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**Datasheet for the decision  
of 18 February 2020**

**Case Number:** T 1867/16 - 3.3.07  
**Application Number:** 02787055.9  
**Publication Number:** 1465604  
**IPC:** A61K9/20, A61K9/14, A61K9/16,  
A61K9/50  
**Language of the proceedings:** EN

**Title of invention:**

CO-PROCESSED CARBOHYDRATE SYSTEM AS A QUICK-DISSOLVE MATRIX  
FOR SOLID DOSAGE FORMS

**Patent Proprietor:**

Spi Pharma, Inc.

**Opponent:**

Roquette Frères

**Headword:**

Co-Processed Carbohydrate System / SPI PHARMA

**Relevant legal provisions:**

EPC Art. 123(2), 100(c)

**Keyword:**

Amendments - added subject-matter (yes)

**Decisions cited:**

T 0099/13



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

Boards of Appeal of the  
European Patent Office  
Richard-Reitzner-Allee 8  
85540 Haar  
GERMANY  
Tel. +49 (0)89 2399-0  
Fax +49 (0)89 2399-4465

Case Number: T 1867/16 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 18 February 2020**

**Appellant:** Spi Pharma, Inc.  
(Patent Proprietor) 321 Cherry Lane  
New Castle, DE 19720 (US)

**Representative:** Maiwald Patent- und Rechtsanwalts-gesellschaft  
mbH  
Elisenhof  
Elisenstraße 3  
80335 München (DE)

**Appellant:** Roquette Frères  
(Opponent) 62136 Lestrem (FR)

**Representative:** Plasseraud IP  
66, rue de la Chaussée d'Antin  
75440 Paris Cedex 09 (FR)

**Decision under appeal:** **Interlocutory decision of the Opposition**  
**Division of the European Patent Office posted on**  
**10 June 2016 concerning maintenance of the**  
**European Patent No. 1465604 in amended form.**

**Composition of the Board:**

**Chairman** A. Usuelli  
**Members:** E. Duval  
P. Schmitz

## Summary of Facts and Submissions

I. European patent 1 465 604 (hereinafter "the patent") was granted on the basis of 9 claims. Claim 1 of the patent as granted read as follows:

"A method for producing a directly compressible and highly compactible composition, said method comprising:  
a) dissolving mannitol powder and sorbitol powder into a solution;  
b) seeding the solution with dry particles of mannitol and sorbitol;  
c) drying the solution in an air stream; and  
d) forming particles having a nonfilamentous microstructure from the solution."

II. An opposition was filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the application as filed.

III. The opposition division took the interlocutory decision that, on the basis of auxiliary request 1, the patent met the requirements of the EPC. The decision was based on the patent as granted as main request, and on auxiliary request 1 filed during the oral proceedings.

In claim 1 of auxiliary request 1, step b) was amended to read as follows:

"b) seeding the solution with a blend of dry particles of mannitol and sorbitol during drying the solution in an air stream;"

IV. The opposition division decided *inter alia* the following:

Claims 1 and 4 of the main request contravened Article 123(2) EPC, because they omitted the essential feature that the step of "seeding the solution with dry particles of mannitol and sorbitol" occurred during the step of drying the particles in an air stream.

However, auxiliary request 1 complied with Article 123(2) and(3) EPC.

V. The appellant-patent proprietor and the appellant-opponent each lodged an appeal against the above decision of the opposition division.

VI. With its statement setting out the grounds of appeal dated 20 October 2016, the appellant-opponent objected *inter alia* that the feature "seeding the solution with dry particles of mannitol and sorbitol" could not be derived directly and unambiguously from the application as filed.

VII. In its reply dated 3 March 2017, the appellant-patent proprietor indicated that it maintained the patent as granted as main request and the request allowed by the opposition division as auxiliary request 1. Additionally it filed auxiliary requests 2-7. Claim 1 of each of auxiliary requests 2-7 related to a method comprising step b) reading as follows:

- auxiliary request 2:

"b) seeding the solution with dry particles of mannitol and sorbitol into the spray-drying chamber;"

- auxiliary request 3:

"b) seeding the solution with a blend of dry particles of mannitol and sorbitol into the spray-drying chamber during drying the solution in an air stream;"

- auxiliary requests 4 and 6:

"b) seeding the solution with dry particles of mannitol and sorbitol in the same proportion as the aqueous solution into the spray-drying chamber;"

- auxiliary request 5 and 7:

"b) seeding the solution with a blend of dry particles of mannitol and sorbitol in the same proportion as the aqueous solution into the spray-drying chamber during drying the solution in an air stream;"

VIII. In a communication sent pursuant to Article 15(1) RPBA 2007, the Board expressed *inter alia* the preliminary opinion that the application as filed did not disclose the seeding of the solution.

IX. Oral proceedings were held before the Board.

X. In the present decision, reference is made to the following documents:

D8: WO 03/055834 A2

D12: EP 0 380 219

XI. The appellant-patent proprietor's arguments regarding compliance with Article 123(2) EPC can be summarised as follows:

Claim 1 as granted differed from claim 1 as originally filed by the introduction of a seeding step "seeding the solution with dry particles of mannitol and

sorbitol" as new step b). This step required that the seed particles be added to the solution and hence before the solution was dried and the particles were formed. On the other hand, in the skilled person's understanding, the seed particles had to be added, at the earliest, very shortly before the solution was dried, otherwise the seeds would be dissolved and would not function as seeds. It was thus an implicit requirement of claim 1 as granted that the seeding occur during the drying step in the drying chamber.

The application as filed, and in particular the passage on page 4, lines 3 to 5, the combination of claims 13 and 1, and the passages on page 12, lines 5-19, page 13, lines 20 to 22 were a direct and unambiguous disclosure for "seeding the solution". According to this disclosure, the dry particles were dry-fed (i.e. seeded) *via* a recycle system into the wet zone of the drying chamber. This wet zone of the drying chamber contained droplets of the solution. Owing to the humid conditions present in the wet zone, the droplets did not dry quickly and remained in the form of a solution. Thus the particles were seeded into the solution. The criteria of Article 123(2) EPC were met.

The same arguments were presented in respect of the same expression in auxiliary requests 1-7.

XII. The appellant-opponent's arguments regarding compliance with Article 123(2) EPC can be summarised as follows:

Claim 1 of the patent as granted defined a step of seeding the solution prior to the step of drying. It was not an implicit feature of claim 1 that the seeding step occurred during the drying step in the drying chamber. In fact, D8 and D12 showed that seeds could

very well be added to a solution outside of the drying chamber and before drying.

The skilled person could not derive from the application as filed, directly and unambiguously, an embodiment comprising the seeding of the solution with dry particles of mannitol and sorbitol. The expression "seeding the solution" did not appear anywhere in the application as filed. The passage of page 12, lines 16-17, did not show the addition of seeds to a solution but rather the agglomeration of dry particles to wet particles. The criteria of Article 123(2) EPC were not met.

The same objection was raised in respect of the same expression, present in each of auxiliary requests 1-7.

- XIII. The appellant-patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted, or as an auxiliary measure, on the basis of the first auxiliary request, i.e. the request considered to be allowable by the opposition division, or on the basis of one of the auxiliary requests 2-7 filed by letter dated 3 March 2017.
- XIV. The appellant-opponent requested that the decision under appeal be set aside and the patent be revoked.



## Reasons for the Decision

*Main request (patent as granted)*

1. Article 123(2) EPC (Article 100(c) EPC)
  - 1.1 Claim 1 of the main request differs from claim 1 of the application as filed as follows (amendments emphasized by the Board):

"A method for producing a directly compressible and highly compactible composition, said method comprising:  
a) dissolving mannitol powder and sorbitol powder into a solution;  
b) seeding the solution with dry particles of mannitol and sorbitol;  
~~b~~c) drying the solution in an air stream; and  
~~e~~d) forming particles having a nonfilamentous microstructure from the solution."

For the purposes of Article 123(2) EPC, the questions arise as to how the step b) introduced in claim 1 is to be interpreted, and whether the application as filed discloses, directly and unambiguously, such a step b).

- 1.2 Interpretation of claim 1 of the main request
  - 1.2.1 It is not disputed that the step b) of seeding the solution involves the addition of dry particles to a solution. The parties however debated the interpretation of claim 1 regarding the moment in time and the location at which the seeding step takes place.
  - 1.2.2 In the Board's view, the wording of step b), namely seeding *the* solution, clearly refers to the solution resulting from step a), i.e. the solution prepared by

dissolving mannitol powder and sorbitol powder into a solution. It also follows from the clear linguistic structure of claim 1, which specifies an alphabetically ordered list of steps, that the seeding step b) is performed before the drying step c).

- 1.2.3 As recalled in T 99/13, the assessment of the requirements of Article 123(2) EPC should be done on the same basis as for all other patentability issues, namely from the standpoint of the skilled person on a technical and reasonable basis avoiding artificial and semantic constructions. In the present case, the above literal reading of claim 1 (see 1.2.2) is neither illogical nor technically unreasonable.

Contrary to the appellant-patent proprietor's opinion, there is no technical impossibility in adding the dry particles or seeds to the solution before drying. Such an addition of seeds prior to drying is shown in D8 (page 8, lines 32-36) and D12 (page 3, lines 31-38). The appellant-patent proprietor also submitted that the feature pertaining to the non-filamentous microstructure of the final particles implicitly required that the seeding be performed during the drying step. However, in the absence of information as to the structure of particles resulting from a seeding before drying, this allegation is not convincing. The fact that the specification, or the description as filed, contains no teaching for an addition of seeds prior to drying is no reason either to depart from the clear and unambiguous wording of claim 1.

- 1.2.4 In conclusion, the skilled person would read claim 1 as defining a process in which the seeds are added to the solution obtained in step a), and wherein this addition takes place before the drying step c).

1.3 Disclosure in the application as filed

1.3.1 It is not contested that the application as filed provides no literal support for the expression "seeding the solution". The Board accepts the appellant-patent proprietor's arguments that, in the context of the application as filed, the expression "seeding" and "dry-feeding" are used interchangeably, in the sense that both refer to the addition of seeds or dry particles. Nonetheless, the application as filed does not explicitly mention any dry-feeding to a solution either.

1.3.2 As basis for the seeding step of claim 1, the appellant-patent proprietor referred to page 12 of the application, describing in more details a spray-drying method in accordance with the general method of claim 1 as filed, and page 13, showing an embodiment of the additional seeding step of claim 13 as filed.

1.3.3 According to page 12 (lines 5-9), referring to Figure 6, the liquid feed (i.e. the solution resulting from step a)) is delivered "to an atomizer which sprays the composition in fine droplets into a hot air stream entering the top of a drying chamber 4. This causes rapid drying due to the large liquid area exposed". The subsequent passages of page 12 (lines 13-19) describe the recycling of fines into the drying chamber: "The fines are recycled to the top of drying chamber 4 into a wet zone 11 where agglomeration takes place, and drop into integrated fluid bed 10." See also page 12, lines 27-29: "The smaller particles ("fines") generated during this process are recycled back to the top of drying chamber 4 for further agglomeration."

1.3.4 Dependent claim 13 of the application as filed discloses a step of dry feeding a blend of dry mannitol powder and sorbitol powder into the spray-drying chamber. According to page 13 (lines 20-28), "the spray-dried mannitol/sorbitol polyol composition may first be seeded with dry particles of mannitol/sorbitol in the same proportion as the aqueous solution prepared for co-spray drying. Referring to Figure 6, the dry particles are introduced into the fines recycle system of the spray dryer."

1.3.5 The appellant-patent proprietor deduces from the above passages that the seeds, i.e. the dry particles, are added to the droplets of solution in the spray-drying chamber. These droplets would constitute a solution in the sense of claim 1 of the main request, because claim 1 did not limit the state of this solution.

1.4 The Board does not share this view, for the following reasons.

1.4.1 Firstly, as explained above (see 1.2), in claim 1 of the main request, the dry particles are added to the solution resulting from step a) before drying, i.e. to the solution prepared by dissolving mannitol powder and sorbitol powder in a solution.

However, in the context of the application as filed, the matter present in the spray-drying chamber is not identical with this solution, because it consists of an atomized spray of fine droplets dispersed in the hot air stream and undergoing drying. For this reason already, it is questionable whether the matter to which the dry particles are added in the context of the application as filed can be regarded as *the* solution produced in step a) of claim 1, and whether this

addition occurs before the drying step c) as claim 1 of the patent requires.

- 1.4.2 Secondly, these droplets, even if *arguendo* regarded as the solution, may have dried and not be anymore in the state of a liquid solution by the time they meet the dry particles.

Indeed, according to the application as filed (see passages cited in 1.3.2 above), the liquid solution is introduced into the drying chamber through the atomizer, whereas the dry particles are introduced through the fines recycle system "into a wet zone 11 where agglomeration takes place". In view of their rapid drying (page 12, line 4), it cannot be affirmed that the droplets are still in the state of a solution in this wet zone. On the contrary, the term "agglomeration" supports the appellant-opponent's view that the droplets have turned into wet particles before they meet the dry particles, with which they agglomerate.

- 1.4.3 In conclusion, the application as filed discloses that both the dry particles and the solution are introduced into the drying chamber. However, it does not disclose that, in this drying chamber, the dry particles are added to the mannitol/sorbitol composition at a point where this is still a solution. A step of seeding the solution is thus not derivable, directly and unambiguously, from the application as filed.

Accordingly, claim 1 of the main request does not meet the criteria of Article 123(2) EPC (Article 100(c) EPC).

*Auxiliary requests 1-7*

2. Article 123(2) EPC

Claim 1 of each of the auxiliary requests 1-7 contains a step of "seeding the solution". Regardless of whether these claims specify the time (before or during the drying step) and the location (in the drying chamber or not) of this seeding step, the fact remains that the application as filed discloses no step of seeding the solution. Consequently, each of the auxiliary requests 1-7 infringes Article 123(2) EPC.

**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:



B. Atienza Vivancos

A. Usuelli

Decision electronically authenticated