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Datasheet for the decision of 17 January 2020

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Title of invention:
Combination of azelastine and mometasone

Patent Proprietor:
Cipla Limited

Opponents:
Sanovel Ilaç San. ve Tic. A.S.
Abdi Ibrahim Ilac Sanayi ve Ticaret Anonim Sirketi

Headword:
Azelastine-mometasone/CIPLA

Relevant legal provisions:
EPC Art. 56
RPBA Art. 12(4)

Keyword:
Inventive step - main request, auxiliary requests III, V, VI (no)
Admission - auxiliary requests I, II, IV (no)

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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
Fax +49 (0)89 2399-4465

Case Number: T 1443/16 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 17 January 2020

Appellant: (Patent Proprietor)	Cipla Limited Cipla House Peninsula Business Park Ganpatrao Kadam Marg Lower Parel Mumbai - 400013 (IN)
Representative:	Turner, Craig Robert A.A. Thornton & Co. 10 Old Bailey London EC4M 7NG (GB)
Respondent I: (Opponent 1)	Sanovel IIaç San. ve Tic. A.S. Balabandere Cad. Ilaç Sanayi Yolu No: 14 Istinye-Sariyer 34460 Istanbul (TR)
Representative:	Beckmann, Claus Kraus & Weisert Patentanwälte PartGmbB Thomas-Wimmer-Ring 15 80539 München (DE)
Respondent II: (Opponent 2)	Abdi Ibrahim Ilac Sanayi ve Ticaret Anonim Sirketi Resitpasa Mahallesi Eski Büyükdere Caddesi No: 4 Maslak - Sariyer 34467 Istanbul (TR)
Representative:	Engelhard, Markus Boehmert & Boehmert Anwaltspartnerschaft mbB Pettenkoferstrasse 22 80336 München (DE)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 20 April 2016 revoking European patent No. 2072051 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman A. Lindner
Members: J. Molina de Alba
L. Bühler

Summary of Facts and Submissions

I. This appeal by the patent proprietor (appellant) lies from the decision of the opposition division revoking European patent No. 2 072 051.

The patent had been granted with 21 claims. Granted independent claim 1 read as follows:

"*1. A pharmaceutical formulation which comprises azelastine, or a pharmaceutically acceptable salt, and mometasone or a pharmaceutically acceptable ester thereof.*"

II. The following documents cited by the parties during the opposition/appeal proceedings are referred to in the present decision:

D3: Comparative tests filed by the appellant with the letter dated 2 November 2010
D5: EP-A-0 780 127
D8: US 5,914,122
D9: P. van Cauwenberge et al., Allergy, 55, 2000, 116-134
D10: R.J. Davies et al., Clinical Therapeutics, 19(1), 1997, 27-38
D11: Highlights of Prescribing Information for NASONEX® (mometasone furoate monohydrate) Nasal Spray, Merck Sharp & Dhome Corp., revised version 03/2013
D20: Declaration of Ms Malhotra dated 11 June 2015, including Exhibits A and B
D23: Declaration of Ms Malhotra dated 30 August 2016, including Exhibit A

III. Two oppositions had been filed against the patent on the grounds that the claimed subject-matter lacked novelty and 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 (Article 100(a), (b) and (c) EPC).

IV. The decision under appeal was based on the patent as granted (main request) and an auxiliary request.

In the decision, the opposition division considered, among other things, that the subject-matter claimed in the patent as granted and the auxiliary request lacked an inventive step starting from Example III of document D5 as the closest prior art.

V. In its statement of grounds of appeal, the appellant requested that the decision be set aside and that the oppositions be rejected. It also filed documents D20 and D23 and six claim sets with their corresponding adapted descriptions as auxiliary requests I to VI. The claims of auxiliary request III are identical to those of the auxiliary request on which the appealed decision was based, and the claims of auxiliary requests I, II and IV are claim sets that had been filed and subsequently withdrawn in the opposition proceedings.

Claim 1 of auxiliary request I differs from claim 1 as granted in the limitation of the mometasone component to **a pharmaceutically acceptable ester of mometasone** and in the specification that the formulation is **in a form suitable for nasal or ocular administration**.

Claim 1 of auxiliary request II differs from claim 1 of auxiliary request I in the specification that the

amount of the ester of mometasone is **from about 50 micrograms/ml to about 5 mg/ml of the formulation.**

Claim 1 of auxiliary request III derives from claim 1 of auxiliary request I by the limitation of the ester of mometasone to **mometasone furoate or mometasone furoate monohydrate.**

Claim 1 of auxiliary request IV derives from claim 1 of auxiliary request I by the addition of the limitations of claim 1 of each of auxiliary requests II and III, and the restriction of the antihistamine component to **azelastine hydrochloride.**

Claim 1 of auxiliary request V reads as follows:

"*1. A pharmaceutical formulation which is an aqueous solution or suspension, which comprises:*
azelastine hydrochloride;
mometasone furoate or mometasone furoate monohydrate;
a surfactant;
an isotonic agent;
a preservative;
a suspending agent or thickening agent; and
a buffer;
wherein the pharmaceutical formulation is in a form suitable for nasal or ocular administration."

Claim 1 of auxiliary request VI reads as follows:

"*1. A pharmaceutical formulation which is an aqueous suspension or solution, which comprises:*
azelastine hydrochloride;
mometasone furoate or mometasone furoate monohydrate;
a surfactant comprising a polysorbate or poloxamer;

an isotonic agent comprising saccharose, glucose, glycerine, sorbitol or 1,2 propylene glycol;
a preservative;
a suspending agent or thickening agent; and
a buffer;
wherein said preservative is selected from edetic acid and its alkali salts, lower alkyl p-hydroxybenzoates, chlorhexidine, phenyl mercury borate, or benzoic acid or a salt, a quaternary ammonium compound, or sorbic acid or a salt thereof, the suspending agent or thickening agent is selected from cellulose derivatives, gelatin, polyvinylpyrrolidone, tragacanth, ethoxose (water soluble binding and thickening agents on the basis of ethyl cellulose), alginic acid, polyvinyl alcohol, polyacrylic acid, or pectin, and the buffer comprises a citric acid-citrate buffer;
wherein the pharmaceutical formulation is in a form suitable for nasal or ocular administration."

VI. In its response to the statement of grounds of appeal, respondent I (opponent I) requested that the appeal be dismissed and provided supporting arguments.

VII. Respondent II (opponent II) filed neither arguments nor requests in these appeal proceedings.

VIII. In a communication dated 28 October 2019, sent in preparation for the oral proceedings, the board gave its preliminary opinion.

Example III of document D5 was the closest prior art and the comparative tests in documents D20 and D23 did not convincingly show a technical effect linked to the particular choice of mometasone as the glucocorticoid. For this reason, the formulation of claim 1 of the main request and auxiliary requests III, V and VI would

likely be considered obvious. The board also drew attention to the issue of the admission of auxiliary requests I, II and IV.

IX. By letters dated 27 December 2019 (appellant), 8 January 2020 (respondent I) and 14 January 2020 (respondent II), the parties announced that they would not attend the scheduled oral proceedings.

X. Oral proceedings were held before the board on 17 January 2020 in the absence of the parties.

XI. The appellant's arguments, where relevant to the present decision, may be summarised as follows:

Main request - inventive step

The closest prior art is document D5 as a whole. The selection of its Example III as the closest prior art can only be made with knowledge of the invention and therefore involves hindsight.

Document D5 teaches the combination of antihistamines and glucocorticoids but not the specific combination of azelastine and mometasone. Moreover, the combinations disclosed in the examples of D5 are neither stable nor effective, as explained in declaration D20. Thus, the technical problem to be solved is the provision of a stable and effective pharmaceutical formulation comprising an antihistamine and a glucocorticoid.

This problem is solved by the formulation of claim 1, as demonstrated by the comparative tests in documents D3, D20 and D23. The tests in Exhibit A of each of documents D20 and D23 are designed for comparison with the formulation in Example III of document D5.

Alternatively, document D3 and Exhibit B of document D20 contain examples for comparison with combinations of azelastine and budesonide. The tests show the superior stability of the claimed formulations. Exhibit A of D20 shows that the formulation of Example III of D5 is so unstable that it is unsuitable and ineffective for nasal administration. Additional reasons why the formulation of Example III is unsuitable for nasal administration is that it is acidic and hyperosmotic. Thus, it would cause irritation of the nasal mucose.

The unsuitability of Example III for any pharmaceutical purpose would have led the skilled person away from the teaching of document D5. This, linked to the unexpected stability of the claimed formulations compared to the combinations of azelastine with other glucocorticoids, especially budesonide and triamcinolone acetonide, renders the claimed formulations inventive.

Auxiliary requests III, V and VI - inventive step

For the reasons put forward in relation to the main request, the formulations of claim 1 of each of auxiliary requests III, V and VI are also inventive.

XII. Respondent I's arguments, where relevant to the present decision, may be summarised as follows:

Main request - inventive step

Example III of document D5 is the closest prior art. Its selection does not involve more hindsight than selecting document D5 as a whole.

The examples in documents D3 and D20 do not provide a proper comparison between the claimed formulations and

the formulation in Example III of D5 because they differ not only in the glucocorticoid but also in the excipients. In this context, the degree of stability of the formulation in Example III is immaterial. For the comparison to be conclusive, the only difference between the formulations should be the glucocorticoid.

The difference between the comparative examples of document D23 is the glucocorticoid. However, the examples are not conclusive. The appellant argued that the formulations containing azelastine and mometasone furoate were more stable than those containing azelastine and triamcinolone acetonide because the amount of impurities at the end of the tests was lower for mometasone than for triamcinolone. The appellant, however, overlooked the fact that the concentration of azelastine remains stable in the compositions according to the prior art but decreases in the compositions according to claim 1. Also, in Experimental No. 4 and 5, the concentration of triamcinolone acetonide does not decrease as much as that of mometasone furoate, and the spray content uniformity of mometasone furoate is poorer. In consequence, the tests of document D23 show neither that the claimed compositions are more stable nor more effective.

Therefore, the technical problem to be solved is the provision of an alternative formulation of azelastine and a glucocorticoid.

The exchange of triamcinolone acetonide in the formulation of Example III by mometasone would be obvious to the skilled person since mometasone is one of the six alternative glucocorticoids suggested in document D5.

Auxiliary requests III, V and VI - inventive step

The feature "*wherein the pharmaceutical formulation is in a form suitable for nasal or ocular administration*" of claim 1 of auxiliary requests III, V and VI is disclosed in document D5. Hence, it is not a distinguishing feature and cannot contribute to inventive step.

The fact that mometasone in claim 1 of auxiliary request III is in the form of mometasone furoate cannot render the claimed formulations inventive either because mometasone furoate was how mometasone was marketed before the priority date (see documents D9, D10 and D11). Moreover, there is no evidence that mometasone furoate brings about any unexpected effect.

With respect to claim 1 of auxiliary request V, the additional difference in relation to Example III of D5 is the presence of a buffer. However, buffers are customary ingredients, and their addition is suggested in D5 (page 3, line 48).

Regarding the formulation of claim 1 of auxiliary request VI, the additional distinguishing feature is that it contains a citric acid-citrate buffer. As this type of buffer is commonly used in pharmaceutical formulations (see D8, column 3, lines 52-66), its addition is also obvious.

XIII. The requests of the parties were as follows:

- The appellant requested in writing that the decision under appeal be set aside and that the patent be maintained as granted, i.e. that the oppositions be rejected (main request).

Alternatively, it requested that the patent be maintained in amended form on the basis of any of auxiliary requests I to VI, filed with the statement of grounds of appeal. In addition, the appellant requested that auxiliary requests V and VI and documents D20 and D23, all filed with the statement of grounds of appeal, be admitted into the appeal proceedings.

- Respondent I requested in writing that the appeal be dismissed.

XIV. At the end of the oral proceedings, the board's decision was announced.

Reasons for the Decision

1. Any reference to the RPBA in this decision concerns RPBA 2020 unless otherwise indicated.

2. The appeal is admissible. It complies with the requirements pursuant to Articles 106 to 108 and Rule 99(2) EPC.

3. None of the parties attended the oral proceedings before the board as announced by the letters dated 27 December 2019 (appellant), 8 January 2020 (respondent I) and 14 January 2020 (respondent II).

In view of this and in accordance with Rule 115(2) EPC and Article 15(3) RPBA, the board maintained the oral proceedings and treated the parties as relying on their written cases only.

Considering that the facts and evidence on which the present decision is based were known to the parties from the written proceedings and that they had sufficient opportunity to submit their comments, the board was in a position to announce a decision at the conclusion of the oral proceedings, in accordance with Article 15(6) RPBA.

4. Main request - inventive step

4.1 The patent concerns (see paragraphs [0001] and [0006]) pharmaceutical formulations for nasal or ocular use which prevent or minimise allergic reactions. The formulations are based on the combination of the antihistamine azelastine and the glucocorticoid mometasone.

4.2 Document D5 deals with (see page 2, lines 5/6 and 36-44) pharmaceutical formulations for use as nasal sprays which, like those in the patent, comprise the combination of an antihistamine and a glucocorticoid. The antihistamine is selected from the group consisting of cetirizine, loratadine and azelastine, and the glucocorticoid is selected from beclomethasone, flunisolide, triamcinolone, fluticasone, mometasone and budesonide. The specific formulation disclosed in Example III contains the following ingredients:

Component	Wgt %
triamcinolone acetonide	0.050
azelastine HCl	0.070
polysorbate 80	0.050
glycerin	2.000
hydroxypropyl methyl cellulose	1.000
sodium chloride	0.900
ethylenediamine tetraacetic acid	0.050
benzalkonium chloride	0.020
distilled water	q.s. to vol.

4.3 In the debate on the selection of the closest prior art, the appellant and respondent I disputed whether the closest prior art was the general teaching of document D5 (appellant) or the specific embodiment in Example III (respondent I).

4.3.1 On this point, the board agrees with the respondent that the formulation of Example III is closer to the invention than the general teaching of D5 since it requires fewer modifications to it to arrive at the composition of claim 1. From Example III, all that is needed is to exchange the glucocorticoid (triamcinolone acetonide vs mometasone), while getting to the composition of claim 1 from the general teaching of D5 requires selecting from two lists the antihistamine azelastine and the glucocorticoid mometasone.

4.3.2 With respect to the appellant's view that the closest prior art must be a whole document rather than a part of it and that the selection of Example III involves hindsight, the board notes the following.

Article 56 EPC requires that the invention be non-obvious having regard to the state of the art. As the article does not make any restriction in relation to

the state of the art, the invention must be non-obvious over every piece of prior art, regardless of whether it is a whole document or a specific embodiment. Hence, a specific embodiment may perfectly constitute the closest prior art.

Furthermore, the issue of hindsight is immaterial to the selection of the closest prior art. Given that the closest prior art is selected on the basis of its proximity to the invention, its selection necessarily requires the knowledge of the invention.

4.4 It was undisputed that the formulation of claim 1 differs from that in Example III of document D5 in the glucocorticoid (mometasone vs triamcinolone acetonide).

4.5 Nevertheless, the appellant and respondent I dissented on the effect brought about by this difference and hence on the formulation of the technical problem to be solved.

Based of the results of the comparative examples in documents D3, D20 and D23, the appellant contended that the distinguishing feature resulted in a more stable and effective formulation. In contrast, respondent I argued that the comparative examples were not conclusive and denied that the formulation of claim 1 provided any improvement over the closest prior art.

For the reasons explained below, the board agrees with respondent I that the evidence on file does not demonstrate that the claimed formulation provides any improvement in relation to the composition of Example III of D5.

4.5.1 Document D3 shows the comparative stability of a formulation according to claim 1 and another comprising azelastine and budesonide. Considering that the glucocorticoid in the comparative formulation is not the glucocorticoid of the closest prior art (triamcinolone acetonide), the tests of D3 are not suitable to demonstrate any effect of the feature distinguishing claim 1 from the closest prior art.

The same is true for the comparative examples in Exhibit B of document D20, where the comparative formulation also contains a combination of azelastine and budesonide.

4.5.2 The tests in Exhibit A of document D20 compare a formulation comprising azelastine hydrochloride and mometasone furoate (according to claim 1) with a formulation containing azelastine hydrochloride and triamcinolone acetonide. These formulations, however, do not differ exclusively in the glucocorticoid but also in the nature and amount of other ingredients. The formulation according to claim 1 contains 2.0 wt.% dispersible cellulose and 0.01 wt.% polysorbate 80, while that reflecting the prior art contains 1.0 wt.% HPMC and 0.05 wt.% polysorbate 80. These additional differences make it impossible to assign any observed effect to the fact that the formulations contain different glucocorticoids. Therefore, the tests are not suitable to demonstrate any advantage of the claimed formulations over the closest prior art.

As noted by respondent I, whether the composition in Example III of D5 is stable is immaterial. The indispensable condition for a conclusive result is that the observed effect may be attributed exclusively to the different glucocorticoid.

4.5.3 Part I of Exhibit A of document D23 shows the composition of five formulations designated as Experimental No.1 to No. 5. Experimental No. 1, 3 and 5 are according to claim 1 and Experimental No. 2 and 4 represent the prior art.

