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Datasheet for the decision of 16 January 2026

Case Number: T 0492/24 - 3.3.07

Application Number: 14781946.0

Publication Number: 3043773

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Language of the proceedings: EN

Title of invention:
STABLE FIXED DOSE PHARMACEUTICAL COMPOSITION COMPRISING MOMETASONE AND OLOPATADINE FOR NASAL ADMINISTRATION

Patent Proprietor:
Glenmark Specialty S.A.

Opponent:
Ter Meer Steinmeister & Partner Patentanwälte mbB

Headword:
STABLE FIXED DOSE PHARMACEUTICAL COMPOSITION COMPRISING MOMETASONE AND OLOPATADINE FOR NASAL ADMINISTRATION/Glenmark Speciality S.A.

Relevant legal provisions:
EPC Art. 123(2), 56
RPBA 2020 Art. 12(4), 12(6)

Keyword:
Main request and auxiliary request 1 - Amendments (No)
Auxiliary request 3 - Amendments (Yes)
Admission of new documents
Auxiliary request 3 - Inventive step (Yes)

Decisions cited:
T 1556/16

Catchword:

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Case Number: T 0492/24 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 16 January 2026

Appellant: (Opponent)	Ter Meer Steinmeister & Partner Patentanwälte mbB Nymphenburger Strasse 4 80335 München (DE)
Representative:	Ter Meer Steinmeister & Partner Patentanwälte mbB Nymphenburger Straße 4 80335 München (DE)
Respondent: (Patent Proprietor)	Glenmark Specialty S.A. Avenue Léopold-Robert 37 2300 La Chaux-de-Fonds (CH)
Representative:	HGF HGF Limited 4th Floor, 1 City Square Leeds LS1 2ES (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 7 February 2024 concerning maintenance of the European Patent No. 3043773 in amended form.**

Composition of the Board:

Chair	A. Jimenez
Members:	D. Boulois
	J. Molina de Alba

Summary of Facts and Submissions

I. The European Patent 3 043 773 B1 had been opposed under Article 100 (a), (b) and (c) EPC on the grounds that its subject-matter lacked inventive step, was not sufficiently disclosed, and extended beyond the content of the application as filed.

II. The appeal lies from the decision of the opposition division finding that the patent in amended form meets the requirements of the EPC. The decision was based on the main request filed on 8 September 2023.

Claim 1 of the main request read:

"1. A stable fixed dose aqueous pharmaceutical composition for nasal administration to a human, said composition being a suspension which comprises
a) 0.025 % w/w to 0.05 % w/w mometasone furoate in particulate form;
b) 0.6 % w/w to 0.7 % w/w olopatadine hydrochloride in dissolved form; and
c) a hydrocolloid which comprises sodium carboxymethyl cellulose at a concentration of at least 0.5 % w/w and sufficient to prevent phase separation for at least 24 hours at ambient condition."

III. The documents cited during the opposition proceedings included the following:

D4: WO 2014/092346 (A1)
D9: Avicel® RC-591 product description, 1995
D10: Avicel® RC/CL, 2001
D19: US Product label Dymista®, 2012
D20: US Product label Patanase®, 2012

D21: US Product label Astelin®, 2011
D22: Kulkarni and Shaw, Formulation and characterization of nasal sprays, Inhalation, 2012, p. 10-15
D31: Prescribing Information for OLOPATADINE HYDROCHLORIDE nasal solution(nasal spray), approved 1996, revised December 2015
D32: Experimental procedure in which examples 3 and 4 of document D4 have been reproduced

IV. According to the decision under appeal, the main request met the requirements of Article 123(2) EPC and Article 83 EPC.

The priority was not valid in view of the disclosure of the amounts of mometasone, olopatadine and CMC. Consequently, D4 was prior art in the sense of Article 54(2) EPC.

With regard to inventive step, D4 was the closest prior art, in particular in view of its examples 3-4. D32 supported a technical effect with regard to the absence of phase separation, and the problem was defined as the provision of a nasal suspension comprising mometasone furoate and olopatadine hydrochloride with improved stability. The claimed solution was the use of (1) lower amounts of olopatadine hydrochloride (0.6-0.7% w/w) and of (2) at least 0.5% (w/w) NaCMC as hydrocolloid. The claimed solution was not obvious in view of D4, D9, D10 or D22.

V. The opponent (hereinafter the appellant) filed an appeal against said decision. With its statement of grounds of appeal, the appellant filed new documents:

D33: Product label of Astepro®, Azelastine hydrochloride nasal spray, 2010
D34: F.D. Marques-Marinho and C.D. Vianna-Soares, Chapter 8: "Cellulose and Its Derivatives Use in the Pharmaceutical Compounding Practice", in: IntechOpen; "Cellulose - Medical, Pharmaceutical and Electronic Applications", ed. Theo G.M. Van De Ven, 29 August 2013;

VI. With its reply to the appeal dated 11 October 2024, the patent proprietor (hereinafter the respondent) filed a main request and auxiliary requests 1 to 7 corresponding to the requests on file during the opposition proceedings.

Independent claim 1 of auxiliary request 1 differed from the subject-matter of claim 1 of the main request in the specification of the concentration of carboxymethyl cellulose as follows:
"c) a hydrocolloid which comprises sodium carboxymethyl cellulose at a concentration **of 0.5 % w/w to 3 % w/w** and sufficient to prevent phase separation for at least 24 hours at ambient condition".

In comparison to the main request, independent claim 1 of auxiliary request 3 was amended with regard to feature c) with a further specification of the pH range, namely:
"c) a hydrocolloid which comprises sodium carboxymethyl cellulose at a concentration of at least 0.5 % w/w and sufficient to prevent phase separation for at least 24 hours at ambient condition, **wherein the composition has a pH between 3.5 to 3.9**"."

VII. A communication from the Board, dated 9 September 2025, was sent to the parties. In it, the Board expressed its

preliminary opinion that D33 should not be admitted into the appeal proceedings and that it had to be debated whether there was a disclosure in the application as filed for using NaCMC at concentrations over "0.5% w/w". With regard to inventive step, the Board noticed *inter alia* that the problem of stability was not known or identified in the closest state of the art D4 and that it appeared questionable for this reason that the skilled person would have envisaged any measure in this perspective.

VIII. Oral proceedings took place on 16 January 2026. Auxiliary request 2 was withdrawn during oral proceedings.

IX. The arguments of the appellant may be summarised as follows:

Main request - Amendments

The application as originally filed did not directly and unambiguously disclose the specific combination of features, which required an amount of sodium carboxymethyl cellulose of at least 0.5% w/w together with the specific amount of mometasone of 0.025% w/w to 0.05% w/w. Original claim 14 was a specific different embodiment and could not constitute a basis for this amendment.

Auxiliary requests 1 - Amendments

Claim 1 of auxiliary request 1 did not comply with Art. 123(2) EPC for the same reason as claim 1 of the main request. The claimed range of the concentration of sodium carboxymethyl cellulose of 0.5 to 3% w/w as claimed represented an artificial range resulting from

the combination of features which were not directly and unambiguously disclosed in the application as filed.

Auxiliary request 3 - Amendments

Claim 1 of auxiliary request 3 did not comply with Art. 123(2) EPC for the same reason as the previous requests. There was no direct and unambiguous disclosure of the claimed combination of features in the original application.

Admission of D33 and D34 into the appeal proceedings

The filing of D33 and D34 was a reaction to amendments carried out in the main request, which was filed by the patentee only at a late stage of the opposition proceedings.

Auxiliary request 3 - Inventive step

The compositions of Examples 3 and 4 of D4 were the starting point for the assessment of inventive step, and comprised between 0.17-0.28% w/w of NaCMC. The only distinguishing feature was the amount of NaCMC, since the disclosed amount of 6,65 w/v % of olopatadine hydrochloride in D4 was not correct and should instead be read 0,665 w/v%. The problem was the provision of an alternative stable dosage form, since no effect was shown. D20 showed that the claimed concentration of olopatadine hydrochloride was known, while D9, D10 and D34 showed that the use of NaCMC was obvious.

X. The arguments of the respondent may be summarised as follows:

Main request - Amendments

There was a clear pointer towards a composition of the embodiment at page 2, lines 19-25 having the two actives plus a hydrocolloid. The page 3, lines 425-31 embodiment then provided the lower limit of 0.1 %w/w for the sodium carboxymethyl cellulose hydrocolloid component. With regard to claim 14, there was a selection from one list, the list was not of considerable length, and there were further disclosures and examples pointing towards the individual selection of NaCMC.

Auxiliary request 1 - Amendments

In auxiliary request 1 the limitation that the NaCMC was present in the range of 0.5% to 3% w/w.,was supported by the description starting from page 3, lines 29-31 which disclosed the range of NaCMC as between about 0.1 % w/w to about 3 % w/w of the composition. Support for the combination of the disclosed end-point of 0.5 % w/w sodium carboxymethylcellulose could also be found in the various embodiments on page 5, line 3 to page 6, line 5. Further, claim 14 as filed disclosed the sub-range of 0.3 to 0.5 % w/w NaCMC. Thus, there was a disclosure of amending the lower end point of the range to 0.5% NaCMC.

Auxiliary request 3 - Amendments

Claim 1 of auxiliary request 3 defined the pH in the range of 3.5 to 3.9, which was supported on page 4, lines 27-32.

Admission of D33 and D34 into the appeal proceedings

D33 and D34 could and should have been filed earlier in the opposition proceedings. None of these documents was furthermore *prima facie* relevant.

Auxiliary request 3 - Inventive step

The claimed subject-matter differed from examples 3 and 4 of D4 in the concentrations of olopatadine hydrochloride and of NaCMC. The examples of the patent and the experiments D32 showed an effect on stability and the problem was the provision of composition with improved stability preventing phase separation. The claimed solution was not obvious.

XI. Requests

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor), requested that the appeal be dismissed. Alternatively, they requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the sets of claims filed as auxiliary requests 1 or 3 with the reply to the statement of grounds of appeal. The respondent also requested that the documents D33 and D34 not be admitted into the appeal proceedings.

Reasons for the Decision

1. Main request - Amendments

1.1 The appellant considers that the application as originally filed does not directly and unambiguously disclose the specific combination of features, which requires an amount of sodium carboxymethyl cellulose (also referred to in the following as "NaCMC") of **"at least 0.5% w/w"** together with the claimed amount of mometasone of 0.025% w/w to 0.05% w/w.

1.2 It is established case-law that the only and fundamental test for determining whether the subject-matter of claim 1 meets the requirements of Article 123(2) EPC, is the "gold standard" disclosure test (see G 1/05 of 28 June 2007, point 5.1 of the reasons, and G 2/10, point 4.3 of the reasons). This standard requires that the subject-matter of a claim of a patent remains within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the earlier application as filed. Moreover, the skilled person may not be presented with new technical information (see G 2/10, point 4.5.1 of the reasons). The combination of thresholds from different levels of preference of ranges is thus allowable only when the new range could be regarded as directly and unambiguously disclosed for the skilled person.

1.3 In the present case, different amounts of NaCMC can be found in several passages of the application as filed in direct association with the claimed amounts of 0.025 % w/w to 0.05 % w/w of mometasone and can serve potentially as basis for the claimed amount of NaCMC:

(a) Page 3, lines 11-17 disclose amounts **"of at least 0.1% w/w"** of the hydrocolloid, which includes NaCMC and xanthan gum;
(b) Page 3, lines 25-31 discloses an amount of **"at least about 0.1% w/w, preferably between 0.1% w/w to about 3% w/w"** of NaCMC;
(c) Page 10, lines 10-16 relates to compositions with **"at least about 0.1% w/w"** of a hydrocolloid which can be NaCMC;
(d) Page 10, lines 24-30 discloses compositions comprising **"at least about 0.1 % w/w, or preferably between 0.1% w/w to about 3% w/w"** of NaCMC;
(e) Original dependent Claim 14 relates to compositions "wherein the hydrocolloid is present at a concentration in the range of **about 0.3% w/w to about 0.5% w/w**, said hydrocolloid includes xanthan gum, carboxymethylcellulose or both". This claim refers *inter alia* to claim 10 wherein the amount of mometasone are between 0.025 to 0.05% w/w.

The specific concentration of **"0.5 % w/w"** of NaCMC, therefore not in the form of a range, is furthermore disclosed in the following passages, however every time in association with further features absent from claim 1 of the main request, and therefore cannot serve for constituting a basis for the feature "at least 0.5 % w/w" in claim 1 of the main request:
- on page 4, lines 27-32, in association with a "pH between about 3.5 to about 3.9";
- on page 5, line 3 - page 6, line 5, in association with specific amounts of specified active agents and excipients;
- on page 14, line 25 to page 15, line 26, in association with specific compounds and in specific amounts.

1.4 There is therefore an explicit basis for concentrations of NaCMC of "at least 0.1% w/w", of "between 0.1% w/w to about 3% w/w" and "about 0.3% w/w to about 0.5% w/w", when in association with the claimed amounts of active agents, but not for a concentration of "at least 0.5% w/w".

The value of 0.5 % w/w in association with the claimed amounts of active agents is in particular only disclosed as the upper limit of the range of "**about 0.3% w/w to about 0.5% w/w**" in claim 14. The respondent has selected the upper limit of 0.5% w/w from the range of "about 0.3% w/w to about 0.5% w/w" originating from claim 14 and switched it to a range starting from said upper limit.

1.5 According to the decision of the opposition division this concentration of "at least 0.5 % w/w" of NaCMC could be unambiguously derived from the combination of the disclosure page 3, lines 29-31 ("at least about 0.1%, or preferably between about 0.1 % w/w to about 3% w/w") and the disclosure of claim 14 (see point 3.4 of the decision).

In the Board's view, the subject-matter of claim 14 cannot however serve as a basis for the claimed amount of NaCMC. Claim 14 relates indeed to the total amount of hydrocolloid(s), which includes xanthan gum, NaCMC or both; the term "includes" further allows the presence of additional hydrocolloids not specified in claim 14 (see for instance the list of hydrocolloids given on page 8 of the original application). The subject-matter of claim 14 is therefore directed to a specific embodiment in which the highest amount of total hydrocolloid is 0.5% w/w and it is not possible

to conclude from this embodiment that NaCMC as such, or any other hydrocolloid, can be present at a concentration of more than 0.5 % w/w. Accordingly, the upper range limit disclosed in original claim 14 cannot serve as lower range limit for a newly created range of "at least 0.5 % w/w". For this reason alone, the claimed amount of NaCMC infringes the requirements of Article 123(2) EPC.

Moreover, it is not possible to combine the subject-matter of claim 14 with the teaching of original page 3, lines 29-32 or the similar disclosure on page 10, lines 28-30; the passages on pages 3 or 10 are indeed directed to the specific use of NaCMC as hydrocolloid (without disclosing the specific value of 0.5% w/w) while claim 14 relates to the amount of total hydrocolloids. Both represent different embodiments or aspects of the claimed invention which cannot be combined to form a new range of concentration of NaCMC.

The respondent referred in particular to decision T 1556/16 during oral proceedings in support of the amendment. This case is however different from the present case, since it related to an allowable new range of value obtained by the combination of an isolated value taken form an example, more particularly a figure, taken as lower limit of the new range, with the upper range limit of an originally disclosed broader range.

1.6 Consequently, the main request does not meet the requirements of Article 123(2) EPC.

2. Auxiliary request 1 - Amendments

2.1 Claim 1 of auxiliary request 1 has been amended with regard to feature c) as follows:
"c) a hydrocolloid which comprises sodium carboxymethyl cellulose at a concentration **of 0.5 % w/w to 3 % w/w** and sufficient to prevent phase separation for at least 24 hours at ambient condition".

2.2 This request does not meet the requirements of Article 123(2) EPC for the same reasons than the main request.

The new concentration range of NaCMC of "0.5 % w/w to 3 % w/w" has indeed been created by the combination of the upper limit of the concentration range disclosed in original claim 14 with the upper limit found on page 3, lines 29-31 or page 10, lines 28-30 of the application as filed. As discussed above, the upper range limit disclosed in original claim 14 cannot serve as lower range limit for a newly created range and can neither be combined with the disclosure of pages 3 or 10, since both disclosures belong to different embodiments. The new concentration range of NaCMC of "0.5 % w/w to 3 % w/w" is therefore not derivable directly or unambiguously from the original application.

3. Auxiliary request 3 - Amendments

3.1 Feature c) of claim 1 of auxiliary request 3 has been amended as shown in bold:
"c) a hydrocolloid which comprises sodium carboxymethyl cellulose at a concentration of at least 0.5 % w/w and sufficient to prevent phase separation for at least 24 hours at ambient condition, **wherein the composition has a pH between 3.5 to 3.9.**"

3.2 The patent application discloses in its description on page 3, lines 29-31 that "the sodium carboxymethyl cellulose may be present at a concentration **of at least about 0.1 % w/w**, or preferably between about 0.1 % w/w to about 3 % w/w of the composition" and on page 4, lines 29-31 that the hydrocolloid comprises "sodium carboxymethyl cellulose at a concentration **of about 0.5 % w/w** of the composition, **wherein the composition has a pH between about 3.5 to about 3.9**".

In the Board's view, the specific value of "0.5% w/w" disclosed on page 4 can serve as a basis for the creation of a new range of concentration, provided that the associated pH features are incorporated in the claim, which is the case. The limitation of the original disclosed range "of at least 0.1 % w/w" by the use of the isolated value taken from the specific embodiment "of about 0.5 % w/w" is allowable, since it does not present the skilled person with information that goes beyond the content of the original disclosure. This is in particular line with the decision T 1556/16 cited by the respondent (see also CLB, E, 1, 1.5.2, a)).

This conclusion is supported by the presence of pointers in the patent application for the presence of NaCMC at more than 0.5% w/w. Thus, page 5 of the patent application discloses several specific preferred embodiments wherein the composition comprises "(3) a hydrocolloid selected from about 0.3 % w/w of xanthan gum and **about 0.5 % w/w carboxymethyl cellulose sodium**, (4) about 1% w/w to about 1.2% w/w mixture of microcrystalline cellulose and **carboxymethyl cellulose sodium**"; the addition of the concentrations of NaCMC provided as mixture with cellulose and as such amounts

to a total concentration of more than 0.5% w/w of NaCMC.

