BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPÉEN DES BREVETS

Internal distribution code:

- (A) [] Publication in OJ
- (B) [] To Chairmen and Members
- (C) [] To Chairmen
- (D) [X] No distribution

Datasheet for the decision of 8 March 2022

Case Number: T 1321/19 - 3.3.07

Application Number: 10793226.1

Publication Number: 2512453

IPC: A61K9/16, A61K9/50, A61K31/609

Language of the proceedings: EN

Title of invention:

Granules for pharmaceutical preparations, methods and apparatus for their production

Patent Proprietor:

Ferring B.V.

Opponents:

Intas Pharmaceuticals Ltd.
Cooke, Richard
Tillotts Pharma AG

Headword:

Granules for pharmaceutical preparations / FERRING B.V.

Relevant legal provisions:

RPBA Art. 12(4) EPC Art. 115, 84, 54(2), 56 RPBA 2020 Art. 13(1)

Keyword:

Late-filed evidence - admitted (no)

Observations by third parties - taken into account (no)

Claims - clarity in opposition appeal proceedings

Novelty - (yes)

Inventive step - main request (no) - auxiliary request (yes)

Decisions cited:

G 0003/14, T 1029/05, T 0671/03, T 1182/01, T 0704/08, T 1404/10, T 0340/12



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 1321/19 - 3.3.07

DECISION
of Technical Board of Appeal 3.3.07
of 8 March 2022

Appellant: Tillotts Pharma AG

(Opponent 3) P.O. Box Baslerstrasse 15 4310 Rheinfelden (CH)

Representative: Lederer & Keller Patentanwälte

Partnerschaft mbB Unsöldstraße 2 80538 München (DE)

Respondent: Ferring B.V.

(Patent Proprietor) Polaris Avenue 144 2132 JX Hoofddorp (NL)

Representative: Hoffmann Eitle

Patent- und Rechtsanwälte PartmbB

Arabellastraße 30 81925 München (DE)

Party as of right: Intas Pharmaceuticals Ltd.

(Opponent 1) 2nd Floor Chinubhai Centre

Ashram Road Ahmedabad 380009

GUJ (IN)

Representative: HGF

HGF Limited 1 City Walk

Leeds LS11 9DX (GB)

Party as of right: Cooke, Richard

(Opponent 2) Elkington and Fife LLP

Patents Department 3-4 Holborn Circus London EC1N 2HA (GB) Representative: Elkington and Fife LLP

Prospect House 8 Pembroke Road

Sevenoaks, Kent TN13 1XR (GB)

Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted on 28 March 2019 concerning maintenance of the European Patent No. 2512453 in amended form.

Composition of the Board:

Chairman A. Usuelli
Members: E. Duval

Y. Podbielski

- 1 - T 1321/19

Summary of Facts and Submissions

I. European patent 2 512 453 (hereinafter "the patent") was granted on the basis of 17 claims.

Claim 1 of the patent essentially related to a pharmaceutical preparation comprising non-spheronized granules characterised by their median aspect ratio, the aspect ratio being defined as granule length along a predetermined axis divided by the smallest cross-sectional dimension.

- II. Three oppositions were 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 the auxiliary request 2 filed with letter of 25 January 2018, the patent met the requirements of the EPC.

Claim 1 of auxiliary request 2 read as follows:

"A pharmaceutical preparation comprising nonspheronized granules of which each has an active pharmaceutical ingredient and of which each has a predetermined axis and the same predetermined crosssectional profile, wherein at least 80% by number of those granules have an aspect ratio less than 2.2 and greater than 0.7, and wherein the granules have a median aspect ratio above 1.1 and below 1.7, the aspect ratio being defined as granule - 2 - T 1321/19

length along the predetermined axis divided by the smallest cross-sectional dimension."

IV. The decision of the opposition division cited the following documents among others:

D1: EP 1 547 601 A1

D6: WO 03/032952 A1

D9: Thommes et al., "Use of K-carrageenan as alternative to pelletisation aid to microcrystalline cellulose in extrusion/spheronisation. II. Influence of drug and filler type", Eur. J. of Pharm. and Biopharm., 63 (2006), 68-75.

- V. Regarding auxiliary request 2, the opposition division decided the following:
 - (a) The requirements of Article 123(2) EPC were met.
 - (b) The definition of aspect ratios greater than of 0.7 in claim 1 of auxiliary request 2 did not introduce any non-compliance with Article 84 EPC.
 - (c) The subject-matter of claim 1 of auxiliary request 2 was sufficiently disclosed and novel over D9 among others.
 - (d) Starting from the closest prior art D1, the distinguishing feature was that "at least 80% by number of those granules have an aspect ratio less than 2.2 and greater than 0.7". The technical problem was the provision of non-spheronized granules which do not fragment during coating, thereby leading to a more homogeneous coating, and a more predictable dissolution profile. The claimed solution involved an inventive step.

- 3 - T 1321/19

VI. Opponent 3 (the appellant) lodged an appeal against the decision of the opposition division. With its statement setting out the grounds of appeal, the appellant submitted the following document:

D18: WO 2007/020508 A1

VII. By letter dated 2 January 2020 filed in reply to the appeal, the patent proprietor (the respondent) defended its case on the basis of a main request, and filed auxiliary requests 1-8.

The main request corresponded to auxiliary request 2 underlying the appealed decision (see III. above)

Claim 1 of auxiliary request 1 differed from claim 1 of the main request by the feature that the granules were "extruded".

- VIII. On 14 February 2020, observations were filed by a third party.
- IX. The Board set out its preliminary opinion in a communication under Article 15(1) RPBA issued on 18 January 2022.
- X. Oral proceedings took place before the Board on 8 March 2022.
- XI. The appellant requested that the decision under appeal be set aside and that the patent be revoked. The appellant further requested that D18 be admitted into the proceedings, and that the third party observations filed on 14 February 2020 be taken into account.

- 4 - T 1321/19

XII. The respondent requested that the appeal be dismissed, i.e. that the patent be maintained on the basis of auxiliary request 2 filed on 25 January 2018 (main request in the appeal proceedings), or that the patent be maintained on the basis of one of auxiliary requests 1-8 filed on 2 January 2020 with the reply to the grounds of appeal. The respondent further requested that D18 not be admitted into the proceedings, and that the third party observations filed on 14 February 2020 not be taken into account.

XIII. The appellant's argument may be summarised as follows:

(a) Admittance of D18

D18 was a simple document which had been known to the respondent. Its filing was in reaction to the appealed decision. In particular, the opposition division allowed auxiliary request 2 which contained a new feature introduced during opposition proceedings, in contrast with the division's preliminary opinion dated 25 June 2018. In addition, D18 had to be admitted due to its high relevance to novelty and inventive step of the claimed invention.

(b) Observations by third party

The observations filed by a third party on 14 February 2020 had to be considered in the appeal proceedings on account of their *prima facie* relevance, in particular regarding the line of argumentation presented on page 5, section 2.3 of these observations.

- 5 - T 1321/19

(c) Clarity

Claim 1 of the main request mandated an aspect ratio of greater than 0.7. As this feature was not present in the granted set of claims, it had to be examined for clarity. The common definition of an aspect ratio did not allow for values below 1. The patent defined the aspect ratio as the granule length along the predetermined axis divided by the smallest cross-sectional dimension. This predetermined axis could however not be recognised for granules other than extruded granules, e.g. having a cylindrical shape. Accordingly, the claims were unclear.

(d) Novelty

The subject-matter of claim 1 lacked novelty over the batches of mesalamine pellets shown in D9, which resulted from an incomplete spheronization step. The expression "non-spheronized" used in claim 1 was unclear and could not delimit the claimed subject-matter from D9.

(e) Inventive step

The closest prior art D1 disclosed extruded, non-spheronized granules with an average aspect ratio of e.g. 1.1, 1.25, 1.3, 1.5 or 1.7. The subject matter of claim 1 of the main request differed from D1 only in that at least 80% by number of those granules had an aspect ratio less than 2.2 and greater than 0.7.

The technical effect of avoiding fragmentation of the granules during coating could not be taken into account in the formulation of the technical problem, because example 5 compared granules differing also in the

- 6 - T 1321/19

median aspect ratio, which was not a differentiating feature over D1. In addition, this alleged advantage did not arise for uncoated granules, which were also covered by claim 1. Lastly, the aspect ratio was only limited for 80% of the granules, while the remaining 20% failed to achieve this effect. The objective technical problem was thus to provide an alternative pharmaceutical preparation. Specifying arbitrary ranges for the aspect ratio of the specific granules could not establish inventive step.

Even if a more ambitious problem was considered, the claimed subject-matter was still obvious, because D1 highlighted that long particles should be removed before the coating process in order to provide a narrow size distribution and thus a narrow distribution of the aspect ratio (see paragraph [0031]). Therefore, the main request did not fulfill the requirements of Article 56 EPC.

The subject-matter of claim 1 of auxiliary request 1 was neither novel nor inventive, because D1 and D9 already disclosed extruded granules.

- XIV. The respondent's arguments may be summarised as follows:
 - (a) Admittance of D18

D18 was prima facie not relevant. In any case, D18 was not to be admitted because it could have been filed during the first instance proceedings (Article 12(4) RPBA 2007). Its filing on appeal was not justified and was not in reaction to the opposition division's decision to maintain the patent on the basis of auxiliary request 2, because auxiliary request 2 had

- 7 - T 1321/19

been filed already in response to the notice of opposition.

(b) Observations by third party

The third party observations raising objections based on D6 were not to be admitted in order to preclude a covert abuse of procedure. D6 was not highly relevant. In particular, regarding the argumentation on page 5 of these observations, the assertion that an analysis of the granules shown in Figures 1A-3A led to median aspect ratios of 1.4-1.6 was not supported by any evidence, and was in direct contradiction with the data presented in Figures 1B, 2B and 2C.

(c) Clarity

The relevant definition of aspect ratio was the one given in paragraph [0056] of the patent: the aspect ratio was the granule length along the predetermined axis divided by the smallest cross-sectional dimension. This ratio had the greatest impact on fracture properties. This was applicable beyond extruded granules to any similarly-formed granules. The predetermined axis was determined by the apparatus, such as an extruder or a mould, used for forming a length of material having the same pre-determined cross-sectional profile prior to the length of material being fragmented into granules. This axis was recognisable, because claim 1 did not relate to a single granule but to a preparation comprising many granules. This definition of the aspect ratio had, from the beginning, allowed for values of 0.7 to 1.0. Thus claim 1 did not lack clarity.

- 8 - T 1321/19

(d) Novelty

The entire disclosure of D9 was concerned with spheronized granules. D9 did not disclose, directly and unambiguously, non-spheronized granules. Accordingly, the requirements of novelty were met.

(e) Inventive step

D1 neither disclosed the feature that "at least 80% by number of those granules have an aspect ratio less than 2.2 and greater than 0.7", nor the feature that "the granules have a median aspect ratio above 1.1 and below 1.7, the aspect ratio being defined as granule length along the predetermined axis divided by the smallest cross-sectional dimension". The average aspect ratio shown in D1 was not the same as the claimed median aspect ratio.

The objective technical problem was to provide non-spheronized granules of a relatively uniform size and shape and which were less likely to fragment during subsequent processing (for example during coating), thereby leading to (i) a more homogeneous coating and (ii) a more predictable dissolution profile. This technical effect was demonstrated in the patent (see figures 5-7, tables 9 and 10, and example 5). The claimed solution was not obvious in light of D1. D1 taught that the particles should be of a similar aspect ratio, but did not indicate what that aspect ratio actually was. The preferred aspect ratio in D1 was of 4-5.

- 9 - T 1321/19

(f) Auxiliary request 1

Auxiliary request 1 differed from the main request in that the independent claims further included the limitation that the granules were extruded. The subject-matter of auxiliary request 1 involved an inventive step for the same reasons as the main request.

Reasons for the Decision

- 1. Admittance of D18
- 1.1 The appellant submitted D18 together with its grounds of appeal filed on 7 August 2019, and raised new objections of lack of novelty and lack of inventive step based on D18. The respondent objects to the admission of D18 into the proceedings.
- 1.2 The admission of D18 is subject to the provision of Article 12(4) RPBA 2007, which gives the Board discretion to hold inadmissible facts, evidence or requests which could have been presented in the first instance proceedings.
- 1.3 According to the appellant, the filing of D18 is a reaction to the opposition division's decision to maintain the patent in amended form on the basis of auxiliary request 2 (now the main request). The Board does not share this opinion, and considers that the filing of D18 only at the appeal stage is not justified by any development in the first instance proceedings. Auxiliary request 2, on which the appealed decision is based, was filed already with the patent proprietor's

reply to the opposition on 25 January 2018. Furthermore, the opposition division's preliminary opinion issued on 25 June 2018 indicated that auxiliary request 2 met the requirements of Article 123(2) EPC and of novelty, and was silent as to inventive step for this request (see page 35, section 6). Thus the appealed decision does not represent a departure from this preliminary opinion. Accordingly, there is no justification for the appellant's further search and submission of D18 at the appeal stage.

In addition, D18 is not submitted to fill in gaps in the argumentation presented in the first instance proceedings, but rather as a new piece of prior art on which entirely new objections are based, i.e. to build a fresh case. The Board concludes that D18 not only could but should have been filed in the proceedings before the opposition division.

1.4 The appellant submits that D18 must be admitted into the proceedings because its filing on appeal does not represent an abuse of proceedings and because it is prima facie relevant. However, in the Board's opinion, the appellant fails to take into account the applicable criteria, which are those of Article 12(4) RPBA 2007. The case law cited by the appellant in his letter dated 17 February 2022 does not justify that the admittance of D18 be decided solely based on its alleged prima facie relevance, without consideration of the criteria of Article 12(4) RPBA 2007. In particular, the early decisions T 1029/05, T 671/03, T 1182/01 and T 704/08do not relate to the application of Article 12(4) RPBA 2007. T 1404/10 took into account prima facie relevance as a necessary, but not a sufficient, condition for admittance (see point 3.3 of the reasons). Lastly, the situation in T 340/12 differed notably in that the

- 11 - T 1321/19

admittance of a late file document had only belatedly been contested (see point 2.3 of the reasons). Therefore, in the present case, the alleged *prima facie* relevance of D18 is in any case not the decisive criterion.

Accordingly, the Board did not admit D18 in the appeal proceedings.

2. Third party observations

On 14 February 2020, i.e. after the appellant and respondent had filed their grounds of appeal and reply thereto, third party observations were submitted under Article 115 EPC. In these observations, objections of lack of novelty over D6 (example 2, figures 1A, 2A and 3A, and the general teaching of D6) and inventive step starting from D6 as closest prior art were raised. The observations contain new evidence in the form of experimental results of a reproduction of the general teaching of D6.

It is established case law that, where third-party observations are filed after the time limit under Article 99(1) EPC, they are subject to the criteria developed in the case law for the Board's exercise of discretion in deciding whether to admit late-filed submissions within the meaning of Article 114(2) EPC (see the Case Law of the Boards of Appeal, 9th edition, 2019, III.N.4.4). The Board has discretion to take such observations into consideration or to disregard them, normally taking into account the same criteria as for late-filed submissions by parties under Articles 12 and 13 RPBA. Here, this means that the third party observations are to be assessed using the criteria of

- 12 - T 1321/19

Article 13(1) RPBA 2020 in addition to those of Article 12(4) RPBA 2007.

The Board finds that the third party observations are not to be taken into account, firstly because these new objections based on D6 amount to presenting a fresh case in the appeal proceedings. None of the parties had previously referred to D6 in the appeal proceedings. Although D6 was presented during the first instance proceedings, it is merely cited in the appealed decision, and is otherwise not relied on. No objection of lack of novelty over D6 was ever raised in the proceedings before the opposition division. Thus, the observations, and the experimental evidence therein, do not aim at filing the gaps in objections previously raised, but instead consist in entirely new objections.

In addition, the lack of prima facie relevance of these objections further justifies that they not be taken into account. In particular, regarding the objection based on example 2 of D6, the third party calculates an aspect ratio by dividing the "particle size" reported in D6 by the width of the extrusion holes. However, this particle size is obtained in D6 by sieve analysis and hence reflects the width of the cylinder-shaped granules rather than their length. As to the objection in section 2.3 of the observations, the third party gives no detail or evidence as to how median aspect ratios of 1.6, 1.5 and 1.4 were calculated from an analysis of figures 1A-3A of D6.

Accordingly, the third-party observations are not taken into account.

- 13 - T 1321/19

3. Main request (filed as auxiliary request 2 on 25 January 2018)

3.1 Clarity

Claim 1 of the main request differs from claim 1 of the patent as granted as follows:

"A pharmaceutical preparation comprising non-spheronized granules of which each has an active pharmaceutical ingredient and of which each has a predetermined axis and the same predetermined cross-sectional profile, wherein at least 80% by number of those granules have a median aspect ratio above 1.1 and below 1.7 an aspect ratio less than 2.2 and greater than 0.7, and wherein the granules have a median aspect ratio above 1.1 and below 1.7, the aspect ratio being defined as granule length along the predetermined axis divided by the smallest cross-sectional dimension." (additions and deletions emphasised by the Board)

The appellant contends that the feature pertaining to an aspect ratio of greater than 0.7 was not present in the granted set of claims and must be examined for clarity. According to the appellant, the feature is ill-defined because the skilled person cannot immediately recognise which is the predetermined axis for granules other than extruded granules.

As set out in G 3/14, 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 Article 84 EPC.

- 14 - T 1321/19

Here, the expressions "predetermined axis", "median aspect ratio" and "aspect ratio" were already part of claim 1 as granted. The definition of the subjectmatter of claim 1 as granted by means of its median aspect ratio already supposed that the skilled person be in a position to identify the predetermined axis and assess the aspect ratio of the granules. It was also already a logical consequence of this definition in claim 1 as granted that the "aspect ratio" could take values below 1. Thus, the alleged lack of clarity regarding the predetermined axis and the aspect ratio does not result from the amendment.

Accordingly, no lack of clarity arises from the amendments.

3.2 Novelty

D9 discloses the preparation of batches of pellets containing mesalamine by a process comprising extrusion and spheronization (see pages 69 and 71, in particular the batches Mes, MesMan and MesSta).

The appellant contends that the granules of D9, which result from a spheronization step, qualify as "non-spheronized" granules in the sense of claim 1.

According to the appellant, the feature "non-spheronized" of claim 1 is unclear and should be interpreted broadly. The aspect ratios above 1.1 reported in D9 for the batches Mes, MesMan and MesSta would be indicative of an incomplete spheronization. Since the pellets of D9 have aspect ratios significantly above that of a sphere (namely 1), these pellets would fall within the scope of claim 1.

- 15 - T 1321/19

In the Board's opinion, spheronization is a commonly known process, and the feature "non-spheronized" of claim 1 is clear. A spheronization does not produce perfectly spherical particles. The patent uses in this respect the expression "sphere-like shapes" (see paragraph [0012]). Thus, it is not technically sensible to interpret the feature "non-spheronized" as excluding only perfectly spherical particles.

The pellet of D9 result from, and have the characteristics imparted by, a spheronization step, in particular a close to spherical shape. Although D9 mentions that mesalamine formulations were comparatively more difficult to spheronize, these formulations are nevertheless not considered "insufficient" in D9 (see paragraph "3.2 Pellet Shape" on page 71). Consequently, the Board considers that the pellets of D9 do not qualify as non-spheronized granules in the sense of claim 1.

The criteria of novelty are accordingly met.

- 3.3 Inventive step
- 3.3.1 The appellant and the opposition division regard D1 as the closed prior art. This is not contested by the respondent.

D1 discloses non-spheronized granules (see paragraphs [0008] and [0021]) having an average aspect ratio of at least 1.1, such as 1.25-10, 1.3-5, 1.5-4.0 or 1.7-3.7 (see paragraph [0023]).

- 16 - T 1321/19

3.3.2 Differences

The lower ends 1.25, 1.3 or 1.5 given in D1 for the average aspect ratio fall within the claimed range of above 1.1 to below 1.7. However, the Board agrees with the respondent that a median aspect ratio is not the same as an average aspect ratio. The median value is the value separating the higher half from the lower half of the aspect ratios distribution, whereas the average value is the sum of the aspect ratios divided by the number of granules.

The appellant argued that median and average aspect values were similar for symmetrical distributions such as those obtained with an extrusion process. This argument is however not convincing, because the size distribution shown in figure 2 of the patent for extruded granules is not symmetrical. It is not shown that the median aspect ratios of the granules of D1 inevitably remain close to the (lowest) average values of 1.1, 1.25, 1.3 or 1.5 and are kept within the claimed range of above 1.1 to below 1.7.

Thus the subject-matter of claim 1 of the main request differs from the granules of D1 in that:

- at least 80% by number of the granules have an aspect ratio (as defined in claim 1) less than 2.2 and greater than 0.7, and
- the granules have a median aspect ratio above 1.1 and below 1.7.

3.3.3 Effect

According to the respondent, the problem is to provide non-spheronized granules of a relatively uniform size and shape and which are less likely to fragment during - 17 - T 1321/19

subsequent processing (for example during coating), thereby leading to (i) a more homogeneous coating and (ii) a more predictable dissolution profile.

To support this effect, the respondent relies on example 5 of the patent, which compares the dissolution of

- coated, classified granules for a sachet ("PENTASA 95% sachet granules") having an aspect ratio distribution as defined in claim 1 (see table 10, median/D50 = 1.4; 80% of the granules have an aspect ratio between D10=1.1 and D90=2) with - coated, unclassified granules for a tablet ("PENTASA tablet granules") having an aspect ratio distribution

The classified granules exhibit dissolutions with a much smaller standard deviation and variance (see table 9). Figures 5a and 5b also show that, during the coating process, longer granules tend to break.

not according to claim 1 (median/D50=1.7; D90=2.7).

3.3.4 The question is whether the effects observed in the patent can be extrapolated to the whole scope of claim 1.

The Board shares the respondent's position that, even though claim 1 of the main request covers also uncoated granules, the above effects credibly arise when the claimed uncoated granules are subsequently processed and coated. The Board also agrees that it is not necessary for claim 1 to specify that all granules have an aspect ratio in the claimed range of 0.7-2.2: claim 1 requires that at least 80% of the granules have the stated aspect ratio, and thus the above effects can be expected to arise to a corresponding extent.

- 18 - T 1321/19

However, the appellant's arguments regarding interpretation of the expression "predetermined axis" and the definition of the aspect ratio as "granule length along the predetermined axis divided by the smallest cross-sectional dimension" must be taken into account in connection with the broadness of claim 1. Claim 1 is not limited to extruded granules, as in the examples of the patent, or even to granules of similar shapes. Even if claim 1 relates to a composition comprising several granules, and requires the granules to have an identical same cross-sectional profile, claim 1 does not require the granules to exhibit varying lengths along an axis, as they would if prepared by extrusion. Claim 1 covers granules of any shape and produced by any means, such as moulding, as long as they are not spheronized. Even though a moulding technique can produce granules which are similar to extruded granules, claim 1 is not limited to such granules. Thus, the predetermined axis of claim 1 may be recognisable for extruded granules or granules of a similar cylindrical shape, but its determination for other shapes is arbitrary. In such cases, this axis does not necessarily reflect the longest dimension of the granules. Accordingly, the limits set in claim 1 for the aspect ratio thus defined do not exclude that the longest dimension of these granules exceed these limits and that these granules break during coating.

In summary, the examples of the patent show that an effect arises, in the context of extruded granules, from the limitation of the length or aspect ratio of the granules. However, the definition of the aspect ratio in claim 1 of the main request departs from the usual acception of the term, and relies on a length along a predetermined axis which does not necessarily correspond to the longest dimension in the broader

- 19 - T 1321/19

context of granules other than extruded granules. There is no demonstration that this parameter of claim 1 based on an undefined dimension of the granules would lead, over the whole scope of claim 1, to the same effects.

3.3.5 Thus, the technical problem is the provision of an alternative pharmaceutical formulation. The specification of ranges for the aspect ratio as defined in claim 1 is, in the absence of an associated technical effect, arbitrary and does not involve an inventive step.

Accordingly, the main request does not meet the requirements of Article 56 EPC.

- 4. Auxiliary request 1
- 4.1 In auxiliary request 1, claim 1 additionally specifies that the granules are extruded.
- 4.2 The subject-matter of claim 1 of auxiliary request 1 is novel over D9 for the same reasons as for the main request (see 3.2 above).
- 4.3 As to inventive step, D1 also describes extruded granules.
- 4.3.1 The subject-matter of claim 1 still differs from D1 in that (see 3.3.2 above):
 - at least 80% by number of the granules have an aspect ratio less than 2.2 and greater than 0.7, and
 - the granules have a median aspect ratio above 1.1 and below 1.7.

- 20 - T 1321/19

- 4.3.2 However, in contrast to the main request, the technical effects discussed above can be acknowledged for the whole scope of claim 1 of auxiliary request 1, as a result of its limitation to extruded granules (see 3.3.4 above). During the oral proceedings before the Board, the appellant took the example of an extrusion with a screen having oval holes, leading to thin granules having a length along the axis of extrusion which is much shorter than the longest dimension of the oval cross-section. The Board is not convinced that this example is realistic, as it would suppose that, during extrusion, the granules break off from the screen essentially in the form of slices with a much shorter extrusion length than one dimension of the hole. Accordingly, this hypothetical example does not cast doubt on the effect observed for extruded granules in the examples of the patent.
- 4.3.3 The technical problem can accordingly be formulated as the provision of non-spheronized granules of a relatively uniform size and shape and which are less likely to fragment during subsequent coating, thereby leading to (i) a more homogeneous coating and (ii) a more predictable dissolution profile.
- 4.3.4 The Board is not convinced that D1 leads the skilled person to the claimed aspect ratios. Even if the size mentioned in paragraph [0031] of D1 is taken as the length of the granules, D1 points to much longer granules, as is apparent from paragraphs [0026] or [0023], where the focus is on granules of 4-5 mm per 0.8-1 mm, or having preferably average aspect ratios of 2.6-2.8.
- 4.3.5 Hence, the subject-matter of claim 1 of auxiliary request 1 meets the requirements of inventive step.

- 21 - T 1321/19

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 on the basis of the claims of auxiliary request 1 filed with letter dated 2 January 2020 and a description to be adapted thereto.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Usuelli

Decision electronically authenticated