Experimental No. 1, 2 and 3 differ only in the nature of the glucocorticoid, which is mometasone furoate anhydrous, triamcinolone acetonide and mometasone furoate monohydrate, respectively. Similarly, Experimental No. 4 and 5 differ only in that they contain triamcinolone acetonide and mometasone furoate anhydrous, respectively. Thus, any difference in the properties of Experimental No. 1, 2 and 3 may be attributed to the different glucocorticoid. The same is true for Experimental No. 4 and 5.

Part III of Exhibit A presents the results of the stability tests of Experimental No. 1 to No. 5, where the formulations were submitted to 25°C and a relative humidity of 60% (25°C/60%RH) or 40°C and a relative humidity of 75% (40°C/75%RH) during one and two months. As indicated by the appellant, after two months at 40°C/75%RH, the formulations according to claim 1 (Experimental No. 1, 3 and 5) did not show any impurities coming from the glucocorticoid (<0.1%), while the compositions according to the prior art (Experimental No. 2 and 4) showed a significant level of impurities (1.34% and 0.94%, respectively). The board nevertheless observes that, as argued by respondent I, the results show a broader picture which does not make it possible to conclude that the compositions containing mometasone furoate are more stable than those containing triamcinolone acetonide. The amount of azelastine, the concentration of

glucocorticoid and the spray content uniformity are particularly relevant.

The concentration of azelastine in Experimental No. 2 remains stable across the whole test while, after two months at 40°C/75%RH, it falls by more than 3 wt.% in Experimental No. 1 and 3 (from 104.9 wt.% to 99.8 wt.%, and from 103.6 wt.% to 100.3 wt.%, respectively). Similarly, in Experimental No. 4, azelastine falls only slightly (from 93.4 wt.% to 92.1 wt.%), while the fall in Experimental No. 5 is above 3 wt.% (from 103.7 wt.% to 99 wt.%).

A similar picture arises when looking at the evolution of the concentration of the glucocorticoid in Experimental No. 1, 2 and 3. Triamcinolone remains stable in Experimental No. 2, while mometasone falls by more than 3 wt.% in Experimental No. 1 (from 100.8 wt.% to 97.2 wt.%) and more than 1 wt.% in Experimental No. 3 (from 101.4 wt.% to 99.8 wt.%). A comparison of the evolution of the glucocorticoid in Experimental No. 4 and 5 is not reliable since Experimental No. 5 shows inconsistent changes in glucocorticoid concentration which, according to footnote C, are due to a lack of uniformity in content.

The lack of content uniformity of Experimental No. 5 is also observed in the results of the spray content uniformity, which, according to footnote D, may be caused by sedimentation of the drug. This statement by the appellant in footnote D clearly points to a lack of stability of the formulation of Experimental No. 5, which is according to claim 1.

Consequently, a consideration of the whole data presented in Exhibit A of document D23 does not allow

concluding that a formulation according to claim 1 is more stable, and hence more effective, than the same formulation containing triamcinolone acetonide as the glucocorticoid.

4.6 In view of the above, the improved stability alleged by the appellant has not been demonstrated, and the technical problem to be solved has to be formulated as the provision of an alternative pharmaceutical formulation for nasal or ocular administration comprising azelastine and a glucocorticoid.

4.7 The use of mometasone as an alternative glucocorticoid for combination with azelastine is suggested in document D5 which, in reference to the intranasal formulations disclosed in its examples, states (page 6, lines 44/45):

"*substantially similar results are also obtained using, in whole or in part, equivalent amounts of other glucocorticoid agents such as fluticasone,* ***mometasone****, budesonide, pharmaceutically acceptable salts thereof and mixtures thereof*" (emphasis added by the board).

4.8 The board therefore concludes that the formulation of claim 1 lacks an inventive step (Article 56 EPC).

5. Auxiliary requests I, II and IV - admission

In point 7 of the communication in preparation for the oral proceedings, dated 28 October 2019, the board drew attention to the issue of the admission of auxiliary requests I, II and IV pursuant to Article 12(4) RPBA 2007. The appellant, having had sufficient time to comment on this point, decided not to react - neither

in writing nor by attending the oral proceedings before the board.

In this case, although a new set of RPBA entered into force on 1 January 2020, the applicable provision remains Article 12(4) RPBA 2007 (transitional provision of Article 25(2) RPBA 2020).

As acknowledged by the appellant in its statement of grounds of appeal (point 3.6), auxiliary requests I, II and IV are requests that had been filed and subsequently withdrawn during the opposition proceedings.

It is common practice by the boards to hold inadmissible under Article 12(4) RPBA 2007 requests that have been abandoned in the first-instance proceedings. In this context, the publication "Case Law of the Boards of Appeal of the EPO" (9th Ed., 2019) states in section V.A.4.11.3, point f, that the board's discretion to refuse to admit requests which could have been presented in the first-instance proceedings applies all the more to requests that were filed and subsequently withdrawn during the first-instance proceedings. This is the direct consequence of a course of events which clearly shows that the requests could have been presented in the first-instance proceedings.

This board endorses this common practice and sees no reason to make any exception in this case. The appellant has not provided any arguments why such an exception should be made either.

Therefore, the board decided to hold auxiliary requests I, II and IV inadmissible (Article 12(4) RPBA 2007).

6. Auxiliary request III - inventive step

6.1 This request corresponds to the auxiliary request on which the appealed decision was based. In relation to the main request, the formulation of claim 1 is now specified to be in a form suitable for nasal and ocular administration, and mometasone is restricted to mometasone furoate or mometasone furoate monohydrate.

Document D5 teaches that the composition of Example III is suitable for nasal administration since it was used for topical nasal application to provide relief from allergy or allergy-like symptoms (see page 6, lines 43/44). Thus, the only difference of the formulation of claim 1 with regard to the closest prior art is that the glucocorticoid is mometasone furoate or mometasone furoate monohydrate instead of triamcinolone acetonide.

6.2 Exhibit A of each of documents D20 and D23 contains comparative examples comprising mometasone furoate anhydrous, mometasone furoate monohydrate or triamcinolone acetonide. However, as explained above (point 4.5), they do not conclusively show any improved stability or efficiency for the formulations containing any of the mometasone furoates.

6.3 Therefore, the technical problem to be solved remains the provision of an alternative pharmaceutical formulation for nasal or ocular administration comprising azelastine and a glucocorticoid.

6.4 As explained in relation to the main request, document D5 suggests (page 6, lines 44/45) the use of mometasone as an alternative to triamcinolone acetonide. Although the document does not mention that mometasone is specifically in the form of furoate or furoate

monohydrate, in 1997, mometasone furoate had already been approved in the US for use as a nasal spray in the treatment of rhinitis (D11) and, before the priority date of the patent, mometasone furoate was known to be particularly suitable for the topical treatment of rhinitis (D9: page 120, left-hand column, last paragraph; D10: abstract and page 28, left-hand column, paragraph 1). Hence, replacing the triamcinolone acetonide in Example III of D5 with mometasone furoate would have been an obvious solution to the technical problem posed.

6.5 Hence, the formulation of claim 1 of auxiliary request III lacks an inventive step (Article 56 EPC).

7. Auxiliary request V - inventive step

Compared to claim 1 of auxiliary request III, the formulation of claim 1 of auxiliary request V is an aqueous solution or suspension; azelastine is in the form of azelastine hydrochloride; and the formulation contains a surfactant, an isotonic agent, a preservative, a suspending or thickening agent, and a buffer.

Considering the ingredients of the composition in Example III of D5 and the preferred ingredients disclosed in the patent in suit in paragraphs [0014], [0016], [0045] and [0055], the composition of Example III is a solution or suspension comprising azelastine hydrochloride, a surfactant (polysorbate 80), an isotonic agent (sodium chloride and glycerin), a preservative (benzalkonium chloride), and a suspending and thickening agent (hydroxypropyl methyl cellulose). Thus, the only additional difference with the closest

prior art is that the formulation of claim 1 contains a buffer.

The appellant has not explained the effect produced by the buffer in the claimed formulation, but it is generally known that buffers are common ingredients in pharmaceutical formulations to maintain the pH at physiological levels. Their addition is also suggested in document D5 (page 3, line 48). Hence, the presence of a buffer in the formulation of claim 1 cannot serve to render the claimed formulation inventive.

Therefore, the subject-matter of claim 1 of auxiliary request V also lacks an inventive step (Article 56 EPC).

8. Auxiliary request VI - inventive step

The additional difference over Example III of D5 provided by claim 1 of auxiliary request VI in relation to claim 1 of auxiliary requests V is the specification that the buffer comprises a citric acid-citrate buffer. However, as citric acid-citrate buffers have always been among the most commonly used buffers in pharmaceutical formulations, the specification that the buffer is a citric acid-citrate buffer cannot render the formulation of claim 1 inventive (Article 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated