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Datasheet for the decision of 5 June 2025

Case Number: T 2512/22 - 3.3.04

Application Number: 14773402.4

Publication Number: 2968243

IPC: A61K31/202, A61K31/232, A61K31/593, A61P27/02, A23L33/12, C07C69/587

Language of the proceedings: EN

Title of invention:
Nutritional supplement targeting meibomian glands

Patent Proprietor:
PRN Physician Recommended Nutriceuticals, LLC

Opponent:
Georgiou, Tassos

Headword:
Nutritional supplement/PRN

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - auxiliary request 2 (no) - auxiliary request 3 (yes)

Decisions cited:
T 0836/01

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Case Number: T 2512/22 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 5 June 2025

Appellant: (Opponent)	Georgiou, Tassos 48 Morfou 2417 Nicosia (CY)
Representative:	Georgiades, Yiannos G. Georgiades & Associates 2 Ayiou Pavlou & Kadmou, 3rd floor 1105 Nicosia (CY)
Respondent: (Patent Proprietor)	PRN Physician Recommended Nutriceuticals, LLC 5 Sentry Parkway East, Suite 210 Blue Bell, PA 19422 (US)
Representative:	Murgitroyd & Company 165-169 Scotland Street Glasgow G5 8PL (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 26 September 2022 concerning maintenance of the European Patent No. 2 968 243 in amended form**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	B. Rutz
	M. Blasi

Summary of Facts and Submissions

I. The appeal of the opponent (appellant) lies from the interlocutory decision of the opposition division holding that European patent No. 2 968 243 as amended in the form of auxiliary request 2 fulfilled the requirements of the EPC.

II. The patent had been opposed on the grounds of Article 100(a) EPC, in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC).

III. With regard to the patent as granted, the opposition division found that the claimed subject-matter was novel, but that the subject-matter of claim 1 lacked an inventive step over the disclosure of document D30 alone or in combination with document D1. The same considerations applied to claim 1 of auxiliary request 1.

IV. With the notice of appeal, the appellant submitted a first set of arguments with regard to a lack of inventive step of the subject-matter of claim 1 of auxiliary request 2, together with copies of various documents already on file.

V. With the statement of grounds of appeal, the appellant submitted a second set of arguments with regard to a lack of inventive step of the subject-matter of claim 1 of auxiliary request 2, together with copies of four decisions of the EPO boards of appeal. These however, were not required for the board to reach its decision and were therefore not considered any further.

VI. With the reply to the appellant's statement of grounds of appeal, the patent proprietor (respondent) defended the amended version of the patent as considered allowable by the opposition division (auxiliary request 2) and filed a set of claims of a new auxiliary request, auxiliary request 3, as well as documents D36 and D37.

VII. The board summoned the parties to oral proceedings as requested, and informed them of its preliminary opinion in a communication under Article 15(1) RPBA.

VIII. In this communication, the board indicated that it was of the preliminarily opinion that the subject-matter of claim 1 of auxiliary request 2 did lack an inventive step within the meaning of Article 56 EPC. Furthermore, it was inclined to admit auxiliary request 3, which it considered to comply with the requirements of Articles 123(2) and 56 EPC.

IX. In a letter dated 22 May 2025, the appellant reiterated his inventive-step objections with respect to the subject-matter of auxiliary request 2 and set out his objections against claim 1 of auxiliary request 3 under Articles 123(2) and 56 EPC.

X. Claim 1 of auxiliary request 2 reads as follows:

"1. Supplementation comprising omega-3 fatty acids in the re-esterified triglyceride form for use in the treatment of dry eye, posterior blepharitis and meibomianitis in a patient by improving the quality of the meibum composition of inflamed or dysfunctional meibomian glands in the patient by oral administration of the omega-3 fatty acids in an effective amount between 2000 mg and 3000 mg delivered on a daily dosage

basis so as to facilitate an increase in levels of anti-inflammatory omega-3s in the meibum composition, a decrease in levels of inflammatory omega-6s in the meibum composition, an increase in tear break up time in the patient and a reduction in tear osmolarity of the patient, wherein said effective amount includes eicosapentaenoic acid (EPA) in an amount greater than 600 mg and docosahexaenoic acid (DHA) in an amount greater than 500 mg."

Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 2 in that the following wording has been added at the end:

"... wherein said administration on a daily dosage basis includes vitamin D in an amount between about 500 IU and 2000 IU."

XI. At the end of the oral proceedings, the chairwoman announced the board's decision.

XII. The following documents are referred to in this decision:

D1 A. Nodoy et al., "Absorption of the n-3 eicosapentaenoic and docosahexaenoic acids as ethyl esters and triglycerides by humans", American Journal of Clinical Nutrition 53, 1991, 1 185-1 190

D10 Exhibit E, filed by the respondent during the opposition proceedings

D30 EP 2 755 647 B1

D36 M. A. Lemp et al., "The Definition and Classification of Dry Eye Disease: Report of the Definition and Classification Subcommittee of the International Dry Eye Workshop (2007)", THE OCULAR SURFACE 5(2), 2007, 75-92

XIII. The appellant's submissions, where relevant, are summarised as follows.

Auxiliary request 2
Inventive step (Article 56 EPC) - claim 1

The use of omega-3 fatty acids in ester form was obvious. The method of treatment was also obvious. The narrowed dosage range lacked an inventive step. The treatment of dry eyes was disclosed and explained in the prior art. The subject-matter of auxiliary request 2 could not be considered to represent a new clinical situation.

Auxiliary request 3
Admittance of objections with regard to added subject-matter and inventive step (Article 13(2) RPBA)

Having previously been under the impression that any issues, including new ones, could only be raised on the day of the oral proceedings, the appellant had then realised upon receipt of the communication under Article 15(1) RPBA that he could make written submissions and therefore did so in his letter dated 22 May 2025. The fact that the board had not admitted his submissions on substance led to an unfair result, because the scope of the claims of auxiliary request 3 were too broad, and to the creation of conflicting case law on Article 123(2) EPC.

XIV. The respondent's submissions, where relevant, are summarised as follows.

Auxiliary request 2
Inventive step (Article 56 EPC) - claim 1

The claim differed from the disclosure of document D30 at least in the following features:
i. oral administration of omega-3 fatty acids in the re-esterified triglyceride form
ii. use of the supplementation in the treatment of dry eye, posterior blepharitis and meibomianitis in a patient by improving the quality of the meibum composition of inflamed or dysfunctional meibomian glands in the patient

A further difference could be seen in the required amounts of EPA and DHA.

The application as filed disclosed that the claimed compositions were particularly useful for treating evaporative dry-eye disease, which was primarily caused by disruption to the meibum composition.

The new clinical situation was the treatment of dry eye, posterior blepharitis and meibomianitis in a patient with inflamed or dysfunctional meibomian glands.

The skilled person starting from document D30 would not have been aware that using the re-esterified triglyceride form of omega-3 for the treatment of dry eye, posterior blepharitis and meibomianitis would prove effective at improving the quality of the meibum in patients with inflamed or dysfunctional meibomian

glands. There was no other document on file that would have led the skilled person to this solution.

Evaporative dry-eye diseases were not mentioned in document D30. The dry-eye diseases referred to in D30 were aqueous tear-deficient dry-eye diseases which resulted in insufficient tear production. Document D30 did not reference meibum or its function in retaining moisture on the surface of the eye. Document D30 did not discuss the proinflammatory actions of omega-6 in the meibum or suggest any method of reducing the concentration of this so as to improve the tear composition on the surface of the eye. Document D30 was thus not suitable for treating dry-eye diseases caused by dysfunctional or inflamed meibomian glands.

Auxiliary request 3
Inventive step (Article 56 EPC)

Compositions including the claimed amount of vitamin D showed advantageous effects. Document D30 did not reference a supplementation with vitamin D; instead it taught away from including vitamins in an omega-3 supplementation.

XV. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed, i.e. that the patent be maintained as amended in the form of auxiliary request 2 considered allowable by the opposition division. Alternatively, the respondent requested that the patent be maintained in amended form based on the set of claims of auxiliary request 3 as filed with the reply to the statement of grounds of appeal.

Reasons for the Decision

Admission of document D10 (Article 13(2) RPBA)

1. During the oral proceedings, the respondent referred to document D10, with the intention of relying on its content in the context of inventive step. The document was considered in the decision under appeal and found not to show that the observed effect was attributable to the esterification status (see point 17.2.8.2 of the decision). The respondent chose not to cite document D10 when replying to the appeal. Document D10 and the line of argument relating thereto therefore represent an amendment to the respondent's appeal case which occurred after notification of a communication by the board under Article 15(1) RPBA. The admittance thereof was thus governed by the provisions of Article 13(2) RPBA. The respondent did not refer to any exceptional circumstances which could have justified the amendment to its appeal case. The board therefore decided not to admit document D10 or the line of argument relating thereto into the appeal proceedings pursuant to Article 13(2) RPBA.

