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Datasheet for the decision of 6 May 2026

Case Number: T 0867/24 - 3.3.07

Application Number: 14181205.7

Publication Number: 2985027

IPC: A61K31/728, A61K33/14, A61K33/04, A61K45/06

Language of the proceedings: EN

Title of invention:
NASAL COMPOSITION COMPRISING MIXTURE OF HYALURONIC ACIDS AND SALINE SOLUTION

Patent Proprietor:
Church & Dwight Co., Inc.

Opponent:
Patentanwalt Dipl.-Ing. Dietze, Ingo

Headword:
Nasal composition / CHURCH & DWIGHT

Relevant legal provisions:
RPBA 2020 Art. 12(3), 12(4), 12(5)
EPC Art. 100(a), 56

Keyword:
Reply to statement of grounds of appeal - reasons set out clearly and concisely (no)
Amendment to case - admitted (no)
Inventive step - (no)

Decisions cited:
T 0321/21

Catchword:
The requirements for clarity and conciseness of Article 12(3) RPBA preclude the presentation of arguments that are either confusing or unnecessarily protracted, to the extent that potentially relevant objections or requests risk being obscured within an overabundance of extraneous or repetitive content. Clarity and conciseness in submissions are essential to ensure that all parties can effectively engage with the core issues and that the proceedings remain efficient and equitable (see points 1.1-1.3 of the reasons).

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Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 0867/24 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 6 May 2026

Appellant: (Patent Proprietor)	Church & Dwight Co., Inc. 469 North Harrison Street Princeton, NJ 08543-5297 (US)
Representative:	August Debouzy 7, rue de Téhéran 75008 Paris (FR)
Respondent: (Opponent)	Patentanwalt Dipl.-Ing. Dietze, Ingo Timmerlahstr. 103 38120 Braunschweig (DE)
Representative:	Von Rohr Patentanwälte Partnerschaft mbB Rüttenscheider Straße 62 45130 Essen (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted/electronically transmitted on 13 May 2024 revoking European patent No. 2985027 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	E. Duval
	L. Basterreix

Summary of Facts and Submissions

I. The appeal was filed by the patent proprietor (appellant) against the decision of the opposition division to revoke the patent in suit.

The decision was based on the patent as granted as the main request, on auxiliary request 1 filed on 17 August 2023, and on auxiliary requests 2-4 filed on 20 September 2023.

II. Claim 1 of the main request read as follows:

"Nasal composition comprising:
- a saline base comprising sodium chloride;
- an active agent comprising copper, a mixture of copper and manganese, manganese, a combination of manganese and a calcium salt, or sulfur;
- a mixture of a first hyaluronic acid with a second hyaluronic acid;
wherein the first hyaluronic acid has a molecular weight of at most 50 000 daltons; and
wherein the second hyaluronic acid has a molecular weight of at least 100 000 daltons and at most 500 000 daltons."

In claim 1 of auxiliary request 1, the molecular weight ranges were respectively amended to "in the range of 20 000 and 50 000 daltons" and "in the range of 100 000 and 300 000 daltons".

In auxiliary request 2, claim 1 was split into independent claims 1, 2 and 3, corresponding to the alternatives for the active agent (respectively,

"copper or a mixture of copper and manganese, as metallic salt(s)", "manganese, as metallic salt, optionally in combination with a calcium salt", and "sulfur, as salt").

In claim 1 of auxiliary request 3, the alternative "sulfur" was deleted from the list of active agents.

Auxiliary request 4 corresponded to auxiliary request 2, wherein claims 3 and 11 corresponding to the "sulfur" alternative were deleted.

III. The following documents were cited in the decision under appeal.

D2: US 2005/0164979 A1
D8: Cantone et al., "Impact of intranasal sodium hyaluronate on the short-term quality of life of patients undergoing functional endoscopic sinus surgery for chronic rhinosinusitis", International Forum of Allergy & Rhinology, Vol. 4, No. 6, June 2014, pages 484-487
D12a: Sterimar® mit Mangan
D12b: Sterimar® mit Kupfer
D12c: Sterimar® mit Schwefel
D13: WO 2006/056801 A1
D19: EP 1 407 776 A1
D21: WO 2013/006548 A2
D22: FR 2 977 494 A1
D54: Declaration of Amina Saaid

IV. The opposition division admitted D54 and auxiliary requests 1-4 into the opposition proceedings. With regard to inventive step, starting from the Sterimar® series of products of D13, the differentiating feature was primarily the addition of two fractions of

hyaluronic acid (HA). The problem to be solved was to provide a composition with improved wound healing. The addition of two distinct fractions of HA with different molecular weights (MW) was obvious for the skilled person, taking into account D22 and D8. Since the evidence on file failed to demonstrate a particular effect that was linked to the choice of the two claimed MW fractions, this choice was arbitrary and hence obvious. The same lack of inventive step applied to each of the auxiliary requests 1-4.

V. The appellant lodged an appeal against the opposition division's decision. With their statement setting out the grounds of appeal, the appellant submitted D68:

D68: Zahedi FD et al., The effect of diluted 1% baby shampoo on biofilm reduction in chronic rhinosinusitis with nasal polyposis, PeerJ 2025 13:e19134

VI. The Board set out its preliminary opinion in a communication under Article 15(1) RPBA.

VII. Oral proceedings were held before the Board.

VIII. The requests of the parties were the following:

(a) The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted, or, subsidiarily, that the patent be maintained on the basis of one of auxiliary requests 1-4 as filed in the first instance proceedings.

The appellant further requested that:
- the respondent's new objection concerning the amendment to the description,

- the respondent's objections of lack of inventive step starting from D31, D35, D36, D44a/D44b, D28 and D19, or relying on a combination of D13 with any of D46, D28, D2, D5, D10, D16, D23, D39a-e, D40a-f, D17, D32, D19, D9, D41, D37, D34, D7 and D35, or with any of D3, D4, D6, D11, D14, D18, D24, D25, D26, D27, D31, D38, D42, D43, D48, D49, D50, D51, D52 and D53, and
- the new argument under Article 123(2) EPC to the effect that the section of the original application disclosing the presence of a drug is directed to a nasal spray and not to a nasal composition,

not be admitted into the proceedings.

(b) The respondent (opponent) requested that the appeal be dismissed. The respondent further requested that D54, D68, auxiliary requests 1-4 and the appellant's new arguments and characterizations of the compositions of D54 not be admitted into the proceedings.

IX. The appellant's arguments may be summarised as follows:

(a) The respondent presented in appeal numerous inventive step attacks starting from different closest prior art documents, often without justification or proper reasoning. This approach made a substantive response impossible.

(b) D54 had been correctly admitted in the first-instance proceedings, and could not be surprising to the respondent because it was already part of the file history.

(c) The explanations submitted with the grounds of appeal, regarding the ingredients of the

compositions tested in D54, merely reflected what had already been discussed at first-instance oral proceedings. No new element was presented. These explanations were a legitimate reaction to the opposition division's misunderstandings in the appealed decision, and were to be admitted into the appeal proceedings.

(d) D68 was filed in reaction to the respondent's arguments about an alleged effect of the surfactant alkylpolyglucoside (APG).

(e) Starting from the Sterimar® nasal products shown in D13, the subject-matter of claim 1 of the main request differed by the presence of a combination of two HA, having a MW of respectively at most 50 000 Da and between 100 000 and 500 000 Da. The experimental report D54 demonstrated that using both low-MW and high-MW HA together improved the film-forming effect of the nasal composition. The data showed that neither APG nor the total HA content explained the improvement. The objective technical problem was to provide a nasal composition with an improved film-forming effect. The claimed solution was not obvious. The skilled person would not consult D22, because D22 did not relate to nasal compositions but to topical skin or ocular formulations. D8 was silent on mixtures of HA or their film-forming effects. Hence the requirement of inventive step was met.

X. The respondent's arguments may be summarised as follows:

(a) The respondent's submissions in appeal were clear, concise, structured, not excessively repetitive,

and addressed the appealed decision. During the proceedings before the opposition division, the respondent had fully maintained all written lines of attack.

(b) The unjustified late filing of D54 was a procedural abuse and had prevented the respondent from properly reacting to these experiments, thus infringing the respondent's right to be heard. Hence D54 was not to be admitted into the proceedings.

(c) The appellant's explanations of the compositions of D54 at the appeal stage constituted new facts as they were neither disclosed in D54 itself nor part of the first-instance proceedings. These new compositional details lacked proper substantiation and relevance, and were not to be admitted.

(d) D68 was filed late, i.e. only at the appeal stage, without justification as to why it could not have been filed earlier, and was irrelevant to the decisive issue. D68 should therefore not be admitted into the appeal proceedings.

(e) Starting from the Sterimar® nasal sprays of D13, the only difference was the addition of the two HA fractions. D54 failed to show any effect linked specifically to the dual-fraction HA. Any observed effects could stem from HA as such, the surfactant APG, or the increased total HA amounts. The objective technical problem was the provision of an alternative nasal composition. The claimed solution was obvious in light of D22, teaching topical compositions comprising exactly the same HA MW ranges and their effects on hydration and wound

healing. Applying this teaching to nasal mucosa was obvious for the skilled person. Furthermore, D8 showed that adding HA to saline improves healing of nasal mucosa. Hence the criteria of inventive step were not met.

Reasons for the Decision

1. Clarity and conciseness of the respondent's submissions

1.1 According to Article 12(3) RPBA, the statement of grounds of appeal and the reply shall contain a party's complete appeal case. Accordingly, they shall set out **clearly and concisely** the reasons why it is requested that the decision under appeal be reversed, amended or upheld, and should specify expressly all the requests, facts, objections, arguments and evidence relied on.

The purpose of this provision is to ensure fair proceedings for all parties and to enable the board to start working on the case on the basis of each party's complete submissions (see the Case Law of the Boards of Appeal, 11th edition, 2025, V.A.4.3.5.a).

Furthermore, as underlined in T 321/21 (see point 6.5 of the reasons), the substantiation requirement of Article 12(3) RPBA is not limited to the statement of grounds of appeal and the reply but must also be complied with for claim requests and objections filed later in the appeal proceedings. The present Board considers that, for the same reasons, the clarity and conciseness requirements of Article 12(3) RPBA also apply to submissions filed later in the appeal proceedings.

Article 12(3) RPBA requires that a party's submission be substantiated, in the sense that it must include at least the minimum level of explanation allowing the Board and the other party to understand the submission and to assess its merits without undue burden. Additionally, in the present Board's view, Article 12(3) RPBA, specifically its requirements for clarity and conciseness, also precludes the presentation of arguments that are either confusing or unnecessarily protracted, to the extent that potentially relevant objections or requests risk being obscured within an overabundance of extraneous or repetitive content. The proliferation of objections or requests not only undermines the submitting party’s own position - by diverting attention from the critical issues at stake - but also contravenes the fundamental principles of fair proceedings and procedural economy. Clarity and conciseness in submissions are essential to ensure that all parties can effectively engage with the core issues and that the proceedings remain efficient and equitable.

1.2 In the present case, the respondent's submissions fail to clearly and concisely set out the reasons for upholding the decision under appeal, for the following reasons.

1.2.1 The respondent's reply extends over 143 pages, is overly repetitive, poorly structured, and burdened with irrelevant or tangential arguments.

(a) The respondent's submissions restate at length the EPC legal standards and basic case law principles, in several instances without a clear link to the actual discussion of the case at hand, and accumulate numerous citations of Board of Appeal

decisions in an unspecific way (see for instance the general legal considerations as to novelty on pages 31-32; as to inventive step on pages 46-47; as to sufficiency of disclosure on pages 98-99, discussing even the criteria of sufficiency of disclosure at priority date, when the patent in suit does not claim any priority in the first place).

(b) Certain arguments are unnecessarily repeated in several contexts (see for instance the arguments as to breadth, undefined MW parameter and MW distribution, hyaluronic acid (HA) amounts/ratio, and types/amounts of saline base and active agent in the general preliminary remarks on pages 18-23 and in the part on insufficiency of disclosure on pages 99-106; see also the repeated criticisms against D54 in the context of procedural admissibility and substantive assessment). While the same facts and arguments may be relevant under several legal grounds, this does not justify their repetition in full. In addition, these duplicated or overlapping parts of the argumentation are further obscured by a multitude of cross-references to other parts of the submission.

(c) Objections of lack of novelty and inventive step in view of D28, D19 and D21 are unnecessarily duplicated by the citation of family members (respectively D30/D2, D1 and D5) with the same relevant content (see the novelty objections on pages 32-44).

(d) Regarding inventive step, the respondent's plethoric case includes objections combining D13 (or D12a, D12b, D12c) with any of D46, D28, D2, D5,

D10, D16, D23, D39a-e, D40a-f, D17, D32, D19, D9, D41, D37, D34, D7 and D35 (see pages 72-78 of the reply). Page 79 adds or repeats objections combining D12a, D12b, D12c, D13 or D44a/D44b with D19/D1, D21/D5, D10, D16 and D22. It is unclear whether the term "bzw. *vice versa*" on the same page 79 should imply an objection exchanging the starting point and the teaching document. Further objections are raised:
- starting from D34, D35 or D46 in combination with D7, D8, D36 and D41, or
- starting from D46, D35, D44a/D44b, D28, D19, D21, D10, D31 in combination with any of D22, D9, D16, D32, D10, D19, D21, D39a, D40a, D23 or D31 (incidentally suggesting that some of these further documents might be prejudicial to novelty, see page 81 regarding D46), or
- combining D44a/D44b with D39a/D40a, or
- taking D36 as closest prior art (without any reasoning, see (ix) on page 86), or
- citing additionally D3, D4, D6, D11, D14, D17, D18, D24, D25, D26, D27, D31, D38, D42, D43, D48, D49, D50, D51, D52, D53 as prejudicial without any proper problem-solution approach.

1.2.2 The respondent's additional submission dated 17 November 2025 of 59 pages does not address a number of points raised by the appellant in their letter dated 3 October 2025, such as the lack of publication date on D39a and D40a. Additionally, it unnecessarily repeats large parts of the argumentation submitted in the reply to the appeal.

1.3 Article 12(5) RPBA provides that the Board has discretion not to admit any part of a submission by a

party which does not meet the requirements of Article 12(3) RPBA.

In the case of (a part of) a submission which is not substantiated, in the sense that it does not provide the minimum level of explanation, the Board's discretion may be applied to that (part of the) submission (see in this respect T 321/21, point 6.6). Likewise, in the case where the submission lacks clarity and conciseness to the point that the Board and the other party or parties cannot assess its merits without undue burden, the discretionary power applies generally to all parts of the submission affected by the lack of clarity and conciseness. It is in such circumstances not for the Board or for the opposing party or parties to identify, within the host of objections raised with varying levels of substantiation, which objections are the most compelling and should be given emphasis.

The Board emphasises that the right to be heard under Article 113(1) EPC requires that those involved be given an opportunity to present comments, including the right for the opponent to present objections and have them considered. However, this right does not allow a party to present their objections or case in such a way as to make the opposing party's exercise of their own right to be heard impossible. In order to be heard, one must express oneself in a manner that is understandable so that the other party and the Board can grasp the scope of the arguments and reply to them.

1.4 In addition, under Article 12(2) RPBA, a party's appeal case shall be directed to the requests, facts, objections, arguments and evidence on which the decision under appeal was based. Under Article 12(4)

RPBA, any part of a party's appeal case which does not meet these requirements is to be regarded as an amendment, unless the party demonstrates that this part was admissibly raised and maintained in the proceedings leading to the decision under appeal. Any such amendment may be admitted only at the discretion of the Board. As explained in the Case Law of the Boards of Appeal (*ibid*, V.A.4.2.2.c).(ii)), as a general rule, the party making a submission bears the burden of showing that it was "admissibly raised and maintained".

Here, the appealed decision is limited, in respect of inventive step, to an assessment starting from D13 (or D12a, D12b or D12c). The respondent did not provide any demonstration that the remaining parts of their exceedingly extensive case were admissibly raised in the first instance proceedings.

In this respect, the respondent submitted that, during the oral proceedings before the opposition division, they had maintained their objections presented in writing (see their request for correction of the minutes dated 21 December 2023). However, this does not change the fact that the respondent failed to demonstrate that the large number of inventive step objections of their appeal case, apart from the objection starting from D13 addressed in the appealed decision, had been admissibly raised during the proceedings before the opposition division. Here also, it is not the task of the opposing party, nor of the Board, to investigate whether and when each of these numerous attacks were submitted to the opposition division. Accordingly, the discretionary power under Article 12(4) RPBA is also applicable.

1.5 The case at hand combines the above deficiencies, in that the reply to the appeal is both confusing and lacks conciseness, in that it is insufficiently substantiated in respect of a number of its objections, and in that there is no explanation as to which objections are to be considered as an amendment to the respondent's case.

1.6 For the above reasons, the Board did not admit the objections of lack of inventive step starting from any documents other than D13 (and D12a/D12b/D12c), or involving combinations with documents other than D22, D8, D19/D1, D21/D5 or D10.

2. Admittance of D54

2.1 The experimental data D54, relied on by the appellant as part of their appeal case, were admitted during the first instance proceedings and form part of the evidence on which the decision under appeal is based (see pages 7-9 of the decision). Under Article 12(2) RPBA, this document consequently forms part of the appeal proceedings. As explained in the Case Law of the Boards of Appeal (11th edition, 2025, V.A.3.4.3), there is no legal basis for excluding in appeal proceedings submissions which were admitted at first instance.

2.2 The respondent essentially expresses the view that the late filing and admission of D54 did not allow them to properly present their comment thereon, contrary to Article 113 EPC, and that this late filing was to be seen as an abuse of proceedings, considering that D54 had already been submitted during the examination proceedings. However, the respondent does not draw any conclusion from these procedural complaints other than requesting the non-admittance of D54. In the Board's

view, these alleged deficiencies do not change the conclusion that D54 belongs to the appeal proceedings for the above reasons. The Board further shares the opposition division's view that, considering that D54 was already available at examination stage, was cited in the B1 publication, and was filed on the last date set under Rule 116(1) EPC, the respondent had sufficient time to react to the filing of D54 and the arguments based thereon.

3. Admittance of the appellant's new arguments and characterizations of compositions referred to in D54

3.1 D54, submitted in the first instance proceedings on 17 August 2023, provides experimental data concerning the properties, in particular film-forming capabilities, of several inventive and comparative compositions, described as follows in D54:

"Example 1 (FF 13081.18), a formula with only one hyaluronic acid (C 13031.41), Sterimar™ Hypertonic (no hyaluronic acids), and a negative control (saline solution 0.9%)" (see point 5 of D54). Point 5 of D54 further indicates that the sole HA in C 13031.41 is a low MW HA.

According to the minutes, during the oral proceedings before the opposition division, the proprietor further stated that comparative composition C 13031.41 contained APG (alkyl polyglucoside) beside LMW hyaluronic acid (see §3.7.3).

Hence the information available in the proceedings before the opposition division on the tested compositions was the following:

- FF 13081.18 corresponds to example 1, hence it contains the Sterimar® "blocked nose" composition (i.e. the copper formulation) plus 0.1-0.3 g APG, 0.1-0.3 g LMW-HA (20-50kDa), and 0.1-0.3 g HMW-HA (100-300kDa) (see paragraphs [0059] and [0003] of the patent);
- C 13031.41 is a formula with only one hyaluronic acid and containing APG;
- Sterimar™ Hypertonic contains no hyaluronic acids; and
- the negative control is a saline solution 0.9%.

3.2 In contrast, the statement setting out the grounds of appeal contains the following additional facts (see pages 4 and 5):

The Table below shows the different compositions that have been compared in point 5 of D54:

	FF13081.18	C13031.41	Saline solution	Sterimar Hypertonic
Saline base 1	x	x		x
Saline base 2			x	
Active agent (Cu+Mn)	x	x		x
First HA (low MW[2])	x	x		
Second HA (high MW)	x			
APG[3]	x	x		

Saline base 1 comprises 75%wt of sea water and 25%wt of purified water
Saline base 2 comprises 32%wt of sea water and 68%wt of purified water.

[1] HA means hyaluronic acid
[2] MW means molecular weight
[3] APG means alkylpolyglucoside

"When present, the active agent has the same concentration in all tested compositions.
When present, the first HA has the same concentration in all tested compositions.
When present, APG has the same concentration in all tested compositions."

Thus the appellant's appeal case departs from their case in opposition and provides additional information as to the two saline bases, the presence and nature of an active agent and of a saline base in C 13031.41, and the concentrations of active agent, HA and APG in the tested compositions.

These facts were not submitted in the first instance proceedings. Contrary to the appellant's view, there is no indication in the minutes that these detailed explanations were given during the oral proceedings before the opposition division. On the contrary, according to the appealed decision, as "confirmed by the PP, comparative composition C 13031.41 differs from the composition according to example 1, FF 13081.18, by the absence of high molecular weight HA, saline and active agent (Cu)" (see §6, page 8 of the reasons, last paragraph).

The respondent argued that the above information could also be inferred from the following statement in item 5 of D54:
" When a low molecular weight hyaluronic acid is used alone (i.e., C 13031.41), the TEER at day 4 decreases significantly as compared to the use of the low molecular weight hyaluronic acid in combination with the high molecular weight hyaluronic acid, as presently claimed."
The Board does not concur. The above statement does not offer any information other than the presence in C 13031.41 of a low MW HA alone (i.e. the absence of high MW HA), and it says nothing of the remaining components or their amounts (e.g. the presence of the active agent copper, or even less copper / manganese).

3.3 The statement setting out the grounds of appeal thus provides information which differs substantially from the indications made in the proceedings before the opposition division. Accordingly, these new facts constitute an amendment to the appellant's case in the sense of Article 12(4) RPBA. The admittance of these new facts is subject to the Board's discretion. The

Board shall exercise its discretion in view of, *inter alia*, the suitability of the amendment to address the issues which led to the decision under appeal.

The Board does not consider that this additional information is suitable to address the lack of convincing comparison in D54 in respect of the differentiating feature, because it still does not allow for a meaningful comparison between a composition as claimed comprising the two HA fractions and an identical composition differing only in the presence of those two HA fractions (see the inventive step assessment below, 5.). Indeed, even taking into account this additional information, Sterimar™ Hypertonic, which is representative of the closest prior art D13, differs from the inventive composition FF 13081.18 not only by the presence of the two HA fractions but also by the presence of APG. The alleged absence of effect of APG can also still not be ascertained either, because Sterimar™ Hypertonic differs from the intermediate composition C 13031.41 not only by the presence of APG, but also by the presence of a low MW HA.

3.4 It must also be stressed that, when experimental data comparing compositions are provided, the information regarding the components and amounts in these compositions, where relevant, should be provided already with the data, so that it can immediately be ascertained whether the comparisons are meaningful. The later filing of explanations as to compositional details cannot be justified by the opposition division's logical finding that the initial data are not conclusive in proving the link between an observed effect and the distinguishing features.

3.5 Accordingly, the Board did not admit the new arguments and characterizations of compositions referred to in D54.

4. Admittance of D68

The appellant filed D68 after they had filed their grounds of appeal, namely on 3 October 2025. D68 represents an amendment to the appellant's appeal case and its admittance is subject to the provision of Articles 13(1) and 12(4) and (6) RPBA.

The appellant relies on D68 to support their argumentation that APG does not impact the film-forming effect of HA in the composition.

In the Board's view, D68 is *prima facie* not relevant, considering that it is entirely silent on APG, but only studies the effect of diluted 1% baby shampoo. D68 is not suitable to show that APG has no impact on the compositions of D54. For this reason, the Board did not admit D68 into the proceedings.

5. Main request (patent as granted), inventive step

5.1 The invention relates to nasal sprays, and seeks to improve in particular the antiviral and film-forming activities (see paragraphs [0002]-[0008]). Other properties are mentioned in the patent, such as mucocilliary clearance, phagocytic activity and elimination of allergens, and wound healing (see the examples on pages 6-9 of the patent).

Claim 1 pertains to a nasal composition comprising:
- a saline base comprising sodium chloride;

- an active agent comprising copper, a mixture of copper and manganese, manganese, a combination of manganese and a calcium salt, or sulfur;
- a mixture of a first HA with a second HA;
wherein the first HA has a molecular weight of at most 50 000 daltons; and
wherein the second HA has a molecular weight of at least 100 000 daltons and at most 500 000 daltons.

5.2 The choice of D13 as starting point for the assessment of inventive step is not debated.

D13 discloses Sterimar products including a saline base comprising sodium chloride (sea water) and an active agent comprising copper, manganese, or sulfur (see page 2). The products of D13 do not contain any HA.

5.3 The subject-matter of claim 1 differs from these known nasal compositions by the presence of a mixture of a first HA with a second HA,
wherein the first HA has a molecular weight of at most 50 000 daltons; and
wherein the second HA has a molecular weight of at least 100 000 daltons and at most 500 000 daltons.

5.4 Technical effect

5.4.1 According to the appellant, the experimental data of item 5 of D54 show that the addition of two HA having these molecular weights improves the film-forming effect of the composition, as evidenced by the higher Trans Epithelial Electric Resistance at four days (TEER D4) of the inventive composition (FF 13081.18) compared to the Sterimar™ Hypertonic composition. The problem to be solved would be the provision of a nasal composition having improved film-forming effect.

If comparative tests are chosen to demonstrate an inventive step on the basis of an improved effect over a claimed area, the nature of the comparison with the closest state of the art must be such that the alleged advantage or 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, item 5 of D54 does not meet this standard. The composition representing the claimed invention (FF 13081.18, i.e. example 1) and the composition representing the starting point (Sterimar™ Hypertonic) are only incompletely characterised as to the nature and amounts of their components and are not shown to differ only in respect of the distinguishing features, namely the two HA fractions (see 3.1 above). On the contrary, it is undebated that FF 13081.18 contains the surfactant APG whereas Sterimar™ Hypertonic does not.

5.4.2 Contrary to the appellant's view, it is not established that APG does not contribute to the film-forming properties. The alleged absence of effect of APG cannot be ascertained by a comparison of Sterimar™ Hypertonic with the intermediate composition C 13031.41, because these compositions differ not only by the presence of APG, but also by the presence of a low MW HA, and because they are not shown to be identical in all other respects. The decreased film-forming / TEER D4 property of C 13031.41 does not demonstrate the absence of positive contribution of APG, and could also be explained by a detrimental effect of the low MW HA which would exceed a positive effect of APG.

In this respect, it is established case law that, if the patent proprietor alleges the fact that the claimed

invention improves a technical effect, then the burden of proof for that fact rests upon them. The Board finds reasonable to expect that the presence of a surfactant, even a non-ionic one such as APG, may impact the film-forming capabilities of the composition. But in any case, it is for the appellant to establish that the effect on film-forming observed for the inventive composition FF 13081.18 in comparison with Sterimar™ Hypertonic finds its origin in the differentiating feature (the two HA fractions) and not in the presence of APG.

Consequently, the difference in film-forming characteristics / TEER D4 between FF 13081.18 and Sterimar™ Hypertonic could be the consequence of APG and/or the combination of the LMW HA and the HMW HA, but it cannot be convincingly ascribed specifically to the two HA fractions.

5.4.3 The same deficiency is apparent in the qualitative, clinical data of point 6 of D54, relating to the feelings of decongestion, relief of cold symptoms and free breathing among others, since these data are obtained from the same compositions as point 5, namely example 1 and Sterimar™.

5.4.4 The appellant did not rely on a technical effect on wound healing, and argued that this effect studied in point 7 of D54 was an additional effect to the film forming effect demonstrated in point 5. It is accordingly not necessary to examine whether a wound healing effect arises from the distinguishing feature.

5.5 Considering that the appellant did not convincingly demonstrate that the improvement in film-forming properties on which they rely is associated with the

differentiating feature over D13, the objective technical problem to be solved is the provision of an alternative nasal composition.

5.6 The claimed solution is obvious in light of either D22 or D8.

5.6.1 D22 relates in general to pharmaceutical, cosmetic or dermocosmetic compositions for topical administration comprising a mixture of HA 50 (i.e. having a MW in the range 20-50 kDa) and HA 300 (i.e. having a MW in the range 100-300 kDa) (see page 7, lines 1-8; page 8, lines 10-13). These bimodal mixtures of HA impart in particular wound-healing properties to the composition (see page 7, lines 9-24).

Contrary to the appellant's view, D22 and D13 are not related to different, non-overlapping technical fields. While D22 does not relate specifically to nasal compositions, it pertains to the broader field of topical compositions, which encompasses nasal application. The skilled person would thus take D22 into account when seeking alternatives to D13, and would all the more be prompted to add the two fractions of HA of D22 to the nasal composition of D13 considering the associated relevant effect of improved wound healing shown in D22.

According to the appellant, the skilled person would not have anticipated that the addition of HA to the nasal spray of D13 would be compatible with an application to the nasal mucosa because of specific issues of mucocilliary clearance. However, this alleged incompatibility is not supported by any document and is instead contradicted by D8 (see 5.6.2 below).

The claimed nasal compositions are consequently obvious starting from D13 in combination with D22.

5.6.2 Alternatively, D8 refers to the established benefits of topical application of HA to the nasal mucosa, including improved healing process (see page 485, left hand column second paragraph). While D8 does not disclose the MW ranges specified in claim 1 for the HA mixture, no effect has been demonstrated for the choice of these parameters. Accordingly, a combination of D13 with D8 also renders the claimed nasal compositions obvious.

5.6.3 The appellant refers to D2, D21 and D19 to support the argument that the skilled person wanting to provide a nasal composition will consider HA having high MW, in particular HA having MW much higher than 50 000 Da. According to the appellant, the prior art contains no teaching that a low MW HA can be used in a nasal spray.

However, these further documents are not suitable evidence of the common general knowledge and do not establish a prejudice, i.e. a widely held but incorrect opinion, against the use of the mixtures shown in D22 in nasal sprays. The documents D2, D21 and D19 do not advise against the use of low MW HA either, but are simply silent on HA other than high MW HA. Thus they do not lead to a different conclusion. In addition, if the appellant's argument that APG has no impact on film-forming properties were to be followed, this would mean that a comparison of the Sterimar™ Hypertonic and C 13031.41 composition in point 5 of D54, if otherwise identical, demonstrates that the presence of a low MW HA has a significantly detrimental effect on film-forming properties. Accordingly, the presence of a low MW HA does not establish an inventive step.

Accordingly, the subject-matter of the main request does not involve an inventive step.

6. Auxiliary requests

6.1 Admittance

Auxiliary requests 1-4, upheld by the appellant as part of their appeal case, were admitted during the first instance proceedings and form part of the requests on which the decision under appeal is based (see pages 10-12 of the decision). Under Article 12(2) RPBA, these requests consequently form part of the appeal proceedings. As explained in the Case Law of the Boards of Appeal (11th edition, 2025, V.A.3.4.3), there is no legal basis for excluding in appeal proceedings submissions which were admitted at first instance.

6.2 Auxiliary requests 1-4 introduce the following limitations:

6.2.1 In claim 1 of auxiliary request 1, the MW ranges are amended to "in the range of 20 000 and 50 000 daltons ~~of at most 50 000 daltons~~" and "in the range of 100 000 and 300 000 daltons ~~of at least 100 000 daltons and at most 500 000 daltons~~".

6.2.2 In auxiliary request 2, claim 1 is split into independent claims 1, 2 and 3, corresponding to the alternatives for the active agent (respectively, "copper or a mixture of copper and manganese, as metallic salt(s)", "manganese, as metallic salt, optionally in combination with a calcium salt", and "sulfur, as salt").

6.2.3 In claim 1 of auxiliary request 3, the alternative "sulfur" is deleted from the list of active agents.

6.2.4 Auxiliary request 4 corresponds to auxiliary request 2, wherein claims 3 and 11 corresponding to the "sulfur" alternative are deleted.

6.3 None of these amendments address the issue of lack of inventive step (see 5. above). The appellant did not contest this finding of the opposition division and provided no specific argument in favour of inventive step for the auxiliary requests.

Accordingly, none of the auxiliary requests 1-4 meet the requirement of inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated