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Datasheet for the decision of 12 December 2023

Case Number: T 2209/21 - 3.3.04

Application Number: 15001790.3

Publication Number: 2957280

IPC: A61K31/198, A61K9/20

Language of the proceedings: EN

Title of invention:
Solid pharmaceutical composition of cytisine and process for preparation thereof

Patent Proprietor:
Aflofarm Farmacja Polska Sp. z o.o.

Opponents:
Sopharma AD
Adamson Jones IP Limited

Relevant legal provisions:
EPC Art. 56
RPBA 2020 Art. 13(2)

Keyword:
Inventive step - (no)
Amendment after summons - exceptional circumstances (no)

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Beschwerdekammern

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Case Number: T 2209/21 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 12 December 2023

Appellant: (Opponent 2)	Adamson Jones IP Limited BioCity Nottingham Pennyfoot Street Nottingham, Nottinghamshire NG1 1GF (GB)
Representative:	Carridge, Andrew Edward Reddie & Grose LLP The White Chapel Building 10 Whitechapel High Street London E1 8QS (GB)
Respondent: (Patent Proprietor)	Aflofarm Farmacja Polska Sp. z o.o. ul. Partyzancka 133/151 95-200 Pabianice (PL)
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Party as of right: (Opponent 1)	Sopharma AD 16, Iliensko Shose Str. Sofia 1220 (BG)
Representative:	Shentova, Violeta Varbanova 11, Damyan Gruev Street 1606 Sofia (BG)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 7 October 2021 concerning maintenance of the European Patent No. 2957280 in amended form.**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	R. Hauss
	L. Bühler

Summary of Facts and Submissions

I. European patent No. 2 957 280 (the patent in suit) was granted with a set of 13 claims. Claim 1 reads as follows:

> *1. Solid pharmaceutical composition comprising cytisine as an active substance, characterized in that said composition does not contain lactose and comprises from 20% to 75% by weight of microcrystalline cellulose, glidant and at least one pharmaceutically acceptable excipient chosen from the group comprising: mannitol, colloidal silicon dioxide, calcium hydrogen phosphate, whereby at least 60% of cytisine particles have size from 10 µm to 200 µm, and the pharmaceutical composition is in a form of tablet manufactured by direct compression method.*

II. The patent in suit was opposed under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked an inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed.

III. In the proceedings before the opposition division, the patent proprietor requested as its main request that the oppositions be rejected and the patent be maintained as granted. It also presented a number of auxiliary claim requests.

IV. The documents cited in the proceedings before the opposition division included the following:

D1: EP 1 586 320 B1

D6: A. Haywood and B. D. Glass, Aust. Prescr. 34, 112-114 (2011)

D8: H.C. Rowe, Handbook of Pharmaceutical Excipients, 5th edn. (2006), 93-99, 132-135, 188-191, 449-452

D10: Informa Healthcare USA, Inc.: Encyclopedia of Pharmaceutical Technology (2007), 3641-3683

D13: Zheng (ed.), Formulation and Analytical Development for Low-Dose Oral Drug Products, Wiley (2009), chapter 7: Development of low-dose solid oral tablets using direct compression

V. The decision under appeal is the opposition division's interlocutory decision, announced on 13 September 2021 and posted on 7 October 2021, rejecting the patent proprietor's main request and finding that the patent as amended in the form of auxiliary request 1 (as filed at the oral proceedings of 13 September 2021) met the requirements of the EPC.

According to the decision under appeal, the subject-matter of claim 4 as granted was insufficiently disclosed (Article 100(b) EPC). This objection did not apply to auxiliary request 1 since this request did not include the claim in question.

Claim 1 of auxiliary request 1 is identical to claim 1 as granted. Inventive step was assessed starting from the disclosure of, *inter alia*, document D1. The subject-matter of auxiliary request 1 was found to involve an inventive step (Articles 100(a), 52(1) and 56 EPC).

VI. Opponent 2 (appellant) appealed against this decision.

VII. With its reply to the appeal, the patent proprietor (respondent) requested that the appeal be dismissed, re-submitting the claims of auxiliary request 1 as its

new main request. The respondent also submitted a new set of claims entitled "Auxiliary Request 2".

Claim 1 according to the new ***main request*** is identical to claim 1 as granted (see points I. and V. above).

Claim 1 of ***auxiliary request 2*** is identical to claim 1 of the main request, except that it additionally specifies that a single tablet contains 1.5 mg of cytisine.

VIII. The non-appealing opponent 1 (party to the appeal proceedings as of right pursuant to Article 107 EPC) did not present any observations in writing (Article 15(3) RPBA and Rule 115(2) EPC).

IX. Oral proceedings before the board took place on 12 December 2023, in the absence of opponent 1, which had been duly summoned (Article 15(3) RPBA and Rule 115(2) EPC).

In the course of the oral proceedings, the respondent presented a further claim request as auxiliary request 1.

Claim 1 of the new ***auxiliary request 1*** is identical to claim 1 of the main request, except that it additionally specifies that the cytisine has an average particle size d_{50} in the range from 10 µm to 30 µm.

The board did not admit auxiliary request 1. At the end of the oral proceedings, the board revoked the patent in suit.

X. The appellant's arguments can be summarised as follows:

Inventive step

The composition of the tablets defined in claim 1 of the main request only differed from the composition of the tablets disclosed in document D1 by the absence of lactose and the mandatory use of at least one excipient chosen from mannitol, colloidal silicon dioxide and calcium hydrogen phosphate. Based on these differences and the technical effects thereof, the objective technical problem was the provision of tablets with improved stability that could also be used by lactose-intolerant patients. Replacing lactose and adding mannitol, colloidal silicon dioxide or calcium hydrogen phosphate as suitable excipients would have been obvious measures in view of the common general knowledge as evidenced in several documents on file, *inter alia* in documents D6, D8, D10 and D13.

Admittance of auxiliary request 1

The filing of the new auxiliary request 1 was an amendment to the respondent's appeal case which had come at a very late stage of the appeal proceedings and was not justified by exceptional circumstances.

XI. The respondent's arguments can be summarised as follows:

Inventive step

The respondent agreed with the decision under appeal on the former auxiliary request 1, which was the current main request.

Document D1 was the closest prior art. The claimed tablets differed from those disclosed in D1 not only by the absence of lactose and the presence of the specified excipients but also by the implied

requirement that a fraction of up to 40% of the cytisine should be in micronised form, and by product features linked to the direct compression process. Since direct compression did not involve water, it yielded tablets with a low water content, which was a stability-enhancing feature.

The technical problem to be solved was the problem defined in the decision under appeal - the provision of a solid dosage form of cytisine that did not contain lactose and had good properties in terms of stability (i.e. a low level of impurities, good stability and a homogeneous distribution of cytisine in the end product).

The tablets according to D1 were prepared by a process involving wet granulation and did not provide satisfactory stability. In this context, reference was made to the test results shown in the table on pages 4 and 5 of D1. D1 did not explain the low stability observed, nor did it link this to the presence of lactose or the water content of the formulations. Thus, D1 did not provide any pointer to the claimed subject-matter.

Starting from the teaching of D1, the person skilled in the art would not have consulted D13 because that document related to a different technology (dry compression only).

The inventors, however, had recognised a problem with tablet stability and, to solve it, had modified the components and manufacturing technology.

Tablets according to the invention also achieved good hardness. This was because the active substance was present in two different size fractions. The prior art neither disclosed nor suggested using different size fractions of cytisine in combination with selected

excipients to achieve excellent homogeneity and good tablet hardness.

D1 itself did not contain any pointers that suggested omitting lactose in the formulation or using specific size fractions of cytisine in combination with the use of selected excipients. Moreover, D1 did not disclose direct compression as a method of preparation.

Admittance of auxiliary request 1

Since the opposition division had acknowledged an inventive step, it was surprising to the respondent that the board deviated from this view. Auxiliary request 1 was filed in response because it was believed to be suitable for overcoming the objection regarding a lack of inventive step. The request was also in line with the respondent's previously submitted arguments relating to the particle size distribution of the active agent.

XII. The appellant (opponent 2) requested that the decision under appeal be set aside and that the patent be revoked. The appellant also requested that auxiliary request 1 not be admitted.

XIII. The respondent (patent proprietor) requested as its main request that the appeal be dismissed, or, in the alternative, that the patent be maintained in amended form on the basis of the claims of auxiliary request 1 as filed on 12 December 2023, or on the basis of the claims of auxiliary request 2 as filed with the reply to the appeal.

XIV. Opponent 1 (party as of right) did not present any requests.

Reasons for the Decision

1. Oral proceedings, absence of opponent 1

1.1 In conformity with Article 15(3) RPBA and Rule 115(2) EPC, the oral proceedings before the board took place in the absence of opponent 1.

1.2 Opponent 1 had been duly summoned and had not presented any requests or arguments in writing (see points VIII. and IX. above). Thus, opponent 1 chose not to avail itself of the opportunity to present its comments on the grounds and evidence in the appeal case (Article 113(1) EPC).

2. Main request - inventive step (Articles 100(a), 52(1) and 56 EPC)

Patent in suit

2.1 Cytisine is a plant alkaloid used in the treatment of pain and nicotine addiction (see paragraphs [0002] and [0003] of the patent in suit). The patent in suit aims to provide stable solid formulations of cytisine, in particular tablet formulations that can be prepared by direct compression (see paragraphs [0001], [0016] and [0018]).

2.2 The patent reports that the presence of lactose was found to impair the stability of cytisine, whereas a number of other excipients showed better compatibility (paragraphs [0014] and [0015]).

2.3 The cytisine tablets according to claim 1 of the main request (see point I. above) are prepared by direct compression. They do not contain lactose, but must contain 20% to 75% by weight of microcrystalline cellulose, a glidant and at least one excipient chosen

from mannitol, colloidal silicon dioxide and calcium hydrogen phosphate. Moreover, it is mandatory that at least 60% of the cytisine particles have a size of 10 µm to 200 µm.

Starting point in the prior art

2.4 It was common ground that D1 represented the closest prior art. Like the patent in suit, D1 relates to solid dosage forms, in particular tablets, containing cytisine (see D1: paragraph [0001] and claim 1).

2.5 Document D1 discloses coated tablets containing cytisine, lactose, microcrystalline cellulose, talc and magnesium stearate (see D1: claim 1; Examples 1 and 2 in paragraph [0006]). Lactose and microcrystalline cellulose are present in a defined ratio ranging from 1:2.0 to 1:2.5, at a total content of 87% to 97% of the tablet mass. The formulations shown in Examples 1 and 2 both contain 1.5 mg cytisine per tablet.

Talc is a tablet glidant (see D10: page 3659, Table 3). According to paragraph [0029] of the patent in suit, magnesium stearate is also to be regarded as a glidant within the meaning of claim 1.

2.6 Among the advantages mentioned in D1 are stability and a homogeneous distribution of cytisine in the tablet mass (see D1: paragraph [0007]).

Distinguishing technical features and associated technical effects

2.7 It was not in dispute that the compositions according to claim 1 differ from the compositions in D1 by

(a) the absence of lactose, and

(b) the mandatory presence of at least one excipient selected from mannitol, colloidal silicon dioxide and calcium hydrogen phosphate

2.8 Feature (a): absence of lactose

2.8.1 As pointed out in paragraph [0020] of the patent in suit, a first technical effect of the absence of lactose is the suitability of the claimed tablets for lactose-intolerant patients.

2.8.2 Increased stability of cytisine during storage was mentioned as a further technical effect of the absence of lactose.

According to compatibility testing described in the patent in suit (paragraphs [0010] to [0015]) and in the application as filed (page 3, line 5 to page 4, line 13), storing a mixture of cytisine and lactose at 50°C/75% RH for 28 days resulted in a high impurity content of 77.1%. Mixtures of cytisine with microcrystalline cellulose or with certain other excipients tested (these included mannitol, colloidal silicon dioxide and calcium hydrogen phosphate) resulted in considerably lower impurity contents of between 1.7% and 0.1%.

The appellant did not dispute in its submissions that replacing lactose in the formulations resulted in better stability.

However, the board is of the view that the compatibility experiment described in the patent cannot demonstrate conclusively that the claimed tablets achieve increased stability compared to that of the tablets according to D1. In the experiment described in the patent in suit, two-component-mixtures of cytisine with varying excipients were compared. However, there was no experiment comparing tablet compositions

according to claim 1 with tablet compositions taught and disclosed in D1. The tablet compositions are more complex than the mixtures compared in the experiment described as they contain more than two components and are characterised by further properties not considered in the compatibility experiment.

Furthermore, the data in D1 itself ("Stability Test Table" on pages 4 and 5) does not suggest unsatisfactory stability, nor does D1 mention any concerns in this regard, and in fact it states in paragraph [0007] that the test results illustrate the compositions' good stability. Two lots of tablets made according to Example 2 were tested (paragraphs [0007] and [0008]). The tablets of the first lot still contained 98.7% of the active agent cytisine after one year and 96.8% after two years of storage, and the tablets of the second lot still contained 98.0% of the active agent after one year and 96.7% after two years of storage (at 25 ± 2°C and 60 ± 5% RH).

Since the information in D1 does not raise any concerns about stability, an experiment providing a direct comparison of tablets according to claim 1 and those according to D1 would have been required to show that the claimed tablets do indeed have superior stability.

In the absence of such evidence, the alleged but unconfirmed technical effect of superior stability cannot be used in the formulation of the objective technical problem.

2.9 Feature (b): mandatory presence of at least one specified excipient

2.9.1 Claim 1 defines three alternative embodiments for this feature. For the purposes of the present decision, it

is sufficient to consider the embodiment according to which the tablets contain mannitol.

2.9.2 According to the results of compatibility testing as reported in the patent in suit (see point 2.8.2 above), mannitol was found to be compatible with cytisine.

2.9.3 Apart from this, there is no evidence on file of any specific technical effect linked to the presence of mannitol beyond its well-known usual function in pharmaceutical tablets as a diluent or filler (see paragraph [0027] of the patent in suit; D8: pages 449 to 452; D10: page 3679, Table 5; D13: 7.4.2).

2.10 According to the respondent, further distinguishing technical features were

(c) the requirement that the cytisine included micronised material (i.e. having particle sizes below 10 µm) in a proportion of up to 40%, as implied by the feature in claim 1 that the size of at least 60% of the cytisine particles was 10 µm to 200 µm, and

(d) product features associated with tablet preparation by direct compression, specifically a lower water content than achievable according to D1

This was contested by the appellant.

2.11 The board reached the conclusion that the respondent's arguments in relation to technical features (c) and (d) and associated technical effects are not convincing, for the following reasons.

2.11.1 Feature (c): particle size

Claim 1 of the main request provides that at least 60% of the cytisine particles have a size from 10 µm to 200 µm (according to the description in

paragraph [0021], this is the size requirement for the cytisine material before tableting).

Claim 1 of D1 does not specify a particle size for cytisine. The description mentions, in paragraph [0004], that the average dimension of the cytisine particles is 90 µm. This is also a feature of dependent claim 2 of D1. While particle size is not mentioned in Examples 1 and 2, the examples may arguably be read together with paragraph [0004], which specifies an average dimension of 90 µm.

The feature "average dimension of 90 µm" in D1, while not incompatible with the definition in claim 1 of the main request, does not translate into a defined particle size range and does not amount to a direct and unambiguous disclosure of at least 60% of the particles having a size of 10 µm to 200 µm. Indeed it is readily apparent that the same average value could be reached with fewer than 60% of the particles being in the size range of 10 µm to 200 µm.

As a consequence, the particle size restriction in claim 1 is considered to be a further distinguishing feature. However, the size definition in claim 1 overlaps with the definition of preferred dimensions stated in D1.

Contrary to the respondent's further assertion, the particle size requirement in claim 1 does not necessarily mean that a fraction of the cytisine is present in micronised form with particle sizes below 10 µm. While this is a possible embodiment, the terms of claim 1 are equally met if, for instance, 100% of the cytisine particles have a size of 60 µm to 120 µm, or of 180 µm to 200 µm.

