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**Datasheet for the decision
of 21 October 2022**

Case Number: T 2970/19 - 3.3.07

Application Number: 15194983.1

Publication Number: 3023110

IPC: A61K47/38, A61K9/16, A61K31/496

Language of the proceedings: EN

Title of invention:
SOLUTION FOR SPRAY DRYING COMPRISING HYPROMELLOSE ACETATE
SUCCINATE AND METHOD FOR PRODUCING SOLID DISPERSION

Patent Proprietor:
Shin-Etsu Chemical Co., Ltd.

Headword:
Solution comprising hypromellose acetate succinate / SHIN-ETSU

Relevant legal provisions:
EPC Art. 56, 111(1)
RPBA 2020 Art. 11

Keyword:
Inventive step - Main request (yes)
Remittal - special reasons for remittal



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Case Number: T 2970/19 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 21 October 2022

Appellant: Shin-Etsu Chemical Co., Ltd.
(Patent Proprietor) 6-1, Otemachi 2-chome
Chiyoda-ku,
Tokyo (JP)

Representative: HGF
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 16 September
2019 revoking European patent No. 3023110
pursuant to Article 101(3) (b) EPC.**

Composition of the Board:

Chairman A. Uselli
Members: J. Lécaillon
L. Basterreix

Summary of Facts and Submissions

I. European patent EP 3 023 110 (hereinafter "the patent") was granted on the basis of 5 claims. The independent claims of the patent as granted read as follows:

"1. A solution for spray drying comprising hypromellose acetate succinate having a hydroxypropoxy molar substitution of 0.40 or more, a solvent, and a drug."

"5. A method for producing a solid dispersion comprising the step of removing the solvent from the solution for spray drying as claimed in any one of Claims 1 to 4."

II. An opposition was filed against the patent on the grounds that its subject-matter lacked novelty and inventive step.

III. The opposition division took the decision to revoke the patent.

IV. The decision of the opposition division, posted on 16 September 2019, cited *inter alia* the following documents:

D6: WO 2014/031422 A1

V. The opposition division decided in particular as follows:

(a) The priority claim met the requirements of Article 87 EPC and the subject-matter of the granted claims was novel over D1, D2, D5 and D7.

- (b) However, the subject-matter of claim 1 of the patent in suit was not novel over D6. In particular, D6 disclosed liquid compositions or solutions comprising a hydroxyalkyl methyl cellulose acetate succinate, an active ingredient, which was preferably a drug, and a liquid diluent or solvent for the preparation of solid dispersions by spray drying. The most preferred hydroxyalkyl methyl cellulose acetate succinates were hydroxypropyl methylcellulose acetate succinates (HPMCAS) having a molar substitution of hydroxypropoxyl (MS(HP)) in ranges whose upper-end points fell within the range defined in granted claim 1. D6 provided an unmistakable disclosure of the combination of all the features of granted claim 1.
- (c) The auxiliary requests 1-2 filed during oral proceedings were admitted into the opposition proceedings. The features introduced in these auxiliary requests 1-2 further defined the molar substitution of the polymer by acetyl groups (auxiliary requests 1 and 2) and/or methoxy and succinyl groups (auxiliary request 2). D6 disclosed data which corresponded to molar substitution ranges extensively overlapping with the claimed ones. Furthermore, the corresponding ranges were directly and unambiguously disclosed in combination with each other to define the most preferred HPMCAS, which could not be delimited from the presently claimed ones.
- (d) The features introduced in the auxiliary requests 1-11 filed on 5 October 2018 (not renumbered), namely specific transmittance, specific solvent, more restricted MS(HP) range, did not further

distinguish the claimed subject-matter from the one disclosed in D6.

- VI. The patent proprietor (appellant) lodged an appeal against the above decision of the opposition division.
- VII. With its statement setting out the grounds of appeal the appellant defended its case on the basis of the patent as granted as the main request, and on the basis of auxiliary requests 1-15 filed therewith.
- VIII. The opponent, The Dow Chemical Company, withdrew its opposition with the letter of 10 March 2022 and is consequently no longer party to the proceedings.
- IX. On 16 May 2022 the Board sent a communication pursuant to Article 15(1) RPBA 2020 including the preliminary opinion of the Board.
- X. With the letter dated 20 September 2022, the appellant provided further arguments in support of the novelty over D6 of auxiliary requests 4, 8 and 12.
- XI. With a communication dated 6 October 2022, the Board informed the appellant, that the auxiliary request 8 was considered novel over D6.
- XII. With the letter dated 7 October 2022, the appellant withdrew its former main request and auxiliary requests 1-7. Former auxiliary request 8 and auxiliary requests 9-15 were resubmitted as main request and auxiliary requests 1-7, respectively.

The content of the claims upon which the present decision is based can be illustrated as follows:

The claims of the main request correspond to the granted claims wherein the feature "and wherein the hypromellose acetate succinate has a molar substitution of the acetyl group of from 0.40 to 0.96" was added at the end of claim 1.

- XIII. The following item of evidence was filed by the appellant with its statement setting out the grounds of appeal:

D20: Inventor declaration dated 23 December 2019

- XIV. The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request filed on 7 October 2022 (corresponding to auxiliary request 8 filed with the statement setting out the grounds of appeal and to auxiliary request 1 underlying the impugned decision) or, alternatively, on the basis of one of the seven auxiliary requests filed on 7 October 2022 (corresponding to auxiliary requests 9-15 filed with the statement setting out the grounds of appeal).

The appellant further requested that the case be remitted to the first instance should novelty of a request be acknowledged.

- XV. The arguments of the appellant, as far as relevant for the present decision, can be summarised as follows:

The subject-matter of claim 1 of the main request was novel over D6.

Starting from D6, the combination of the features concerning the suitability for spray drying, the presence of a drug, the choice of the hydroxyalkyl as

being hydroxypropyl and having a molar substitution of hydroxypropoxy (MS(HP) wherein "MS" stands for "molar substitution" and "HP" stand for "hydroxypropoxy") of 0.40 or more as well as the choice of the molar substitution of the acetyl group (MS(Ac) wherein "MS" stands for "molar substitution" and "Ac" stand for "acetyl") would require selections of (non-preferred) embodiments from more than one list.

Moreover the ranges of molar substitution disclosed in D6 were not disclosed specifically in combination with HPMCAS but merely in general for hydroxyalkyl methyl cellulose acetate succinates, *i.e.* for the total amount of hydroxyalkyl groups in the polymer.

Finally, D6 would not provide a direct and unambiguous disclosure of the claimed molar substitution of the acetyl group, let alone in combination with the claimed molar substitution of hydroxypropoxy.

Reasons for the Decision

Main request

1. Novelty
 - 1.1 The Board agrees with the opposition division that the main request (which corresponds to auxiliary request 1 underlying the opposition division's decision) is novel over D1, D2, D5 and D7.
 - 1.2 The opposition division considered that the subject-matter of claim 1 of the present main request was not novel over D6. The Board disagrees for the reasons detailed below.

- 1.3 D6 relates to hydroxyalkyl methyl cellulose acetate succinate compounds and their use in the preparation of solid dispersions of active ingredients. D6 generally discloses liquid compositions preferably comprising a drug (see page 16 lines 21 and 22) and subsequently the use thereof to prepare solid dispersion by spray drying (page 17 line 21 to page 18 line 7). This preferred embodiment is individualised in D6 and does not require any selection.
- 1.4 The reference in said embodiment to a hydroxyalkyl methyl cellulose acetate succinate "defined above" (see page 16 line 17 and page 17 lines 24 and 25) is considered by the Board as referring to any one of the previously described polymers. As recognised by the opposition division, HPMCAS is the preferred hydroxyalkyl methyl cellulose acetate succinate disclosed in D6 (see page 6 lines 24 and 25). The combination of the embodiment relating to a liquid composition containing a drug and suitable for spray drying disclosed on pages 16 to 17 and the preferred cellulose derivative HPMCAS is hence directly and unambiguously derivable from D6.
- 1.5 Furthermore claim 1 of the main request further limits the HPMCAS by defining the MS(HP) as being of at least 0.40 and the MS(Ac) as being of from 0.40 to 0.96.
- 1.5.1 The Board observes that D6 generally states that the hydroxyalkyl methyl cellulose acetate succinate of the invention have a (hydroxyalkoxyl) molar substitution of 0.05-1.00 or within preferred sub-ranges, all having an upper end-point above 0.40 (see page 6 lines 11 to 14). The disclosure of page 6 of D6 goes on by specifying the degree of substitution of hydroxyl groups (*i.e.* hydroxyl groups directly bound to the cellulose

backbone and hydroxyl groups of hydroxylalkoxyl substituents) by methyl groups (to form methoxy groups) and then specifies that in the case of HPMCAS (*i.e.* hydroxyalkoxyl being hydroxypropoxyl, HP), the "above-mentioned preferred ranges of MS(hydroxypropoxyl) [...] are preferred" (see page 6 lines 24-25). The Board is therefore of the opinion that there is no doubt that the preferred MS(HP) values for HPMCAS are the ones disclosed on page 6, lines 11-14 of D6. All these ranges overlap with the claimed range and the individualised upper end-points of said prior art ranges all fall within the claimed range. The disclosure of these individual upper end-points therefore anticipates the range of MS(HP) of claim 1 of the main request.

- 1.5.2 However, D6 describes the extent of substitution with acetyl by merely providing the ranges of concentration of acetyl group (in wt%; see claim 3 and page 7 lines 1 to 3 and 13 to 14). As argued by the appellant, it is not possible to convert a disclosed range of wt% of acetyl groups directly to a molar substitution thereof because these are independent variables and one is not an implicit disclosure of the other. As demonstrated in D20, the conversion of a concentration in wt% to a molar substitution requires to know the specific concentration of the other substituents. It follows that, while this conversion is possible for specific polymers, it is not feasible for a generic group of polymers. Even if the table 2 of D6 provides the correlation between the concentration in %wt and the MS(Ac) for specific polymers, no general unambiguous correlation between these two features may be derived from this table. Since the MS(HP) of the polymers of table 2 of D6 do not correspond to the presently claimed range, any inferred approximate correlation may

furthermore not inevitably apply to the presently claimed polymers.

Accordingly D6 does not provide a direct and unambiguous disclosure of an HPMCAS having a MS(Ac) of from 0.40 to 0.96. Contrary to the opinion of the opposition division, it cannot either be unambiguously concluded that the HPMCAS polymers of D6 would necessarily extensively overlap with those of present claim 1 and could not be delimited therefrom.

1.6 The subject-matter of the claims of the main request is therefore novel over D6. The main request hence meets the requirements of Article 54 EPC.

2. Remittal

2.1 Under Article 11 of the Rules of Procedure of the Boards of Appeal (RPBA) 2020 (OJ EPO 2019, A63), which applies in the present case according to Article 25(1) RPBA 2020, the Board may remit the case to the department whose decision was appealed if there are special reasons for doing so.

2.2 In the present case, the appealed decision did not address the grounds for opposition under Articles 100(a) EPC in combination with Article 56 EPC. As recalled in Article 12(2) RPBA 2020, the primary object of the appeal proceedings is to review the decision under appeal in a judicial manner. This principle would not be respected if the Board were to conduct a complete examination of all the opposition's grounds. Furthermore, the opposition has been withdrawn during the present appeal proceedings. Consequently, under these circumstances, the Board considers that special reasons for remitting the case to the

opposition division exist. Therefore, the Board considers it appropriate to accede to the appellant's request for a remittal (Article 111(1) EPC).

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division for further prosecution.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated