

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 21 November 2024**

Case Number: T 0670/22 - 3.3.04

Application Number: 14708015.4

Publication Number: 2964215

IPC: A61K31/20, A61K31/201,
A61K31/202, A61P29/00,
A61P17/00, A61P25/00,
A61P19/00, A61P27/00,
A61K45/06, A61K9/14

Language of the proceedings: EN

Title of invention:

Mixture of fatty acids for use in the treatment of
inflammatory pathologies

Patent Proprietor:

Again Life Italia Srl

Opponent:

N.V. Nutricia

Relevant legal provisions:

RPBA 2020 Art. 13(2)

EPC Art. 123(2), 83, 54, 56

Keyword:

Amendment after notification of Art. 15(1) RPBA communication
(yes)

Amendments - added subject-matter (no)

Sufficiency of disclosure - (yes)

Novelty - (yes)

Inventive step - non-obvious alternative



Beschwerdekammern
Boards of Appeal
Chambres de recours

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

Case Number: T 0670/22 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 21 November 2024

Appellant:

(Opponent)

N.V. Nutricia
Eerste Stationsstraat 186
2712 HM Zoetermeer (NL)

Representative:

Wohlfahrt, Jan Günther
Gleiss Große Schrell und Partner mbB
Patentanwälte Rechtsanwälte
Leitzstraße 45
70469 Stuttgart (DE)

Respondent:

(Patent Proprietor)

Again Life Italia Srl
Via Lago D'Orta 1
Palazzo Work
36015 Schio (VI) (IT)

Representative:

Dragotti & Associati S.R.L.
Via Nino Bixio, 7
20129 Milano (IT)

Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
8 February 2022 concerning maintenance of the
European Patent No. 2964215 in amended form.**

Composition of the Board:

Chairwoman M. Pregetter
Members: R. Hauss
R. Romandini

Summary of Facts and Submissions

- I. European patent No. 2 964 215 (patent in suit) was granted with a set of six claims.
- II. The patent in suit was opposed under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed.
- III. The patent proprietor requested that the opposition be rejected (main request) and submitted a number of amended sets of claims as auxiliary requests.
- IV. The documents cited in the proceedings before the opposition division included the following:
 - D2: WO 2009/131939 A2
 - D3: WO 2010/049954 A1
 - D4: US 2010/0113387 A1
 - D5: WO 2010/118761 A1
 - D6: C. Remacle, B. Reusens (ed.), "Functional Foods, Ageing and Degenerative Disease" (2004), ISBN: 9781855737259, pages 359, 364, 373, 382
 - D10: G. Lambertsen, O.R. Brækkan, "The Fatty Acid Composition of Cod Liver Oil", 1-14, Fiskeridirektøren, Bergen (1965)
 - D19: H.J. Spoor, "External Cod Liver Oil Therapy in Infantile and Atopic Eczema", New York State J. Med., 2863-2868 (1960)

- D21: R. Migliaccio, "Clinical study to evaluate the efficacy of two products in cream, one with 2 Fatty Acids (linoleic acid and alpha linolenic acid) and the second with 9 Fatty Acids (palmitic acid, oleic acid, linoleic acid, alpha linolenic acid, gamma linolenic, stearic acid, myristic acid, EPA, DHA) in patients with atopic dermatitis"
- D22: Declaration R. Migliaccio (10 September 2021)
- D23: R. Migliaccio, "Study for the evaluation of the activity and efficacy of a topical product based on nine fatty acids, FAG, in controlling the symptoms of xerophthalmia related to Sjogren's syndrome"

V. The decision under appeal is the opposition division's interlocutory decision, announced on 24 November 2021 and posted on 8 February 2022. The decision found that the patent as amended in the form of auxiliary request 1 met the requirements of the EPC. Claim 1 of the request held allowable by the opposition division reads as follows:

1. Mixture of at least nine fatty acids, selected from palmitic acid, oleic acid, stearic acid, linoleic acid, alpha-linolenic acid, and gamma-linolenic acid, eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), azelaic acid and myristic acid for use in the treatment and/or prevention of inflammatory pathologies selected from atopic dermatitis, dermatomyositis, scleroderma, psoriasis, polymyositis, pemphigus, pemphigoid epidermolysis bullosa, and ophthalmic [sic] pathologies selected from Sjogren's syndrome, sympathetic ophthalmia, uveitis, and uveo-retinitis.

