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**Datasheet for the decision
of 22 January 2019**

Case Number: T 0774/18 - 3.3.03

Application Number: 11812644.0

Publication Number: 2599820

IPC: C08H1/00, A61K8/65, A61K38/00,
C08J3/14, C08L89/00

Language of the proceedings: EN

Title of invention:
COLLAGEN POWDER AND/OR COLLAGEN-DERIVED POWDER, AND PRODUCTION
METHOD FOR SAME

Applicant:
NIPPI, INCORPORATED

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

Keyword:
Clarity (yes) after amendment
Amendments - allowable (yes)
Remittal to the department of first instance

Decisions cited:
G 0010/93, G 0002/10



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Case Number: T 0774/18 - 3.3.03

D E C I S I O N
of Technical Board of Appeal 3.3.03
of 22 January 2019

Appellant:
(Applicant)

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Decision under appeal:

**Decision of the Examining Division of the
European Patent Office posted on 2 November 2017
refusing European patent application No.
11812644.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman D. Semino
Members: F. Rousseau
C. Brandt

Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division to refuse European patent application No. 11 812 644.0, filed as International application PCT/JP2011/067556 by a decision posted on 2 November 2017. The decision was based on a main request and an auxiliary request 1, both submitted with letter of 20 September 2017, as well as an auxiliary request 2 submitted during the oral proceedings on 23 October 2017.

- II. According to the reasons for the decision, it was unclear whether the term "*in the range of 12 to 50% by mass of collagen*" present both in claim 1 of the main request and in claim 1 of auxiliary request 1 referred to the dispersion in a hydrophilic organic solvent or to the crude collagen precipitate. In claim 1 of auxiliary request 2 that expression was clearly defined to refer to the concentration of the crude collagen precipitate resulting from adjustment of the concentration of the precipitate obtained in step (A). However, the concentration was "*defined idem per idem as resulting collagen precipitate [...] based on the mass of the crude collagen precipitates, i.e. the term to be defined*" was "*used in its definition*". In addition, an interpretation of the claims in the light of the description, in particular of the examples, did not make the unclear formulation of the claims understandable. The examining division held that since the claims and the description were unclear under Article 84 EPC, the application was to be refused.

- III. The decision was appealed with letter of 29 December 2017 and the statement setting out the grounds of appeal was submitted with letter of

21 February 2018 to which a main request and auxiliary requests 1 and 2 were attached.

IV. Following the Board's communication sent in preparation of the oral proceedings the appellant submitted with letter of 20 December 2018 three sets of amended claims labelled Auxiliary Requests III to V.

V. Oral proceedings were held on 22 January 2019 in the course of which all pending claim requests were replaced by a new main request, whose claims read as follows:

"1. A method of producing a collagen powder and/or a collagen derivative powder, which is characterized by comprising the steps of:

(A) obtaining isoelectric precipitates having an average particle size of 1 to 1,000 μm by isoelectrically precipitating a solution containing a collagen and/or a collagen derivative at a pH of 3.5 to 10 while controlling association of the collagen and/or the collagen derivative, or by pulverizing the resulting isoelectric precipitates;

(B) adjusting the concentration of the resulting collagen precipitate and/or collagen derivative precipitate contained in the isoelectric precipitates to prepare a crude collagen precipitate containing 12 to 50% by mass of collagen and/or collagen derivative;

(C) dispersing the thus obtained crude collagen precipitate in a hydrophilic organic solvent; recovering solids; and

(D) drying the solids to obtain a collagen powder and/or a collagen derivative powder.

2. The method according to claim 1, wherein the association of the collagen is controlled by stirring the solution containing the collagen and/or the collagen derivative.

3. A method of producing a collagen powder and/or a collagen derivative powder, which is characterized by comprising the steps of:

(A) obtaining salt precipitates having an average particle size of 1 to 1,000 μm by subjecting a solution containing a collagen and/or a collagen derivative to salt precipitation while controlling association of the collagen and/or the collagen derivative, or by pulverizing the resulting precipitates;

(B) adjusting the concentration of the resulting collagen and/or collagen derivative contained in the salt precipitates to 12 to 50% by mass, thereby preparing a crude collagen precipitate;

(C) dispersing the thus obtained crude collagen precipitate in a hydrophilic organic solvent; recovering solids; and

(D) drying the solids to obtain a collagen powder and/or a collagen derivative powder.

4. The method according to any one of claims 1 to 3, wherein the hydrophilic organic solvent is an alcohol, a ketone, an ether or a mixture thereof.

5. A collagen powder and/or a collagen derivative powder obtained by the method according to claims 1 to 4."

VI. The appellant essentially submitted that the amendments contained in claims 1 and 3 overcame the clarity objection raised by the examining division, while being based on paragraphs [0030], [0031] and the examples of the application as filed.

