claim 9; claim 6 corresponds to original claim 10; claim 7 corresponds to original claim 11; claim 8 corresponds to original claim 12; claim 9 corresponds to original claim 13; claim 10 corresponds to original claim 23; claim 11 corresponds to original claim 24; claim 12 corresponds to original claim 25; claim 13 corresponds to original claim 26; claim 13 corresponds to original claim 27;

claim 15 corresponds to original claim 28; claim 16 corresponds to original claim 29; claim 17 corresponds to original claim 31, the references in these claims having been adapted accordingly.

Therefore, the Board concludes that the requirements of Article 123(2) EPC are fulfilled.

3. *Article 84 EPC*

3.1 The decision under appeal dealt with a then pending main request and auxiliary request. The decision on these requests was based exclusively on the independent claims 1, which were all directed to a method for preparing a collagen device, which according to the decision under appeal did not comply with the requirements of Article 84 EPC (see paragraph II supra).

3.2 Before the Board for the first time a main request was presented, which contained substantial amendments taking into account the statements in paragraphs 2.5 and 3.3 of the decision under appeal. By incorporating these essential features into claim 1 of the main request the grounds for refusal of the application in suit were overcome, with the consequence that the appeal is well founded.

4. *Remittal*

Having so decided, the Board has not taken a decision on the whole matter, since the Examining Division decided solely on the issue of whether claim 1 fulfilled the requirements of Article 84 EPC. As the Examining Division has not yet ruled on sufficiency of

disclosure (Article 83 EPC), novelty and inventive step of the claimed subject-matter, the Board considers it appropriate to exercise the power conferred on it by Article 111(1) EPC to remit the case to the Examining Division for further prosecution on the basis of the claims according to the main request in order to enable the first instance to decide on the outstanding issues.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside
2. The case is remitted to the department of first instance for further prosecution upon the basis of the main request.

The Registrar:

The Chairman:

C. Rodríguez Rodríguez

P. Gryczka