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**Datasheet for the decision
of 28 February 2017**

Case Number: T 0446/13 - 3.3.07

Application Number: 05744221.2

Publication Number: 1755578

IPC: A61K9/00

Language of the proceedings: EN

Title of invention:

CHEWABLE, SUCKABLE AND SWALLOWABLE TABLET CONTAINING A
CALCIUM-CONTAINING COMPOUND AS AN ACTIVE SUBSTANCE

Patent Proprietor:

Takeda Nycomed AS

Opponent:

Bayer Consumer Care AG

Relevant legal provisions:

EPC Art. 123(2), 123(3), 84, 101(3), 100(b), 56

Keyword:

Amendments - allowable (yes)
Claims - clarity in opposition appeal proceedings
Grounds for opposition - insufficiency of disclosure (no)
Inventive step (yes)

Decisions cited:

G 0003/14



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Case Number: T 0446/13 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 28 February 2017

Appellant: Bayer Consumer Care AG
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
19 December 2012 concerning maintenance of the
European Patent No. 1755578 in amended form.

Composition of the Board:

Chairman A. Usuelli
Members: R. Hauss
I. Beckedorf

Summary of Facts and Submissions

- I. European patent No. 1 755 578 was granted with thirty-six claims. The only independent claim of the patent, which is identical to claim 1 of the application as published (WO 2005/117829 A2), reads as follows:
- "1. A calcium-containing tablet suitable for dispensing via a dose-dispensing machine, the tablet comprising a regularly shaped calcium-containing compound as an active substance and a pharmaceutically acceptable sugar alcohol having a particle size ($D(v;0.5)$) below about 150 μm , which tablet has a porosity below 20%."
- II. The patent was opposed under Article 100(a) and (b) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step and was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
- III. The documents referred to in the course of the opposition and appeal proceedings include the following:
- D1: WO 00/28973 A1
D3: JP 2001-316249 A
D3c: English translation of D3 (submitted with the notice of opposition)
D24: Experimental data of porosity measurements, dated 11 November 2008
- IV. The appeal by the opponent (appellant) lies from the interlocutory decision of the opposition division, announced on 9 November 2012 and posted on 19 December 2012, finding that the patent proprietor's main request, filed during oral proceedings on 9 November 2012, met the requirements of the EPC.

Claim 1 of that request was directed to a tablet which was defined as in claim 1 of the opposed patent, with the additional requirement that the mandatory regularly shaped calcium-containing compound was to be present in the tablet at a concentration of 55 to 90% (w/w).

- V. In the decision under appeal, the opposition division found that the amendments to the claims did not give rise to a lack of clarity (Article 84 EPC), and that the information provided in the patent enabled the person skilled in the art to reproduce the invention (Article 100(b) EPC).

The claimed tablet was not anticipated by the disclosure of documents D1 (specifically, example 2) or D3, in view of the requirements specified in claim 1 with regard to tablet porosity and (in the case of D3) the concentration of the calcium-containing compound (Articles 100(a), 52(1) and 54(2) EPC).

The opposed patent sought to provide a calcium-containing tablet with acceptable taste and mouthfeel and suitable for dispensing via a dose-dispensing machine. Document D1 was regarded as representing the closest prior art. Since document D1 taught away from low porosities, the tablets according to claim 1 of the main request were a non-obvious alternative to the tablets disclosed in document D1.

- VI. The opponent (appellant) filed an appeal against that decision in due time and form.
- VII. With letter dated 30 August 2013, sent in reply to the statement setting out the grounds of appeal, the patent proprietor (respondent) submitted three sets of claims as main request, first auxiliary request and second auxiliary request, and introduced document D24

containing porosity data of tablets made according to example 1 of the patent in suit.

Claim 1 of the main request was identical to claim 1 of the request considered in the decision under appeal.

VIII. In a communication issued in preparation for oral proceedings and advising the parties of the board's preliminary opinion, the board mentioned *inter alia* the following points (see the board's communication, points 1.4, 2.2.3, 2.2.4, 5.7.1 and 5.7.2):

(a) In the absence of any limiting criteria in claim 1 defining the conditions to be met for the tablets to be deemed suitable for dispensing via a dose-dispensing machine, any tablet which could withstand normal handling and packaging had to be regarded as suitable for that purpose.

(b) The parameters particle size, porosity, crushing strength, friability, disintegration time and dissolution were well known in the galenic field and could be determined by the person skilled in the art, who was also competent to select the most suitable method. If different methods of determination existed which might yield different results, that was usually an issue associated with the scope of the claims, and thus the clarity of what was claimed (Article 84 EPC), rather than a question of sufficiency of disclosure. Since the features objected to were already present in the claims as granted, the objection regarding lack of clarity was not available in opposition appeal proceedings (see G 3/14, OJ EPO 2015, A102). As "taste" and "mouthfeel" were not mentioned in the claims, there was no basis for an objection of insufficiency with regard to those properties.

(c) The comparative test data presented in the patent in suit and supplemented by document D24 were not conclusive, *inter alia* because the samples tested differed from each other in several aspects.

(d) No specific technical effect had been shown in connection with tablet porosities below 20%.

IX. Oral proceedings before the board took place on 28 February 2017 (see the minutes of the oral proceedings for the issues discussed and the progress of the proceedings).

In the course of the oral proceedings, the respondent stated that the former second auxiliary request was its new main request.

The only independent claim of the **new main request** reads as follows:

"1. A method of manufacturing a calcium-containing tablet suitable for dispensing via a dose-dispensing machine, the tablet comprising 55 percent to 90 percent (w/w) of a regularly shaped calcium-containing compound as an active substance and a pharmaceutically acceptable sugar alcohol having a particle size ($D(v;0.5)$) below about 150 micrometres, which tablet has a porosity below 20 percent, wherein said method comprises wet granulation in a high-shear mixer and then compressing the obtained powder into tablets."

- X. The appellant's arguments with regard to the new main request may be summarised as follows:

Amendments (Article 123 EPC)

The introduction of a specific manufacturing method into amended claim 1 contravened the requirements of Article 123(2) EPC because it involved a selection from several manufacturing methods listed in the original application.

Definition of the claims (Article 84 EPC)

The definition of the concentration range of 55 to 90 percent (w/w) was not clear as to whether the reference weight (100 percent) was the total weight of the tablet or the weight of active components only.

It was not specified by which method and under which conditions the porosity of the tablets was to be determined.

Furthermore, several technical features which appeared to be essential to the invention (viz. the presence of a coating, lack of dust and specified tablet dimensions) were nevertheless not mentioned in claim 1.

Sufficiency of disclosure (Article 100(b) EPC)

The patent in suit did not specify how to evaluate taste and mouthfeel, or how to determine particle sizes or the porosity of the tablets, and did not specify in detail how to determine the parameters crushing strength, friability, disintegration time and dissolution (mentioned in the dependent claims).

Furthermore, the patent did not indicate any definitive criteria of suitability for dispensing via a dose-dispensing machine.

The technical feature "suitable for dispensing via a dose-dispensing machine" was arbitrary and could not be

reproduced, as it was mentioned in paragraphs [0047] to [0052] of the patent in suit that different models and designs of dose-dispensing machines were available, different regulatory requirements existed from country to country, and the requirements with respect to tablet size which ensured that the tablets could be packed in a dose-dispensing machine were dynamic and liable to change over time.

Claim 1 did not mention which type of high-shear mixer should be used or define the mixing conditions which were required.

Inventive step (Articles 100(a), 52(1) and 56 EPC)

The granules manufactured according to example 1 of D1 with a porosity of 20% to 30% and containing the components required in claim 1 should be regarded as tablets. The porosity value of 20% was within the tolerance of the range "below 20%" defined in claim 1 of the main request.

Even if the specified porosity (below 20%) was regarded as a technical feature distinguishing the claimed subject-matter from the disclosure of examples 1 and 2 of document D1, that feature did not give rise to any advantageous effect. While it could be assumed that porosity was linked to tablet size, it had been shown in example 3 of the patent in suit that tablets formulated and obtained according to document D1 (represented by batch 4 of example 1 of the patent in suit) were not too large, and were therefore suitable for dispensing via a dose-dispensing machine.

Furthermore, picking one method of manufacture from a range of conventional, well-known options which were described in the patent in suit as equally suitable did not involve an inventive step.

Thus, the subject-matter of claim 1 was an obvious alternative to the tablets and method of manufacture disclosed in document D1.

Inventive step could also be assessed starting from the teaching of document D3. Example 2 of that document (see D3c: page 12) disclosed the preparation of tablets containing a calcium compound and a sugar alcohol with the help of a high-shear mixer. In comparison, the tablets according to claim 1 of the main request contained a higher proportion of calcium-containing compound. Thus the technical problem to be solved could be seen in the provision of larger tablets with a higher content of calcium. Since tablets having a higher content of calcium were known from prior-art document D1, it did not require inventive skill to arrive at that solution.

According to dependent claim 35, the tablet could include further amounts of sugar alcohols of any particle size. As a consequence, any technical effect linked to a particle size ($D(v;0.5)$) below 150 μm would not be achieved over the entire scope claimed.

- XI. The respondent's arguments with regard to the new main request may be summarised as follows:

Amendments (Article 123 EPC)

The amendment introducing a specific manufacturing method into claim 1 found word-for-word support in the passage on page 25, lines 23 to 25 of the original application. The selection of a method from one list did not contravene Article 123(2) EPC.

Sufficiency of disclosure (Article 100(b) EPC)

The patent in suit set out in sufficient detail the requirements to be met for a tablet to be suitable for dispensing via a dose-dispensing machine.

The person skilled in the art also knew how to carry out wet granulation in a high-shear mixer, since that method was part of the common general knowledge of the formulator in the field of pharmacy and was furthermore illustrated in the examples of the patent in suit.

Inventive step (Articles 100(a), 52(1) and 56 EPC)

Example 2 of document D1, which described the preparation of calcium-containing tablets involving fluid-bed granulation, represented the closest prior art. The subject-matter of claim 1 differed therefrom in the porosity of the tablet, which was lower, and in the granulation technique employed.

As acknowledged both in D1 and in the patent in suit, since relatively high doses of calcium typically had to be administered, it was generally desirable to reduce tablet bulk. Based on the results of a comparative test presented in table 2 of the patent in suit, showing that smaller tablets could be obtained with the less porous granules prepared by wet granulation in a high-shear mixer, the technical problem to be solved could be seen as a further reduction in tablet bulk.

Document D1 relied on a fluid-bed granulation technique which was presented as essential for obtaining highly porous granulates and thereby achieving good sensoric properties in chewable tablets prepared on the basis of such granulates. If embodiments such as lozenges were desired, D1 taught the use of higher compression forces to increase tablet hardness (and presumably reduce porosity and tablet size) rather than a different granulation technique. Neither document D1 nor any other document of the cited prior art provided any incentive to the person skilled in the art to adopt a method of manufacture involving wet granulation in a high-shear mixer.

For the same reasons, the claimed method would still not be obvious from the prior art even if the technical problem were to be seen in the provision of an alternative method of manufacture.

Contrary to the appellant's statement, document D3 did not disclose a wet granulation process. Thus the person skilled in the art would not arrive at the method defined in claim 1 of the main request by combining the teaching of documents D1 and D3.

- XII. The appellant requested that the decision under appeal be set aside and that European patent No. 1 755 578 be revoked.
- XIII. The respondent requested that, when setting aside the decision under appeal, the patent be maintained in amended form on the basis of the set of claims filed with letter of 30 August 2013 as second auxiliary request (new main request).

Reasons for the Decision

1. Amendments (Article 123 EPC)

1.1 Added subject-matter (Article 123(2) EPC)

The passage on page 25, lines 21 to 28 of the application as published mentions, in a general disclosure, several possible methods of manufacturing the tablets of the invention, including a method involving wet granulation in a high-shear mixer followed by compression into tablets, as defined in amended claim 1.

It will be inferred that each of those generally disclosed methods is directly applicable to all

embodiments, including tablets with a content of the regularly shaped calcium-containing compound of 55 to 90% (w/w) as disclosed on page 19, lines 30 to 34, or in claim 28 of the application as published.

For this reason, the board considers that the subject-matter of claim 1 of the main request does not extend beyond the content of the application as filed within the meaning of Article 123(2) EPC.

1.2 Extension of protection (Article 123(3) EPC)

No objection under Article 123(3) EPC was raised by the appellant, and the board sees no reason for such an objection.

2. Definition of the claims (Article 84 EPC)

2.1 Lack of compliance with the requirements of Article 84 EPC is not a ground for opposition listed in Article 100 EPC.

2.2 As established in the decision of the Enlarged Board of Appeal G 3/14 (OJ EPO 2015, A102, order),

"In considering whether, for the purposes of Article 101(3) EPC, a patent as amended meets the requirements of the EPC, the claims of the patent may be examined for compliance with the requirements of Article 84 EPC only when, and then only to the extent that, the amendment introduces non-compliance with the EPC."

2.3 The objections raised by the appellant in this context against claim 1 of the main request (see point X above) all relate to issues which have not arisen as a result of the amendments as compared with the patent as granted:

- 2.3.1 The concentration range of 55 to 90% by weight was already present in claim 24 as granted.
- 2.3.2 The feature specifying that the porosity of the tablets must have a value below 20% was already present in claim 1 as granted.
- 2.3.3 The features which are not mandatory in amended claim 1 but are regarded by the appellant as essential for defining the invention (viz. the presence of a coating, lack of dust and specified tablet dimensions) were not mandatory in claim 1 as granted, either.
- 2.4 As a consequence, in application of the criterion defined in decision G 3/14, the appellant's objections raised under Article 84 EPC against claim 1 of the main request cannot be examined in the present opposition appeal proceedings.
- 3. Sufficiency of disclosure (Article 100(b) EPC)
 - 3.1 The question to be answered with regard to sufficiency of disclosure of the subject-matter of claim 1 is whether the method as defined in the claim can be carried out to manufacture a tablet as defined in the claim, taking into account the information provided in the patent in suit and common general knowledge.
 - 3.2 Preparation of a tablet having a porosity below 20% involving wet granulation in a high-shear mixer
 - 3.2.1 In this regard, the board has no reason to doubt that tablets containing 55 to 90% by weight of a calcium-containing compound and a sugar alcohol as specified in claim 1 can be manufactured with a porosity below 20%, with a method involving wet granulation in a high-shear mixer and subsequent compression.

- 3.2.2 For instance, document D24 indicates 19% (18.55% and 18.62%) for the porosity of tablets prepared from granulates obtained by wet granulation in a high-shear mixer according to batches 2 and 3 of example 1 of the patent in suit; those values were not contested by the appellant.
- 3.2.3 The person skilled in the art would be able to carry out a wet granulation process in a high-shear mixer, since both the method and type of apparatus are commonly known. The method is also illustrated in examples 1 and 4 of the patent in suit (see paragraphs [0139]-[0140] and [0160]-[0163] of the patent specification). The board has no reason to assume that the method can only be carried out with a specific mixer model or under specific process conditions not available to the skilled person within the framework of the information provided in the patent and by common general knowledge and conventional routine practice. Thus, contrary to what was argued by the appellant, the claim does not have to mention a specific mixer design or further restrictions with regard to the process conditions in order to meet the requirement of sufficiency of disclosure.
- 3.3 Suitability for dispensing via a dose-dispensing machine
- 3.3.1 Claim 1 of the main request does not define any criteria which must be met for the tablet to be considered suitable for dispensing via a dose-dispensing machine, nor does it specify any restricting technical features of the dose-dispensing machine or the dispensing process. Under these circumstances, the board considers that there are no specific limitations involved, and that any tablet which is not manifestly unsuitable for dispensing with any conceivable type of

machine must be regarded as suitable. Tablets which withstand normal handling and packaging are therefore suitable for dispensing via a dose-dispensing machine.

- 3.3.2 In application of this criterion, the board has no reason to assume that the tablets mentioned in point 3.2.1 above, prepared in accordance with the other technical features of claim 1, would typically not withstand normal handling and packaging, and that it would therefore require an undue effort of further research and process optimisation to arrive at "suitable" tablets.
- 3.3.3 Since the feature "suitable for dispensing via a dose-dispensing machine" does not involve any requirement with regard to tablet size, the appellant's objection that the size requirement may change over time has no relevance. The same applies to the appellant's objection to limitations based on unspecified regulatory requirements or construction designs of dose-dispensing machines.
- 3.4 In the board's communication issued in preparation for oral proceedings pursuant to Article 15(1) RPBA, the board explained, in the context of the former main request filed with the reply to the statement setting out the grounds of appeal, why the appellant's objections under Article 100(b) EPC with regard to various parameters mentioned in the claims and with regard to the properties "taste" and "mouthfeel" could not succeed (see point VIII.(b) above). The appellant did not subsequently make any further submissions regarding that issue. Hence the board confirms and maintains its opinion as set out in section 2.2 of the communication, which equally applies to the amended claims of the new main request (see section 8 of the board's communication).

3.5 For these reasons, the board considers that the subject-matter of claim 1 is disclosed in the patent in suit in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Thus the ground mentioned under Article 100(b) EPC is no reason not to maintain the patent on the basis of the claims of the main request.

4. Inventive step (Articles 100(a), 52(1) and 56 EPC)

Patent in suit

4.1 The patent in suit seeks to provide a chewable or suckable calcium-containing tablet suitable for dispensing via a dose-dispensing machine. To achieve that, it aims to provide sufficiently robust tablets which are not too bulky and which have acceptable taste and mouthfeel (see paragraphs [0001], [0003], [0004], [0007] and [0008] of the patent in suit).

4.2 Claim 1 of the present main request defines a method of manufacture of a tablet which contains 55 to 90% by weight of a regularly shaped calcium-containing compound in combination with a specific sugar alcohol, said tablet having a porosity below 20%. The method comprises wet granulation in a high-shear mixer followed by a compression step to obtain tablets.

Starting point in the prior art

4.3 Document D1, mentioned in the application as filed, has been used as the starting point for the assessment of inventive step.

4.4 Document D1 seeks to provide oral calcium compositions, *inter alia* chewable tablets and suckable lozenges, which are not too bulky and which have good sensoric properties despite having a high calcium content. To

that end it proposes a process of preparation which involves fluid-bed granulation of a combination of a particulate calcium compound with a high degree of crystallinity, a water-soluble diluent and a binder (see D1: page 2, paragraph 1; page 11, line 30 to page 12, line 4; claim 1). Suitable diluents include sugar alcohols (page 5; claim 8).

D1 teaches that the porosity of the granulate is desirably between 20% and 30% to obtain improved sensoric properties of chewable tablets. Lozenges, i.e. suckable dosage forms which will last longer in the mouth, are compressed with a stronger force to obtain greater hardness and crushing strength (D1: page 18, lines 19 to 24; examples 3, 8, 11, 12).

In example 1 on pages 12 and 13, document D1 describes the preparation of a granulate containing calcium carbonate (Scoralite 1B, also used in the examples of the patent in suit) and sorbitol (Neosorb P100T). The respondent did not contest that Neosorb P100T is a sugar alcohol as defined in claim 1 of the present main request.

In example 2 on pages 13 to 15, document D1 describes chewable tablets made with the granulate of example 1. The tablets contain 72% by weight of calcium carbonate. They have a porosity of 25% to 30%, a breaking strength which gives rise to satisfactory chewability and at the same time resistance towards handling and packaging in tablet bottles, and low friability which ensures sufficient firmness during handling and packaging (see D1: page 14, lines 20 to 40 and page 15: lines 10 to 14).

The lozenges according to example 3 on page 15 of D1 have a similar composition but contain xylitol (CM50) instead of sorbitol.

Technical problem and solution

4.5 A tablet is a compressed dosage form prepared from powders and/or granules. Thus, contrary to what was argued by the appellant, a granule as disclosed in example 1 of D1 cannot itself be regarded as a tablet. The combination of technical features which comes closest to the subject-matter of claim 1 of the main request is found in example 2 of document D1, describing the preparation of tablets containing the components specified in present claim 1 (see point 4.4. above).

4.5.1 Document D1 states on page 15 that the tablets prepared according to example 2 had porosity values in the range of 25% to 30%, as determined by mercury intrusion porosimetry and helium adsorption. Thus, tablets prepared according to example 2 of D1 do not inevitably have porosity values below 20% as determined by those methods. Furthermore, it has not been shown that other suitable methods of measurement exist which would give values below 20%.

Hence the porosity of below 20% is a technical feature distinguishing the subject-matter of claim 1 from the disclosure of example 2 of D1.

4.5.2 The method of manufacture according to claim 1 of the main request involves wet granulation in a high-shear mixer, while the tablets according to example 2 of document D1 were prepared using fluid-bed granulation.

The granulation technique is therefore another technical feature distinguishing the subject-matter of claim 1 from the disclosure of D1.

4.6 In support of inventive step, the respondent cited test results reported in example 1, table 2 of the patent

in suit and argued on that basis that tablets prepared in accordance with claim 1 (batches 1 to 3) presented advantages over the prior-art tablets (represented by batch 4) in terms of tablet bulk.

4.7 The board considers, however, that the experimental data presented in example 1 of the patent in suit cannot be regarded as conclusive, for the following reasons:

Porosity values for tablets manufactured in accordance with batches 1 to 4 of example 1 are not indicated in the patent in suit, but have been provided separately in document D24. Batch 4 is based on granules prepared with a fluid-bed granulation method, to yield tablets with a porosity of 29%. The granules used for batches 1 to 3 were prepared via wet granulation in a high-shear mixer, resulting in tablets with lower porosities of 20% (batch 1) and 19% (batches 2 and 3). While the porosity of tablets according to batch 1 was indicated as 19.99% in D24, corresponding to 20% within the accuracy of claim 1, the respondent still regarded batch 1 as representative of low-porosity tablets.

Batch 4 is representative of tablets prepared in accordance with document D1. However, when the composition of the tablets of batch 4 is compared to that of the tablets of batches 1 to 3, it is evident that several features were varied besides the method of manufacture and the porosity, viz. the type, quantity and quality of the sugar alcohol, and also the type, quantity and quality of further excipients (see table 1 on page 17 of the patent specification).

A technical effect cannot be convincingly linked to a particular technical feature if several features were varied in the comparison. From the information

available it cannot be excluded that the additional changes in the tablet composition may be relevant to any technical effects observed in a comparison of batch 4 to batches 1 to 3, in particular tablet bulk which is the property relied on by the respondent.

- 4.8 Thus, the board arrives at the conclusion that no specific technical effect has been shown in connection with tablet porosities lower than 20% or in connection with the granulation technique.
- 4.9 Nor is it implicit that tablets with porosities of 20% or higher are unsuitable for dispensing via any conceivable type of dose-dispensing machine (see, for instance, example 2 of D1, page 14, lines 20 to 34, where it is mentioned that tablets with a porosity of 25 to 30% had good breaking strength and resistance to handling and packaging).
- 4.10 Starting from the technical teaching of document D1, the technical problem to be solved is, accordingly, the provision of a further method of manufacturing a further calcium-containing tablet.
- 4.11 In view of the examples of the patent in suit and the porosity data provided in document D24, the board is satisfied that the technical problem is solved by the method defined in claim 1 of the main request.
- 4.12 The appellant's objection with regard to the possible presence of further quantities of sugar alcohol of any particle size has not been substantiated by any evidence showing that in such cases the above-mentioned problem would not be solved over the scope claimed, e.g. that such tablets could not be manufactured. Thus the objection does not affect the definition of the technical problem.

Obviousness of the solution

4.13 Tablet porosity

4.13.1 According to document D1 (pages 11-12), a porosity of the granulate of 20 to 30% is desirable for improved dispersion and reduced stickiness of chewable tablets prepared from such a granulate. The board observes that this teaching is restricted to chewable tablets, and that two inferences may be drawn from this:

i) Presumably, a granulate with a porosity of 20% may provide, upon compression with or without further powder excipients, a tablet with a porosity below 20%, which is thus not excluded by the teaching of document D1.

ii) The reader would not assume from the above statement that tablets with lower porosities, e.g. 19%, would be entirely unacceptable, but at most that they would not necessarily be superior with regard to dispersion and stickiness.

4.13.2 Present claim 1 is not restricted to the manufacture of chewable tablets. In addition to chewable tablets, document D1 also covers lozenge-type tablets prepared applying a stronger compression force (see D1: page 18), thus characterised by increased hardness and, presumably, lower porosities than the chewable tablets.

4.13.3 The board concludes from this that document D1 does not, in fact, appear to teach away from lowering tablet porosity to values below 20% as an obvious measure for obtaining further tablets.

4.14 Granulation technique

4.14.1 Thus, if the person skilled in the art wanted to prepare tablets differing from those of example 2 of

document D1 by having a lower porosity value, this could be achieved within the framework covered by document D1 by selecting granules in the lower part of the preferred porosity range and/or by using a high compression force and suitable powder excipients. Document D1 does not suggest the use of granulation techniques other than fluid-bed granulation, in this or any other context.

- 4.14.2 According to the appellant, document D3 discloses, in example 2, the preparation of calcium-containing tablets involving granulation in a high-shear mixer. However, the board finds upon closer analysis that no granulation fluid is involved and that document D3 describes dry mixing of the components to obtain a powder mixture, rather than a wet granulation method (see D3c: paragraph [0021] on page 12). The board therefore considers that the combination of documents D1 and D3 cannot, in any case, suggest the method defined in present claim 1 to the person skilled in the art, irrespective of which of those two documents is used as the starting point for the assessment of inventive step.

- 4.14.3 The appellant also submitted that wet granulation was a well-known manufacturing technique, and that picking one method of manufacture from a range of conventional, well-known options which were described in the patent in suit as equally suitable did not involve an inventive step.

However, the patent in suit itself does not form part of the state of the art which was available to the person skilled in the art at the relevant date. The appellant has failed to provide any other document of the prior art in support of the argument that it would have been obvious to the person skilled in the art to

change the granulation technique in order to solve the technical problem.

- 4.15 For these reasons, the board concludes that the objections raised against inventive step of the main request are not convincing.

5. Since the appellant did not raise any further objections to the main request, the board finds that the patent can be maintained on the basis of the claims of the main request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent in amended form on the basis of the set of claims filed with letter of 30 August 2013 as second auxiliary request and a description to be adapted.

The Registrar:

The Chairman:



S. Fabiani

A. Usuelli

Decision electronically authenticated