VI. The decision under appeal found the following.

- (a) Documents D21 and D22 were admitted.
- (b) The main request was not allowable.
- (c) Claim 1 of auxiliary request 1 met the requirements of Article 123(2) and (3) EPC.
- (d) The subject-matter of claim 1 met the requirement of sufficiency of disclosure (Article 83 EPC). The claimed mixture's therapeutic efficacy was backed up by the experimental data provided in the opposed patent and the additional experimental data provided by the patent proprietor in documents D21 to D23. The subject-matter of dependent claims 4 and 5 was also sufficiently disclosed.
- (e) The subject-matter of claim 1 of auxiliary request 1 was novel over the disclosure of documents D2, D3, D5, D6 and D19. None of these citations disclosed a fatty acid mixture that consisted of either nine or ten fatty acids of the list of ten fatty acids recited in the claim.
- (f) Inventive step was assessed starting from the disclosure of document D19, which described the use of cod liver oil in the treatment of infantile and atopic eczema. As shown in document D10, cod liver oil contained nine of the fatty acids listed in claim 1. The objective technical problem was the provision of an alternative composition for use in the treatment of the inflammatory pathologies according to claim 1. The cited prior art did not point to a composition as defined in claim 1 of auxiliary request 1 for solving this problem.

- VII. The opponent (appellant) filed an appeal against this decision. In its statement setting out the grounds of appeal, the appellant proposed document D19 and, alternatively, document D4 as possible starting points for the assessment of inventive step.
- VIII. With its reply to the appeal, the patent proprietor (respondent) requested, as its main request, that the appeal be dismissed. Furthermore, it filed amended sets of claims as auxiliary requests 1 to 17. It also submitted additional documents, numbered D25 to D28, in support of its reasoning on inventive step. With a later submission, the respondent withdrew auxiliary requests 2, 3, 8 and 13.
- IX. In a communication under Article 15(1) RPBA issued in preparation for oral proceedings and advising the parties of its preliminary opinion, the board drew attention to the following points.
- (a) The term "mixture of at least nine fatty acids", in combination with the requirement that these were to be selected from a specified list of ten compounds, was understood to mean that the mixture in question consisted of either nine or all ten of the listed compounds (see section 1 of the board's communication).
 - (b) The board was of the preliminary view that claim 1 of the main request did not include added subject-matter (see section 2 of the board's communication).
 - (c) However, the board was not convinced that the evidence in the application as filed would have rendered the claimed therapeutic use credible at the relevant date for all the pathologies mentioned

in claim 1 of the main request (see point 4.3 of the board's communication; for the wording of the claim in question, see point V. above).

- (d) Irrespective of any doubt that the appellant's objections for lack of novelty had been adequately substantiated, the claimed subject-matter was in any case novel over the disclosure of documents D2, D3, D5, D6 and D19 (see section 5 of the board's communication).
- (e) Starting from the technical teaching of document D19, the claimed subject-matter also involved an inventive step (see section 6 of the board's communication).
- (f) In view of the evidence on file, it could not be confirmed that the appellant in the proceedings before the opposition division had maintained the line of argument that considered inventive step starting from the disclosure of document D4. Reference was made to the provisions of Article 12(4) and (6) RPBA (see section 6 of the board's communication).
- (g) The board pointed out that the chemical difference between fatty acids and fatty acid glycerides must be taken into account when comparing the claimed subject-matter to prior-art disclosures of oils and lipids, such as, for instance, found in D19 (see the board's communication, points 5.4, 5.6 and 6.3).

X. By letter dated 5 November 2024, the respondent filed three further sets of claims as auxiliary requests 18, 19 and 20. Independent claim 1 and dependent claims 2, 3 and 5 of auxiliary request 18 read as follows:

1. Mixture of at least nine fatty acids, selected from palmitic acid, oleic acid, stearic acid, linoleic acid, alpha-linolenic acid, and gamma-linolenic acid, eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), azelaic acid and myristic acid for use in the treatment and/or prevention of atopic dermatitis.

2. Mixture for use according to claim 1, characterized in that it comprises ten fatty acids.

3. Mixture for use according to any one of the previous claims, characterised in that it comprises nine fatty acids, selected from palmitic acid, oleic acid, stearic acid, linoleic acid, alpha-linolenic acid, and gamma-linolenic acid, eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and azelaic acid.

5. A mixture for use according to any one of the previous claims, characterised in that said mixture is administered daily, within a range of one to four doses a day, preferably said dose contains from 0.1 to 50 mg of composition/kg of the patient's bodyweight, and more preferably from 0.5 to 20 mg/kg of the patient's bodyweight.

XI. Oral proceedings before the board took place on 21 November 2024. At the oral proceedings, the patent proprietor withdrew its main request and all remaining auxiliary requests except auxiliary requests 18, 19

and 20. The board admitted auxiliary request 18 and found it allowable.

XIII. The appellant's arguments on auxiliary request 18 may be summarised as follows.

Admittance of auxiliary request 18

By restricting the therapeutic indications to the only pathology backed up by the experimental data in the application as filed, auxiliary request 18 addressed an objection that had been part of the debate before the department of first instance and that had also been maintained and pursued by the appellant in its grounds of appeal. Hence, this request should have been presented at an earlier stage of the proceedings. Its filing could not be regarded as having been occasioned by a new objection raised by the board.

Claim construction

An oil was a product according to claim 1. The expression "a mixture of" employed in claim 1 of auxiliary request 18 did not rule out the presence of further components in the mixture other than the ten fatty acids listed in the claim. The same interpretation applied to claim 1 as filed.

Amendments

The definition of the mixture of fatty acids in claim 1 of auxiliary request 18 did not find a basis in the application as filed, specifically in claim 2 as filed. In addition, the restriction to atopic dermatitis as the only pathology involved a further selection within the disclosure of the application as filed.

Sufficiency of disclosure

For a medical-use claim to fulfil the requirement of sufficiency of disclosure, it should be credible on the basis of the information in the application as filed, in light of common general knowledge at the effective date, that the claimed therapeutic efficacy was achieved by the claimed product.

The appellant conceded that the *in vivo* data in Study 3 (application as filed) showed favourable results for the tested mixture's efficacy against atopic dermatitis.

However, only one mixture (that according to Example 9) had been tested. This mixture did not contain myristic acid. The opposition division had been wrong in asserting that myristic acid was disclosed in the application as filed as an equally active component of the fatty acid mixture (see the decision under appeal, Reasons 8.2). Since the application as filed did not provide any evidence of the therapeutic efficacy of myristic acid, post-filed evidence such as D21, which provided data obtained with a mixture that included myristic acid, could not be taken into account.

Furthermore, claim 1 did not indicate dosages or amounts of the fatty acids. The concentration ranges indicated in the description and in claim 4 were rather broad and could not provide the necessary guidance.

Dependent claim 5 related to a composition in which the fatty acids were diluted further. This meant that therapeutic efficacy could not be achieved over the entire scope of possible compositions.

Novelty

In its written appeal submissions, the appellant had argued that the disclosure of documents D2, D3, D5, D6 and D19 anticipated the subject-matter of claim 1 of the main request. This objection also applied to claim 1 of auxiliary request 18.

Inventive step

Starting from the disclosure of document D19, the subject-matter of claim 1 of auxiliary request 18 did not involve an inventive step.

Document D19 related to external cod liver oil therapy in infantile and atopic eczema.

For the inventive-step analysis, it was accepted that the subject-matter of claim 1 differed from the treatment disclosed in document D19 firstly by defining a mixture of fatty acids instead of an oil and, secondly, by the teaching that the claimed medical use was based on a limited number of specified fatty acids, namely a combination of at least nine of the ten fatty acids listed in claim 1. The objective technical problem was the provision of an alternative composition for use in the treatment of atopic dermatitis.

The person skilled in the art would have been well aware that administering fatty acids in this context was equivalent to administering an oil (see, for instance, D4: claims 19 and 20 and Table 2, or D2).

Furthermore, it was known, e.g. from D10, that cod liver oil contained 41 fatty acids, including nine of the acids listed in claim 1. Administering cod liver oil inherently involved administering a combination of fatty acids as defined in claim 1. Naming the ten specified fatty acids as those responsible for the therapeutic benefit was, however, an arbitrary feature.

At the oral proceedings before the board, and in relation to claim 1 of auxiliary request 18, the appellant no longer pursued the line of argument (see point VII. above) according to which the claimed subject-matter also lacked an inventive step starting from the disclosure of document D4.

XIII. The respondent's arguments on auxiliary request 18 may be summarised as follows.

Admittance of auxiliary request 18

Auxiliary request 18 differed from the main request by limiting the claimed treatment to atopic dermatitis. It was filed in response to paragraph 4.3 of the board's communication under Article 15(1) RPBA, where the board observed that the evidence presented in the application as filed did not appear to be clearly linked to all the pathologies mentioned in claim 1 and that the animal data in the application as filed was limited to inflammation in the ear and eyelid regions. This objection had never been raised by the appellant, which, in the notice of opposition and the statement setting out the grounds of appeal, merely alleged that the therapeutic effect shown for skin inflammatory pathologies could not extend to the ophthalmic pathologies listed in claim 1. Since the board had raised a new objection in the communication under Article 15(1) RPBA, this represented an exceptional circumstance under Article 13(2) RPBA which justified the filing of the new auxiliary request 18.

Claim construction

The respondent agreed with the board's views on claim construction as set out in the communication under Article 15(1) RPBA.

Amendments

The embodiment with a mixture of nine or ten of the fatty acids was disclosed directly and unambiguously in the application as filed. The only selection involved was the restriction of the therapeutic indication to atopic dermatitis. With Study 3, the application as filed provided a clear indication that atopic dermatitis was a pathology of interest.

Sufficiency of disclosure

It had not been contested that the claimed therapeutic effect was shown for the treatment of atopic dermatitis in Study 3 of the application as filed. Moreover, documents D21/D22 reported favourable results for the treatment of atopic dermatitis in human patients, achieved with a different mixture of fatty acids that conformed to claim 1 and contained myristic acid. The appellant had failed to present serious doubts substantiated by verifiable facts that the claimed invention could not be put into practice across the scope claimed.

Novelty

None of the documents cited by the appellant against novelty disclosed a mixture of fatty acids as defined in claim 1 of auxiliary request 18.

Inventive step

Starting from the technical teaching of document D19 on cod liver oil, the person skilled in the art would not have considered the mixture of fatty acids as defined in claim 1 of auxiliary request 18 an alternative composition for treating atopic dermatitis. The appellant's line of argument using D4 as a supplementary document had been presented for the first

time at the oral proceedings before the board and should not be admitted under Article 13(2) RPBA. In any case, D4 did not relate to the treatment of atopic dermatitis and also, as a patent document, could not serve as evidence of common general knowledge on the functional equivalence of fatty acids and oils.

XIV. The parties' final requests were as follows.

The appellant requested

- that the decision under appeal be set aside and that the patent be revoked
- that auxiliary request 18 and any non-convergent auxiliary request not be admitted
- that documents D25 to D28 not be admitted
- that the post-filed evidence in documents D21 to D23 not be taken into account for the assessment of sufficiency of disclosure.

The respondent requested

- that the patent be maintained in amended form on the basis of the claims of one of auxiliary requests 18, 19 and 20, all filed by letter dated 5 November 2024
- that the appellant's submissions on sufficiency of disclosure in the appeal proceedings not be admitted under Article 12(5) RPBA.

Reasons for the Decision

1. Admittance of the appellant's submissions in the appeal proceedings on sufficiency of disclosure

1.1 The board was of the view that the grounds of appeal, in section 3, addressed and substantiated the issue of sufficiency of disclosure, including in relation to certain points made by the opposition division in the decision under appeal. The board, therefore, saw no reason to hold any part of the appellant's reasoning inadmissible and concluded that the appellant's objections in relation to sufficiency of disclosure were part of the scope of the appeal proceedings (Articles 12(3) and 12(5) RPBA).

1.2 Since the assessment of sufficiency of disclosure for the highest-ranking still pending claim request turned out in the respondent's favour (see section 5. below), it is not necessary to address the issue of admittance in further detail.

2. Admittance of auxiliary request 18 (Article 13(2) RPBA)

2.1 In the board's communication under Article 15(1) RPBA (see point IX. above), the board expressed doubt that the limited evidence in the application as filed would have rendered the claimed therapeutic use credible at the relevant date for all the pathologies mentioned in claim 1. Since (i) no direct link of the *in vitro* model to any of the specified pathologies had been shown, and (ii) the *in vivo* animal data was limited to inflammation in the ear and eyelid regions, the board was of the preliminary view that the application as filed did not establish a clear link between the evidence provided and most of the pathologies mentioned

in claim 1 of the main request (see point 4.3 of the board's communication).

- 2.2 The respondent argued that this was a new objection in so far as it extended also to most of the skin pathologies listed in claim 1. In the respondent's understanding, the appellant, both in its notice of opposition and in the statement setting out the grounds of appeal, had only alleged that any therapeutic effect shown for skin inflammatory pathologies could not be extended to support ophthalmic pathologies.
- 2.3 The board observes that the appellant did not provide very detailed substantiating reasons for its general objection that the various pathologies in claim 1 were not backed up by pertinent data in the application as filed. The appellant's submissions on this issue as presented in the notice of opposition (points 6.4 and 6.5) are nearly identical to its corresponding submissions in the statement setting out the grounds of appeal (point 3.3). The appellant's more specific arguments indeed seem to have focused on the objection that the experimental data on skin pathologies reported in the application as filed could not be taken to demonstrate a therapeutic benefit in ophthalmic pathologies. The additional paragraph in point 3.1 of the statement setting out the grounds of appeal, while pointing out that claim 1 of the main request relates to very specific pathologies, does not address the issue of a possible lack of support for the various skin pathologies, either.
- 2.4 Thus, the appellant did not make it unambiguously clear in its submissions that its general objection for lack of evidence of therapeutic efficacy also extended to the therapeutic indications relating to skin pathologies. In its reasoning in the decision under

appeal (see point 9.1.2 of the Reasons), the opposition division held, in the respondent's favour, that the data shown in the application as filed did provide sufficient evidence in support of the claimed mixture's therapeutic efficacy in all pathologies claimed.

- 2.5 Under these circumstances, the respondent could not fairly have been expected to present auxiliary claim requests in which not only the ophthalmic pathologies but also most skin pathologies were deleted.
- 2.6 During the appeal proceedings, the appellant's general comments summarised in point 2.3 above were then supplemented by the board's *ex officio* considerations outlined in the preliminary communication under Article 15(1) RPBA (see point 2.1 above).
- 2.7 In light of this, and as the opposition division previously found the subject-matter of auxiliary request 1 (i.e. the main request of the appeal proceedings) sufficiently disclosed, the filing of auxiliary request 18 can be regarded as an appropriate reaction to objections raised during the appeal proceedings.
- 2.8 Auxiliary request 18 is suitable for overcoming the objection set out in point 2.1 above because its claims are restricted to atopic dermatitis as the only therapeutic indication. Experimental data on atopic dermatitis is provided in Study 3 in the application as filed.
- 2.9 In this situation, the board was of the view that exceptional circumstances under Article 13(2) RPBA applied and decided to admit auxiliary request 18.

3. Claim construction

3.1 Claim 1 of auxiliary request 18 is directed to a further medical use and is drafted in the format of a purpose-related product claim provided under Article 54(5) EPC.

The product - definition of the mixture

3.2 The definition: "mixture of at least nine fatty acids", with the requirement that these are to be selected from a list of ten acids, can only mean, in normal language use, that the mixture in question consists of either any nine or all ten members of this list.

3.3 The term "fatty acid" and the chemical compound names recited in claim 1 are unmistakably clear in designating the acids as such - in other words, the free acids not chemically bound to, or associated with, other compounds.

Contrary to the appellant's view, it is not necessary that the term "free" be mentioned in the claim for a reader to reach this understanding as this information is implicit in the term "fatty acid" and in the individual compound names (see also paragraphs [0037] to [0046] and Figure 1 of the patent in suit).

On the contrary, chemically modified compounds such as fatty acid esters (e.g. triglycerides) would only be included as possible components of the mixture if this were expressly indicated in the claim. This is not the case.

3.4 The appellant referred to paragraphs [0001] and [0002] of the patent in suit, where it is mentioned that fatty acids "represent the constituent ingredients" of fats and complex lipids. This passage is part of the general technical background. It has no relevance for claim

construction since claim 1 already specifies that the mixture is a mixture of fatty acids and not a mixture of fats or lipids or containing fats or lipids.

- 3.5 Contrary to the appellant's view, the use of the expression "comprises" in dependent claims 2 and 3 (see point X. above for the wording of these claims) does not have the effect of broadening the definition of the mixture in independent claim 1.
- 3.5.1 Dependent claim 2 simply relates to the embodiment of claim 1 in which the fatty acid mixture consists of (i.e. comprises as its only components) the ten fatty acids listed in claim 1. While the "open" expression "comprises" is used, the back-reference to claim 1 nonetheless excludes any embodiment where the mixture comprises more than these ten components.
- 3.5.2 In the same way, the back-reference in claim 3 to claim 1 excludes any embodiment where the mixture comprises components other than nine or ten fatty acids from the list. Indeed, dependent claim 3 has the same scope as claim 1 because a mixture of all ten fatty acids from the list also meets the criterion of comprising nine fatty acids from the list.
- 3.6 The wording of claim 1 does not exclude embodiments where the therapeutic use may involve administering the mixture as defined in claim 1 in a suitable dosage form in combination with further components, such as pharmaceutical excipients (see also paragraphs [0088] to [0094] of the patent in suit) or, conceivably, further fatty acids. However, this consideration regarding its possible use does not broaden the definition of the mixture itself.

The purpose - claim format and therapeutic use

- 3.7 Article 54(5) EPC provides that the patentability of a substance or composition comprised in the state of the art, for any specific use in a method referred to in Article 53(c) EPC, is not excluded, provided that such use is not comprised in the state of the art.
- 3.8 Claim 1 of auxiliary request 18 restricts the use of the claimed composition (in this case, the mixture of fatty acids) to the treatment and/or prevention of atopic dermatitis, which constitutes a therapeutic use as addressed in Article 53(c) EPC.
- 3.9 This also means that claim 1 defines the mixture of fatty acids as the therapeutically active agent responsible for the therapeutic benefit.
- 3.10 In accordance with the claim format and special concept of patentability provided for in Article 54(5) EPC, the therapeutic indication "use in the treatment and/or prevention of atopic dermatitis" is a limiting "functional" technical feature of the claim that must be taken into account in the assessment of novelty and inventive step.
4. Amendments (Article 123(2) EPC)
- 4.1 Claims 1, 2, 6, 19 and 22 of the application as filed read as follows:

1. Mixture of at least three fatty acids selected from palmitic acid, oleic acid, stearic acid, linoleic acid, alpha-linolenic acid, gamma-linolenic acid, eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), azelaic acid and myristic acid.

2. Mixture according to claim 1, characterised in that said mixture comprises between three and ten fatty acids.

6. Mixture according to any one of claims 1 or 2, characterised in that said mixture comprises nine fatty acids, such as palmitic acid, oleic acid, stearic acid, linoleic acid, alpha-linolenic acid, and gamma-linolenic acid, eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) and azelaic acid.

19. A mixture and/or composition according to any one of claims 1 - 18 for use in the treatment and/or prevention of inflammatory pathologies.

21. A mixture and/or composition according to claim 19, characterised in that said inflammatory pathologies include atopic dermatitis, dermatomyositis, scleroderma, psoriasis, polymyositis, pemphigus, pemphigoid epidermolysis bullosa.

4.2 The appellant objected, *inter alia*, that the definition of the mixture of fatty acids in claim 1 of the main request did not find a basis in the application as filed, specifically in claim 2 as filed.

4.3 The appellant's reasoning was based on the understanding that the expression "a mixture of" did not rule out the presence, in the mixture, of further components other than the ten fatty acids listed in claim 1 as filed.

4.4 As set out above, this is not deemed correct. Instead, the meaning established in point 3.2 applies regarding the qualitative composition of the mixture.

4.5 The required basis is found in claim 6 of the application as filed as follows.

4.5.1 Claim 1 of the application as filed relates to a "mixture of" at least three fatty acids selected from the members of the same list of ten fatty acids as recited in claim 1 of auxiliary request 18. Accordingly, the maximum possible number in these combinations is ten fatty acids, as also spelt out in claim 2 as filed.

For the meaning of the expression "mixture of", the considerations in points 3.2 and 3.3 above apply analogously. Moreover, with regard to the expression "comprises" in dependent claim 2 as filed, the considerations in section 3.5 above apply analogously. The scope of claim 2 as filed is thus identical to that of claim 1 as filed.

4.5.2 Discarding the alternative embodiments of mixtures consisting of three to eight fatty acids does not add subject-matter. While the embodiment "at least nine fatty acids" is not explicitly mentioned in claim 1, dependent claim 6 as filed ("mixture according to any one of claims 1 or 2, characterised in that said mixture comprises nine fatty acids, such as (...)") is restricted to mixtures of nine or ten fatty acids from the list of claim 1. The exemplary composition of nine fatty acids following the expression "such as" in claim 6 is not regarded as limiting. Mixtures of all ten fatty acids are not excluded here as they meet the requirement of comprising nine of the fatty acids (as pointed out above, see point 3.5.2). The embodiment according to which the mixture consists of nine or ten of the permitted acids is thus individualised in claim 6 as filed.

- 4.6 The relevant therapeutic indication, i.e. the treatment and/or prevention of atopic dermatitis, is derived from claims 19 and 21 as filed, which refer back to any of claims 1 to 18. While this constitutes a selection from the list of pathologies recited in claim 21 as filed, the description provides a pointer to this pathology in Study 3, described on pages 37 to 38 of the application as filed, which relates to a clinical study in animals suffering from atopic dermatitis. The skilled reader would gather that this was considered a pathology of particular interest, supported by clinical evidence.
- 4.7 For these reasons, the subject-matter of claim 1 of auxiliary request 18 request does not extend beyond the content of the application as filed (Article 123(2) EPC).
5. Sufficiency of disclosure (Article 83 EPC)
- 5.1 The requirement of sufficiency of disclosure must be satisfied at the effective date of the patent, i.e. on the basis of the information provided in the patent application together with the common general knowledge then available to the person skilled in the art.
- 5.2 As already mentioned, claim 1 of auxiliary request 18 is directed to a further medical use and is drafted in the format provided under Article 54(5) EPC. With this claim format, attaining the stated therapeutic effect is considered a technical feature of the claim (see point 3.10 above). In order to meet the requirement of sufficiency of disclosure, the suitability of the claimed mixture for the claimed therapeutic indication must, therefore, be credibly disclosed in the application as filed, unless this was already known to the person skilled in the art.

- 5.3 The animal study described in the application as filed as Study 3 (see pages 37 to 38) was carried out with a mixture according to Example 9 that conforms to the definition of the mixture in claim 1. It was not in dispute that the results reported for this study credibly supported the mixture's therapeutic efficacy against atopic dermatitis.
- 5.4 The appellant objected, however, that only one mixture (the mixture according to Example 9) had been tested. This mixture did not contain myristic acid. The application as filed did not provide any evidence of the therapeutic efficacy of myristic acid.
- 5.5 This argument is not convincing because it is the mixture of fatty acids that is the therapeutically active agent (see point 3.9 above). According to current claim 1, either all ten of the specified fatty acids may be used or one of them may be left out. Thus, the correct question to be asked would be whether using a mixture containing all ten acids, or a mixture of nine of the acids containing myristic acid but leaving out one of the other acids, would lead to the absence of any therapeutic effect. The appellant failed to provide any specific reason why this would be the case.
- 5.6 The appellant also objected that claim 1 did not indicate dosages or amounts of the fatty acids. According to the appellant, the concentration ranges indicated in the description and in claim 4 were rather broad and could not provide the necessary guidance.
- 5.7 However, this objection has not been adequately substantiated.

- 5.7.1 In line with the established case law of the boards, sufficiency of disclosure within the meaning of Article 83 EPC must be assessed on the basis of the application as a whole - including the description and claims (see, for instance, Case Law of the Boards of Appeal of the European Patent Office, 10th ed. 2022, II.C.3.1). The board sees no reason for proceeding differently in the case in hand.
- 5.7.2 In the claims and description as filed, various passages can be found that provide general guidance on dosage and possible concentrations of all fatty acids in the claimed mixture and in compositions for administration containing the mixture (see claims 7, 17 and 33 as filed and the description as filed, paragraph bridging pages 8 and 9; page 11, line 13 to page 12, line 15; first paragraph on page 13; page 13, lines 20 to 22 in combination with page 14, line 14 to page 15, line 2 and page 17, line 16 to page 18, line 18; page 19, lines 16 to 18; page 21, lines 24 to 27).
- 5.7.3 The appellant did not provide specific reasons as to why dosages and concentration ranges would be needed in the claims, especially claim 1. The appellant's comment that the concentration ranges mentioned in current dependent claim 4 and in the description as filed were broad remains vague and does not identify any problem that could substantiate serious doubt in relation to disclosure.
- 5.8 The appellant's objection to claim 5 regarding an allegedly too "diluted" composition fails to take into account that claim 5 relates to the mixture according to any of claims 1 to 4 as such (i.e. not to a composition containing it, see point 3.6 above), and, with regard to the mixture's use, claim 5 even

indicates the dosage which is to be administered to provide the desired therapeutic benefit.

- 5.9 In its submissions on sufficiency of disclosure, the appellant also mentioned briefly that the mixture could be administered by oral or by topical route, whereas the experimental data only related to topical compositions. However, the appellant did not provide any related reasoning that could amount to adequate substantiation of an objection of insufficiency in the sense of raising substantiated serious doubt.
- 5.10 For these reasons, the appellant's objections regarding insufficient disclosure of the subject-matter claimed in auxiliary request 18 were not found convincing (Article 83 EPC). This conclusion was reached without taking the content of the respondent's post-filed data in documents D21 to D23 into account.
6. Novelty (Articles 100(a), 52(1) and 54 EPC)
- 6.1 At the oral proceedings before the board, the appellant relied, for the subject of novelty, on its written submissions, which according to the appellant also applied to claim 1 of auxiliary request 18 (see point XII. above).
- 6.2 In its grounds of appeal (last paragraph of section 4), the appellant stated that the subject-matter of claim 1 (of the main request) lacked novelty in view of D2, D3, D5, D6 and D19. However, it did not specify any passages of those documents believed to anticipate the claimed subject-matter.
- 6.3 In the passage preceding this statement, the appellant merely referred to the opposition division's reasoning in point 10.2 of the decision under appeal, which in its turn mentions paragraph [0029] of D2,

claims 22 and 26 of D3, Table 1 of D5 (see D5: page 32), and Table 15.4 and the title on page 364 of D6. No passage in D19 is mentioned.

6.4 In these circumstances, it might be questioned whether the appellant's objection for lack of novelty was adequately substantiated.

6.5 In any case, in view of the considerations set out in section 3. above, a prior-art disclosure would only anticipate the subject-matter of claim 1 of auxiliary request 18 if it identified a fatty acid mixture as defined in this claim as the therapeutic agent for the use of preventing and/or treating atopic dermatitis.

6.6 None of the specified passages in documents D2, D3, D5, D6 and D19 provides direct and unambiguous disclosure in this regard because none of these documents discloses a mixture of fatty acids consisting of nine or ten acids as defined in claim 1 of auxiliary request 18. Moreover, not all of them mention atopic dermatitis.

D2, in paragraph [0029], refers to lipid formulations which may contain a variety of fatty acids (23 acids and combinations thereof are mentioned), presumably in chemically bound form.

Claims 22 and 26 of D3 relate (by back-reference to claim 19) to a fatty acid for use as a medicament for inducing the process of defecation which may be selected from a list of 35 acids or any mixture of these, and a pharmaceutical dosage form containing it.

D5 is about a process for obtaining and purifying highly unsaturated fatty acids. Table 1 in D5 presents melting points for a selection of fatty acids.

The title on page 364 of D6 reads "Dietary fatty acids and immune function". Table 15.4 lists 12 fatty acids contained in human peripheral blood mononuclear cells. D19 relates to cod liver oil and not to fatty acids.

6.7 Thus, none of the cited prior-art disclosures can anticipate the subject-matter of claim 1 or dependent claims 2 to 6 of auxiliary request 18 (Article 54 EPC).

7. Inventive step (Articles 100(a), 52(1) and 56 EPC)

Patent in suit and claimed subject-matter

7.1 The patent in suit aims to provide compounds and compositions for the treatment of inflammatory pathologies, including atopic dermatitis (see paragraphs [0030], [0035] and [0146]).

7.2 The suggested solution is a mixture of specific fatty acids (see paragraphs [0032] and [0035]). Claim 1 of auxiliary request 18 relates to a mixture of at least nine out of ten specified fatty acids for use in the treatment and/or prevention of atopic dermatitis (see point X. above).

Starting point in the prior art

7.3 Document D19 relates to external cod liver oil therapy in atopic eczema (i.e. atopic dermatitis) and infantile eczema. The authors report that unsaturated skin oils, which are deficient in eczema patients, may be replenished or restored by topical application, and suggest that cod liver oil may be of benefit in such ointment preparations (see page 2864, paragraph bridging columns and right column, lines 8 to 12; Figure 2). Experiments using a preparation (Desitin®) containing cod liver oil in combination with, *inter*

alia, zinc oxide, lanolin, petrolatum and talcum, specified as being "therapeutic agents", did not generally produce satisfactory treatment results in adult patients with atopic eczema and seemed to provide relief in only two of seven cases (see D19: page 2864, right column, lines 21 to 25, Table III; page 2867, paragraph bridging columns). The ointment preparation was shown to be useful against diaper rash in infants (see D19: Table II, page 2867, paragraph bridging columns).

- 7.4 With reference to document D10, the appellant pointed out that cod liver oil contains nine of the acids listed in claim 1.

The fatty acid composition of cod liver oil (shown in Table 4 of D10) was determined by gas chromatography, a standard method for analysing the fatty acid composition of oils which involves converting the constituent fatty acid triglycerides into methyl esters for sample preparation (see D10: page 9, first paragraph underneath Table 3 and page 5).

Technical problem and solution

- 7.5 As it is directed to a further medical use and drafted in the format provided in Article 54(5) EPC, claim 1 of auxiliary request 18 is restricted to embodiments which achieve the claimed therapeutic effect of treating and/or preventing atopic dermatitis (see point 3.10 above).
- 7.6 Claim 1 of auxiliary request 18 differs from the disclosure in D19 by specifying that the active agent having efficacy against atopic dermatitis is a mixture of nine or ten specific acids as listed in claim 1, whereas D19 proposes cod liver oil as the active agent

(which was, moreover, tested only in admixture with further components).

- 7.7 In this context, it is pointed out that the administration of a composition containing the required fatty acids only in chemically bound form (e.g., in the form of triglycerides such as in cod liver oil) is not in line with the use of the fatty acid mixture as defined in claim 1 (see points 3.3 and 3.9 above).
- 7.8 The board is of the view that the experimental set-up described in D19 (see point 7.3 above) was not, in fact, suitable for showing a therapeutic effect in atopic dermatitis that can conclusively be attributed to cod liver oil. This is because the preparation that was used for testing contained cod liver oil in admixture with further components, including pharmacologically active components such as zinc oxide or lanolin, and the patients concomitantly received other medicaments and/or underwent further measures such as allergen-elimination diets (see D19: Tables II and III). Since D19 distinguishes between infantile eczema and atopic eczema, there is also doubt whether infantile eczema is considered a subgroup of atopic dermatitis.
- 7.9 The following analysis is nevertheless based on the assumption, in the appellant's favour, that cod liver oil was shown to be suitable for the treatment of atopic dermatitis.
- 7.10 In that case, the objective technical problem is to provide an alternative agent for the treatment of atopic dermatitis.

Obviousness of the solution

- 7.11 Starting from the disclosure of D19, which relates to external cod liver oil therapy of eczema, the person skilled in the art would not have arrived at the claimed subject-matter in the first place because cod liver oil is a triglyceride composition and not a fatty acid mixture.
- 7.12 It has not been established what the skilled person's incentive would have been for using free fatty acids instead, which are chemically different entities. Moreover, nothing would have pointed the skilled person to the mixtures of nine or ten free acids defined in claim 1 as the active agent as these would not have been regarded as obvious equivalents to cod liver oil, a mixture of triglycerides of more than 40 fatty acids.
- 7.13 The appellant argued that the person skilled in the art would have been aware that fatty acids and oils were equivalent. The appellant relied, in this context, on D2 and, alternatively, D4 (claims 19 and 20 and Table 2) as supplementary documents.
- 7.14 The board does not find this argument convincing.
- 7.14.1 Document D2 relates to lipid-based compositions, specifically dietary compositions, and cannot provide a pointer to the use of fatty acids in the context of the external treatment as disclosed in D19, or to the specific combination of mandatory acids according to claim 1.
- 7.15 While claims 19 and 20 of D4 relate to, among other dosage forms, ointments containing fatty acids, and mention, among other uses and pathologies, the treatment of inflammations, document D4 is not concerned with the treatment of atopic dermatitis.

The disclosure, in Table 2 of D4, of the fatty acid composition of triglycerides found in cod liver oil does not imply any teaching on an equivalent use of cod liver oil and the fatty acids of current claim 1 in the therapeutic indication of atopic dermatitis.

7.16 For these reasons, the subject-matter of claim 1 of auxiliary request 18 involves an inventive step within the meaning of Article 56 EPC. The same applies to the remaining claims 2 to 6, which are all dependent claims.

8. Admittance of new evidence (Article 12 RPBA)

8.1 The respondent filed documents D25 to D28 in support of its reasoning in relation to inventive step (see point VIII. above).

8.2 Since the board, without taking documents D25 to D28 into account, arrived at a conclusion on inventive step in the respondent's favour, it was not necessary to take a decision on these documents' admittance.

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 suit on the basis of claims 1 to 6 of auxiliary request 18, filed by letter of 5 November 2024, and a description and drawings to be possibly adapted.

The Registrar:

The Chairwoman:



L. Stridde

M. Pregetter

Decision electronically authenticated