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Datasheet for the decision of 6 December 2024

Case Number: T 1597/22 - 3.3.07

Application Number: 13826599.6

Publication Number: 2919761

IPC: A61K9/48, A61K9/14, A61K31/435

Language of the proceedings: EN

Title of invention:
SOLID DOSAGE FORM COMPRISING MICRONIZED CYTISINE

Patent Proprietor:
Aflofarm Farmacja Polska SP. Z O.O.

Opponent:
Reddie & Grose LLP

Headword:
Solid dosage from comprising cytisine / AFLOFARM

Relevant legal provisions:
RPBA 2020 Art. 12(4), 12(6) sentence 2, 12(2), 11
EPC Art. 123(2), 84, 83, 111(1)
EPC R. 139

Keyword:

Late-filed evidence - admitted (yes)
Amendments - allowable (yes)
Claims - clarity and conciseness after amendment (yes)
Sufficiency of disclosure - (yes)
Remittal - special reasons for remittal (yes)

Decisions cited:

G 0003/14, G 0002/98, G 0001/03, T 1845/14, T 2096/12

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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

Case Number: T 1597/22 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 6 December 2024

Appellant: (Patent Proprietor)	Aflofarm Farmacja Polska SP. Z O.O. Ul. Partyzancka 133/151 95-200 Pabianice (PL)
Representative:	Krauss, Jan SKM-IP PartGmbB Oberanger 45 80331 München (DE)
Respondent: (Opponent)	Reddie & Grose LLP 10 Whitechapel High Street London Greater London E1 8QS (GB)
Representative:	Reddie & Grose LLP The White Chapel Building 10 Whitechapel High Street London E1 8QS (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 26 April 2022 revoking European patent No. 2919761 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	J. Lécaillon
	L. Basterreix

Summary of Facts and Submissions

I. European patent 2 919 761 (hereinafter "the patent") was granted on the basis of 4 claims. The independent claims of the patent as granted read as follows:

"1. A solid dosage form containing cytisine and ancillary substances, characterised in that it contains from 0.1% to 5% micronised cytisine, wherein all molecules have a diameter less than 10µm, corn starch from 40% to 60% wherein 99,9% particles sized from 5 µm to 25 µm, microcrystalline cellulose in an amount from 40% to 60% wherein the particle size is: 99% below 38µm and wherein the mass ratio of the active ingredient to ancillary substances is from 1:19 to 1:999 and is in the form of a hard capsule."

"3. A method of obtaining a hard capsule containing cytisine, defined in Claim 1 or 2 characterised in that it encompasses:

a) mixing micronised cytisine with a portion, preferably from 0.70% to 0.90%, of the microcrystalline cellulose necessary for the whole process,
b) mixing the formed mixture from stage a) with a portion, preferably from 12% to 16% of the remaining quantity of microcrystalline cellulose necessary for the whole process,
c) mixing the mixture from stage b) with the remaining quantity microcrystalline cellulose necessary for the whole process as well as the remaining ancillary substances to homogeneity;
d) encapsulation."

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

III. The opposition division took the decision to revoke the patent. The decision, posted on 26 April 2022, was based on an amended main request and three auxiliary requests filed on 11 November 2021.

IV. The following documents cited in the decision of the opposition division are relevant for the present decision:

D8: Li *et al.*, Particulate Science and Technology, Vol. 23, p. 265-284, 2005
D9: Rowe *et al.*, "Handbook for pharmaceutical Excipients", 6th Ed. 2009, Pharmaceutical Press and American Pharmacists Association, p. 129-133, 193 & 194, 404-407, 685-691, 741-744

V. The opposition division decided in particular as follows:

(a) The amended main request met the requirement of Article 123(2) EPC and amended claim 3 of the main request met the requirements of Article 84 EPC.

(b) The main request did not meet the requirement of Article 83 EPC, because insufficient information regarding the determination of the particle sizes prevented the skilled person from putting the invention into practice.

(c) Auxiliary requests 1 to 3 did not fulfil the requirement of Article 83 EPC for the same reasons as the main request.

VI. The patent proprietor (appellant) lodged an appeal against the above decision of the opposition division.

VII. With its reply to the appellant's statement setting out the grounds of appeal the appellant defended its case on the basis of the amended main request and the three auxiliary requests forming the basis of the impugned decision.

Independent claims 1 and 3 of the main request, upon which the present decision is based, read as follows:

"1. A solid dosage form containing cytisine and ancillary substances,
characterised in that it contains
from 0.1% to 5% micronised cytisine, wherein all molecules have a diameter less than 10µm, corn starch from 40% to 60% wherein 99,9% particles sized from 5 µm to 25 µm, microcrystalline cellulose in an amount from 40% to 60% wherein the particle size is: 99% below 38µm,
and wherein the mass ratio of the active ingredient to ancillary substances is from 1:19 to 1:999,
and wherein said solid dosage form is in the form of a hard capsule and does not contain lactose."

"3. A method of obtaining a hard capsule containing cytisine, defined in Claim 1 or 2, characterised in that it encompasses:
a) mixing micronised cytisine with a portion, preferably from 0.70% to 0.90%, of the microcrystalline cellulose necessary for the whole process,

b) mixing the formed mixture from stage a) with a portion, preferably from 12% to 16% of the remaining quantity of microcrystalline cellulose necessary for the whole process,
c) mixing the mixture from stage b) with the remaining quantity microcrystalline cellulose necessary for the whole process as well as the remaining ancillary substances to homogeneity;
d) encapsulation,
wherein the hard capsule does not contain lactose."

VIII. The following items of evidence which are relevant for the present decision were filed by the appellant with its statement setting out the grounds of appeal:

D22: Report for determination of the particle size distribution of cytisine dated 12 May 2022 - filed as "Annex 2"
D23: Abstracts of product specifications of commercial products - filed as "Annex 3"

IX. Oral proceedings were held before the Board on 6 December 2024.

X. The appellant requested that the decision under appeal be set aside and optionally the case be remitted back to the first instance or the patent be maintained on the basis of the main request, or one of auxiliary requests 1 to 3, forming the basis of the decision under appeal.

XI. The respondent requested that the appeal be dismissed, *i.e.* that the patent be revoked. The respondent further requested that documents D22 and D23 not be admitted into the appeal proceedings.

XII. The arguments of the appellant, as far as relevant for the present decision, can be summarised as follows:

(a) Documents D22 and D23 were to be admitted into the appeal proceedings because they provided merely further evidence of subject-matter already discussed in the proceedings or were filed in direct response to the impugned decision.

(b) The claims of the main request found basis in the original application as indicated in the first instance decision. The main request fulfilled the requirement of Article 123(2) EPC.

(c) The main request met the requirement of Article 84 EPC. No lack of conciseness could result from the addition of the feature defining the absence of lactose in claim 3. The alleged issue of clarity concerning the part of the dosage form lacking lactose was either based on issues already present in the granted claims or amounted to a question of claim interpretation.

(d) The main request fulfilled the requirement of Article 83 EPC. The lack of specification of a particle size measuring method in the patent did not prevent the skilled person from preparing the claimed solid dosage form, as further supported by D22 and D23. Furthermore, the achievement of technical effects mentioned only in the description was not relevant when assessing sufficiency of disclosure.

XIII. The arguments of the respondent, as far as relevant for the present decision, can be summarised as follows:

(a) D22 and D23 should have been filed already in the first instance proceedings in reply to the objection of lack of sufficiency of disclosure raised in the notice of opposition. They were thus not to be admitted into the appeal proceedings.

(b) Amended claims 1 and 3 of the main request did not meet the requirement of Article 123(2) EPC, for the following reasons:
- the feature defining the absence of lactose constituted an unallowable intermediate generalisation of more specific embodiments disclosed in the original description, and
- the inversion of the mass ratio of active ingredient to ancillary substances did not constitute the correction of an obvious error.

(c) The amendments performed to the claims of the main request resulted in an infringement of Article 84 EPC. The addition of the feature defining the absence of lactose in claim 3 led to a lack of conciseness of the claim. Furthermore, it would be unclear to which part of the dosage form the absence of lactose would apply (the capsule mass, the capsule shell or the entire dosage form).

(d) The lack of disclosure of a method of measurement of the particle sizes of the claimed components together with the ambiguous definition of the claimed particle sizes (*i.e.* ambiguity regarding the particle size descriptor and the reference for the defined percentage) resulted in a fundamental lack of disclosure of the invention. The skilled

person was not in a position to determine whether a given composition fell within the scope of the claims or not. Furthermore, according to the patent, the particle sizes of the components were crucial for the achievement of the effects reported in the patent, in particular homogeneity of dispersion of the active ingredient. It followed that the skilled person was not able to identify without undue burden the technical measures necessary to solve the technical problem underlying the invention. The main request did thus not fulfil the requirements of Article 83 EPC.

Reasons for the Decision

1. Admittance of items of evidence

1.1 Documents D22 and D23 were submitted by the appellant with its statement setting out the grounds of appeal. The respondent requested that documents D22 and D23 not be admitted into the appeal proceedings because they were late-filed and would not be convincing. The admittance of these documents is to be decided on the basis of Article 12(4) and Article 12(6) 2nd sentence of the Rules of Procedure of the Boards of Appeal (RPBA).

1.2 Document D22 provides new data regarding cytisine particle size measurements with two different commonly used methods. These data were submitted in reply to the decision of the opposition division considering that different measurement methods would lead to different results.

1.3 Document D23 was filed in reply to the decision of the opposition division on sufficiency of disclosure and

aims at showing that excipients having particle sizes as defined in claim 1 are commercially available.

1.4 The respondent considered that documents D22 and D23 should have already been filed during the first instance proceedings. They argued that the issue of measurement of the particle sizes had been raised in the notice of opposition and that the appellant despite having requested an extension of the time limit to reply thereto with experimental data did not file any such data in its response.

The Board observes that the preliminary opinion of the opposition division was positive on the issue of sufficiency of disclosure (see Annex to the summons to oral proceedings dated 11 June 2021 item 4. pages 2 to 5). In its preliminary opinion the opposition division considered in particular that the respondent did not raise serious doubts that the invention could not be carried out. The issue of particle size was not the main focus of the discussion. Furthermore the respondent did not provide any further experimental evidence regarding the issue of particle size measurement in reply to the preliminary opinion of the opposition division. The reference of the respondent to the submission of the appellant of 27 April 2021 regarding the irregular shape of cytisine particles does not appear to constitute new evidence that would have rendered the filing of document D22 and D23 (which do not concern the shape of cytisine particles) necessary. It follows that the appellant could not have been expected to necessarily file such evidence during the opposition proceedings.

There is therefore no reason not to admit these documents in the appeal proceedings on the basis of Article 12(6) RPBA 2nd sentence.

1.5 It remains to be assessed whether these amendments to the case of the appellant may be admitted in line with Article 12(4) RPBA. The Board observes that these amendments are not complex, they are directed towards the issues raised in the decision and they were filed as early as possible during the appeal proceedings. In this context, the question of whether the documents D22 and D23 indeed convincingly support the case of the appellant, as disputed by the respondent, is not decisive when assessing admittance under Article 12(4) RPBA.

1.6 Accordingly, the documents D22 and D23 are admitted into the appeal proceedings (Article 12(4) and 12(6), 2nd sentence RPBA).

Main request

2. Amendments

2.1 Claim 1 of the main request corresponds to original claim 1 wherein:

(a) the particle size features are no longer optional features,
(b) the claimed mass ratio was amended from "of ancillary substances to the active ingredient" to "of the active ingredient to ancillary substances",
(c) the dosage form was further defined as being "in the form of a hard capsule", and
(d) the dosage form was further defined by the feature "does not contain lactose".

Claim 3 of the main request (referring to claims 1-2) corresponded to original claim 3 with the addition of the feature "wherein the hard capsule does not contain lactose".

Dependent claims 2 and 4 correspond to original dependent claims 2 and 4.

2.2 In the appeal proceedings, the respondent contested that the amended features of the absence of lactose and the inversion of the mass ratio would be originally disclosed (see amendments (b) and (d) above).

2.3 Absence of lactose

2.3.1 As mentioned in the impugned decision, the absence of lactose is disclosed on page 3 (last paragraph, line 30) and page 5 (lines 26 to 27) of the original application.

2.3.2 According to the respondent, the sole explicit mention of the absence of lactose in the original application was made in specific contexts, namely:

- (i) gelatine capsules (ii) containing a homogenously dispersed active ingredient and (iii) prepared without the use of increased moisture and temperature (see original page 3, last paragraph), and
- an even more specific example containing specific excipients in specific amounts, a specific amount of cytisine and certain process steps (see original page 5).

The respondent further explained that there would be a functional interrelationship between the absence of

lactose and the features (i) to (iii) disclosed in the embodiment on original page 3. Example 2 and example 3 of the patent would substantiate that lactose (see example 2) as well as increased moisture and temperature (example 3) have a detrimental effect on stability. Regarding the absence of lactose and the homogenous dispersion of the active ingredient, the respondent stated that during the first instance proceedings the appellant had acknowledged the importance of particle size on homogeneity and had indicated that all the features work together (see section 7.1 of the minutes of the oral proceedings in opposition), so that also these features would be functionally interrelated. Finally, when using a gelatine capsule there would be no browning of the shell, so that the same effect would be achieved as when avoiding the presence of lactose in the composition (see original page 2 lines 1 to 4).

The introduction in independent claims 1 and 3 of the main request of the feature "does not contain lactose" without the additional features disclosed in the passages of original pages 3 and 5 defined above would therefore constitute an unallowable intermediate generalisation of these specific embodiments.

2.3.3 The Board observes that, as indicated by the opposition division (see impugned decision page 11 last paragraph), it is directly and unambiguously derivable from the original application that avoiding lactose is generally one of the purposes of the invention. This appears from the discussion of the drawbacks of the prior art to be overcome by the invention on original pages 1 to 2. In particular, avoiding a Maillard reaction (*i.e.* implicitly avoiding lactose) is mentioned on page 2 lines 12-15.

Furthermore it has not been demonstrated that the absence of lactose is inextricably linked to the other features disclosed in the passages of original pages 3 and 5. While the avoidance of the Maillard reaction due to the absence of lactose may contribute to the same effects as the features (i) to (iii) defined above (namely stability, homogeneity and no browning of the composition), there is no indication that anyone of these features necessarily requires the absence of lactose to achieve the corresponding effect and *vice versa*. The fact that two features may contribute by different mechanisms to a same effect does not mean that the features are functionally interrelated.

Accordingly, the Board considers that it is directly and unambiguously derivable from the original application as a whole that the absence of lactose applies for any claimed dosage form and is not limited to the compositions containing the further features defined in the embodiments of original pages 3 and 5. In the present case, the absence of lactose disclosed in the embodiments of original pages 3 and 5 can therefore be generalised to the subject-matter of present independent claims 1 and 3.

2.3.4 In this context, the argument of the respondent that the whole dosage form would be without lactose in present claims 1 and 3 whereas on original pages 3 and 5 it would only be the capsule mass ("formulation without lactose") is not convincing.

In the Board's view, the term "formulation" in these passages of the original description refers also to the entire dosage form because the corresponding paragraphs

consistently refer to "(capsule or homogeneous) mass" for the capsule mass and not to "formulation".

Contrary to the respondent's opinion, the fact that example 4 on page 11 mentions "formulations of capsule masses" is not inconsistent with this conclusion. This expression does not refer to the term "formulation" in general, nor in particular as used on original pages 3 and 5, but to specific formulations of capsule masses prepared in this example.

Finally the respondent's argument that in example 2 on original pages 6-7 lactose monohydrate is used as a replacement for corn starch in the capsule mass, hence highlighting that it is the absence of lactose in the capsule mass that is critical, is also not convincing. This example does not preclude the absence of lactose in the entire dosage form. Moreover there is no mention of the term "formulation" in example 2 of the original application, so that it cannot provide any meaning of this term used in the relevant passages of original pages 3 and 5.

2.4 Inversion of the mass ratio

2.4.1 In their written submissions, the respondent objected to the inversion of the mass ratio in claim 1 of the main request.

2.4.2 The Board agrees with the opposition division that this amendment constitutes an allowable correction of an obvious error (Rule 139 EPC).

2.4.3 In view of the percentages of micronized cytisine and excipients defined in claim 1, the skilled person would

indeed immediately have recognised that there was an error in the originally claimed mass ratio.

The argument of the respondent that the formulation may contain non-micronised cytisine so that the originally claimed ratio would then make sense is not convincing. In view of the description, including the examples, the skilled person would understand the active ingredient in original claim 1 as referring to micronized cytisine (not to micronized cytisine and any undefined non-micronized cytisine).

2.4.4 The remaining question is thus whether the performed correction would have been immediately apparent. As stated by the opposition division (see impugned decision, paragraph bridging pages 10 and 11), the skilled person would understand from the original application as a whole that the active ingredient is the minority component so that the correction would be obvious.

2.4.5 Moreover, the Board agrees with the opposition division (see impugned decision page 9 last paragraph) that the correction of obvious errors is not limited to typographic spelling and/or grammatical errors.

2.4.6 Hence, the Board considers that this amendment fulfils the requirements of Rule 139 EPC and Article 123(2) EPC.

2.5 As a consequence, the main request meets the requirement of Article 123(2) EPC.

3. Article 84 EPC

3.1.1 Lack of conciseness

The respondent argued that the addition of the feature "wherein the hard capsule does not contain lactose" in dependent claim 3 would infringe Article 84 EPC due to a lack of conciseness. The requirement of absence of lactose would already be defined in claim 3 by the reference to claim 1.

The Board considers that the feature introduced in claim 3 does not result in a lack of conciseness. A potential redundancy of a few words due to the reference to claim 1 cannot render the claim not concise.

3.1.2 Lack of clarity

The respondent stated that there would be inconsistencies in the definition of the absence of lactose so that it would be unclear whether it refers only to (i) the capsule mass, only to (ii) the capsule shell or to (iii) the entire dosage form. In this context the respondent presented alleged basis for the different possible interpretations based on the original description and the impugned decision.

The Board however notes that the wording of claim 1 of the main request is clear in itself with respect to the absence of lactose. Claim 1 unambiguously defines that the "solid dosage form", *i.e.* the entire unit dosage, does not contain lactose.

The respondent argued that it would not be clear whether the percentages defined in claim 1 are with

respect of the entire dosage unit or only the capsule mass. This would possibly lead to the conclusion that the absence of lactose concerned only the capsule mass in claim 1. As stated above, the Board is of the opinion that claim 1 unambiguously defines that the entire dosage unit must be free of lactose. The issue of clarity of the percentage of each ingredient (whether it is in respect of the capsule mass or entire dosage unit) was already present in the granted claim. The specification of the absence of lactose may have highlighted it but it is not the origin thereof. This issue cannot therefore be considered in the present proceedings according to G 3/14 since it does not arise from the amendments made. In any case, as stated before there is no ambiguity with respect to the absence of lactose in claim 1 of the main request.

It follows that, whether the added feature in claim 3 relates to (iii) the entire dosage unit or only (ii) the capsule shell (in view of the reference in claim 3 to the preparation of a "hard capsule" and not a "solid dosage form" as in claim 1) or even only (i) the capsule mass, does not lead to a lack of clarity, as the entire dosage unit (*i.e.* including the capsule shell) must be free of lactose due to the undisputed reference to claim 1 in the introductory part of claim 3.

3.2 Accordingly, the amendments performed in the main request do not infringe Article 84 EPC.

4. Sufficiency of disclosure

4.1 Claim 1 of the main request defines parameters characterising the particle size of the components, namely the active ingredient cytisine and the

excipients corn starch and microcrystalline cellulose (MCC).

4.2 The respondent considered that:

(a) the patent would not disclose any measuring method for the claimed parameters,

(b) different measuring methods would lead to different results for the given parameters,

(c) the uncertainty as to the obtained value would be reinforced by the issue of lack of definition of a reference for the claimed percentages for the MCC and corn starch particles (it would not be specified whether they refer to a percentage by volume, by weight or relative to the total number of particles) and of the particle size descriptor (*e.g.* equivalent circular area diameter, equivalent circular perimeter diameter, length (maximal Feret diameter) or width (minimal Feret diameter)),

(d) the claimed parameters would constitute crucial features of the invention which would be essential to achieve the technical effects and solve the problem mentioned in the patent.

According to the respondent, it would follow that the skilled person would not be able to identify without undue burden the technical measures necessary to solve the problem underlying the invention.

4.3 Lack of disclosure of a method in the patent

4.3.1 The Board observes that there is indeed no measuring method disclosed in the patent. The argument of the

appellant that the patent would indicate the use of mesh and hence the related measurement method (see paragraph [0026]) is not convincing. As argued by the respondent, the reference to mesh in the mentioned paragraph concerns only comparative cytisine particles. The skilled person would not consider that it necessarily also applies to micronized cytisine of the invention, let alone to the claimed excipients.

4.3.2 However, the measurement of particle size is standard in the field of pharmaceutical formulation and several well-known methods are available to the skilled person (see *e.g.* D8).

4.4 Uncertainty concerning the measured values

4.4.1 The respondent argued that different measurement methods would lead to different results, especially for non-spherical particles (as evidenced by D8). The respondent further stated that the claimed particles would be non-spherical (see D9 for corn starch and MCC). According to the respondent this was acknowledged by the appellant for cytisine.

Furthermore, according to the respondent, this uncertainty as to the obtained value would be reinforced by the issue of lack of clear definition of the parameter. It would indeed not be specified whether (i) the claimed percentage refers to a percentage by volume, by weight or relative to the total number of particles and (ii) the particle size refers to equivalent circular area diameter, equivalent circular perimeter diameter, length (maximal Feret diameter) or width (minimal Feret diameter).

4.4.2 The Board agrees that differences in the results obtained by different methods are to be expected and that the definition of the percentage and actual measured size may be ambiguous.

However, the appellant provided experimental data for cytisine particles, substantiating that there is only a minor deviation between measurement by Scanning Electron Microscopy (SEM) and laser diffraction, *i.e.* two commonly known methods, amounting to measuring accuracy (see document D22). Furthermore the provided data render it credible that cytisine particles having a diameter, which is a commonly used descriptor of particle size, of less than 10 µm can be prepared. In this context, the respondent argued that not all commonly available methods were tested, in particular not the mesh method mentioned by the appellant. It remains however that it has not been demonstrated that any differences obtained by other available methods would be such as to prevent the skilled person from preparing formulations according to claim 1.

Regarding the excipients particles, as argued by the appellant with reference to document D23, MCC and corn starch fulfilling the claimed particle size distribution appear to be commercially available. In this context, the argument of the respondent that the particle size distributions of claim 1 of 99% (MCC) and 99.9% (corn starch) are "narrow" and do not correspond to those obtained in document D23 is not convincing. The respondent did not explain why the skilled person would not be in a position to use the commercially available particles to prepare a sample of particles fulfilling the claimed size distribution.

Finally, concerning the definition of the percentage of particles, the appellant argued that the patent indicated that it was meant as relative to the total number of particles as shown in paragraph [0026] mentioning "100% particles below 10 µm" for the active ingredient. In this context, the Board observes that the table provided by the respondent on page 10 of its reply to the statement of the grounds of appeal to illustrate the importance of the definition of the percentage is an artificially created theoretical example. It cannot substantiate that in the present specific case such a situation would occur, let alone that the skilled person would not indeed have understood the percentage as relative to the total number of particles.

Hence, the evidence provided by the appellant indicate that the skilled person would be able to prepare a composition containing the claimed ingredients with the claimed particle size distribution. As argued by the appellant during oral proceedings, the respondent has not provided any evidence that any of the identified ambiguities (differences in obtained results due to the measurement method and the definition of the particle size descriptor and percentage of particles) would be such as to prevent the skilled person from preparing formulations according to claim 1.

4.4.3 During oral proceedings, the respondent referred several times to T 2096/12. In this decision, the board considered that the results of the parameter measurement would differ significantly dependent on the method used. In particular, no evidence had been provided from the patent proprietor substantiating its allegation that the results would not vary significantly dependent on the chosen method of

measurement. In view of the above discussion (see point 4.4.2), the Board considers that the present case differs from the one underlying the decision T 2096/12 so that the conclusion reached therein does not apply to the present case.

4.5 Achievement of technical effect(s)

4.5.1 According to the respondent, the particle sizes were crucial for solving the technical problem defined in the patent. As a result of the uncertainty when measuring the particle sizes of the components, the skilled person would not know when a product according to the alleged invention had been arrived at and hence if it fulfilled the requirements necessary for the alleged technical effects.

4.5.2 The Board disagrees.

According to T 1845/14 (see point 9 of the reasons), in case of an unclear parameter defined in a claim whose values required in the claim are indicated in the specification to be essential to solving the problem underlying the patent at issue, the ability of the skilled person to solve that problem by reproducing what is claimed is not a suitable criterion for assessing sufficiency of disclosure when the problem or an effect derivable from it are not explicitly or implicitly part of the definition of the claimed subject-matter. As detailed in the Case Law of the Boards of Appeal, 10th edition, 2022, II.C.5.5.1 a), the board in T 1845/14 reached this conclusion based on the principle set in G 2/98 and supported by G 1/03, that the term "invention" corresponded to the specific combination of features in a claim. This passage of the Case Law of the Boards of Appeal makes furthermore

clear that T 1845/14 became meanwhile established case law in this respect.

In the present case, none of the several technical effects mentioned in the patent (see paragraphs [0002] and [0006], including *inter alia* homogeneity but also stability) constitutes a feature of claim 1. The Board is therefore of the opinion that the achievement of the technical effect(s) mentioned in the description is not relevant to the issue of sufficiency of disclosure of present claim 1.

4.5.3 The respondent argued that independent claim 3 of the main request encompassed the technical effect of homogeneity as a feature of the claim. At least for this claim the achievement of said effect was hence to be taken into account when assessing sufficiency of disclosure.

4.5.4 The appellant disputed that the expression "mixing [...] to homogeneity" in claim 3 of the main request corresponded to an even or homogenous dispersion of the active ingredient as mentioned in paragraphs [0002] and [0006] of the patent.

4.5.5 The Board considers that, even if the term "homogeneity" used in present claim 3 corresponded to homogeneity of the active ingredient dispersion, there is still no evidence that any ambiguity as to the measurement of the claimed particle sizes would be such as to prevent the skilled person from preparing compositions indeed achieving said technical effect. In particular, the particle size of the components was only shown to have together with further features (such as the amounts of excipients) an impact on the homogeneity of the capsule mass (see example 4 of the

patent), which would mitigate the influence of the particle size on the homogeneity of the active ingredient's dispersion.

4.6 In the written proceedings (see reply to the statement of the grounds of appeal) the respondent reiterated the following arguments already provided in the first instance proceedings and considered not convincing by the opposition division:

- The particle sizes of cytisine and the excipients were defined by different terms in claim 1 ("diameter" for cytisine versus "size" for MCC and corn starch) so that the definition of the composition was not clear and complete enough for a skilled person to carry out the invention.
- The lack of specification of whether the percentages of ingredients related to the entire dosage form or only the capsule mass prevented the skilled person from performing the invention.
- Informations on the preparation method of claim 3 (*e.g.* temperature, equipment used, duration of each step, how to perform the mixing) which were crucial for ensuring stability and homogeneity were not disclosed.

During the oral proceedings the respondent did not make any submission in relation to these arguments. The Board agrees with the conclusion of the opposition division (see impugned decision item 14.7) that these objections are not convincing and mostly amount to objections of lack of clarity rather than of lack of sufficiency of disclosure.

4.7 As a result, the main request complies with the requirement of Article 83 EPC.

5. Remittal

5.1 Under Article 11 RPBA, the Board may remit the case to the department whose decision was appealed if there are special reasons for doing so.

5.2 In the present case, the appealed decision does not address the ground for opposition under Article 100(a) EPC in combination with Article 56 EPC. As recalled in Article 12(2) RPBA, the primary object of the appeal proceedings is to review the decision under appeal in a judicial manner. This principle would not be respected if the Board were to conduct a complete examination of all the opposition's grounds. Consequently, under these circumstances, the Board considers that special reasons for remitting the case to the opposition division exist. The respondent had no objection against a remittal. Therefore, the Board considers it appropriate to accede to the appellant's request for a remittal (Article 111(1) EPC).

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division for further prosecution.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated