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Datasheet for the decision of 11 June 2012

Case Number: T 2119/09 - 3.3.02

Application Number: 99913182.4

Publication Number: 1071464

IPC: A61K 47/00

Language of the proceedings: EN

Title of invention:
Spray-dried powders with high edible-oil loadings based on non-hydrolyzed gelatin and a method of making such spray-dried tablettable powders

Patentee:
BASF CORPORATION

Opponent:
DSM NUTRITIONAL PRODUCTS AG

Headword:
Spray-dried powders/BASF CORPORATION

Relevant legal provisions:
EPC Art. 123(2), 54, 56
RPBA Art. 13

Keyword:
"Main request - allowability of amendments (no): new combination of features"
"Auxiliary request 1 - inventive step (no): beneficial effects not related to the subject-matter as claimed"
"Auxiliary request 2 - admission (no): late-filed"
"Admission of objection concerning validity of priority (no): late-filed"

Decisions cited:
-

Catchword:
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Case Number: T 2119/09 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 11 June 2012

Appellant: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 4 August 2009 concerning maintenance of European patent No. 1071464 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
L. Bühler

Summary of Facts and Submissions

I. European patent No. 1 071 464, based on application No. 99 913 182.4, was granted on the basis of 7 claims.

II. Notice of opposition was filed against the patent. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step.

III. The documents cited during the opposition and appeal proceedings included the following:

(1) EP-A-0 841 010
(3) US-A-5 478 569
(9) US-A-5 120 761

IV. The appeal lies from a decision of the opposition division pronounced on 8 July 2009 and posted on 4 August 2009, wherein the European patent was maintained on the basis of the main request, filed with letter dated 17 May 2006.

V. In said decision, the opposition division decided that the subject-matter of the main and sole request was novel, as the preferred concentration range of the fat soluble substance in document (3) was completely outside the range of the present claims.

Regarding inventive step, the opposition division defined document (9), which disclosed spray-dried powders comprising gelatin and vitamin E, as closest prior art. Starting from this prior art, it was not obvious that a higher amount of fat-soluble vitamin would still yield tablets of sufficient strength, nor

was is predictable that the droplet size would have an influence on the resulting tablet strength. Furthermore, there was no incentive in any of the prior art documents to increase the vitamin loading. As a consequence, the requirements of Article 56 EPC were met.

VI. The appellant (opponent) lodged an appeal against that decision.

VII. At the oral proceedings before the board, which were held on 11 June 2012, the respondent (patentee) submitted auxiliary requests 1 and 2.

VIII. The independent claims of the requests on file read as follows:

(i) Main request

"1. A spray-dried powder containing droplets of a fat-soluble vitamin or mixtures thereof, comprising:

(a) 65 to 80% of a fat-soluble vitamin or mixtures thereof,

(b) 20 to 35% gelatin,

wherein further, said droplets of a fat-soluble vitamin or mixtures thereof have an average diameter of ≤ 0.8 µ.

5. A method for making a spray-dried powder containing droplets of vitamin E comprising:

(a) 65 to 80% vitamin E,

(b) 20 to 35% gelatin

Wherein further, said vitamin E droplets have an average diameter of ≤ 0.8 µm.

Comprising the steps of:

(a) dissolving said gelatin or a mixture of a said gelatins in hot water;

(b) adding vitamin E to the gelatin in hot water to form an emulsion;

(c) homogenizing said emulsion formed in step (b) until the average oil-droplet size is ≤ 0.8.

(d) Spray drying the homogenized emulsion from step (c)."

(ii) Auxiliary request 1

"1. A spray-dried powder containing droplets of vitamin E comprising:

(a) 65 to 80% of vitamin E,

(b) 20 to 35% gelatin,

wherein further, said droplets of a fat-soluble vitamin or mixtures thereof have an average diameter of ≤ 0.8 µ.

4. A method for making a spray-dried powder containing droplets of vitamin E comprising:

a) 65 to 80 % vitamin E;

b) 20 to 35 % gelatin,

Wherein further, said vitamin E droplets have an average diameter of ≤ 0,8 pm.

Comprising the steps of:

a) Dissolving said gelatin or a mixture of said gelatins in hot water;

b) adding vitamin E to the gelatin in hot water to form an emulsion;

c) homogenizing said emulsion formed in step b) until the average oil-droplet size is ≤ 0,8.

d) Spray drying the homogenized emulsion from step c)."

(ii) Auxiliary request 2:

"1. A spray-dried powder containing droplets of vitamin E comprising:

(a) 65 to 80% of vitamin E,

(b) 20 to 35% gelatin,

wherein further, said droplets of vitamin E have an average diameter of ≤ 0.8 µ and wherein said gelatin is non-hydrolyzed.

3. A method for making a spray-dried powder containing droplets of vitamin E comprising:

a) 65 to 80 % vitamin E;

b) 20 to 35 % gelatin,

Wherein further, said vitamin E droplets have an average diameter of ≤ 0,8 µm and wherein said gelatin is unhydrolyzed

Comprising the steps of:

a) Dissolving said gelatin or a mixture of said gelatins in hot water;

b) adding vitamin E to the gelatin in hot water to form an emulsion;

c) homogenizing said emulsion formed in step b) until the average oil-droplet size is ≤ 0,8.

d) Spray drying the homogenized emulsion from step c)."

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

Auxiliary requests 1 and 2 were late filed and therefore not admissible.

Regarding novelty, the appellant argued that the claimed subject-matter was a selection from the disclosure according to document (3), as far as the concentration of vitamin E was concerned. However, the criteria for a selection invention, i.e. the selected range must be narrow as compared to the disclosure of the prior art, far away from the specific values of the examples and accompanied by a new effect, were not fulfilled.

The claimed subject-matter was obvious in the light of document (9) as the selection of a concentration range of 65 to 80 % for gelatin, which constituted the only potentially distinguishing feature, was not accompanied by any unexpected effect.

X. The respondent's arguments can be summarised as follows:

Auxiliary request 1 was filed as a reaction to objections raised for the first time at the oral proceedings before the board. Auxiliary request 2 was additionally limited to non-hydrolysed gelatin in order to further delimit the claimed subject-matter from document (9).

The claimed subject-matter was novel, as document (3) did not disclose a spray-dried powder with a gelatin concentration of 65 to 80%.

In addition, the claimed subject-matter involved an inventive step over document (9), which neither disclosed a particle size of ≤0.8 µm nor a gelatin content of 65 to 80%. Moreover, a different type of

gelatin was used in document (9). Spray-dried powder comprising these features yielded tablets with superior hardness and enhanced vitamin E content, which was unexpected in the light of the prior art.

XI. The appellant requested that the decision under appeal be set aside and that the European patent No. 1071464 be revoked.

The respondent requested that the appeal be dismissed or, alternatively, that the patent be maintained on the basis of one of the auxiliary requests 1 and 2, both submitted at the oral proceedings of 11 June 2012.

Reasons for the Decision

1. The appeal is admissible.

2. Admission of auxiliary requests 1 and 2

These requests were filed at of the oral proceedings before the board and therefore at a very late stage of the appeal proceedings. The admission of these requests is therefore at the board's discretion and depends upon the overall circumstances of the case under consideration including the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy (see Article 13(1) of the Rules of Procedure of the Boards of Appeal (RPBA)).

2.1 Regarding the amendments made in claim 1 of auxiliary request 1, the board notes that the feature "fat-

soluble vitamin or mixtures thereof" was replaced by "vitamin E". This amendment constitutes a reaction to objections under Article 123(2) EPC which were raised for the first time at the oral proceedings before the board. As a consequence, auxiliary request 1 is admitted into the proceedings (Article 13(1) RPBA).

2.2 Independent claims 1 and 3 of auxiliary request 2 comprise the additional feature that the gelatin is non-hydrolysed. The respondent argued that the limitation to non-hydrolysed gelatin was introduced in order to further delimit the claimed subject-matter from the teaching of document (9), in which partially hydrolysed gelatin was used. Taking into account that the appellant (then opponent) had included document(9) in its reasoning of lack of inventive step already in the first instance proceedings and that document (9) had been defined as closest prior art in the notice of opposition, the board concludes that an auxiliary request in which the gelatin was limited to non-hydrolysed gelatin should already have been filed in the reply to the notice of opposition. In the reply to the notice of opposition, the respondent discusses document (9) and, making reference to its comparative example 5, mentions the disadvantages of non-hydrolysed gelatin, without, however, submitting an accordingly amended set of claims (see page 2 of the reply to the notice of appeal dated 15 April 2010). As a consequence, the appellant had to assume that such an amendment was not envisaged by the respondent and was therefore taken by surprise by the submission of auxiliary request 2 at the oral proceedings before the board. As this amendment draws the invention into a new direction, possibly requiring new evidence, the appellant was not

in a position to appropriately react to these new circumstances without adjournment of the oral proceedings. Therefore, the board decided not to admit auxiliary request 2 into the proceedings (Article 13(3) RPBA).

3. Admission of the objection as to the validity of the priority

The validity of the priority was objected to for the first time at the oral proceedings before the board. As the publication date of document (1) (13 May 1998) lies between the priority date and the filing date of the contested patent (23 February 1998 and 23 February 1999, respectively), an invalid priority would mean that this document could be used in the assessment of inventive step. In view of the fact that this objection could have been raised much earlier and that the respondent was taken by surprise so that an adjournment of the oral proceedings would have been inevitable, the board decided not to admit the objection as to the validity of the priority into the proceedings (Article 13(3) RPBA).

4. Main request - Article 123(2) EPC

Claim 1 comprises droplets of a fat-soluble vitamin or mixtures thereof comprising 65 to 80% of a fat-soluble vitamin or mixtures thereof and 20 to 35% gelatin. In the original application, both the lower and the upper limits are disclosed only in connection with edible oils or vitamin oils (see page 7, lines 26-43, page 8, lines 11-12, claims 1, 2 and 6 or the original application). According to these disclosures, the

edible oil may only consist of vitamin oil(s) or it may comprise a mixture of a non-vitamin edible oil with vitamin oil(s) and/or vitamin(s) in solid form. However, the original application does not provide a basis for droplets consisting only of gelatin and a fat-soluble vitamin in solid form, which are encompassed by present claim 1. The board wants to emphasise in this context that vitamin D, which is solid, is included in the list of fat-soluble vitamins (see page 7, line 29 of the original application). It is additionally noted that the term "droplet" does not require the presence of any oil, as mixtures consisting of gelatin and a fat-soluble vitamin in solid form are able to form droplets. As a consequence, the subject-matter of claim 1 of the main request does not meet the requirements of Article 123(2) EPC.

5. Auxiliary request 1

5.1 Allowability of the amendments

In view of the limitation to vitamin E, which is the most preferred fat-soluble vitamin (see page 1, lines 11-30, page 7, lines 30-32, and examples 1-19, which all relate to vitamin E), the objections raised in point 4 above do not longer apply. The requirements of Article 123(2) EPC are therefore met.

5.2 Novelty

Document (3) discloses compositions having a mean particle size of ≤0.6 µm in diameter comprising a fat-soluble substance selected from the group consisting of a vitamin A, a vitamin D, a vitamin E, a vitamin K, a

carotinoid, and a polyunsaturated fatty acid, and a protective colloid of fish gelatin enveloping said fat-soluble substance (see claims 1 and 4). The ratio of fat-soluble substances to the accompanying substances amounts from 1 to 99% to 60 to 40%. As a consequence, document (3) does not disclose droplets comprising 65 to 80% vitamin E. In view of the fact that the vitamin E content in document (3) cannot exceed 60%, the concentration range of 65 to 80% according to present claim 1 does not constitute a selection in which a narrow range lying within a more general range is selected, as was alleged by the appellant. The requirements of Article 54 EPC are therefore met.

5.3 Inventive step

According to paragraph [0001] of the contested patent, the present invention concerns the provision of spray-dried tablettable powders with high edible-oil loadings.

Document (9), which constitutes the closest prior art, discloses a spray dried free flowing powder comprising about 50% by weight of an edible oil, which is preferably vitamin E acetate, and about 50% by weight of partially hydrolysed gelatin (see column 3, lines 23-43). Powders in which the vitamin E content exceeds 50% are also disclosed in document (9) (see example 6 in which the vitamin E content amounts to 51.8%). Document (9) does not specifically disclose the particle diameter of the free-flowing powder, which may be filled into capsules or be used for direct compression into tablets (see column 3, lines 24-33).

Regarding definition of the problem to be solved vis-à-vis document (9), the respondent, making reference to table 2 of the contested patent, which showed a superior tablet hardness, insisted on an improvement. The subject-matter of claim 1 of auxiliary request 1 is, however, directed to a spray-dried powder, which may certainly be compressed to tablets but which may just as well be filled into hard gelatine capsules, which does not require any compression step at all. The board concludes that for the definition of the problem to be solved over the closest prior art, it is not allowable to take into consideration an effect which does not relate to the product as claimed (spray-dried powder) but concerns a product to which the claimed product may or may not be further processed (tablet). Such an approach would be in contradiction to the established concept, according to which the problem underlying the claimed invention must be solved over the entire breath of the claim. In the present case, a spray-dried powder filled into capsules can for obvious reasons not solve the problem of insufficient tablet hardness. At the oral proceedings, the board enquired whether the improved tablet hardness was in any way reflected in the properties of the spray-dried powder as claimed. If, for instance, the improved tablet hardness was caused by an enhanced stability of the spray-dried powder droplets, this enhanced stability would then be an inherent property of the subject-matter claimed in present claim 1 which, being independent of its further application, could be taken into consideration for the definition of the problem underlying the present invention. However, the respondent confirmed that stability was completely

irrelevant when the spray-dried powder was filled into capsules.

As a consequence, the problem underlying the present invention can be defined as the provision of a further vitamin E containing powder composition. The proposed solution to this problem consists in an increase in vitamin E content from about 50% to a range of 65 to 80% by weight and in limiting particle size to ≤0.8µm. In view of the examples figuring in the contested patent, the board is satisfied that this problem was plausibly solved.

Regarding the question whether the solution to the problem defined above is obvious or not, the board notes that both modifications concern features which are well-known in vitamin E containing powders. Thus, vitamin E tablets (which are obtained by compressing the corresponding powder) comprising hydrolysed gelatin and 65% of vitamin E are cited as prior art in paragraphs [0003] and [0005] of the contested patent. Concerning a particle size of ≤0.8 µm, reference is made to example 4 of document (3) which discloses a powder obtained by spray-drying an emulsion in which the internal phase, which comprises vitamin E, fish gelatin and matodextrin, has an average particle diameter of 0.34 µm. In the absence of any unexpected effects, the selection of these features can therefore not establish an inventive step. As a consequence, the requirements of Article 56 EPC are not met. In this context, it is noted that structural differences between the gelatin in document (9) and the gelatin used in the present invention are not reflected in the

wording of the claims. These differences can therefore not be taken into consideration.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

N. Maslin U. Oswald