In its reasoning in support of inventive step, the respondent did not rely on any technical effect associated with the size range defined in claim 1, except in relation to the presumed presence of a substantial micronised fraction with particle sizes below 10 µm. Since the presence of a micronised fraction is not mandatory in claim 1, this is not a feature that distinguishes the entire scope of claim 1 from the disclosure of D1. As a consequence, any alleged technical effect associated with this feature (such as tablet hardness, as mentioned by the respondent) cannot be taken into account in the formulation of the objective technical problem.

2.11.2 Feature (d): product-by-process feature(s)

Claim 1 of the current main request is directed to a pharmaceutical composition in the form of a tablet. The claim also specifies that the tablet is manufactured by direct compression.

Document D1 does not disclose any method for tablet preparation. In its reply to the grounds of appeal (see page 3, penultimate paragraph), the respondent stated that it was not possible to know what the preparation method in D1 was. In contrast, at the oral proceedings before the board the respondent argued that the preparation method according to D1 could only be a wet granulation method.

The board is of the view that it cannot be derived from the information in D1 which method was used for preparing, for instance, the two lots of tablets according to Example 2 that underwent testing. The board is not persuaded by the respondent's reasoning that direct compression can be ruled out as being encompassed by the teaching of D1. D1 simply does not discuss tablet preparation and does not teach or

disclose any preferred method. Even if one were to assume, in the respondent's favour, that D1 restricts tablet preparation to wet granulation methods, there is no evidence of a specific technical effect linked to this alleged difference in process.

The following considerations apply:

Claim 1 is directed to a product in tablet form. Any method steps relating to its preparation are not technical features of the product. Any distinction of the claimed subject-matter over D1 on account of the direct compression method would have to reside in structural features or properties of the tablets resulting from this manufacturing method. Thus, the question to be answered is whether there is any evidence that the tablets according to claim 1 differ from those taught in D1 as a result of the method of preparation thereof.

According to the established case law of the Boards of Appeal, if a patent proprietor wishes to rely on a "product-by-process" feature as a distinguishing feature, the burden is on the patent proprietor (here: the respondent) to show that the claimed product does indeed differ from products of the prior art by its structural features and/or properties.

In the case at hand, this could only have been shown by means of experiments performed to provide a direct comparison of cytisine tablets prepared by different tableting methods. Such comparative data is not on file. It was not shown how tablets according to claim 1 might differ in their structure or properties from tablets prepared by a wet granulation process, nor how this would result in a technical effect relevant for inventive step.

The respondent submitted that tablets prepared according to D1 were less stable than tablets according to claim 1 obtained by direct compression. However, the available data on tablet stability does not permit this conclusion to be drawn. Firstly, as mentioned above (see point 2.8.2), the data provided in D1 does not confirm the respondent's assertion that the tablets in the example lacked stability. Secondly, no direct comparison with tablets according to claim 1 is available.

In its submissions in relation to tablet stability, the respondent referred in particular to water content.

In fact, claim 1 does not set an upper limit for the tablets' water content. The respondent argued that low water content was nevertheless an inherent feature of the process of preparation by direct compression.

In a process that involves wet granulation (as postulated by the respondent for D1), the granulation liquid is removed by evaporation before the granules are used for tableting. No evidence was provided to show that the hypothesised potential adverse effects of wet granulation will actually materialise in the circumstances of the case at hand, e.g. that wet granulation will impair the stability of cytisine during processing or that the product of a direct compression process will inevitably have a lower water content than the product of a process involving wet granulation. Moreover, the respondent did not provide any evidence for its allegation that only a direct compression process would result in tablets with a low enough water content to ensure storage stability.

Objective technical problem and solution

2.12 In view of these considerations, the objective technical problem starting from the disclosure of document D1 is the provision of a modified pharmaceutical cytisine tablet with better tolerability.

2.13 This problem is solved by the tablet defined in claim 1, which is suitable also for patients suffering from lactose intolerance (see point 2.8.1 above).

Obviousness of the solution

2.14 D1 describes cytisine tablets containing both lactose and microcrystalline cellulose in a specified ratio. The rationale behind these technical features is not explained.

2.15 However, a commonly known drawback of the use of lactose as a tableting excipient is the unsuitability of the resulting tablets for patients with lactose intolerance (see, for instance, D6: Table 2).

2.16 In light of common general knowledge, it would thus have appeared obvious to the person skilled in the art seeking to solve the objective technical problem to consider developing modified lactose-free formulations, in order to provide cytisine tablets that could also be administered to patients with lactose intolerance.

2.17 The function of lactose in tablet formulations is that of a diluent (or filler). If lactose was to be omitted, it would have appeared obvious to replace it with another widely-used diluent, such as mannitol. The mere fact that D1 happens to rely on lactose is not a technical reason why it cannot be replaced by an

equivalent diluent if there is an incentive for doing so.

2.18 There was no technical prejudice against combining mannitol with cytisine, and it would not have been surprising that mannitol, which has the advantage of not being a reducing sugar, proved to be compatible with cytisine (see point 2.8.2 above).

2.19 D1 does not teach any particular tableting process. Since direct compression has the advantages of simplicity and economy and avoids exposure of the active agent to heat and moisture, the skilled person would have envisaged and sought formulations that can be tableted by direct compression as the method of choice.

2.20 In this context, it was known that both mannitol and microcrystalline cellulose can be used in both granulated and directly compressed tablet formulations (see D8: page 132, point 7, page 449, point 7; D10: page 3656, Table 1, page 3664, Table 6).

2.21 The optimisation of the ratios and particle sizes of the components of a tablet is part of a pharmaceutical formulator's routine actions. The particle size of cytisine as defined in claim 1 is not unusual, overlaps with particle sizes taught in D1, and has not been associated with any particular technical effect.

2.22 Thus, the incentive for changing the formulation taught in D1 would have been the known problem of lactose intolerance in certain patients. The person skilled in the art would have had no reason to doubt the suitability of mannitol as a diluent and of direct compression as the method for preparing the tablets. They would have implemented these features as a matter of routine, without using inventive skill and without

being dissuaded by the teaching of any of the prior-art documents on file.

2.23 As a consequence, the subject-matter of claim 1 of the main request does not involve an inventive step within the meaning of Article 56 EPC.

3. Auxiliary request 1 - admittance (Article 13(2) RPBA)

3.1 Auxiliary request 1 was filed for the first time on the afternoon of the oral proceedings before the board. It constitutes an amendment of the respondent's appeal case because no request had previously been on file with an independent claim containing the feature "*the cytisine has average particle size d_{50} in the range from 10 µm to 30 µm*".

3.2 The respondent failed to provide convincing reasons as to why this late amendment to its case would be justified by exceptional circumstances.

3.3 In opposition-appeal proceedings, it is often the case that the board does not arrive at the same conclusions as the opposition division, or that it agrees with arguments made by the opposing party. This is not an exceptional situation.

3.4 If the respondent intended to rely on the feature defining a range of d_{50} as a fallback position, it should have filed a corresponding set of claims at an earlier stage of the proceedings.

3.5 For these reasons, the board did not admit auxiliary request 1, in accordance with Article 13(2) RPBA.

3.6 Auxiliary request 2 - inventive step (Articles 52(1) and 56 EPC)

3.7 Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that it specifies that the tablet contains 1.5 mg cytisine (see point VII. above).

3.8 This is not a feature distinguishing the claimed tablets from those described in D1 (see D1: Examples 1 and 2 in paragraph [0006]; the formulations disclosed in Examples 1 and 2 of D1 both contain 1.5 mg cytisine in 100 g uncoated tablet).

3.9 Hence, this feature cannot have any impact on the formulation of the objective technical problem and on the assessment of inventive step as set out in section 1 above.

3.10 As a consequence, the subject-matter of auxiliary request 2 does not involve an inventive step within the meaning of Article 56 EPC, for the same reasons as those set out with respect to claim 1 of the main request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated