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Datasheet for the decision of 20 March 2024

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Language of the proceedings: EN

Title of invention:
MAGNESIUM OXIDE GRANULES FOR PHARMACEUTICAL APPLICATIONS OR FOOD ADDITIVE APPLICATIONS

Patent Proprietor:
Konoshima Chemical Co., Ltd.

Opponent:
Dead Sea Bromine Company Ltd.

Headword:
Magnesium oxide granules/KONOSHIMA

Relevant legal provisions:
EPC Art. 100(a), 54, 56

Keyword:

Novelty - (yes)
Inventive step - (yes)

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Case Number: T 1336/22 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 20 March 2024

Appellant: (Opponent)	Dead Sea Bromine Company Ltd. Makleff House 12 Kroitzer St. P.O. Box 180 84101 Beer-Sheva (IL)
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Representative:	Plougmann Vingtoft a/s Strandvejen 70 2900 Hellerup (DK)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 1 April 2022 rejecting the opposition filed against European patent No. 3111957 pursuant to Article 101(2) EPC**

Composition of the Board:

Chairman	A. Usuelli
Members:	J. Molina de Alba
	S. Ruhwinkel

Summary of Facts and Submissions

I. The decision under appeal is the opposition division's decision rejecting the opposition filed against European patent No. 3111957.

II. The patent was granted with 14 claims. Granted independent claims 1, 12, 13 and 14 read as follows:

"*1. Magnesium oxide granules for pharmaceutical applications or for use as a food additive having a BET specific surface area of 7 to 50 m^2/g and CAA80/CAA40 of 2 to 7, wherein CAA80 is the time after the addition of the predetermined amount of magnesium oxide to citric acid until 80 mol% of the total amount of magnesium oxide has reacted with the citric acid, and CAA40 is the time after the addition of the predetermined amount of magnesium oxide to citric acid until 40 mol% of the total amount of magnesium oxide has reacted with the citric acid.*"

"*12. A method for producing the magnesium oxide granules according to any one of claims 1 to 11, comprising the steps of mixing a medium-active magnesium oxide and a low-active magnesium oxide at a weight ratio of 10:90 to 80:20, applying pressure to the mixture, and grinding the mixture, wherein the low-active magnesium oxide is a magnesium oxide obtainable by calcination of magnesium hydroxide at a calcination temperature of 1000 to 2000°C, and the medium-active magnesium oxide is a magnesium oxide obtainable by calcination at a calcination temperature of 450 to 900°C.*"

"*13. A method for producing a magnesium oxide tablet, comprising tableting the magnesium oxide granules according to any one of claims 1 to 11.*"

"*14. A magnesium oxide tablet containing the magnesium oxide granules according to any one of claims 1 to 11.*"

III. The following documents are referred to in the present decision:

D1 English translation of JP2006-249052A
D2 US2004/0022872A1
D3 Experimental report dated 16 August 2019
D4 US2012/0156293A1
D5 US6436447B1
D6 English translation of JP2003-33159A
D8 English machine translation of JPH11-158558A
D9 English machine translation of JPH11-181525A
D10 M.E. Aulton, "Pharmaceutics - The Science of Dosage Form Design", 2nd edn., 2002, 365
D11 "European Pharmacopoeia", 3rd edn., 1997, 1749
D12 D. Jones, "Pharmaceutics - Dosage Form and Design", 2008, 232
D13 Declaration by K. Sakamoto dated 27 October 2020
D14 Declaration by R. Rozen dated 26 August 2021
D18 Reply to communication dated 16 April 2018
D19 Definition of granule, Merriam-Webster online
D20 EP1004311A1

IV. In the decision under appeal, the opposition division concluded, among other things, that the claimed subject-matter was sufficiently disclosed, novel over D1, D8 and D9, and inventive starting from D1 or D4 as the closest prior art.

V. The opponent (appellant) filed an appeal against the decision. With its statement of grounds of appeal, the appellant filed documents D18 to D20.

VI. With its reply to the statement of grounds of appeal, the patent proprietor (respondent) filed three sets of claims as auxiliary requests 1 to 3.

VII. The board scheduled oral proceedings, in line with the parties' requests, and set out its preliminary opinion on the case.

VIII. Oral proceedings were held before the board. At the end of the oral proceedings, the board announced its decision.

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

Admittance of D18 to D20

D18 to D20 did not change the appellant's case and they were not late filed.

D18 was a letter filed by the respondent during the examination proceedings. The appellant had referred to this letter in the opposition proceedings. D18 showed the contradictory position of the respondent in the examination and opposition proceedings.

D19 was an English dictionary entry relating to the term "granule", which constituted common general knowledge with respect to the meaning of this term. D19 countered D10 and D11, which were limited to the field

of pharmacy. This was necessary because the claims of the patent also covered food applications.

D20 was filed in reaction to the decision, in which the opposition division took the view that granulation was not an obvious measure. D20 showed that granulating magnesium oxide (MgO) powder was a well-known process in the industry.

Novelty

The granules of claim 1 were anticipated by the MgO particles disclosed in D1, D8 and D9. The term "granule" should not be limited to its meaning in the pharmaceutical field, as defined in D10 and D11, since claim 1 was also directed to food additives. A granule was simply a small particle, as defined in any English dictionary. This definition was technically sensible and could not be excluded.

Inventive step starting from D1

D1 was a suitable starting point for assessing inventive step. Even if the granules of claim 1 were considered novel over the particles in D1, their BET and CAA80/CAA40 values were not distinguishing features. D3 was an experimental report reworking the particles in Example 1 of D1 and subsequently granulating them by the method in D2 as used in the patent. D3 showed that the particles in Example 1 of D1, and the granules obtained from them, had BET and CAA80/CAA40 values according to claim 1. Thus, the subject-matter of claim 1 differed from the particles in Example 1 of D1 only in that MgO was in granulated form.

This difference did not produce any technical effect. The respondent had not demonstrated that the BET and CAA80/CAA40 ranges in claim 1 were associated with a reduction in tableting problems. The comparative examples in Table 1 of the patent and in D13 were not conclusive because they contained different amounts of binder or two types of MgO particles vs a single one. In addition, the criticality of the limit ranges in claim 1 had not been shown.

Therefore, starting from D1 the objective technical problem was to provide an alternative.

Granulation and the advantages associated with it were generally known. Furthermore, D2, D4, D5, D6, D10 and D11 showed that in the food and pharmaceutical fields it was common to granulate MgO particles before tableting. Therefore, the granules of claim 1 were obvious.

Inventive step starting from D4

The granules of claim 1 differed from those in D4 only in their CAA80/CAA40 value. They did not differ in BET values because it was common general knowledge that MgO granules used for pharmaceutical purposes had a BET within the range specified in claim 1. The absence of the excipients essential in D4 was not a difference either, since claim 1 did not exclude excipients. The granules in the examples of patent also contained excipients.

The distinguishing feature did not produce any technical effect, for the reasons submitted when starting from D1 as the closest prior art. Therefore,

the objective technical problem was also to provide an alternative when starting from D4.

The skilled person would arrive at the granules of claim 1 in an obvious manner. Firstly, the CAA80/CAA40 values in claim 1 were arbitrary since they did not produce any effect. Secondly, the skilled person would replace the MgO particles in D4 with those in D1. The incentive to do so was the advantage that the particles of D1 reduced tablet surface darkening during the tableting process. As shown in D3, the particles in D1 and the granules obtained from them had BET and CAA80/CAA40 values as required by claim 1.

X. The respondent's arguments relevant to the present decision can be summarised as follows:

Admittance of D18 to D20

D18 to D20 could and should have been filed during the opposition proceedings.

D18 had been introduced in the examination proceedings but was not automatically part of the opposition proceedings. While the appellant did refer to D18 during the opposition proceedings, it did not file it. Moreover, contrary to the appellant's contention, the document did not show any contradiction in the respondent's position.

The dispute on the meaning of the term "granule" was on file from the outset of the opposition proceedings. The respondent had filed D10 and D11 in support of its position, as these documents reflected the skilled person's understanding of the term. D19 defined the meaning of the term in everyday usage, which was

irrelevant, and it could have been filed in the opposition proceedings.

D20 related to the granulation of MgO. It was not relevant and could have been filed in the opposition proceedings since other documents were filed for the same purpose, namely D2, D4 and D5. D20 was the counterpart of D5.

Novelty

The passages cited by the appellant in D1, D8 and D9 did not anticipate the subject-matter of claim 1 because they disclosed particles instead of granules. According to D10 and D11, which represented common general knowledge in pharmaceutical formulations, a granule was an aggregate of powder particles. This meaning was not limited to the pharmaceutical field. It was also applicable to food additives, as shown in D6. The meaning of the term "granule" in everyday usage was irrelevant here and technically incorrect in the context.

Inventive step starting from D1

D1 was not the closest prior art because it did not deal with the kind of tableting problems discussed in the patent and because its solution taught away from granulation. The distinguishing feature in claim 1 was that the MgO was granulated and had specific BET and CAA80/CAA40 values. The alleged reworking of Example 1 of D1 reported in D3 did not prove that the particles in D1 had a CAA80/CAA40 as defined in claim 1.

Table 1 of the patent and D13 showed that the distinguishing features reduced tableting problems such

as sticking, capping and chipping. The examples in Table 1 were designed for comparison. They contained the same amount of binder, and the use of one or two types of MgO particles merely reflected a CAA80/CAA40 value below or above 2, respectively. Table 1 and D13 showed that a reduction in tableting problems was achieved across the whole breadth of claim 1 and not outside it.

It was not obvious that the granules of claim 1 could reduce tableting problems associated with the internal structure of the tablets. D1 was concerned with improving the external appearance rather than the internal structure of tablets. Furthermore, D1 taught away from granulation. Even if granulation was generally known as an optional step before tableting, it was also generally known that tablets could be prepared by direct compression of particles without prior granulation. According to D12, which represented common general knowledge, direct compression could be advantageous over granulation followed by compression.

Inventive step starting from D4

The granules of claim 1 differed from those in D4 in their BET and CAA80/CAA40 values. This difference resulted in improved granules, because the granules of claim 1 reduced tableting problems, such as those mentioned in D4, without the need to add certain excipients or to form the tablets in a particular way.

The objective technical problem was the provision of improved MgO granules that reduce tableting problems, such as chipping, capping, etc., when compressed into tablets.

The granules of claim 1 were not an obvious solution. D4 was silent on how the granules could be modified to reduce tableting problems in a different way from the one proposed. Furthermore, D4 did not refer to BET or CAA80/CAA40 values at all. This information could not be found in D1 either.

XI. The parties' final requests were as follows.

- The appellant requested that the decision under appeal be set aside and that the patent be revoked in its entirety. It also requested that documents D18 to D20 be admitted into the appeal proceedings.

- The respondent requested that the appeal be dismissed and that the patent be maintained as granted. In the alternative, it requested that the patent be maintained in amended form on the basis of one of the sets of claims filed as auxiliary requests 1 to 3 with the reply to the statement of grounds of appeal. In addition, the respondent requested that documents D18 to D20 and the inventive-step objections starting from D1 in combination with D6, D10 and D11 not be admitted into the appeal proceedings.

Reasons for the Decision

1. Admittance of D18 to D20 (Article 12(4) and (6) RPBA)

1.1 Documents D18 to D20 were filed by the appellant for the first time with the statement of grounds of appeal. They are new pieces of evidence and therefore the

filing thereof constitutes an amendment to the appellant's case in relation to the opposition proceedings (Article 12(2) and (4), first sentence, RPBA).

Article 12(6), second sentence, RPBA provides that the board shall not admit requests, facts, objections or evidence which should have been submitted in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify their admittance.

In the board's view, D18 to D20 could and should have been filed during the opposition proceedings and there are no circumstances justifying their admittance during the appeal proceedings, as explained in the following.

1.2 D18 was filed to show that the respondent had argued during the examination proceedings that a CAA80/CAA40 value higher than 2 could only be obtained if at least two different types of MgO particles are used. This issue had been raised by the appellant in its notice of opposition (paragraph bridging pages 3 and 4) and was discussed during the opposition proceedings, including in the opposition division's communication in preparation for oral proceedings (points 2.2. and 2.3). Therefore, D18 could and should have been filed in the opposition proceedings.

1.3 D19 is an English dictionary entry relating to the term "granule". The dispute on the meaning of this term was also raised in the notice of opposition (page 4, penultimate paragraph). In its reply to the notice of opposition, the respondent filed documents D10 and D11 to counter the appellant's submissions. The opposition division agreed with the respondent in its preliminary

opinion in preparation for oral proceedings (page 7, second paragraph). The decision merely confirmed this position (page 7, first and second paragraphs). Therefore, D19 should also have been filed in the opposition proceedings.

1.4 D20 was filed to prove that granulating MgO particles was a well-known operation in the technical field of pharmaceutical formulations. This argument was raised in the notice of opposition (page 10, penultimate paragraph) with reference to D2, D4 and D5. The content of D20 is essentially the same as that of D5. Therefore, D20 also could and should have been filed in the opposition proceedings.

1.5 Consequently, D18 to D20 have not been admitted into the appeal proceedings.

2. Technical background

Claim 1 as granted is directed to MgO granules having a BET specific surface area of 7 to 50 m^2/g and a CAA80/CAA40 of 2 to 7.

BET specific surface area is a well-known parameter in solid materials that defines the total surface area of a solid per mass unit. It is generally known that MgO particles can be prepared by calcination of magnesium hydroxide, and that the calcination temperature serves to modulate the BET specific surface area of the resulting MgO particles. The higher the calcination temperature, the lower the BET value (see e.g. patent, paragraphs [0008], [0036], [0055] and [0056]).

CAA is also a well-known parameter indicating the time required for MgO to react with citric acid. CAA40 and

CAA80 are the times until 40% and 80% of MgO has reacted, respectively. As chemical reactions involving a solid reactant occur at the solid surface, CAA and BET values are directly related. The higher the BET value of MgO, the more reactive it is. According to the patent (paragraph [0008]), MgO produced at a temperature of 1500°C or higher has little activity and is used as refractory material. When MgO is produced at 450 to 1300°C, it has relatively high activity and can be used, among other things, as a food additive and medicinal product.

In a granule, i.e. an aggregate of particles, the relationship between CAA40 and CAA80 can vary depending on the geometry and distribution of the agglomerated particles, as well as on the extension of particle surface covered by the binder. When a granule contains a single type of MgO particles, it may be expected that the specific surface available for reaction increases as reaction progresses, because the particles gradually become smaller and because they are freed from the binder. This means that the time required for reacting 80% of MgO is usually less than double the time required for reacting 40%. Accordingly, the CAA80/CAA40 value can be expected to be lower than 2. In contrast, when the granule contains more than one type of MgO particle, the reaction rate can be expected to be higher at the beginning, when the more active particles react, i.e. those having higher BET values. As the reaction progresses, the more active particles are used up, leaving less active particles. Therefore, the reaction rate may be expected to slow down at some point. If this point is reached between 40% and 80% of conversion, the granule will have a CAA80/CAA40 above 2.

Thus, a CAA80/CAA40 value of 2 to 7 as defined in claim 1 implies that the claimed granules contain at least two types of MgO particles, i.e. particles having different BET specific surface areas and reactivity. This was agreed by the parties at the oral proceedings before the board.

3. Sufficiency of disclosure (Article 100(b) EPC)

In its statement of grounds of appeal, the appellant raised a sufficiency objection based on the assumption that claim 1 could encompass granules containing a single type of MgO particle. As explained in the technical background above, such granules could not be expected to have a CAA80/CAA40 value higher than 2.

At the oral proceedings before the board, the respondent explained that the granules of claim 1 did indeed contain at least two types of MgO particles having different BET values. However, this did not mean that the claimed granules could only be obtained by mixing MgO particles that had been prepared separately, as illustrated in the patent examples. A heterogeneous population of MgO particles could also be obtained *in situ* by calcining magnesium hydroxide at different temperatures, as illustrated in D6 (paragraph [0013]). Another option was to calcine a heterogeneous mixture of magnesium hydroxide particles, as in D13.

The appellant declared that if claim 1 was interpreted as being directed to granules containing at least two types of MgO particles, it would not maintain its sufficiency objection. As that was the respondent's and the board's interpretation of claim 1, the sufficiency objection was no longer pursued.

For the sake of completeness, the board notes that it sees no reason to object to the sufficiency of the disclosure. It was undisputed that BET, CAA80 and CAA40 are well-known parameters and that the skilled person would be able to determine them without undue burden. It was also undisputed that the application as filed teaches how MgO granules having the BET and CAA80/CAA40 values required by claim 1 can be prepared. This is disclosed, for instance, in paragraph [0028] and in the examples. Reference Example 1 discloses the preparation of medium-active MgO particles having a BET value of 51 m^2/g by calcining magnesium hydroxide at 900°C for two hours. Reference Example 2 discloses the preparation of low-active MgO particles having a BET value of 3 m^2/g by calcining magnesium hydroxide at 1100°C for two hours. In Examples 1 to 5, the particles from the reference examples were mixed at different ratios and granulated. Table 1 shows that the resulting granules had BET values ranging from 8 to 42 m^2/g and CAA80/CAA40 values ranging from 2.2 to 4.5.

Therefore, the ground for opposition of Article 100(b) EPC does not preclude the maintenance of the patent as granted.

4. Novelty (Articles 100(a) and 54 EPC)

4.1 According to the appellant, the MgO particles disclosed in D1 (Example 1), D8 (paragraph [74] and claim 1) and D9 (paragraph [56] and claim 1) anticipate the granules of claim 1 as granted.

The respondent did not dispute that the particles in D1, D8 and D9 have BET values as defined in claim 1. It was also undisputed that the particles in D8 and D9 had CAA80/CAA40 values according to claim 1. The matter of

dispute was whether a granule within the meaning of claim 1 could be equated to a particle, and whether the particles in Example 1 of D1 had a CAA80/CAA40 value between 2 and 7.

4.2 On the first point, the appellant submitted that the term granule should be interpreted in its broadest sense, as defined in any English dictionary: a granule merely meant a small particle. It refuted the respondent's argument that the term was limited to the meaning defined in D10 and D11, since the granules of claim 1 were not limited to medical purposes; they were also intended as food additives. Therefore, the MgO particles in D1, D8 and D9 had to be regarded as granules covered by claim 1.

4.3 The board disagrees. The term "granule" has a clear meaning in chemical formulations, namely an aggregate of powder particles. This is confirmed by documents D10 (page 365, first sentence and Figure 25.1) and D11 (page 1749), which represent common general knowledge in the field of pharmaceutical formulations. Moreover, D1 makes a distinction between granules and particles. In paragraphs [0003] and [0004], D1 refers to the MgO granules of the prior art, while the invention refers to MgO particles.

The appellant is right that the granules of claim 1 are not limited to pharmaceutical uses and that they can also be used as food additives. However, the board holds that the meaning of granule as set out in D10 and D11 is not limited to the pharmaceutical field. The term "granule" is well known and has a uniform meaning for chemical formulations, including food additive formulations. This is apparent from the examples in D6, in which a food additive was prepared by mixing a MgO

powder (i.e. MgO particles) with maltose or scallop shell powder and the mixture was subsequently formulated into granules.

In the board's view, it is technically incorrect to equate particles with granules when talking about chemical formulations. For this reason alone, D1, D8 and D9 do not anticipate the subject-matter of claim 1, and the ground for opposition of Article 100(a) EPC in combination with Article 54 EPC does not preclude the maintenance of the patent as granted.

5. Inventive step (Articles 100(a) and 56 EPC)

5.1 The patent (paragraphs [0003] to [0006] and [0011]) is directed to the preparation of high-purity MgO tablets for pharmaceutical and food applications. The tablets are prepared by compression molding of MgO granules, a process that involves repeated compression at a high speed and may produce a heterogeneous distribution of particles within the tablet. Tablets with a heterogeneous internal structure may present problems such as capping, laminating, sticking and chipping. The granules of claim 1 are intended as starting material for preparing MgO tablets. They reduce tableting problems and quality defects in the tablets.

5.2 In the decision under appeal, inventive step was discussed starting from D1 and D4 as the closest prior art. In the written appeal proceedings, the appellant raised additional inventive-step objections starting from D8 and D9. The latter objections were withdrawn during the oral proceedings before the board.

5.3 Starting from D1

5.3.1 D1 is concerned with the preparation of MgO tablets for pharmaceutical applications by direct compression of particles (paragraphs [0002] and [0005]). D1 deals with the problem that the surface of MgO tablets darkens during compression due to the abrasion caused by the hardness of MgO particles. D1 refers to prior-art documents in which darkening was avoided by granulating MgO before tableting (paragraphs [0003] and [0004]). In contrast, the solution proposed in D1 is coating the surface of MgO particles with a softer material, namely magnesium hydroxide or magnesium carbonate (paragraphs [0006] and [0009]). MgO particles can then be compressed directly without prior granulation. The MgO particles of D1 have a preferred specific surface area within the range of 1 to 50 m^2/g (paragraph [0012]). In Example 1 of D1, MgO particles having a specific surface area of 10 m^2/g were coated and compressed to tablets. The tablet surface did not darken.

5.3.2 According to the respondent, the subject-matter of claim 1 differs from the teaching in D1 in that it is directed to MgO granules having a CAA80/CAA40 of 2 to 7, not coated MgO particles.

The appellant contested that the CAA80/CAA40 value of 2 to 7 constituted a difference over the prior art. It referred to experimental report D3 in which the particles in Example 1 of D1 had been reworked. However, the MgO particles obtained in D3 had a BET value of 15.9 m^2/g, while the BET value disclosed in Example 1 of D1 was 10 m^2/g. This divergence between the original and reworked examples casts doubts on the suitability of D3 for proving that the particles in

Example 1 of D1 had a CAA80/CAA40 value within the range defined in claim 1.

Therefore, the board agrees with the respondent that the CAA80/CAA40 value constitutes a difference over the closest prior art.

5.3.3 The technical effect provided by the distinguishing features is a reduction of tableting problems associated with the internal structure of tablets, such as sticking, capping and chipping. This effect is shown in Table 1 of the patent and Table X of D13.

Table 1 of the patent, reproduced below, shows that granules according to claim 1, e.g. those prepared in Examples 1 to 5, could be compressed into tablets without sticking, capping and chipping. This was not the case for the granules which did not meet the BET and/or CAA80/CAA40 requirements of claim 1, i.e. the granules in Comparative Examples 1 to 3.

	Medium-active MgO	Low-active MgO	BET	CAA40	CAA80	CAA80/40	Purity	Bulk density	Pb	As	Tablet strength	Sticking, capping, chipping, etc.
	weight%	weight%	m^2/g	s	s	-	%	g/L	ppm	ppm	N	
Ex.1	80	20	42	105	312	3.0	96.0	770	< 10	< 1	105	No
Ex.2	60	40	32	121	548	4.5	96.7	830	< 10	< 1	98	No
Ex.3	40	60	22	171	635	3.7	97.4	970	< 10	< 1	86	No
Ex.4	20	80	12	286	694	2.4	98.1	980	< 10	< 1	74	No
Ex.5	10	90	8	327	712	2.2	98.4	990	< 10	< 1	61	No
Comp.Ex. 1	100	0	51	82	151	1.8	95.1	680	< 10	< 1	112	Yes
Comp.Ex. 2	0	100	5	415	732	1.8	98.8	1070	< 10	< 1	46	Yes
Comp.Ex. 3	Medium low-active MgO		22	164	315	1.9	95.5	810	< 10	< 1	74	Yes
Ex.: Example Comp. Ex.: Comparative Example												

Similarly, the example in Table X of D13 shows that granules having a BET value of 26 m^2/g and a CAA80/CAA40 value of 4.0 can be compressed into tablets without sticking, capping and chipping.

5.3.4 The appellant contested that Table 1 showed that the granules of claim 1 were particularly suitable for preparing MgO tablets for two reasons. First, the examples in Table 1 could not be compared with each other. Second, even if the examples were compared, Table 1 did not prove that the BET and CAA80/CAA40 ranges in claim 1 were critical for reducing tableting problems.

With regard to the first reason, the appellant argued that the examples in Table 1 were not comparable because the tablets had been prepared using different amounts of binder, and because the granules in Examples 1 to 5 contained two types of particles while in the comparative examples they contained a single type. Concerning the amount of binder, the appellant referred to paragraph [0054] of the patent, which describes how the tablets in Table 1 were prepared. A mixture containing 300 mg of MgO granules and 4 to 10 wt.% binder was compacted to produce tablets of a fixed dimension. The appellant noted that the volume and weight of the tablets were fixed but that according to Table 1, the starting granules had different bulk densities. This meant that it was necessary to add different amounts of binder in each tablet to compensate for the difference in bulk density of the granules.

The board does not agree. The argument that the granules in Table 1 contain different amounts of binder is based on speculation. The board sees no reason why a mixture containing a fixed weight of granules having different bulk densities and a fixed amount of binder cannot be compressed to a fixed volume. As submitted by the respondent, the resulting tablets will merely have different degrees of compaction, a factor that is

associated with tablet strength. As to the use of granules containing a single type or two types of particles, this merely reflects the difference in CAA80/CAA40 values, as explained in point 2 above. Therefore, the appellant's arguments do not cast doubts on the comparability of the examples in Table 1.

With regard to the second reason, the appellant submitted that Table 1 does not show that the lower limit of the CAA80/CAA40 range, i.e. 2, was critical for reducing tableting problems. The appellant referred to Example 5 and Comparative Example 3. In both cases the BET value was within the range defined in claim 1, but the CAA80/CAA40 values were 2.2 in Example 3 and 1.9 in Comparative Example 3. Noting that the lower limit of the CAA80/CAA40 range in claim 1 is 2, the appellant argued that Comparative Example 3 was closer to that limit than Example 5. Therefore, the cut-off CAA80/CAA40 value of 2 was not critical.

As has already been discussed with respect to sufficiency of disclosure, it was undisputed that a CAA80/CAA40 value higher than 2 implies that the granules contain at least two different types of particles, while a value below 2 is typical (albeit not exclusive) of granules containing a single type of particle. For this reason alone, a cut-off value of 2 makes technical sense. Table 1 shows BET and CAA80/CAA40 values varying from 8 to 42 m^2/g and 2.2 to 4.5, respectively. These values are representative of the claimed ranges 7 to 50 m^2/g and 2 to 7. Therefore, the breadth of the ranges in claim 1 is justified by the evidence provided in the patent.

5.3.5 In view of the technical effect identified above, the objective technical problem is to provide a form of MgO

for the formulation of MgO tablets by compression which prevents sticking, capping and chipping.

5.3.6 The solution proposed in claim 1 was not obvious from the cited prior art.

D1 is concerned only with to the problem that the surface of MgO tablets darkens during tableting. It acknowledges that this problem had been previously solved by granulating MgO particles before tableting. Yet D1 is silent on tableting problems other than surface darkening. Neither D1 nor any of the other documents cited by the appellant suggests that sticking, capping and chipping can be prevented by compressing MgO granules having BET and CAA80/CAA40 values as defined in claim 1.

The appellant cited D2, D4, D5, D6, D10 and D11 in support of its argument that granulating MgO particles having a BET as in claim 1 was a common procedure for preparing MgO tablets in the food or pharmaceutical field. It also submitted that granulation and the advantages associated with granules were generally known.

D2 states in paragraph [0022] that MgO tablets may be prepared from particles or granules. Granules are preferred because they prevent abrasion of the tableting machine.

D5 discloses how MgO particles with a given BET value can be prepared (column 3, lines 37 to 44). MgO particles for use as a laxative preferably have a BET value between 21 and 50 m^2/g (column 4, lines 30 and 31). Example 1 of D5 discloses the preparation of MgO

granules and the compression thereof to form tablets. The example gives no information on the BET and CAA80/CAA40 values of the granules. As to the occurrence of tableting problems, D5 merely states that the tablets were not darkened.

D6 discloses MgO particles having a specific surface area of 1 to 50 m^2/g as food additives (paragraph [0009]). In Example 1, the particles were granulated.

D10 teaches that granules constitute an intermediate product for producing tablets in the pharmaceutical field. D11 discloses different types of granules that may be prepared for oral administration.

Thus, none of D2, D5, D6, D10 and D11 relates to tableting problems associated with the internal structure of tablets, such as sticking, capping and chipping. None of the documents mentions CAA80/CAA40 values, nor the relationship thereof with the occurrence of sticking, capping and chipping. The only problem dealt with in the cited documents was the darkening of the tablet surface. Furthermore, the patent shows that granulation is not a suitable solution on its own. The granules must have a combination of BET and CAA80/CAA40 values as defined in claim 1 in order to prevent sticking, capping and chipping.

D4 relates to the use of MgO granules in the pharmaceutical field for preparing tablets with improved strength and reduced wear and chipping (paragraphs [0001] and [0007]). However, D4 is silent as to the BET and CAA80/CAA40 values of the granules. The solution proposed in D4 for preventing tableting problems is a particular combination of disintegrating

agents and binder and a particular shape (paragraph [0009]).

Therefore, irrespective of the admittance of some of the arguments submitted by the appellant when starting from D1 (see the respondent's requests in point XII above), the granules of claim 1 are not obvious when D1 is taken as the closest prior art.

5.4 Starting from D4

5.4.1 D4 is directed to the preparation of antacid or laxative tablets containing MgO particles as the main component. The aim of D4 is to reduce the cracking, wearing and chipping that occurs when MgO granules are tableted (abstract and paragraphs [0001], [0006] to [0010], and [0018] to [0029]). This problem is solved by two measures: by giving the tablet a particular shape, and by using a combination of two particular disintegrating agents and a binder. D4 does not disclose any BET or CAA80/CAA40 values for the MgO particles and granules described therein.

5.4.2 The parties agreed that the granules of claim 1 differ from those in D4 in their CAA80/CAA40 range. At the oral proceeding before the board, the appellant disputed that the BET values in claim 1 constituted a further distinguishing feature. It argued that the BET values in claim 1 were implicit in the granules of D4 because those were the BET values generally required for MgO particles intended for pharmaceutical purposes. The appellant did not provide evidence of such common general knowledge. The board is aware that D5, discussed when D1 was taken as the closest prior art, discloses that MgO particles for laxative use have a preferred BET value of 21 to 50 m^2/g (column 4, lines

26 to 41). Nevertheless, D5 does not constitute common general knowledge, nor does it teach that MgO particles must have a BET value within that preferred range. Therefore, the board holds that the BET range in claim 1 is a distinguishing feature.

Consequently, the granules of claim 1 differ from those in D4 in their BET and CAA80/CAA40 values.

5.4.3 With regard to the technical effect produced by these differences, the respondent submitted that the granules of claim 1 were superior to those of D4 because they did not require particular tableting ingredients or a particular tablet shape.

This argument is not convincing. Claim 1 does not exclude the presence of excipients. In fact, the granules of claim 1 do need to be mixed with common tableting ingredients such as a binder. In the examples of the patent, the granules contain starch as a binder. An effect associated with tablet shape is not demonstrated either. The patent does not disclose the exact shape of the tablets prepared in the examples, nor does it compares tablets of different shapes. As there is no direct comparison between tableting the granules of claim 1 and those of D4, the board considers that in both cases tableting problems associated with the tablet internal structure can be avoided.

5.4.4 In view of the above, the objective technical problem starting from D1 is to provide alternative MgO granules that reduce tableting problems associated with the tablet internal structure.

5.4.5 It has already been discussed in point 5.3.3 above that the granules of claim 1 are a suitable solution to this objective technical problem since they reduce sticking, capping and chipping.

5.4.6 The appellant contended that the combination of D4 with D1 rendered the solution proposed in claim 1 obvious.

The board disagrees. D4 teaches that tableting problems related to the internal structure of the tablet may be reduced by using particular excipients and by giving the tablet a particular shape. In contrast, D1 teaches that the darkening of a tablet surface, which occurs during tableting, can be reduced by coating MgO particles with a softer material. It is not clear why the skilled person would consider combining two documents dealing with different problems and providing different solutions. Furthermore, even if the information in D4 and D1 were to be combined, the skilled person would still not find any incentive to prepare granules having a CAA80/CCA40 value within the range of 2 to 7. Therefore, the granules of claim 1 are not obvious starting from D4 as the closest prior art.

5.5 In view of the above, the granules of claim 1 as granted are inventive. The other independent claims are directed to a method of producing the granules of claim 1 (claim 12), a method of producing a tablet comprising the granules of claim 1 (claim 13), and a tablet containing the granules of claim 1 (claim 14). Therefore, the subject-matter claimed by the patent as granted involves an inventive step, and the ground for opposition of Article 100(a) EPC in combination with Article 56 EPC does not preclude the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Sánchez Chiquero A. Usuelli

Decision electronically authenticated