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**Datasheet for the decision
of 9 June 2016**

Case Number: T 1040/13 - 3.3.07

Application Number: 06779620.1

Publication Number: 1928422

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Language of the proceedings: EN

Title of invention:

IMPROVEMENTS IN THE STABILISATION OF BIOLOGICAL MATERIALS

Applicant:

Nova Bio-Pharma Technologies Limited

Headword:

IMPROVEMENTS IN THE STABILISATION OF BIOLOGICAL MATERIALS/Nova
Bio-Pharma Technologies Limited

Relevant legal provisions:

EPC Art. 123(2), 84, 54, 111(1)

Keyword:

Main request 1A - amendments (yes)
Main request 1A - Support by the description (yes)
Main request 1A - novelty (yes)
Remittal to the department of first instance

Decisions cited:

Catchword:



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Case Number: T 1040/13 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 9 June 2016

Appellant: Nova Bio-Pharma Technologies Limited
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted on 7 December 2012 refusing European patent application No. 06779620.1 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman J. Riolo
Members: D. Boulois
P. Schmitz

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division to refuse European patent application n°06 779 620.1. The decision was based on 4 sets of claims filed with letter of 29 October 2012 as main request and auxiliary requests 1-3.

Claim 1 of the following requests read as follows, the difference with respect to the main request being indicated in **bold**:

(a) Main request

"1. A method of making a glassy product for stabilizing a biological material comprising the steps of:
i) mixing (a) a first liquid material comprising a biological material and capable of forming a glass with (b) a second material that forms a gas when heated; and
ii) causing the first liquid material to form a glass at the same time as the second material forms the gas; whereby a glassy structure is formed comprising a glass containing the gas."

(b) Auxiliary request 1

"1. A method of making a glassy product for stabilizing a biological material comprising the steps of:
i) mixing (a) a first liquid material comprising a biological material and capable of forming a glass with (b) a second material that forms a gas when heated; and
ii) causing the first liquid material to form a glass at the same time as the second material forms the gas **by the application of heat**;
whereby a glassy structure is formed comprising a glass containing the gas."

(c) Auxiliary request 2

"1. A method of making a glassy product for stabilizing a biological material comprising the steps of:
i) mixing (a) a first liquid material comprising a biological material and capable of forming a glass with (b) a second material that **is a blowing agent** which forms a gas when heated; and
ii) causing the first liquid material to form a glass at the same time as the second material forms the gas **by the application of heat;**
whereby a glassy structure is formed comprising a glass containing the gas."

(d) Auxiliary request 3

"1. A method of making a glassy product for stabilizing a biological material comprising the steps of:
i) mixing (a) a first liquid material comprising a biological material and capable of forming a glass with (b) a second material that **is a blowing agent** which forms a gas when heated; and
ii) causing the first liquid material to form a glass at the same time as the second material forms the gas **by the application of heat, wherein the second material is such that it decomposes at a time when the first material is in a transition state between liquid and glassy solid; and**
whereby a glassy structure is formed comprising a glass containing the gas."

II. The following documents were cited during the examination procedure:

D1: US 6 630 169

D7: US2003/0180283

D9: WO00/72827

III. According to the decision under appeal, the subject-matter of claim 1 of the main request did not meet the requirements of Article 54 EPC in view of documents D1, D7 and D9:

- D1 disclosed the preparation of hollow particles comprising a biological material and a glassy material such as lactose or hydroxyethylstarch. After addition of an emulsion comprising phospholipid and perflubron to an emulsion comprising the active water and the glass-forming agent, the composition was spray dried and the water evaporated during formation of a powder (see examples I and XXI). The water formed a gas upon heating and lactose built a glassy matrix.
- D7 described porous particles comprising a protein, a sugar such as sucrose or maltodextrin, and ammonium carbonate as pore forming agent. The mixture was combined with ethanol, the second material and spray dried (see par. [0094]).
- D9 disclosed a method of making porous particles which comprised dissolving a drug in a volatile solvent, combining a pore forming agent with the drug solution and removing the volatile solvent. Example 4 showed the preparation of a spray dried powder comprising PEG as glass forming agent, Tween, lecithin and ammonium carbonate

Claim 1 of auxiliary request 1 was also not novel. D1, D7 and D9 related all to a spray drying process. D1 used temperatures of 85°C inlet temperature and 61°C outlet temperature (example XXI). D7 used a temperature of 170°C inlet temperature and 61°C outlet temperature (examples). D9 used an outlet temperature of about 30°C (examples 2 and 8) and it was expected that the inlet temperature was higher.

As regards claim 1 of Auxiliary request 2 and according to the description the term "blowing agent" was used as synonym for the term "gas forming agent" (see page 6, line 2). Since D1 used water, which evaporated upon spray drying and D7 or D9 used ammonium carbonate, the examining division concluded that all documents disclosed a "blowing agent". The subject-matter of claim 1 of auxiliary request 2 was thus not novel over D1, D7 and D9.

The term "wherein the second material is such that it decomposes at a time when the first material is in a transition state between liquid and solid" in claim 1 of auxiliary request 3 was considered unclear by the examining division, contrary to the requirements of Article 84 EPC. As to novelty, the term did not provide any further limitation, and the subject-matter of claim 1 of auxiliary request 3 was not novel over D7 and D9.

- IV. The applicant (hereinafter called appellant) filed an appeal against the decision of the examining division.
- V. With the statement setting out the grounds of appeal dated 17 April 2013, the appellant submitted a main request and auxiliary requests 1-3.

In comparison to the main request which was the object of the decision of the examining division, the subject-matter of the main request was amended by the addition of the feature "which is a blowing agent" specifying the first liquid material.

Claim 1 of auxiliary request 1 was amended by the additional feature "which is ammonium carbonate" specifying the second material.

Claim 1 of auxiliary request 2 comprised the features "which is a blowing agent" and "wherein the glassy structure is formed into particles in a spray drier with a gas inlet temperature of 150°C to 210°C".

Claim 1 of auxiliary request 3 was amended by the features "which is ammonium carbonate" and "wherein the glassy structure is formed into particles in a spray drier with a gas inlet temperature of 150°C to 210°C"

- VI. A communication expressing the board's preliminary opinion of the board was sent to the applicant. In said communication the Board pointed out that the subject-matter of the main request and auxiliary request 1 did not appear to be novel over D7 and D9, and that it did not meet the requirements of Article 84 EPC, because of a lack of support of the claimed subject-matter. The subject-matter of auxiliary request 2 and 3 did not appear to meet the requirements of Article 123(2) EPC. The Board also considered to remit the case to the first instance, should inventive step become the point to discuss.
- VII. With a letter 17 May 2016, the appellant submitted a new main request 1A and a new auxiliary request 1A, and withdrew all the requests previously submitted.
- VIII. Oral proceedings before the board of appeal took place on 9 June 2016 during which a new set of claims 1-6 was submitted as main request 1A.

Claim 1 of the following main request 1A reads as follows, the difference with respect to the main request which was the subject of the decision of the examining division being indicated in **bold**:

"1. A method of making a glassy product for stabilizing a biological material comprising the steps of:
i) mixing (a) a first liquid material comprising a biological material and capable of forming a glass, **in which the first liquid material comprises a glutamic acid or salt thereof**, with (b) a second material which is **a blowing agent that undergoes decomposition** and forms a gas when heated, **in which the second material comprises ammonium bicarbonate**; and
ii) causing the first liquid material to form a glass at the same time as the second material forms the gas; wherein a glassy structure **in the form of particles containing the gas is formed in a spray drier.**"

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

Claim 1 of the main request 1A corresponded to the previous main request with clarification as to the materials used. A basis could be found on page 3, lines 12 to 15 of the specification as filed. Features of previous claims 5 and 8 of the main request had also been incorporated into claim 1.

These amendments addressed the objections raised under Article 84 EPC, since the application related to the use of glutamic acid and of ammonium carbonate, now specified in the claim. Moreover, the fact that the claimed process now related to particles obtained by spray drying responded also to an objection of the Board.

As none of the cited documents D1, D7 or D9 disclosed the use of glutamic acid or a salt thereof and ammonium carbonate, the documents were not relevant for novelty.

X. Requests

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request 1A filed during the oral proceedings of 9 June 2016.

Reasons for the Decision

1. Main request - Amendments

Claim 1 of the main request is based on claim 15 as originally filed as regard the process and on claim 1 as originally filed as regards the presence of a biological material, with the following supplementary features:

- a) **"in which the first liquid material comprises a glutamic acid or salt thereof",**
- b) **"a blowing agent that undergoes decomposition and forms a gas when heated",**
- c) **"in which the second material comprises ammonium carbonate",**
- d) **"wherein a glassy structure in the form of particles containing the gas is formed in a spray drier".**

All these amendments find a basis in the application as originally filed (see specification (see WO2007/026180):

- Features a) and c) find an explicit basis on respectively page 3, lines 12-15 and page 4, line 27 or claim 19 of the application as originally filed.
- Feature b) originates from original claim 14, as well as from page 6, line 2 as regards the term "blowing agent".
- Feature d) corresponds to the reformulated subject-matter of original claim 22.

Hence, the main request 1A meets the requirements of Article 123(2) EPC.

2. Main request - Article 84 EPC

An objection of lack of support of the invention claimed in claim 1 of the main request and auxiliary request 1 filed with letter dated 17 April 2013 was raised by the Board, in view of the absence of any teaching in the description as regards any alternative glass-forming and blowing agents, apart from glutamic acid or its salts and ammonium carbonate, as well as regards the ratios, amounts and process conditions required to use such alternative compounds, apart from glutamic acid or its salts and ammonium carbonate, in the claimed process.

Since the subject-matter of claim 1 of the main request 1A has been restricted by the presence of "glutamic acid or salt thereof" and "ammonium carbonate", this objection has been overcome.

Hence, the claimed subject-matter meets the requirements of Article 84 EPC.

3. Main request - Novelty

Documents D1, D7 and D9 were cited as novelty-destroying by the examining division in its decision.

D1 discloses the preparation of hollow particles comprising a biological material and a glassy material such as lactose or hydroxyethyl starch (see examples I or XXI). The composition was spray dried and the water evaporated forming the hollow particles.

D7 discloses several spray drying processes with a high inlet temperature of a composition comprising a biological agent, a glass forming material such as sucrose, maltodextrin or PEG together with ammonium carbonate (see par. [0094], [0107], [0109]).

D9 discloses inter alia in examples 5 and 8 a spray drying process with ammonium carbonate and PEG as glass-forming agent.

As the use of glutamic acid or a salt thereof is not disclosed in any of these documents, they cannot be relevant for the novelty of claim 1 of the main request 1A.

Consequently, the subject-matter of the main request 1A is novel and this request meets the requirements of Article 54 EC.

4. Remittal to first instance

The essential function of an appeal proceedings is to consider whether the decision which has been issued by the first instance department is correct. Hence, a case is normally remitted if further criteria of patentability have not yet been examined and decided by the department of first instance. This is the situation here. Inventive step was indeed not discussed during the first instance proceedings and was not the subject of the decision of the examining division.

Hence, the Board considers it appropriate to remit the case to the examining division for further prosecution on the basis of the main request 1A filed during oral proceedings of 9 June 2016.

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.

The Registrar:

The Chairman:



S. Fabiani

J. Riolo

Decision electronically authenticated