Auxiliary request 2 (amended version of the patent held allowable in the decision under appeal)
Summary of technical background as apparent from the patent

2. Dry eye is a condition in which there are insufficient tears to lubricate and nourish the eye. Tears are produced by several glands in and around the eyelids. When the normal amount of tear production decreases or tears evaporate too quickly from the corneal surface, symptoms of dry eye can develop.

3. Tears are made up of oil, water and mucus. A smooth oil layer helps to prevent evaporation of the water layer, while the mucin layer functions in spreading the tears evenly over the surface of the eye. If the tears evaporate too quickly or do not spread evenly over the cornea as a result of deficiencies with any of the three tear layers, symptoms of dry eye or posterior blepharitis may ensue.

4. Along the margin of the eyelids are a series of small sebaceous glands called meibomian glands. The meibomian glands create and distribute a supply of meibum, an oily substance, that makes up the lipid layer of the tear. The supply of meibum functions to help keep the eye moist and tends to protect the tear film from evaporation. Meibomianitis refers to inflammation or dysfunction of the meibomian glands, which is also referred to in the art as meibomian gland dysfunction.

Claim interpretation - claim 1

5. The claim is formulated as a purpose-limited product claim according to Article 54(5) EPC. The medical use stated in the claim is "*the treatment of dry eye, posterior blepharitis and meibomianitis in a patient*".

6. The claim contains two dosage requirements:
   (a) "*by oral administration of the omega-3 fatty acids in an effective amount between 2000 mg and 3000 mg delivered on a daily dosage basis*"
   (b) "*wherein said effective amount includes eicosapentaenoic acid (ERA) in an amount greater than 600 mg and docosahexaenoic acid (DHA) in an amount greater than 500 mg*".

   The meaning of these dosages was not disputed by the parties.

7. In addition to the treatment of dry eye, posterior blepharitis and meibomianitis, the claim contains two further functional features:

(c) "*by improving the quality of the meibum composition of inflamed or dysfunctional meibomian glands in the patient*"

(d) "*so as to facilitate an increase in levels of anti-inflammatory omega-3s in the meibum composition, a decrease in levels of inflammatory omega-6s in the meibum composition, an increase in tear break up time in the patient and a reduction in tear osmolarity of the patient*"

The meaning of these functional features was under dispute and will be addressed in the following.

(c) "by improving the quality of the meibum composition of inflamed or dysfunctional meibomian glands in the patient"

8. The respondent argued that feature (c) defined a new clinical situation and a new patient group, namely the treatment of patients with a poor-quality meibum composition due to inflamed or dysfunctional meibomian glands (see also the reply to the appeal, point 3.5). It had been indicated in the patent (and in the application as filed) that this condition leads to an abnormally rapid evaporation of tears (see the patent, paragraphs [0006] to [0008]), and was commonly known as evaporative dry-eye disease (EDE), in contrast to aqueous tear-deficient dry-eye disease (ADDE) (see document D36, Figure 1).

9. The board finds that neither EDE nor ADDE are explicitly mentioned in the patent, let alone in the claim. Evaporation is, however, referred to in the patent as one of the causes of dry eye (see, for

example, paragraphs [0003] to [0005], and [0007] and [0008]). Measurements for tear evaporation include tear break-up time and osmolarity, as confirmed by the respondent's expert Mr Gross during the oral proceedings before the opposition division (see the minutes, point 38). It thus has to be assessed whether or not feature (c), and possibly also feature (d), implicitly establish a new clinical situation or sub-group of patients to be treated.

10. The case law of the boards of appeal is consistent in that a new clinical situation has to bring about a new technical effect (see Case Law of the Boards of Appeal of the EPO, 10th edition, 2022, I.C.7.2.4.c).

11. The board does not recognise such a new technical effect in the case at hand. Rather, the treatment of a known disease, dry eye, is achieved with a known composition, EPA and DHA, with a known dosage regime. The effects resulting from the treatment, i.e. an improved tear break-up time and reduced tear osmolarity, were known in the art as being indicative of the treatment of dry eye (see document D30, paragraphs [0012] and [0250]; Table 41: "*TFBUT:fluorescein tear break-up time*").

12. The contribution provided by the patent application could be seen as being the measurement of omega-3 and omega-6 fatty acids in the meibum of treated patients and the recognition that this might contribute to the therapeutic effect. However, merely providing a mechanism by which the supplementation achieves treatment of the listed diseases, i.e. dry eye, posterior blepharitis and meibomianitis, does not limit the treatment to a specific sub-group of patients. In other words, the claim does not require patients to be

tested for their meibum composition or for having inflamed or dysfunctional meibomian glands, as argued by the respondent (see the reply to the appeal, point 3.5). The meibum composition is not defined in the claim either, and therefore a stratification of patients according to this parameter, even if desired, would not be possible. All that is required by the claim is that the quality of the meibum composition can be improved in inflamed or dysfunctional glands. In other words, patients having these conditions would particularly benefit, but are not the only patients who can be treated according to the claim. Moreover, prior-art document D30 already mentions "[M]*eibomian gland disease*" (MGD) as being characteristic of the more severe stages of dry eye (see Table 41 and paragraph [0252]: "*The patients had most of the symptoms and signs of severity score 3 and 4 (moderate to severe dry eyes)*") and reports an improvement in tear break-up time.

13. The respondent also referred to decision T 836/01 and argued that as the underlying case was similar to the current case the same findings should apply.

14. The board does not agree, because a new clinical situation to be taken into account for novelty or inventive step has to be reflected in the claims and not just in certain parts of the description. In the case underlying decision T 836/01, the claims defined a new clinical situation by requiring that the medicament was "*for influencing tumor cell growth and differentiation*" or "*for influencing terminal differentiation of cancer cells*", i.e. the claims prescribed a clinical situation in which the medicament was to be used. This clinical situation was different from that disclosed in the prior art, which was for

"*activating mature lymphoid cells exerting cytolytic T cell activity on cancer cells*" or "*to stimulate the immune system of patients undergoing (cancer) radio- or chemotherapy*", i.e. indirect effects working through the intermediary of immune cells (see points 7. and 10. of the Reasons for the decision).

15. This is different from the present claim, which prescribes use for the treatment of dry eye, posterior blepharitis and meibomian gland dysfunction, which are all synonymous diseases according to the patent (see paragraph [0012]) and which have been treated in the prior art with a composition similar to the one claimed (see document D30, paragraphs [0250] to [0252]). The effects in case T 836/01 "*for influencing tumor cell growth and differentiation*" or "*for influencing terminal differentiation of cancer cells*" can be seen to be similar to the "*increase in tear break up time in the patient and a reduction in tear osmolarity of the patient*" in the present case. However, these effects, in contrast to the case underlying decision T 836/01, were already known from the prior art (see document D30, paragraphs [0012] and [0250]). Moreover, as set out in point 9. above, the claim does not require that a certain patient group is selected. This distinguishes the present case from the situation in decision T 836/01, where the claimed invention addressed a different cell type from the prior art, namely cancer or tumour cells, and could thus at least potentially lead to the treatment of a different (sub-)group of patients.

16. The board therefore concludes that feature (c) does not establish a new clinical situation or a new patient group.

(d) "so as to facilitate an increase in levels of anti-inflammatory omega-3s in the meibum composition, a decrease in levels of inflammatory omega-6s in the meibum composition, an increase in tear break up time in the patient and a reduction in tear osmolarity of the patient"

17. Feature (d) can be divided into two parts: (i) the (facilitated) change of meibum composition and (ii) the (facilitated) improvement of symptoms of dry eye. As set out in point 12. above, the changed meibum composition provides a mechanistic explanation for the improved tear break-up time and osmolarity, which according to the patent underlies the treatment achieved by the supplementation (see Tables 7 and 8; paragraphs [0057] to [0059], and paragraphs [0064] to [0066]). However, the mere explanation of an effect, in this case an improved tear break-up time and reduced osmolarity (feature (ii)), obtained when using a compound in a known composition, even if the explanation relates to a pharmaceutical effect which was not known to be due to that compound in the known composition, cannot confer novelty onto a known use in a method if the skilled person was already aware of the occurrence of the desired effect when applying the known use (see Case Law of the Boards of Appeal of the EPO, I.C.7.2.4.i)) unless the discovery of this mechanism leads to a new clinical situation (see Case Law of the Boards of Appeal of the EPO, I.C.7.2.4.). As set out in points 8. to 16. above, this is not the case here.

18. In conclusion, the features "*by improving the quality of the meibum composition of inflamed or dysfunctional meibomian glands in the patient*" and "*so as to facilitate an increase in levels of anti-inflammatory omega-3s in the meibum composition, a decrease in*

levels of inflammatory omega-6s in the meibum composition, an increase in tear break up time in the patient and a reduction in tear osmolarity of the patient" do not limit the purpose of the claimed product beyond use in the treatment of dry eye, posterior blepharitis and meibomianitis in a patient.

Inventive step (Article 56 EPC) - claim 1
Closest prior art, difference(s)

19. The decision under appeal assessed inventive step starting from document D30, which had been cited by both parties as the closest prior art. Document D30 discloses that esters of eicosapentaenoic acid (EPA) and of docosahexaenoic acid (DHA) can be used to treat dry eyes with a combined oral dosage of EPA and DHA of 5 mmol to 25 mmol per day, and wherein the molar ratio of EPA to DHA is in the range of 1:1 to 5:1 (see, for example, claims 1, 14 and 15). The appellant's calculation that the dosages cited in document D30 amount to approximately 1 500 mg to 7 500 mg per day has not been contested by the respondent. Document D30 does not disclose the ester form in which EPA and DHA are present in the preferred composition Omega 3RX® (Enerzona) as used in the examples, but refers in other parts of the description to the ethyl ester form as a preferred embodiment (see paragraphs [0028] and [0057].

Amount of EPA and DHA

20. The respondent was of the opinion that "*eicosapentaenoic acid (EPA) in an amount greater than 600 mg and docosahexaenoic acid (DHA) in an amount greater than 500 mg*" constituted a further difference (see point 2.46 of the reply to the appeal). However, in the absence of substantiated arguments from the

respondent to the contrary, the board agrees with the opposition division that this does not in fact constitute a difference over the closest prior art (see point 17.2.3 in the decision under appeal) because these ranges are covered by the range of approximately 1 500 mg to 7 500 mg per day when split between EPA and DHA in a 1:1 ratio, as disclosed in document D30 (see, for example, claim 1 thereof). This is also apparent from Table 3 of document D30, which shows that 100 g Omega 3RX® contains 40 g EPA and 20 g DHA. A daily dose of 5 to 10 ml of this composition thus corresponds to ranges of approximately 2 000 mg to 4 000 mg EPA and 1 000 to 2 000 mg DHA, which fall within the claimed range.

Achieving a therapeutic effect

21. The respondent referred to document D30, which stated in paragraph [0251] that "*patients had been treated for long periods of time with most of the current therapies available in the market such as steroid eye drops, artificial tear drops and ointments, Restasis® eye drops, punctual plugs, other omega 3 supplements etc. with no relief of their symptoms*". Document D30 thus disclosed that not all omega-3 supplements could cure all types of dry-eye disease.

22. The board interprets this argument as implying that the composition disclosed in document D30 would not achieve the therapeutic effect of "*treatment of dry eye, posterior blepharitis and meibomianitis in a patient*" as required by the claim.

23. The board cannot follow this reasoning. Document D30 describes that after one month of treatment with the composition used in the examples (Omega 3RX®),

improvements of between 70% and 90% of the superficial punctate keratitis and tear break-up time were achieved. Thus, document D30 makes it credible that Omega 3RX®, i.e. a composition comprising mainly omega-3 fatty acids in the form of EPA and DHA, presumably esterified, is suitable for treating dry eye (see paragraphs [0071] and [0250] to [0252], and Table 41).

24. The respondent has not provided any counter-evidence that a therapeutic effect on dry eye could not be achieved with the composition of document D30.

25. Achieving a therapeutic effect therefore does not constitute a difference over the disclosure of document D30.

Re-esterified triglycerides

26. The parties agreed that one difference over the disclosure of document D30 lies in the triglycerides being re-esterified.

Technical effect and objective technical problem

27. The subject-matter of claim 1 thus differs from the disclosure of document D30 only in that re-esterified triglycerides of EPA and of DHA are used in the treatment of dry eye. This ester form specified in the claim has not been shown to achieve an effect different from that of the esters disclosed in document D30, e.g. ethyl ester (see also points 17.2.4.2 and 17.2.8 of the decision under appeal) or the specific composition Omega 3RX® disclosed therein (see Table 4).

Objective technical problem

28. The objective technical problem is thus formulated as the provision of an alternative composition for use in a method of treating dry eye.

Obviousness

29. The solution to this problem is obvious over the disclosure of document D30 because it would have been a routine activity for the skilled person to replace the ethyl ester form of EPA and DHA disclosed therein with the triglyceride form, which was a commonly known alternative for providing fatty acids (see, for example, document D1, page 1 185, Introduction). Document D1 further shows that EPA and DHA can be used either as ethyl esters or as triglycerides, without concern about their absorbability (see page 1 189, right-hand column, last paragraph).

30. The subject-matter of claim 1 of auxiliary request 2 does not involve an inventive step within the meaning of Article 56 EPC.

Auxiliary request 3
Admission of objection under Article 123(2) EPC
(Article 13(2) RPBA)

31. The feature "*wherein said administration on a daily dosage basis includes vitamin D in an amount between about 500 IU and 2000 IU*" in combination with the feature "*use in the treatment of dry eye, posterior blepharitis and meibomianitis in a patient*" was already present in claim 14 as granted in combination with claim 10 as granted, to which claim 14 refers. The ground of added subject-matter (Article 100(c) EPC)

was, however, not invoked in the notice of opposition or later during the opposition proceedings. Moreover, the issue of added subject-matter was only raised in the appellant's letter dated 22 May 2025, i.e. about two years after the respondent's reply to the appeal and only after notification of a communication under Article 15(1) RPBA by the board. The objection thus represented an amendment of the appellant's appeal case and its admittance is thus governed by the provisions of Article 13(2) RPBA. The appellant did not refer to any exceptional circumstances which could have justified the amendment. The board therefore decided not to admit the objection or the line of argument associated with it into the appeal proceedings pursuant to Article 13(2) RPBA.

Amendments (Article 123(2) EPC)

32. Nevertheless, in view of Article 101(3)(a) EPC, compliance with Article 123(2) EPC has to be assessed. Instead of remitting the case to the opposition division for further prosecution, the board considered it appropriate to examine whether the amendments in auxiliary request 3 have a basis in the application as filed (Article 111(1) EPC and Article 11 RPBA). In its reply to the appeal, the respondent referred in this regard to "*claim 5 of the AR2 claims, paragraphs [0012] and [0022], and examples 7, 9 and 11 to 13 of the Patent*" (point 4.2). While amended claims and the patent as granted cannot provide a basis for amendments within the meaning of Article 123(2) EPC, since the basis has to be found in the application as filed, the corresponding passages can, however, be easily identified in the application as filed, i.e. claims 13 and 20 as filed; page 6, lines 3 to 6; page 8, lines 23 to 25; and Examples VIII to XIII. The board finds that,

in particular, page 6, lines 3 to 6, and page 8, lines 23 to 25, of the application as filed provide a basis for the amendment. The board is thus satisfied that the requirements of Article 123(2) EPC are fulfilled.

Admission of objection under Article 56 EPC (Article 13(2) RPBA)

33. The appellant did not react to the respondent's reply to the statement of grounds of appeal dated 31 May 2023, with which auxiliary request 3 was re-filed, until his letter dated 22 May 2025, i.e. about two years later and only after notification of a communication under Article 15(1) RPBA by the board. In this letter, inventive-step objections were raised against the subject-matter of claim 1 of auxiliary request 3. A further line of argument was provided by the appellant during the oral proceedings, referring to a document relating to Sjögren's syndrome, which, however, was not filed in any form. The objection under Article 56 EPC against the claim of auxiliary request 3 represents an amendment of the appellant's appeal case, and its admittance is thus governed by the provisions of Article 13(2) RPBA. The appellant did not refer to any exceptional circumstances which could have justified the amendment. The board therefore decided not to admit the objection or the line of argument associated with it into the appeal proceedings.

Inventive step (Article 56 EPC)

34. The additional feature "*wherein said administration on a daily dosage basis includes vitamin D in an amount between about 500 IU and 2000 IU*" further distinguishes the claimed subject-matter from the disclosure of

document D30, which does not contain a reference to vitamin D and, according to the respondent, was associated with advantageous effects which could not be expected from the prior art (see the respondent's reply to the appeal, points 4.4 and 4.5.). In the absence of counter-evidence from the appellant, the technical effect can be acknowledged. The problem can therefore be formulated as the provision of an improved supplementation for treating dry eye. There was no indication or motivation in the disclosure of document D30 to add vitamin D to the composition. The board does not consider the presence of the indicated daily dosage of vitamin D in the supplementation to be obvious within the meaning of Article 56 EPC.

35. No further objections against auxiliary request 3 have been raised by the appellant.

36. The board considers auxiliary request 3 to be allowable.

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, with claims 1 to 5 of auxiliary request 3 filed with the reply to the statement of grounds of appeal, and a description to be possibly adapted thereto.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated