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Datasheet for the decision of 11 June 2013

Case Number: T 0814/10 - 3.3.07

Application Number: 01995012.0

Publication Number: 1459728

IPC: A61K 7/00, A61K 47/42, B01F 17/30

Language of the proceedings: EN

Title of invention:
Emulsifier and process for producing the same

Applicant:
NATIONAL INSTITUTE OF AGROBIOLOGICAL SCIENCES
Eaudeleman Co., Ltd.

Headword:
Process for producing an emulsifier/NATIONAL INSTITUTE OF AGROBIOLOGICAL SCIENCES, EAUDELEMAN CO. LTD

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step, all requests (no)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0814/10 - 3.3.07

D E C I S I O N
of the Technical Board of Appeal 3.3.07
of 11 June 2013

Appellant: (Applicant 1)
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 9 November 2009 refusing European patent application No. 01995012.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: J. Riolo
Members: D. Boulois
M.-B. Tardo-Dino

Summary of Facts and Submissions

I. European patent application No. 01 995 012.0 was refused by a decision of the examining division pronounced on 16 October 2009 on the grounds of non-compliance with Article 56 EPC.

II. The decision was based on the main request filed during the oral proceedings.

The independent claims of the main request read:
"1. A method for production of an emulsified cosmetic material, having skin cell growth-promoting property, whereby an emulsifier comprising an aqueous solution of silk protein composed mainly of amorphous silk fibroin with a crystallization degree of less than 10% and molecular weight ranging from 40.000 to 370.000 is dried to produce an amorphous silk substance which substance is then reimmersed in water to obtain a silk aqueous solution, is used for emulsifying an oily component, wherein the aqueous solution of silk protein is obtained by dissolving unscoured, partially scoured or scoured spun silkworm fibers (cocoon filaments) with a neutral salt and then dialyzing the solution.

2. A method for production of an emulsified cosmetic material, having skin cell growth-promoting property, whereby an emulsifier comprising an aqueous solution of silk protein composed mainly of amorphous silk fibroin with a crystallization degree of less than 10% and molecular weight ranging from 40.000 to 370.000 is allowed to stand at 40°C-130°C for gelling to obtain an aqueous gel, is used for emulsifying an oily component, wherein the aqueous solution of silk protein is

obtained by unscoured, partially scoured or scoured spun silkworm fibers (cocoon filaments) with a neutral salt and then dialyzing the solution."

III. The documents cited during the examination proceedings included the following:
(1) EP 1 241 178 A
(2) US 6 218 357 B1
(3) Patent Abstracts of Japan, vol. 1997, no. 02, 28 February 1997 (1997-02-28) & JP 08 268905 A
(6) Database CA [Online], Chemical Abstracts Services, Columbus, Ohio, US; Ni, Li et al.: "Functional properties of silk fibroin", XP002317063, retrieved from STN Database accession no. 2001:348758

IV. In the decision under appeal, the examining division held that the main request did not meet the requirements of Article 56 EPC.

Document (2) was considered to represent the most relevant state of the art. It disclosed a dispersion of silk fibroin (claim 1; col. 1, l. 63- col. 2, l. 6) and explicitly explained that silk fibroin had both a hydrophilic and a hydrophobic portion, as well as an affinity to oils and alcohol (col. 3, l. 33-36).
The subject-matter of claims 1 and 2 therefore differed in that the silk fibroin has been treated in a certain way and has a certain degree of crystallisation and a certain molecular weight.
As the applicant did not provide any data showing the influence of these features on the emulsification properties, the problem was regarded as the provision of a method of making a cosmetic emulsion comprising an alternative emulsifier based on silk fibroin.

The solution was considered to be obvious in view of cosmetic compositions of silk fibroin known from documents (1), (2), (3) or (6).
The examining division concluded that the person skilled in the art, looking for alternative forms of silk fibroin, would use any silk fibroin solution or aqueous gel already known in the art for preparing cosmetic compositions. Such silk fibroin solutions and aqueous gels were known from documents (1)-(3).
For these reasons, the subject-matter of claims 1 and 2 did not involve an inventive step.

V. The applicant (appellant) lodged an appeal against that decision. A new main request and arguments regarding inventive step were enclosed with the statement of grounds of appeal.

VI. A communication expressing the board's preliminary opinion of the board was sent to the applicant.

For the discussion on inventive step of the main request, document (1) was seen as the closest prior art for independent claim 1, and document (2) for independent claim 2.

VII. With a letter dated 27 May 2013, the appellant filed a new main request and auxiliary requests 1, 2 and 3, to replace the request on file, and arguments regarding Articles 123(2) and 56 EPC.

Each request comprised two unique independent claims. Independent claim 1 of the different requests read as follows:

a) Main request

"1. A method for production of an emulsified cosmetic material, whereby an emulsifier, having a skin cell growth-promoting property, comprising an aqueous solution of silk protein composed mainly of amorphous silk fibroin with a crystallization degree of less than 10% and average molecular weight ranging from 40.000 to 370.000 is dried to produce an amorphous silk substance which substance is reimmersed in water to obtain a silk aqueous solution having a sericin proportion not exceeding 50% and is used for emulsifying an oily component, wherein the aqueous solution of silk protein is obtained by dissolving unscoured, partially scoured or scoured spun silkworm fibers (cocoon filaments) with a neutral salt and then dialyzing the solution, thereby removing low molecular weight substances of 5000 or less."

b) Auxiliary request 1

Only claim 2 of auxiliary request 1 was amended, the subject-matter of claim 1 remaining identical to the main request.

c) Auxiliary request 2

The subject-matter of claim 1 of auxiliary request 2 differed from the main request in the molecular weight of the amorphous silk protein, namely an *"average molecular weight ranging from* ***60.000 to 300.000***".

d) Auxiliary request 3

Only claim 2 of auxiliary request 3 was amended, the subject-matter of claim 1 remaining identical to auxiliary request 2.

VIII. Oral proceedings before the board of appeal took place on 11 June 2013.

IX. The appellant's arguments can be summarised as follows:

The invention was based in the provision of a method for producing an emulsified cosmetic material having a pleasant touch and feel. This objective was achieved in particular by the method comprising the step of removing low molecular weight substances of 5.000 and less. The silk protein was also produced in a certain way, with specific process features which conferred specific characteristics on the silk protein.
The method also allowed the production of a material having a good spreadability on the skin and improved skin cell growth-promoting effect
There was no hint in the prior art that the dialysis step provided such benefits. The dialysis step was used in documents (1) and (2) to remove inorganic salts from a fibroin aqueous solution.
Moreover, document (1) related to un-degraded fibroin with a high molecular weight.

As regards auxiliary request 2 and 3, the claimed molecular weight was chosen in order to prevent fibrillation of the fibroin, while still keeping the cell growth-promoting effect. It was a compromise between both effects.

X. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, alternatively, of one of auxiliary requests 1 to 3 filed with the letter of 27 May 2013.

Reasons for the decision

1. The appeal is admissible.

2. Main request - Inventive step

2.1 The invention concerns a method of producing emulsified cosmetic materials having skin cell growth-promoting properties using a silk protein based emulsifier possessing this property.
The starting product is an aqueous solution of amorphous silk protein obtained from spun silkworm fibres, namely the cocoon filaments, through treatment with a neutral salt and further dialysis to remove the substances of molecular weight of 5 000 or less. The amorphous silk protein is composed mainly of amorphous silk fibroin having a crystallisation degree of less than 10% and an average molecular weight of 40 000 to 370 000. This aqueous solution is dried, re-immersed in water and used for emulsifying an oily component.

2.2 Document (1) relates to a process for making un-degraded silk fibroin having excellent cell proliferation promoting action and to its further incorporation in preparations for external use.

The process comprises degumming the cocoon layer or cocoon yard of fresh, dry or cooked cocoons by treatment with an alkali solution, followed by dialysis for demineralisation, whereby the un-degraded silk fibroin is obtained with a molecular weight of 350 000 to 370 000 (see par. [0010], [0015], [0020], [0023], [0027]). The solution is dried to obtain a powder (see example 8).
Such a powder can be used in the form of a cream or ointment, by incorporating the un-degraded silk fibroin directly into the ointment or cream base (see par. [0029]-[0031]).
The particular step of removal of the low molecular weight substances of 5 000 or less in the preparation of the aqueous solution of silk protein through dialysis, and the step of re-immersion in water for a further use for emulsifying an oily component, are not disclosed in document (1).

This document constitutes the closest prior art for claim 1 of the main request.

Document (2) was considered to be more remote since it did not mention the cell growth-promoting properties and related to the production of a fibroin fluid, i.e. a cream-like product (col. 3, l. 5-58).

The choice of document (1) as closest state of the art was agreed by the appellant during the oral proceedings.

2.3 According to the appellant, the problem consists in providing a method for producing an improved emulsified

cosmetic material with a pleasant touch and feel, while still preserving the cell growth-promoting properties.

2.4 As a solution to this problem, claim 1 of the main request proposes a method of production of an emulsified material, with in particular a step of removing the low molecular weight substances of 5 000 or less in the preparation of the aqueous solution of silk protein, and a step of re-immersion in water of the dried silk fibroin and its use for emulsifying an oily component.

2.5 The application comprises several examples, but none of them shows any evidence in the form of results or data regarding the production of an improved emulsified cosmetic material with a pleasant touch and feel, or any improved emulsifying power and feel during use linked with the silk protein based emulsifier.

As regards the dialysis step, this step is used to remove the low molecular weight substances of about 5,000 or lower (see page 16, 4th par. and last par.). Indeed, according to the description of the application, only fibroin with an average molecular weight of 5 000 or greater acts as an emulsifier. The description does not however provide any teaching or plausible argumentation, let alone any evidence, that the removal of molecules with a molecular weight of 5 000 or less, through a dialysis step as claimed, brings any improvement with regard to the behaviour of the emulsifying material and to any consequent pleasant touch or feel. Nor can it be deduced from the cited passages referring to the dialysis that the presence of molecules with a molecular weight of less than 5 000

has a detrimental effect on the emulsifying properties of the fibroin or on the formation of an emulsion (see page 16, 4th par. and last par.).
Rather, the removal of fibroin molecules with a molecular weight of 5 000 or less seems linked with the selection of fibroin having a cell growth-promotion effect, since the description of the application links a higher molecular weight of fibroin with this particular effect (see page 17, 1st-4th par.). There is however no evidence or plausible argumentation showing that the dialysis step improves the cell growth-promotion properties.

As regards the step of re-immersion in water of the dried silk fibroin and its further use for emulsifying an oily component, there is no further teaching in the description that this particular sequence provides an improvement or has any positive influence on the production of an emulsified cosmetic material.

Thus, in the absence of any evidence or arguments establishing a minimum plausibility for the presence of an improvement vis-à-vis the closest state of the art, the problem underlying the present invention can only be seen as the provision of an alternative method for producing an emulsified cosmetic material with cell growth-promoting properties.
In view of the information found in the description of the application, in particular in the Experiment examples 2 and 3 which show the cell growth properties, the board is convinced that the problem has been plausibly solved.

2.6 A dialysis step being also performed in the process disclosed in document (1), the removal of molecules with a molecular weight of 5 000 or less through dialysis can only be seen as a choice that would be made as a matter of routine by a skilled person. Moreover, the step of re-immersion in water of the dried silk fibroin and its further use for emulsifying an oily component is an obvious alternative to the simple addition of the fibroin powder to an existing ointment or cream base.

Consequently, the steps of removing the low molecular weight substances of 5 000 or less in the preparation of the aqueous solution of silk protein, and of re-immersion in water of the dried silk fibroin and its use for emulsifying an oily component, constitute a common and obvious solution. The subject-matter of claim 1 of the main request is not inventive, since it amounts merely to an arbitrary choice among known possibilities.

Under these circumstances it is not necessary to consider independent claim 2 of the main requests.

2.7 Further arguments of the appellant

- According to the appellant, the essential difference between the subject-matter of claim 1 and the disclosure of document (1) was the presence of the dialysis step which removes the fibroin molecules with a molecular weight of 5 000 or less. However, other differences were present and lay in the degree of crystallisation and the sericin proportion which does not exceed 50%.

The board could not however follow this argumentation. It is indeed not clear from the subject-matter of claim 1 or from the teaching of the description which steps of the process are responsible or may influence the characteristics of degree of crystallisation or the sericin proportion. The process of preparation in document (1) is indeed similar to the process of preparation of the fibroin as claimed in claims 1 and 2 or as taught by the description. There is therefore no reason to doubt that the silk protein of document (1) is different from the claimed silk protein.
As regards the quantities of sericin, document (1) anyway mentions that the process used involved the separation of silk fibroin from silk sericin (see par. [0016] and examples 2-5 and 8).

- According to the appellant, document (1) focuses on the preparation of un-degraded fibroin, since the higher the molecular weight, the better the cell growth-promoting effects, and does not relate in any way to emulsification. The skilled person would therefore not perform any modification starting from the teaching of document (1) in view of an emulsification.

The board could not follow this argument, since document (1) is explicitly concerned about the preparation of compositions for external use in order to operate the cell growth properties (see par. [0030], [0031], [0044]). These compositions for external use are in the forms of creams or ointments, which are by definition emulsions. The disclosure of document (1) is

thus relevant for a method of production of an emulsified cosmetic material.

2.8 It results from above that the main request does not meet the requirements of Article 56 EPC.

3. Auxiliary request 1 - Inventive step

Since the subject-matter of claim 1 of auxiliary request 1 is the same as the subject-matter of claim 1 of the main request, the reasoning and the conclusions drawn for the main request apply *mutatis mutandis*.

Consequently, auxiliary request 1 does not meet the requirements of Article 56 EPC.

4. Auxiliary request 2 - Inventive step

4.1 Claim 1 of auxiliary request 2 differs from the main request in respect of the claimed average molecular weight of the amorphous silk protein, namely an "*average molecular weight ranging from 60,000 to 300,000*".

4.2 Document (1) is still the closest prior art and disclosed a process wherein the obtained un-degraded silk fibroin has a molecular weight of 350 000 to 370 000 (see examples 2 and 8 and paragraph [0015]).

4.3 According to the appellant, the claimed molecular weight of 60 000 to 300 000 allowed a compromise between the cell growth promoting effect and avoidance of fibrillation.

Indeed, fibrillation of the silk fibroin is linked with a high molecular weight, and is a cause of less pleasant feel, due to water-insoluble masses (see page 16, paragraphs 7-9). On the other hand, cell growth promotion is observed at higher molecular weights between 40 000 and 370 000 (see page 17, paragraphs 2-4).

There is however no evidence in the application relating to the avoidance of fibrillation of the silk fibroin and the consequent effect of improved feel. Nor is there any evidence relating to its link with the claimed average molecular weight.
Moreover, according to the description, the fibroin aqueous solution tends to gel and fibrillate under strong shear forces, whereby high molecular weight silk protein is included in the solution, since it helps prevent fibrillation by allowing gentler methods of emulsification (see page 5, penultimate paragraph and page 16, penultimate paragraph). The presence of a high molecular weight silk fibroin is also necessary for the cell growth-promotion effect (see page 17, paragraphs 2 and 3). Thus high molecular weight silk fibroin must be present in the solution, and in the absence in the claim of any quantification of the amount of silk fibroin, the existence of an effect on fibrillation linked with the claimed molecular weight is technically not credible and plausible.

Thus, the problem underlying the present invention can only be seen as the provision of an alternative method for producing an emulsified cosmetic material with cell growth-promoting properties.

4.4 The solution proposed by claim 1 of auxiliary request 2 is a method of production of an emulsified material, with in particular the choice of silk protein, namely an "*average molecular weight ranging from 60,000 to 300,000*" and the particular dialysis and re-immersion steps.

4.5 In the absence of any element to the contrary, the choice of the claimed average molecular weight can only be seen as an arbitrary choice that would be made as a matter of routine by a skilled person.

The subject-matter of claim 1 of auxiliary request 2 is not inventive.

4.6 Consequently, auxiliary request 2 does not meet the requirements of Article 56 EPC.

5. Auxiliary request 3 - Inventive step

As the subject-matter of claim 1 of auxiliary request 3 does not differ from the subject-matter of claim 1 of auxiliary request 2, the same conclusion applies.

Consequently, auxiliary request 3 does not meet the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Fabiani J. Riolo