The presence of NaCMC in an amount higher than 0.5 %w/w is furthermore confirmed by the composition of all examples comprising NaCMC as hydrocolloid (examples 1 and 2). Said examples comprise a combination of 0.5% w/w of NaCMC with 1.0 % w/w of Avicel RC 591 (a blend of microcrystalline cellulose and NaCMC).

Accordingly, the feature c) in claim 1 of auxiliary request 3 is the combination of the features disclosed on pages 3 and 4 as mentioned above, and is derivable directly and unambiguously from the application as filed.

3.3 Auxiliary request 3 meets the requirements of Article 123(2) EPC.

4. Admission of D33 and D34 into the appeal proceedings

4.1 These documents have been filed by the appellant with their statement of grounds of appeal. According to the appellant, the filing of these documents is a reaction to amendments carried out in the main request on late stage of the opposition proceedings, i.e. on the last day for making submissions under Rule 116 EPC . In claim 1 according to the main request, said amendments were carried out based on passages disclosed in the general specification, such as the introduction of the new lower limit of the amount of sodium carboxymethyl cellulose of at least 0.5% w/w.

Therefore, the appellant submits that it was not possible to adequately react to these late amendments by reference to the documents filed together with the

notice of opposition or with submission under Rule 116 EPC.

4.1.1 D33 is the notice giving the prescribing information for commercial product Astepro®, a nasal spray comprising 0.1 or 0.15% of azelastine hydrochloride.

This document has been submitted to support that the commercial products of azelastine comprise consistently the same amount of active agent and to support the argument that the Examples in D4 are intended to be the same as the marketed products and that therefore the skilled person would read the 6.65% olopatadine in D4 as being 0.665%.

4.1.2 D34 is a review relating to the use of cellulose and its derivatives in pharmaceutical compositions. It mentions in point 2.2.6 that CMC-Na acts as a capsule disintegrant and a stabilizing, a suspending, an emulsifying (0.25- 1%), a gel-forming (3-6%) and a viscosity-increasing (0.1-1%) agent in compounded medicines

4.2 These documents constitute evidence that was not part of the facts on which the decision under appeal was based. For this reason, their filing amounts to an amendment of the appellant's case and the Board has discretion to admit them pursuant to Articles 12(4) and 13(1) RPBA. Relevant criteria for the exercise of the Board's discretion are the complexity of the amendment, the suitability of the amendment to address the issues which led to the decision under appeal and the need for procedural economy.

Moreover, the Board shall not admit evidence which should have been submitted in the proceedings leading to the decision under appeal (Article 12(6) RPBA).

4.2.1 D33 was cited to support the argument that the skilled person would have known that the amounts of olopatadine in D4 were clearly erroneous. This point was raised as soon as the start of the opposition proceedings, i.e. in the response to the notice of opposition, and D33 could and should have been filed at this stage.

With regard to its content, D33 does neither appear to have been filed in response to amendments filed late in the proceedings as the appellant suggests. Moreover, its relevance is questionable, since it does not relate to the common olopatadine concentrations in nasal sprays, but to the concentration of azelastine, and is redundant with the disclosure of D19 and D21, and also less relevant than D20 or D31.

Consequently, the Board does not see any reason to admit document D33 into the appeal proceedings (Articles 12(4) and 12(6) RPBA).

4.2.2 D34 is a common general knowledge document and relates specifically to the use and concentration of NaCMC in compositions, and can be seen as a reaction to the decision of the opposition division and to the filing of the requests by the respondent.

The document D34 is admitted into the appeal proceedings (Article 12(4) and 12(6) RPBA).

5. Validity of the priority

In the absence of any argument of the respondent challenging the correctness of the decision of the opposition division, the Board sees no reason to depart from that decision, namely that the priority is not valid and that D4 is a state of the art under Article 54(2) EPC. During oral proceedings before the Board, the respondent did not contest that D4 was prior art under Article 54(2) EPC.

6. Auxiliary request 3 - Inventive step

6.1 The claimed invention relates to a stable fixed dose, aqueous pharmaceutical composition for nasal administration comprising mometasone furoate in particulate form and olopatadine hydrochloride in dissolved form.

6.2 D4 was considered to be the closest prior art by the opposition division in its decision; this choice is confirmed by the appellant and the respondent.

6.2.1 D4 discloses in examples 3 and 4 a composition comprising mometasone furoate, olopatadine hydrochloride and *inter alia* NaCMC in the form of the commercial product Avicel RC591 (mixture of microcrystalline cellulose and NaCMC). The amount of olopatadine is 6.65% w/v and the total amount of NaCMC in the compositions of examples 3 or 4 is about **0.17-0.28% w/v** as calculated by the appellant on the basis of D10 (D10 states in the table on page 12 that Avicel RC 591 contains 8.3-13.8 % NaCMC).

The full composition is showed by the following Table 2 of D4:

[Table 2]

Ingredient (w/v%)	Example 3	Example 4
Mometasone furoate	0.05	0.05
Olopatadine hydrochloride	6.65	6.65
Avicel RC-591	2.0	2.0
Glycerin	2.1	2.1
Disodium edetate hydrate	0.1	0.1
Citric acid hydrate	0.2	0.2
Sodium citrate hydrate	0.28	0.28
Polysorbate 80	0.01	0.01
Benzalkonium chloride	0.02	0.02
D-sorbitol	6.6	6.6
Thaumatin	0.25	0.25
Steviol glycoside	1.0	-
Enzymatically modified stevia	-	1.0
Distilled water	Residual quantity	Residual quantity

D4 does therefore not disclose a composition comprising a claimed amount of 0.6 % w/w to 0.7 % w/w of olopatadine hydrochloride and of at least 0.5% w/w of NaCMC.

6.2.2 The appellant considers that the claimed amount of olopatadine hydrochloride could not constitute a distinguishing feature over the amount disclosed in examples 3 or 4 of D4. According to the appellant, the amount of 6.65% of olopatadine hydrochloride in examples 3 and 4 of D4 is indeed a typographical error and should be read as 0.665% w/v.

The reasons given are the following:
- the commercial product Patanase® disclosed in D4 (see page 1, line 35) has a concentration of olopatadine Hydrochloride of 0.665% w/v (see D20 and D31: 665 µg of olopatadine HCl delivered in each 100 microliter spray);
- the skilled person would appreciate that it is not safe to administer 10X more olopatadine than delivered by the commercially available product Patanase®;

- the skilled person would not expect it to be possible to dissolve the specified amounts of olopatadine HCl of examples 3 and 4, as required by the process instructions of example 1 of D4;
- the amounts of mometasone furoate and azelastine HCl in D4 are the same as in the corresponding commercial products.

On the same point, the opposition division considered that there was no passage in D4 showing or suggesting any ambiguity concerning the disclosed value of 6.65% w/v of olopatadine HCl in D4. The respondent also considers that it is not possible to derive from D4 that an error has occurred, since the 6.65% w/v concentration of olopatadine HCl falls under the range of 0.1 to 20 w% disclosed on page 4 of D4.

6.2.3 The Board does not see any reason to deviate from the conclusion of the opposition division on this point in the absence of any identifiable error. It is impossible to conclude from D4 whether the examples of D4 were intended to comprise the products in the same concentration as in the marketed products.

The Board notes furthermore that the comparative example 5 of D4 comprises also 6.65% w/v of olopatadine HCl.

The discussion on the administered dose appears furthermore to be irrelevant, since there is no disclosure in D4 relating to the volume of the spray dose or the number of sprays to be administered.

Finally and importantly, even if the concentration reported in D4 were incorrect, this would not necessarily lead to the conclusion that the correct

concentration corresponds to that of the commercial products.

6.2.4 Consequently, the Board maintains that the distinguishing features between the claimed subject-matter and the disclosure of D4 are the amounts of olopatadine hydrochloride and of NaCMC present in the composition.

6.3 The opposition division defined the problem as the provision of a nasal suspension comprising 0.05 % (w/w) mometasone furoate and olopatadine hydrochloride with improved stability. The respondent agrees with this definition of the problem and defines it as providing an improved composition which prevents phase separation.

The appellant defines the problem as the provision of an alternative stable fixed-dose aqueous pharmaceutical composition for nasal administration which prevents phase separation.

6.4 Examples 1 and 2 of the contested patent, and the experiments D32 were cited by the respondent in support of the technical effect.

6.4.1 The compositions of examples 1 and 2 of the contested patent are suspensions comprising *inter alia* 0.050% w/w mometasone furoate monohydrate, 0.665% w/w olopatadine hydrochloride, 1.2% w/w of Avicel RC 591 (Microcrystalline cellulose and NaCMC) and 0.5% w/w of NaCMC as such. After 24 hours, there is no phase separation observed for any of the composition of example 1 and 2, while comparative examples A and B differing mainly through the presence of only 1.0 % w/w of Avicel RC 591 and the respective total absence of

NaCMC as such or the presence of only 0.150% w/w of NaCMC, show a phase separation. In view of these results, it appears that the stabilization is a result of the presence of at least 0.5 % w/w NaCMC in Examples 1 and 2.

The Board concurs with the appellant that the examples of the patent do not provide an exact and direct comparison with the compositions disclosed in examples 3 and 4 of D4 in particular in view of the presence of only 1.0% w/w of Avicel RC 591 in comparative examples A and B, instead of 2.0% w/w in examples 3 and 4 of D4. When comparative tests are submitted, it is however not always necessary to provide an exact comparison, but it is sufficient that an alleged effect is convincingly shown to have its origin in the distinguishing feature of the invention compared with the closest state of the art. In the Board's view this is demonstrated by the examples of the contested patent; it is indeed rendered credible that adding NaCMC in amounts of over 0.5 wt% *per se* to compositions containing 0.665 wt% olopatadine hydrochloride would lead to **more** stable suspensions compared to compositions of D4 containing only 2.0 wt% Avicel RC-591.

Accordingly, the examples of the patent show an explicit technical effect on stability linked with the claimed amount of NaCMC as such, in particular that a minimal amount of NaCMC is required to achieve a stable suspension and that this technical feature is the main element of stabilization of the composition. **For this reason alone and independently from the second distinguishing feature, the problem appears to be as defined by the respondent or by the opposition division in its decision.**

6.4.2 The experiments of D32 aim to be a reproduction of the examples 3-4 of the closest prior art D4. The active ingredients used therein are mometasone furoate (0.05% w/w) and olopatadine hydrochloride (6.65% w/w), and NaCMC is in the form of 2% (w/w) Avicel RC 591. The experiments show a phase separation of the composition after 2-3 hours. Hence, D32 shows that the suspensions of D4 are not stable, contrary to the compositions of examples 1 and 2 of the patent.

The appellant has contested the experimental results shown in D32. According to the appellant, the occurrence of phase separation after 2-3 hours of compositions including 6.65 wt% olopatadine hydrochloride, i.e. of a tenfold higher amount than used in the commercial Patanase® product, is not at all surprising and only confirms that the skilled person would not have seriously considered this amount to be an amount directly and unambiguously disclosed in D4. This result instead supports that the amount of 6.65 wt% olopatadine hydrochloride is an obvious typographical error.

In addition, the appellant notes that claim 1 of the main request does not include any upper limit of the NaCMC concentration. Hence, claim 1 encompasses compositions containing several weight percent of this hydrocolloid. However, it is not demonstrated by the respondent, neither in the opposed patent nor in D32, that such a composition still achieves the desired effect of stabilization by inhibiting phase separation.

The Board is not convinced by the appellant's arguments. First, the Board does not see any reason to question the experiments of D32 or, as discussed above under point 6.2.3, the concentration of olopatadine

hydrochloride in examples 3 and 4 of D4. The compositions of D32 are a fair reproduction of the examples 3-4 of the closest prior art D4 and the experiments show a clear result that it is not possible to ignore. In the Board's view, these results are corroborated by the experimental results shown in comparative examples A and B of the patent, which show a phase separation even when olopatadine hydrochloride is present at a lower concentration and therefore the ineffectiveness of Avicel RC 591 in stabilizing the composition.

Then, the appellant did not provide any evidence or credible technical argumentation that the claims do not achieve the desired effect across the full scope. The Board concurs with the conclusion of the opposition division on this point, namely that, in view of the limited number of suspending agents commonly used in nasal suspensions (see D9, D10, D22), the actual scope of the claims which limits the claimed compositions specifically to suspensions, and in the absence of contrary evidence concerning the effect, the appellant's arguments are not found convincing (see point 7.3.5 of the decision).

6.5 It remains to determine whether the claimed solution for providing an improved composition which prevents phase separation, namely a composition comprising a claimed amount of 0.6 % w/w to 0.7 % w/w of olopatadine hydrochloride of at least 0.5% w/w of NaCMC, is obvious.

The documents D9, D10, D20, D34 and the common general knowledge were cited. D22 was also cited by the respondent.

6.5.1 The Board notes first that there is no mention in D4 of stability issues or phase separation. There is therefore no suggestion or even motivation to modify the nasal suspensions disclosed in D4 to improve the stability and achieve suspension with no phase separation. The skilled person has in particular no valid reason to add at least 0.5% w/w NaCMC as hydrocolloid to stabilize the suspension. For this reason alone, the claimed solution does not appear to be obvious.

6.5.2 With regard to the first distinguishing feature, the concentration of 0.665% w/w of olopatadine hydrochloride appears to be commonly known. D20 relates to the commercial product Patanase® which has a concentration of olopatadine hydrochloride of 0.665% w/w, since 665 µg of olopatadine HCl delivered in each 100 microliter (see D20, page 3, "3. Dosage forms and strength" or page 8 "11. Description")). The Patanase® nasal spray also contains benzalkonium chloride, dibasic sodium phosphate, edetate disodium, sodium chloride, hydrochloric acid and/or sodium hydroxide to adjust pH, and purified water. The same information is provided in D31.

In view of this disclosure, the skilled person would indeed envisage to reduce the amount of olopatadine hydrochloride to an amount as in the commercial product, i.e. 0.665 wt%. This appears to be an obvious solution.

The Board however disagrees with the appellant that this obvious solution would also solve the underlying technical problem of stability. This conclusion is indeed clearly contradicted by the comparative examples of the patent, which demonstrate that a lower

concentration of olopatadine hydrochloride is not a guarantee of better stability.

6.5.3 With regard to the second distinguishing feature, the Board considers that the skilled person would neither have incorporated at least 0.5% w/w of NaCMC in an obvious manner and that an enhanced stability was not predictable from any of the common general knowledge documents D9, D10 and D34, nor would the skilled person have combined 2% Avicel as known from D4 with a further amount of NaCMC to arrive to a concentration of at least 0.5% w/w.

In the Board's view, none of documents D9, D10 or D34 provide an incentive for solving the technical problem:

(a) D9 teaches on page 7 that suspensions with Avicel RC 591 can be further stabilized using xanthan gums, CMC or hydroxypropylmethylcellulose to form long-lasting suspensions. Page 14 of D9 states that "to prevent flocculation, we recommend that a protective colloid be added immediately after dispersing Avicel. Carboxymethylcellulose and xanthan gum are the best protective colloids and should be added at 15-20% of the weight of Avicel. These colloids can also beneficially affect suspension properties".

As argued by the opposition division in its decision, the document D9 points to several solutions for obtaining stable suspension, namely the use of Avicel RC 591 as such at concentration of 1.5% w/w or 1.2% w/w (see D9, pages 8 or 7), the addition a protective colloid which can be selected from xanthan gum, NaCMC or hydroxypropylmethylcelulose (see page 7, last

paragraph), or the addition of NaCMC at preferably 15-20% based on the weight of Avicel RC 591. The skilled person has therefore the choice between different alternatives, without any direct pointer for NaCMC, even less at a concentration of at least 0.5% w/w.

Moreover, if the skilled person would have selected NaCMC among the alternatives given in D9, and combined it with Avicel RC 591 as taught, this would result in a range of total NaCMC of 0.28 % w/v to 0.47 % w/v, as calculated by the respondent. This is lower than the claimed range of NaCMC.

(b) D10 discloses on page 14, right-hand column, from point 11. to the end that "xanthan gum, CMC, guar gum" are the best protective colloids for use with colloidal Avicel, in particular Avicel RC-591, again to form long-lasting suspensions.

The same conclusion than for D9 applies with regard to the disclosure of D10. D10 teaches that several alternatives, namely xanthan gum, CMC, guar gum, are the best protective colloids for use with colloidal Avicel, in particular Avicel RC-591, without any particular pointer to NaCMC, and again even less at a concentration of at least 0.5% w/w.

(c) D34 teaches that NaCMC is conventionally used in amounts between 0.25-1% as a stabilizing and suspending agent, i.e. in amounts overlapping with that required by claim 1 of the opposed patent (see point 2.2.6 page 147).

This document is a common general knowledge document relating to celluloses and cellulose

derivatives, and discloses several alternative cellulose ethers which can be used as stabilizing agent or suspending agent, without any pointer to NaCMC in particular.

6.5.4 The use of the claimed concentration of NaCMC in the field of nasal suspensions appears furthermore to be uncommon as illustrated by the teaching of D22.

D22 relates to nasal sprays and provides in Table 2 the FDA inactive ingredient guidance limits for nasal sprays. The maximum cellulose/CMC, such as for the product Avicel, is given at 2 % w/w, and the maximum CMC-Na is given as 0.15 % w/w, which is lower than the claimed amount of NaCMC. Even if cellulose/CMC and NaCMC would be used in combination, the total amount of NaCMC would still be lower than 0.5% w/w, as calculated by the respondent. D22 teaches therefore away from the claimed solution.

6.6 Accordingly, the claimed solution is not obvious and auxiliary request 3 meets the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent in amended form on the basis of claims 1 to 14 of auxiliary request 3 filed with the reply to the statement of grounds of appeal and a description to be adapted thereto, if necessary.

The Registrar: The Chair:

B. Atienza Vivancos A. Jimenez

Decision electronically authenticated