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**Datasheet for the decision
of 12 May 2021**

Case Number: T 0060/19 - 3.3.01

Application Number: 12727411.6

Publication Number: 2691086

IPC: A61K31/015, A61K31/201,
A61K31/202, A61K31/203,
A61K31/355, A61K9/08,
A61P25/16, A61P25/28, A61P43/00

Language of the proceedings: EN

Title of invention:
COMPOSITIONS FOR THE TREATMENT OF NEUROLOGIC DISORDERS

Patent Proprietor:
Palupa Medical Ltd.

Opponent:
N.V. Nutricia

Headword:
Long chain polyunsaturated fatty acids / PALUPA

Relevant legal provisions:
RPBA Art. 12(4)
RPBA 2020 Art. 13(1)
EPC Art. 100(a), 54

Keyword:

Construction of claim

Grounds for opposition - lack of novelty (yes)

Late-filed auxiliary requests - requests could have been filed
in first instance proceedings (yes)

Late-filed auxiliary requests - justification for late filing
(no)



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Case Number: T 0060/19 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 12 May 2021

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 18 October 2018
revoking European patent No. 2691086 pursuant to
Article 101(2) and 101(3)(b) EPC**

Composition of the Board:

Chairman A. Lindner
Members: S. Albrecht
P. de Heij

Summary of Facts and Submissions

- I. European patent No. 2 691 086 ("the patent") is based on European patent application No. 12727411.6 ("the application"). The patent was granted with thirty claims.

Claim 1 as granted reads as follows:

"1. A liquid oral composition selected from the group consisting of a pharmaceutical, nutritional, medical food, functional food, clinical nutrition, medical nutrition or dietetic preparation, comprising a long chain polyunsaturated fatty acid (PUFA) fraction, comprising eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), linoleic acid (LA) and gamma linolenic acid (GLA); one or more other omega-3 PUFAs; and one or more monounsaturated fatty acid (MUFA); and wherein the EPA is present in an amount of 500 mg to 5000 mg; and/or wherein the DHA is present in an amount of 1000 mg to 12000 mg."

- II. Opposition proceedings were based on the grounds for opposition under Article 100(a) EPC (lack of novelty and lack of inventive step) and under Article 100(b) EPC.
- III. The documents filed during the opposition proceedings included:

D5: US 7,045,143 B1
D9: US 8,030,348 B2
D12: EP 1 401 259 B1

D27: Excerpt from Wikipedia, entitled "Fraction (chemistry)"

IV. The opposition division's decision to revoke the patent was based on a main request and fourteen auxiliary requests. The main request was the patent as granted. Auxiliary requests 1 to 13 were filed on 30 June 2018. Auxiliary request 14 was filed during the oral proceedings of 4 September 2018.

V. In the decision under appeal, the opposition division concluded *inter alia* that the formulation disclosed in the sixth column ("blend C") of table 3 of D5 anticipated the subject-matter of claim 1 (see points 2.4 and 2.5 of the grounds for the decision). The opposition division reached this conclusion on the basis of the interpretation of the term "fraction" recited in claim 1 as having the general meaning of "portion" or "part" (see point 2.3 of the grounds for the decision).

As to the auxiliary requests, the opposition division found that

(a) claim 1 of each of auxiliary requests 1 to 5 and 14 comprised added subject-matter

(b) the amendments made to several claims of auxiliary requests 6 to 13 did not meet the requirements of Rule 80 EPC

VI. The patent proprietor ("appellant") lodged an appeal against the opposition division's decision.

VII. In the statement setting out the grounds of appeal, the appellant requested as its main request that the

decision under appeal be set aside, that the opposition be rejected, and that the patent be maintained as granted. As an auxiliary measure, the appellant requested that the patent be maintained in amended form on the basis of one of the sets of claims of auxiliary requests 1 to 6, filed with its statement setting out the grounds of appeal. With its letter dated 27 December 2019, the appellant filed two further auxiliary requests 7 and 8.

VIII. In its reply to the statement setting out the grounds of appeal, the opponent ("respondent") requested that the appeal be dismissed, not to admit any of auxiliary requests 1 to 6, or, alternatively, that the case be remitted to the opposition division for consideration of inventive step should the board hold that any claim request complies with the requirements of Rule 80 EPC and Articles 123(2), 123(3), 84, 83 and 54 EPC. The respondent also submitted *inter alia* the following evidence:

A34: Excerpt from the Merriam-Webster online dictionary, entitled "fraction"

In an additional submission, the respondent requested not to admit also auxiliary requests 7 and 8.

IX. In the course of the appeal proceedings, the board issued a communication pursuant to Article 15(1) RPBA 2020 dated 19 March 2021 ("communication of 19 March 2021") setting out its preliminary opinion on relevant issues.

X. The parties were summoned to oral proceedings as they had requested.

- XI. In a communication dated 19 April 2021, the board informed the parties of its intention to hold the oral proceedings as a videoconference. A date was fixed for submitting any objections to holding the oral proceedings in this format. No objections were received by the fixed date. Consequently, on 4 May 2021, the format of the oral proceedings was changed to a videoconference.
- XII. Oral proceedings were held on 12 May 2021 in the presence of both parties.
- XIII. At the end of the oral proceedings, the chairman announced the board's decision.
- XIV. The appellant's case relevant for the present decision may be summarised as follows:

(a) Main request - Construction of the term "long chain polyunsaturated fatty acid (PUFA) fraction" ("LCPUFA fraction") in claim 1

In the technical context of the patent this term had the clear technical meaning for the skilled person of "fractionated/separated from a source", as evidenced by D27, D9 and D12.

(b) Main request - novelty of claim 1 over D5

The compositions disclosed in table 3 of D5 were based on blends of natural oils and thus contained, in addition to EPA, DHA, LA and GLA, all the other constituents of the respective oils employed in the blends. Such blends did not constitute a LCPUFA fraction within the meaning of claim 1.

(c) Auxiliary requests 1 to 6 - admission into the proceedings

Auxiliary requests 1 to 6 should be admitted into the proceedings. They constituted a fair attempt to overcome all objections raised by the opposition division in the impugned decision and their subject-matter was similar to the subject-matter of the auxiliary requests underlying the impugned decision. They had been filed in reaction to the outcome of the proceedings before the opposition division and could therefore not have been presented earlier.

XV. The respondent's case relevant for the present decision may be summarised as follows:

(a) Main request - Construction of the term "long chain polyunsaturated fatty acid (PUFA) fraction" in claim 1

The patent did not contain any indication on the basis of which the skilled person would read the special meaning invoked by the appellant into the term "LCPUFA fraction". In fact, the terminology employed in paragraph [0049] of the patent contradicted the appellant's interpretation of this term. As a consequence, the term "fraction" had to be given the general meaning of "part" or "portion", as indicated in A34.

(b) Main request - novelty of claim 1 over D5

Based on this interpretation of the term "LCPUFA fraction", the subject-matter of claim 1 lacked novelty over the composition disclosed in the sixth column of table 3 of D5.

(c) Auxiliary requests 1 to 8 - admission into the proceedings

These requests should not be admitted into the proceedings. They could and should have been filed in the opposition proceedings. There had not been any new issues that could have surprised the appellant. The decision of the opposition division was fully consistent with its preliminary opinion set out in the annex to the summons to oral proceedings.

XVI. The parties' final requests, in so far as relevant to the present decision, were as follows:

The appellant's final requests were those set out in point VII. above. In addition, the appellant requested the dismissal of the respondent's request pursuant to Article 12(4) RPBA that auxiliary requests 1 to 6 not be admitted into the proceedings.

The respondent's final requests were those set out in point VIII. above. In addition, the respondent requested that auxiliary requests 1 to 8 not be admitted into the proceedings.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 EPC and Rule 99 EPC and is therefore admissible.

Main request (patent as granted)

2. Construction of the term "long chain polyunsaturated fatty acid (PUFA) fraction" in claim 1

- 2.1 As the meaning of the term "LCPUFA fraction" in claim 1 is decisive for the assessment of novelty of claim 1 over D5 (see point 3.1 below), the board will deal with this point first.
- 2.2 The general rule of claim construction is that the terms used in a claim should be given their ordinary meaning in the relevant technical field, unless in the context of the patent a particular meaning was adopted.
- 2.3 In the case at hand, the claimed invention undoubtedly lies within the technical fields of medicine and nutrition.
- 2.4 In the respondent's view, the skilled person working in these fields would understand the term "fraction" in the claimed context to have the general meaning of "a portion" or "a part" (of the claimed liquid oral composition). This was evidenced by A34 (see the third line of the chapter entitled "Definition of *fraction*") and further corroborated by the second sentence of paragraph [0049] of the patent.
- 2.5 The appellant took a different view. It submitted at the oral proceedings that the skilled person working in the technical fields recited in claim 1 had knowledge of chemistry. Hence, the claimed invention was set in a chemical context. In such a context, the term "fraction" had the clear technical meaning of "fractionated/separated from a source", as evidenced for instance by D27, D9 (see column 1, lines 40, 43 and 51) and D12 (see reference to "fractionated coconut oil" in paragraphs [0157] and [0158]). Accordingly, the skilled person would understand the term "LCPUFA fraction" in the technical context of claim 1 as a group of compounds including the LCPUFAs listed in this

claim which has been separated from or extracted out of natural oils. A "LCPUFA fraction" in the context of claim 1 was thus the exact opposite of a blend of natural oils containing the claimed LCPUFAs.

2.6 It is undisputed that the term "fraction" is associated with different meanings in different technical fields, which include the interpretation put forward by the appellant (see A34, the fourth line below the chapter entitled "Definition of *fraction*"). The board also agrees with the appellant that the skilled person would understand the term "fraction" to mean fractionated/separated from a (single) source in the specific contexts of the disclosures of D9 and D12.

2.7 However, the board is not convinced that this definition also applies in the context of the claimed invention.

2.7.1 Firstly, as noted by the respondent, the patent discloses the term "fraction" in the second sentence of paragraph [0049]. This sentence reads as follows:

"In one embodiment, the inventive oral liquid formulation comprises the following fractions:

- *Fraction (a) comprising omega-3 long chain polyunsaturated fatty acids (LCPUFA);*
- *Fraction (b) comprising of omega-6 LCPUFA, which fraction contains at 3 to 4 (or more) different MUFA molecules selected from the group of LCMUFA with no more than a 24 carbon chain and no less than a 18 carbon chain, which fraction contains at least 1 to 2 different saturated fatty acids (SFA) molecules selected from the group of long chain fatty acids with no more than a 20 carbon chain and no less than*

a 16 carbon chain;

- *Fraction (c) comprising of gamma-tocopherol; and*
- *Fraction (d) comprising an antioxidant."*

2.7.2 In the board's judgement, this disclosure does not, by itself, rule out the appellant's interpretation of the term "fraction" (see point 2.5 above). However, the patent does not make reference to any fractionating or separation process nor does it contain any information concerning the source or starting material from which fractions a) to d) could be separated from. What is more, fractions a) to d) are rather diverse in terms of their components. For instance, fraction d) comprises an antioxidant which is not further defined, whereas fractions a) and b) contain fatty acids. Fraction c), in turn, comprises gamma-tocopherol. Accordingly, it seems rather unlikely that these four fractions can be separated from a single source. It follows that the skilled person would not have any reason to adopt the appellant's interpretation of the term "fraction" in the context of the second sentence of paragraph [0049], but would rather understand this term to mean "portion" or "part" of the "inventive oral liquid formulation".

2.7.3 Secondly, it is commonly known that the fatty acid components EPA, DHA, LA and GLA of the claimed LCPUFA fraction originate from different source oils (see paragraphs [0022] to [0025] of the patent). Thus, the skilled person would not understand that a fractionation from a single source is used to acquire the composition referred to as "LCPUFA fraction" in claim 1. Accordingly, for this reason too, the appellant's definition of the term "LCPUFA fraction" cannot be accepted in the context of claim 1. The appellant alleged at the oral proceedings that the claimed LCPUFA fraction originated from a mixture of

these oils as the fractionation source. However, in the absence of any evidence in this respect, the appellant's contention is not considered persuasive.

2.7.4 Thirdly, contrary to the appellant's opinion, the elevated amounts of EPA and DHA in the formulations of examples 1 to 11 of the patent do not constitute proof that these components have been fractionated from a source. The amounts of EPA and DHA specified in claim 1 can also be achieved by blending natural oils, as evidenced by the liquid food composition disclosed in the sixth column of table 3 of D5. This formulation is based on a fat blend named "blend C" composed of several raw materials including fish oil and borage oil (see table 1 of D5). These materials provide *inter alia* the following fatty acids in the formulation:

- (a) EPA in an amount of 3391 mg
- (b) DHA in an amount of 1057 mg
- (c) LA
- (d) GLA
- (e) the omega-3 PUFA stearidonic acid (SA)
- (f) the MUFA oleic acid (see the sixth column of table 3 in conjunction with the fourth column of table 2)

2.8 In the light of the above considerations, the appellant's arguments are not considered persuasive. It follows that the term "LCPUFA fraction" in claim 1 has to be construed as meaning an LCPUFA "part" or "portion" of the claimed liquid oral composition, this part or portion being characterised by the fact that it comprises EPA, DHA, LA and GLA; one or more other omega-3 PUFA; and one or more MUFA; wherein the EPA is present in an amount of 500 mg to 50000 mg; and/or wherein the DHA is present in an amount of 1000 mg to 12000 mg.

3. Novelty of claim 1 over D5 (Article 100(a) EPC in conjunction with Article 54 EPC)
 - 3.1 It was common ground between the parties, and the board agrees, that the liquid food disclosed in the sixth column of table 3 of D5 ("liquid food based on blend C"; see point 2.7.4 above) encompasses all features of claim 1 other than the contentious feature "LCPUFA fraction". Since this latter feature is to be construed as "part" or "portion" for the reasons set out above and the liquid food based on blend C undoubtedly contains such a LCPUFA part, it follows that D5 is prejudicial to the novelty of the subject-matter of claim 1.
 - 3.2 The appellant submitted at the oral proceedings that the liquid food based on blend C disclosed in D5 was completely unrelated to the claimed compositions and therefore amounted to an accidental anticipation.
 - 3.3 The board notes that the foods disclosed in table 3 of D5 equally serve dietetic and pharmaceutical purposes (see column 7, lines 53 to 67 of D5) and hence for this reason alone, the disclosure of the liquid food based on blend C in D5 does not constitute an accidental anticipation.
 - 3.4 It follows that the ground for opposition under Article 100(a) EPC in conjunction with Article 54 EPC prejudices the maintenance of the patent as granted.

Auxiliary requests 1 to 6

4. Admission of auxiliary requests 1 to 6 into the appeal proceedings (Article 12(4) RPBA 2007)
 - 4.1 These requests were filed for the first time with the statement setting out the grounds of appeal. Thus, according to Article 12(1) RPBA 2007, these requests form part of the basis of the appeal proceedings, unless the board exercises its discretion under Article 12(4) RPBA 2007, first half of the sentence, not to admit them into the proceedings.
 - 4.2 The appellant submitted that auxiliary requests 1 to 6 resulted from the outcome of the proceedings before the opposition division and thus could not have been presented earlier.
 - 4.3 The board does not agree.
 - 4.3.1 The objection of lack of novelty over D5 as well as the objections of added subject-matter that these auxiliary requests attempt to address were already addressed in the opposition division's communication annexed to the summons to attend oral proceedings ("opposition division's communication"). In this communication, the opposition expressed the preliminary view that
 - (a) D5 anticipated the subject-matter of claims 1, 2, 5, 10 to 12 and 28 to 30 of the main request (see point 9.3.2 b) of the opposition division's communication)
 - (b) the then pending auxiliary requests 1 and 2 comprised added subject-matter because the application as filed did not directly and

unambiguously disclose specific daily doses of EPA and DHA

- 4.3.2 The appellant submitted at the oral proceedings that it only became evident from the overall discussion at the oral proceedings that the opposition division was going to concur with the respondent's interpretation of the claimed feature "LCPUFA fraction". Hence, it could not have been anticipated that the main request would fail for lack of novelty over D5.
- 4.3.3 It is indeed correct that the question concerning the interpretation of the claimed feature "LCPUFA fraction" had not been addressed in the opposition division's communication. This is due to the fact that this issue had been brought up by the appellant itself for the first time in its letter of reply to the summons issued by the opposition division. However, the meaning of this feature was extensively discussed at the oral proceedings, and this was followed by the chairperson's announcement of the opposition division's conclusion that the expression "fraction" could not be interpreted as being limiting for the purposes of novelty (see points 14 to 16 and 19 of the minutes of the oral proceedings).
- 4.3.4 Furthermore, following the chairperson's announcement of the opposition division's conclusions that the then pending auxiliary requests 1 to 13 did not meet the requirements of the EPC, the appellant was offered the opportunity to file a further request to overcome the outstanding objections (see point 40 of the minutes of the oral proceedings).

4.4 Accordingly, the appellant could and should have filed auxiliary requests 1 to 6 at the latest in the oral proceedings before the opposition division.

4.5 As a consequence, the board decided, exercising its discretion pursuant to Article 12(4) RPBA 2007, first half of the sentence, to hold auxiliary requests 1 to 6 inadmissible.

Auxiliary requests 7 to 8

5. Admission of auxiliary requests 7 and 8 into the appeal proceedings (Article 13(1) RPBA 2020)

5.1 These requests were filed by the appellant with letter dated 27 December 2019, i.e. after the statement setting out the grounds of appeal had been received.

5.2 In points 3.4 of its communication of 19 March 2021, the board indicated its intention not to admit auxiliary requests 7 and 8 into the proceedings in the absence of any justification on the part of the appellant for the filing of these requests at this stage of the proceedings.

5.3 At the oral proceedings the appellant did not present any arguments on this issue. It merely stated that it did not have any further comments on this point and that it left the admission of these requests to the discretion of the board.

5.4 As a consequence, the board sees no reason to deviate from its preliminary opinion. Therefore, it decided not to admit auxiliary requests 7 and 8 into the proceedings (Article 13(1) RPBA 2020).

Overall conclusion

6. In view of the preceding reasons and considerations the present appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated