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Datasheet for the decision of 14 June 2023

Case Number: T 1095/21 - 3.3.05

Application Number: 13827551.6

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Language of the proceedings: EN

Title of invention:
METHOD FOR PRODUCING STABILIZED AMORPHOUS CALCIUM CARBONATE

Patent Proprietor:
Amorphical Ltd.

Opponent:
Schaefer Kalk GmbH & Co. KG

Headword:
Stabilized ACC/Amorphical

Relevant legal provisions:
EPC Art. 100(a), 100(b), 100(c)

Keyword:
Grounds for opposition - insufficiency of disclosure (no) - added subject-matter (no) - lack of patentability (no)

Decisions cited:
T 1244/13

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 1095/21 - 3.3.05

D E C I S I O N
of Technical Board of Appeal 3.3.05
of 14 June 2023

Appellant: (Opponent)	Schaefer Kalk GmbH & Co. KG Louise-Seher-Strasse 6 65582 Diez (DE)
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Respondent: (Patent Proprietor)	Amorphical Ltd. P.O.B. 15021 Beer Sheva 84120 (IL)
Representative:	Féaux de Lacroix, Stefan Patentanwälte Isenbruck Bösl Hörschler PartG mbB Eastsite One Seckenheimer Landstrasse 4 68163 Mannheim (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 16 June 2021 rejecting the opposition filed against European patent No. 2882687 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	P. Guntz
Members:	G. Glod
	J. Roider

Summary of Facts and Submissions

I. The appellant's (opponent's) appeal lies from the opposition division's decision rejecting the opposition against European patent No. 2 882 687.

II. The following documents cited in the impugned decision are of particular relevance:

D1: S. Bentov et al., Journal of Structural Biology, 207-15
D3: CA 2 806 131
D14: G.B. Cai et al., CrystEngComm, 12, 2010, 234-41

For the other documents briefly cited below, reference is made to the impugned decision (point I.3).

III. Claim 1 of the patent reads as follows:

"*1. A method of preparing amorphous calcium carbonate (ACC), comprising the steps of:*
i) combining an aqueous solution comprising a soluble calcium salt and a first stabilizer with an aqueous solution comprising a soluble carbonate so as to form an ACC suspension; and
ii) adding a water miscible organic solvent and a solution comprising a second stabilizer, simultaneously or sequentially in any order so long as said second stabilizer and organic solvent contact said ACC suspension within 2 minutes of its formation, thereby obtaining a stabilized suspension of ACC;
wherein the first stabilizer and the second stabilizer are the same or different; and wherein the total amount of the stabilizer constitutes up to 12 wt% of the stabilized ACC suspension, and the water miscible

organic solvent constitutes at least 5 wt% of the stabilized ACC suspension."

Claims 2 to 11 directly refer to claim 1.

Claims 12 and 13 read as follows:

"*12. A suspension of stabilized ACC produced in accordance with method of claim 1, comprising between 2.5 and 5 wt% ACC, between 0.05 and 0.2 wt% phosphorylated organic acid, and between 10 and 15 wt% ethanol; or*
comprising between 2.5 and 5 wt% ACC, between 0.05 and 0.2 wt% organic acid, and between 10 and 15 wt% ethanol; or
containing between 2.5 and 5 wt% ACC, between 1 and 4 wt% saccharide, 0.5 wt% hydroxide, and between 10 and 15 wt% ethanol; or
containing between 2.5 and 5 wt% ACC, between 1 and 4 wt% non-phosphorylated hydroxyl-bearing amino acid, 0.5 wt% hydroxide, and between 10 and 15 wt% ethanol.

13. A powder of stable ACC which is produced in accordance with method of claim 11,
comprising between 75 and 88 wt% $CaCO_3$, less than 10 wt% water, and phosphorylated organic acid; or
comprising between 75 and 88 wt% $CaCO_3$, less than 10 wt% water, and organic acid; or
comprising between 75 and 88 wt% $CaCO_3$, less than 10 wt% water, and between 1 and 5 wt% saccharide; or
comprising between 75 and 88 wt% $CaCO_3$, less than 10 wt% water, and between 1 and 5 wt% nonphosphorylated hydroxyl-bearing amino acid."

Claim 14 refers to claim 12 or 13.

IV. The appellant's arguments relevant to the present decision can be summarised as follows.

The requirements of Article 123(2) EPC were not met. An essential feature was omitted.

The requirements of Article 83 EPC were not met since the term "stabilizer" was not specified. In addition, essential information was lacking for carrying out the claimed invention. No example was in accordance with granted claim 13.

D3 anticipated the novelty of claim 13. In the method according to example 1, a composition according to claim 13 was formed in the filter during filtration.

The subject-matter of claims 1 to 14 lacked an inventive step when starting from D3 as the closest prior art. The problem to be solved was to provide an alternative method or suspension or powder. The solution was obvious when considering documents D1 to D2, D4 to D10 and D12 to D25. The product of D3 obtained after drying at 130 °C was very similar to the two first options of claim 13 of the patent. It was further evident from D1 and D14 that amorphous calcium carbonate (ACC) can contain up to 15% of structural water, this rendering the subject-matter of claim 13 obvious.

V. The respondent's (patent proprietor's) arguments are reflected in the reasoning below.

VI. At the end of the oral proceedings of 14 June 2023, the requests of the parties were as follows.

The appellant requested that the decision under appeal be set aside and that the patent be revoked. In addition, they requested that the case be remitted to the opposition division if the auxiliary requests were to be discussed.

The respondent requested that the appeal be dismissed, alternatively, that the patent be maintained in amended form on the basis of one of auxiliary requests 1 to 14, submitted with the reply to the appeal.

Reasons for the Decision

Main request (patent as granted)

1. Article 100(c) EPC

The board sees no reason to deviate from the opposition division's conclusion.

Claim 1 is identical to claim 1 of the application as filed with the exception of the deletion of the word "about". In the current case, this deletion does not lead to a problem of added matter. In fact, the skilled person would directly and unambiguously derive from claim 1 that the term "about" in combination with a value includes the value itself.

The fact that the description may describe other features, not present in claim 1, as essential does not lead to a problem under Article 123(2) EPC. It could possibly give rise to an objection under Article 84 EPC, which is, however, not a ground for opposition.

2. Article 100(b) EPC

Again the board sees no reason to deviate from the opposition division's conclusion.

In the patent, stabilised is understood by the skilled person as avoiding crystallisation of ACC (see column 1, lines 25 to 29; column 2, lines 9 to 13 and paragraph [0010]). It is true that the patent does not contain any definition of "stabilized" in terms of time period and temperature. However, it is evident to the skilled person consulting the examples of the patent that the process should lead to an ACC that is stable for at least a couple of hours. The process of claim 1 is exemplified by six examples. There is no evidence on file that these examples could not be reworked. There is also no reason to doubt that executing the process according to claim 1 leads to a suspension that is more stable than a suspension obtained by a process not comprising the stabilisers.

The sufficiency objection against claim 13, regardless of whether it is a new ground for opposition (see T 1244/13, Reasons 12.3), does not in any case prejudice the maintenance of the patent. There is no convincing evidence on file that a skilled person executing the process according to claim 11, which includes separating the ACC obtained by the method of claim 10 and drying, would not be able to obtain the powder according to claim 13. The skilled person understands from paragraph [0064] and the examples of the patent how the separation and drying according to claim 11 are supposed to be done.

3. Article 100(a) EPC and 54 EPC

The requirements of Article 54 EPC are met for the following reasons.

Claim 13 relates to a powder of stable ACC obtainable according to the method of claim 11. It can have one of the four compositions indicated in claim 13. These only differ in the type of stabiliser present.

The board understands that the appellant argues that the precipitate obtained in example 1 of D3 would during separation from the mother liquor by filtration at one stage fall within the scope of claim 13 and therefore anticipate the novelty of this claim.

However, the board is not convinced by this argument. There is no evidence that during the filtration step described in example 1 of D3, the water content would be inevitably less than 10 wt% considering that water present on the surface and within the pores of ACC can normally only be removed by additional process steps.

Furthermore, there is also no evidence that the process features according to claims 11, 10 and 1 do not have an impact on the distribution of the stabiliser in the product and the morphology of the product.

4. Article 100(a) EPC and 56 EPC

The requirements of Article 56 EPC are also met. The reasons are as follows.

4.1 Claim 1

4.1.1 The invention relates to a process for preparing ACC.

4.1.2 In agreement with the parties, D3 and the process of example 1 is considered the closest prior art.

4.1.3 The alleged problem to be solved is to provide a process leading to an ACC with increased stability.

4.1.4 The proposed solution to this problem is a process according to claim 1 characterised at least in that a water miscible organic solvent and a solution comprising a second stabiliser are added to the ACC suspension within two minutes of its formation, thus obtaining a stabilised suspension of ACC in which the total amount of the stabiliser constitutes up to 12 wt% of the stabilised ACC suspension and the water miscible organic solvent constitutes at least 5 wt% of the stabilised ACC suspension.

4.1.5 The board is not convinced that there is evidence proving that the problem has been solved successfully. The product of example 1 of D3 is stable for at least five days (D5: page 22, fifth paragraph). There is no direct comparison of the process according to claim 1 of the patent with the exact process of example 1 of D3, which would prove that the process stability of the claimed product is superior. D30 to D32, regardless of whether they should be admitted into the proceedings (Article 12(4) and (6) RPBA 2020), do not include the exact process of D3 but a change of stabiliser. Furthermore, experimental details are rather limited in D30 to D32.

Therefore, the problem needs to be redefined in less ambitious terms as the provision of an alternative process for producing a stable ACC product.

4.1.6 The solution to the problem is not obvious for the following reasons.

D3 discusses when the stabiliser should be added. It discloses that it should be added most preferably at least five minutes after the reactants are mixed (page 15, fourth line from bottom). It is not credible that the skilled person would consider doing the addition within two minutes considering that the addition in example 1 of D3 was only done after 14.75 minutes. Furthermore, D3 is completely silent about the addition of part of the stabiliser in a second step. This teaching is also not available from the many documents cited by the appellant. To argue that the skilled person would contemplate this addition is based on hindsight. Therefore, the board concurs with the opposition division's conclusion since at least this second process step is not obvious in view of the prior art.

Consequently, the subject-matter of claim 1 and claims 2 to 11 depending on it involve an inventive step.

4.2 Claim 13

4.2.1 The invention relates to a powder of stable ACC. The powder is defined by the amounts of $CaCO_3$, water and the specified stabilisers. Therefore, the amount of water is understood as the total amount of water present, including structural water.

4.2.2 In agreement with the parties, D3 is considered the most relevant prior-art document. ACC obtained after drying at 200 °C from the process of example 1 is also stable and a good starting point for assessing inventive step. Although there is no information about

the stability of the intermediate product obtained after drying at 130 °C, it is accepted, to the appellant's benefit, that this intermediate product containing structural water has also a certain stability and is a possible starting point for inventive step.

The exact water content of this intermediate product is not indicated and not known. The 7 to 10 wt% water disclosed in D3 (page 2, first paragraph, last line) refers to prior art. The exact process conditions of the prior art are not disclosed, and precise information on the drying is not even available (page 2, lines 5 and 6). To argue that the intermediate product of example 1 of D3 had a water content in the range of 7 to 10 wt% is speculative. There is no data to support this speculation.

4.2.3 The alleged problem to be solved is to provide an ACC with increased stability.

4.2.4 The proposed solution to this problem is a powder according to claim 13 characterised in that it is obtainable by the two-step process of claim 1 and that it comprises between 75 and 88 wt% $CaCO_3$, less than 10 wt% water and one compound chosen from phosphorylated organic acid, an organic acid, between 1 and 5 wt% saccharide, and between 1 and 5 wt% nonphosphorylated hydroxyl-bearing amino acid.

4.2.5 D3 does not disclose the stability of the intermediate product. However, to the appellant's benefit, it is accepted that even this intermediate product has some stability. The problem is consequently redefined in less ambitious terms to the provision of an alternative stable ACC product.

4.2.6 The solution to the problem is not obvious for the following reasons.

D3 relates to improved long-term stability (page 5, last paragraph, line 6), and the calcium carbonate particles according to the invention of D3 have an extremely low residual water content (page 5, last paragraph, lines 4 and 5 from bottom). The water content should be less than 5.0 wt% (claim 1). Preferably, the water content is even lower (page 8, last paragraph). Furthermore, the calcium carbonate particles should preferably not contain any structural water (page 9, second full paragraph).

Therefore, the skilled person trying to solve the posed problem would consider all the compositions having reduced water content to be suitable alternatives. This applies all the more when starting from the intermediate product as in the current case. There is no reason why the skilled person would aim at an intermediate product having about 10 wt% structural water when the overall teaching of the document clearly leads towards lower water contents.

When preparing a composition with a very low overall water content, which is certainly below 7 wt%, the skilled person would arrive at ACC contents outside the claimed range of 75 to 88 wt%. This is evident from the calculations shown in the table on page 3 of the appellant's submission of 25 April 2023 and was confirmed by the appellant during the oral proceedings.

D1 (page 207, right-hand column, line 3) and D14 (page 236, right-hand column, first full paragraph, line 3) show that ACC can contain approximately 15 wt% water.

However, these documents do not relate to the process according to D3. The skilled person has no reason to expect that these water contents would be acceptable in a process according to D3 when trying to get an alternative stable ACC. Even if the skilled person considered these documents, the content of 15 wt% would be outside the claimed range of less than 10 wt% water.

There is also no evidence showing that the claimed compositions are less stable than the intermediate products of D3 obtained after drying at 130 °C or than the final products of D3. The argument that the claimed compositions constituted a disadvantageous modification of the known compositions is therefore not accepted.

To conclude, there is no teaching in the prior art that the combination of the specific amounts of water, $CaCO_3$ and the indicated stabilisers leads to a powder of stable ACC. The indicated amounts are not considered arbitrary since they are the direct consequence of the fact that the powder is obtainable by a process according to claim 11, referring indirectly back to claim 1. The inventive process according to claim 1 allows obtaining an alternative powder of stable ACC. The skilled person would not have arrived without inventive skills at such a process and the resulting product when starting from a known process.

4.2.7 Consequently, the subject-matter of claim 13 involves an inventive step.

4.3 Claim 12

The suspension can be considered an intermediate product which allows obtaining the powder according to claim 13. Since the process for producing the

suspension and the final product obtained from the suspension are considered to be based on an inventive step, the same applies to the suspension.

The subject-matter of claim 12 involves an inventive step.

4.4 Claim 14

This claim relates to the use of the inventive products according to claims 12 and 13 and consequently also involves an inventive step

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Vodz P. Guntz

Decision electronically authenticated