VII. 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 filed during the oral proceedings on 22 January 2019.

Reasons for the Decision

Clarity

1. The amended set of claims submitted during the oral proceedings before the Board defines in an unambiguous manner that the term "in the range of 12 to 50% by mass" refers to the amount of collagen and/or collagen derivative contained in the crude precipitate obtained after step (B) of claim 1 or claim 3. The Board is therefore satisfied that the clarity objection on the basis of which the decision to refuse the present application was based has been overcome, as no ambiguity remains.
2. According to decision G 10/93 of the Enlarged Board of Appeal (OJ 1995, 172) proceedings before the boards of appeal in ex parte cases are primarily concerned with examining the contested decision, but the board has the

power to enforce any grounds for refusal of an application, in particular grounds which the examining division did not consider at all or held to be satisfied. This does not however mean that boards of appeal carry out a full examination of the application as to patentability requirements, as this is the task of the examining division. The board must decide after due assessment of the particular circumstances whether it will rule on the case itself or whether it will remit the matter for further prosecution to the examining division (Article 111(1), second sentence, EPC) (see points 3 to 5 of the Reasons for the Decision).

3. In the present case the whole examination before the examining division essentially focused on the clarity issue on the basis of which the contested decision was taken. While pursuant to Article 111(1) EPC the board may exercise any power within the competence of the department which was responsible for the decision, the board would consider it appropriate in the present situation to remit the case to the examining division for further prosecution, as among others the fundamental issue of novelty, in particular that of the powder obtainable by the claimed methods and inventive step were not or not fully examined. However, before doing so, the Board should be satisfied that the amendments introduced in the new claims, at least those which are introduced to overcome the objections leading to the refusal of the application, are not manifestly unallowable, in particular having regard to the requirements of Article 123(2) EPC.

Amendments

4. The method defined in claim 1 of the new request has been indicated to be based on paragraph [0030] of the application as filed (the board noting that an equivalent basis can be found in claims 4 and 6) in which the expression "*a crude collagen precipitate containing 12 to 50% by mass of the collagen precipitate and/or collagen derivative precipitate*" has been amended to read "*a crude collagen precipitate containing 12 to 50% by mass of the collagen and/or collagen derivative*".

5. The skilled person would recognize that the definition of an amount of 12 to 50% by mass of the collagen precipitate or collagen derivative precipitate in paragraph [0030] or claims 4 and 6 of the application as filed is obviously in error, as it does not make sense to define that the collagen/collagen derivative precipitate obtained in step (B) contains only a part of itself, i.e. from 12 to 50% by mass of the same precipitate. The skilled person would rather understand based on the examples of the application as filed (example 1, page 36, line 19; example 4, page 40, line 23; example 5, page 42, line 2; example 6, page 42, line 15; example 7, page 43, line 6; example 8, page 44, line 2; example 9, page 45, line 1; example 10, page 45, line 25 and example 11, page 46, line 14), which disclose that the crude collagen precipitate is defined by reference to a collagen concentration (and not a concentration of collagen precipitate) by mass with specific values disclosed in the examples ranging from 12 to 42% by mass, that the concentration of the collagen precipitate / collagen derivative precipitate defined in paragraph [0030] and claims 4 and 6 of the application as filed is meant to

refer to a concentration of collagen or collagen derivative in said precipitate. Any different understanding would not make technical sense.

6. Accordingly, operative claim 1 does not result in the skilled person to be presented with new technical information in comparison to the application as filed, which in accordance with the established Case Law of the Boards of Appeal of the EPO is the relevant question to be decided in assessing whether the subject-matter of an amended claim extends beyond the content of the application as filed (see G 2/10, OJ 2012, 376, point 4.5.1 of the Reasons and Case Law of the Boards of Appeal, 8th Edition, 2016, II.E.1).
7. As to operative claim 2, stirring of the solution containing the collagen and/or the collagen derivative as a means for controlling association of the collagen when carrying out isoelectric precipitation is disclosed in claim 5 as filed, which refers back to claim 4 defining the same method as in paragraph [0030] of the application as filed, but limited to a method comprising control of the association of the collagen. Therefore, the subject-matter of operative claim 2 is also disclosed in the application as filed.
8. The method defined in operative claim 3 is the same as that defined in paragraph [0031] or in claims 7 and 8 of the application as filed in which the crude collagen precipitate is characterized like in operative claim 1 by an amount by mass of collagen and/or collagen derivative from 12 to 50%. This amendment meets the requirements of Article 123(2) EPC for the same reasons as explained in above point 5. Moreover, in the context of the obtention of salts precipitates, the expression "*by pulverizing the resulting precipitates*" instead of

the original expression "*by pulverizing the resulting salt precipitates*" does not change the meaning of the methods disclosed in paragraph [0031] or claim 8 as filed. Consequently, the subject-matter of operative claim 3 also does not extend beyond the content of the application as filed.

9. The use of a hydrophilic organic solvent which is an alcohol, a ketone, an ether or a mixture thereof, is disclosed in claim 9 as filed which is dependent on method claims 4, 6, 7 and 8 of the application as filed on which operative claims 1 and 3 are based. The disclosure in the application as filed of the methods in accordance with any of operative claims 1 to 4 provides also a disclosure for the collagen powder and for the collagen derivative powder which are obtainable by said methods. Hence, the subject-matter defined in operative claims 4 and 5 also do not result in the skilled person be presented with new technical information.
10. Consequently, the Board concludes that the claim request submitted by the appellant during the oral proceedings before the board is in keeping with the requirements of Article 123(2) EPC.

Remittal

11. Having regard to the remarks in above point 3 the Board consider it appropriate in the present situation to remit the case to the examining division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division for further prosecution on the basis of the main request filed during the oral proceedings on 22 January 2019.

The Registrar:

The Chairman:



B. ter Heijden

D. Semino

Decision electronically authenticated