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

Case Number: T 2682/18 - 3.3.01

Application Number: 11742864.9

Publication Number: 2575825

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A61K31/4415, A61K31/519,
A61K31/495, A61P25/18

Language of the proceedings: EN

Title of invention:

COMPOSITIONS AND METHODS FOR TREATING DEPRESSION

Applicant:

Gentelon, Inc.

Headword:

Compositions for treating depression / GENTELON

Relevant legal provisions:

EPC Art. 56

Keyword:

Inventive step - obvious combination of known features



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 2682/18 - 3.3.01

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

Appellant:

(Applicant)

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Representative:

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Decision under appeal:

**Decision of the Examining Division of the
European Patent Office posted on 13 June 2018
refusing European patent application No.
11742864.9 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman

J. Molina de Alba

Members:

S. Albrecht

P. de Heij

Summary of Facts and Submissions

- I. The appeal of the applicant (appellant) lies from the decision of the examining division to refuse European patent application No. 11742864.9 ("the application"), published as WO 2011/100550.
- II. The decision under appeal was based on the claims of a main request and three auxiliary requests, all filed by letter dated 27 March 2018.

Claim 1 of the main request reads as follows:

"1. A composition for use in treating depression in a subject consisting essentially of S-adenosyl methionine or a salt thereof, methyl folate or a salt thereof, and one or more omega-3 fatty acids or salts thereof, wherein the one or more omega-3 fatty acids or salts thereof comprise about 60% to about 100%, inclusive, eicosapentaenoic acid."

- III. The following documents were among those cited in the examination proceedings:

D2: WO 99/37155 A1

D6: J. Sarris et al., Nutrition Reviews® 67(3), 2009,
125-31

- IV. In its decision, the examining division concluded *inter alia* that the subject-matter of claim 1 of the main request lacked an inventive step based on D6 as the closest prior art in combination with D2.

- V. With the statement setting out the grounds of appeal, the appellant resubmitted all the claim requests considered in the decision under appeal. The appellant requested that the decision of the examining division be set aside and that a patent be granted on the basis of the set of claims of the main request or, alternatively, the first, second or third auxiliary request. Oral proceedings were requested if the board was unable to grant these requests based on the appellant's written submissions.
- VI. The appellant was summoned to oral proceedings in view of its conditional request to this effect.
- VII. In a communication pursuant to Article 15(1) RPBA 2020 issued on 11 May 2020 ("the board's communication"), the board expressed the preliminary opinion that the subject-matter of claim 1 of the main request would have been obvious based on D6 as the closest prior art.
- VIII. In a letter dated 12 July 2021, the appellant announced that it would not be attending the oral proceedings appointed for 16 July 2021. It also withdrew all auxiliary requests on file and maintained the request that the impugned decision be set aside and a patent be granted on the basis of the claims of the main request as its sole request.
- IX. By registered letter dated 15 July 2021, the registry of the board informed the appellant that the oral proceedings had been cancelled.
- X. The appellant's arguments made in writing, as far as they are relevant to the present decision, can be summarised as follows:

The examining division's finding of lack of inventive step of the claimed subject-matter was incorrect. The skilled person would not have had any reason to refer to the disclosure of D2 when wishing to alter the disclosure of D6 because the composition of D2 comprised different components. Moreover, the teaching of D2 would not have motivated the skilled person to replace the folic acid disclosed in D6 with methyl folate. The prior art relied on by the examining division did not contain any motivation for the skilled person to select the particular combination of active agents recited in claim 1, to provide these compounds in the form of a single composition and to exclude the presence of further active agents in this composition.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is therefore admissible.
2. Procedural matters - oral proceedings
 - 2.1 The appellant requested oral proceedings as an auxiliary measure (see point V above).
 - 2.2 In response to the board's communication in which it expressed the preliminary view that the subject-matter of claim 1 of the main request lacked an inventive step, the appellant informed the board that it would not be attending the oral proceedings.
 - 2.3 The board interprets the appellant's declaration as withdrawal of its previous auxiliary request for oral

proceedings. In these circumstances, the board found it appropriate to cancel the oral proceedings.

Main request

3. The claimed subject-matter

3.1 Claim 1 is worded as a purpose-related product claim pursuant to Article 54(5) EPC, wherein the product is a composition consisting essentially of the following three components:

(a) S-adenosyl methionine or a salt thereof ("SAME")

(b) methyl folate or a salt thereof

(c) one or more omega-3 fatty acids or salts thereof, wherein the one or more omega-3 fatty acids or salts thereof comprise about 60% to about 100%, inclusive, eicosapentaenoic acid ("EPA")

Methyl folate is also known as 5-MTHF (see paragraph 0047 of the application).

4. Inventive step (Article 56 EPC) - claim 1

The closest prior art

4.1 In point 2.2 of its decision, the examining division identified D6 as a valid starting point for the assessment of inventive step of the subject-matter of claim 1. The appellant does not contest this finding.

4.2 D6 (see abstract and paragraph bridging pages 125 and 126) is a review article on major clinical evidence for nutritional interventions in depression. The nutrients

discussed are omega-3 fatty acids, folate, SAME, inositol and certain amino acids.

- 4.3 In point 1.2.2 of its communication, the board expressed the preliminary opinion that the disclosure of D6 regarding the use of SAME in the treatment of depression (see the paragraph bridging pages 127 and 128) constituted a promising starting point for the assessment of inventive step of the claimed invention.
- 4.4 The appellant did not submit any facts or substantive arguments in reaction to the board's communication (see point 2.2 above).
- 4.5 Given these circumstances, the board sees no reason to change its preliminary opinion. Accordingly, the aforementioned disclosure of D6 regarding SAME represents the closest prior art.
- 4.6 The subject-matter of claim 1 differs from this disclosure in that the claimed composition
- (i) further contains the components (b) and (c) defined in point 3.1 above, and
 - (ii) essentially consists of the components (a), (b) and (c) defined in point 3.1 above.

Objective technical problem and solution

- 4.7 To formulate the objective technical problem effectively solved by the claimed subject-matter over the closest prior art, the technical effects associated with the distinguishing features need to be identified.

- 4.8 In points 1.3.1 to 1.3.3 of its communication, the board expressed the preliminary view that, as stated in item 2.3 of the appealed decision, the distinguishing features defined in point 4.6 above did not provide a particular technical effect vis-à-vis the teaching of the closest prior art. The objective technical problem to be solved by the claimed invention thus appeared to be the provision of further means to treat depression in a subject.
- 4.9 In the absence of any evidence or counter-arguments submitted by the appellant in response to the board's communication, the board does not see any reason to deviate from its preliminary opinion.
- 4.10 As a solution to the posed technical problem, a composition in accordance with claim 1 is provided.

Assessment of obviousness

- 4.11 In the board's judgment, the addition of components (b) and (c) (see point 3.1 above) to the SAME disclosed in D6 represents an obvious modification for a skilled person faced with the technical problem of providing further means to treat depression in a subject. The reasons are as follows.
- 4.11.1 D6 itself teaches that folate is most notably involved with the endogenous synthesis of SAME from homocysteine and that folate deficiency is associated with the increased homocysteine levels characteristic of depressive groups (see D6, page 127, left column, second full paragraph). D2 concerns therapeutic compositions for the treatment of mental disturbances such as depressive states (see abstract). As the goal of D2 is the same as that of the application, it

represents an obvious source of alternative compositions which the skilled person would have considered in their search for further means to treat depression. D2, page 8, line 11 to page 9, line 5 discloses that methyl folate is the active form of folate and presents several advantages over folic acid. In the following paragraph on page 9, lines 6 to 11, D2 even teaches that SAME and 5-MTHF are preferred methylating agents that may be added to the therapeutic compositions individually or in mixtures with themselves or with other methylating agents. Accordingly, the skilled person faced with the technical problem defined in point 4.11 above would have immediately contemplated the combination of SAME with methyl folate.

4.11.2 From D6 (see page 126, right column, second full paragraph) the skilled person would furthermore have learned that the use of a combination of 400 mg/day of EPA and 200 mg/day of DHA (i.e. an EPA:DHA ratio of 2:1) in children with diagnosed major depressive disorder resulted in a significant reduction in depression compared to the placebo group. In light of this teaching, the skilled person would also have readily considered adding EPA and DHA in a ratio of 2:1 to SAME and methyl folate in order to solve the technical problem as posed.

4.12 The appellant argued that

(a) the skilled person would not have been motivated to combine the teaching of D2 with D6 to arrive at a composition falling within the claims of the main request, since D2 disclosed compositions comprising different components to those set out in claim 1 and to those disclosed in D6 ("argument (a)")

(b) there was no teaching in D6 that would have motivated the skilled person to select SAME and omega-3 fatty acids over the remaining agents disclosed therein and to include an additional active component from an unrelated composition as described in D2, let alone to include methyl folate as the additional component whilst excluding the presence of any other active agent ("argument (b)")

4.13 The board does not agree.

4.13.1 As correctly observed by the appellant, the invention disclosed in D2 relates to compositions comprising any two or more of tyrosine, one or more methylating agents, one or more phospholipids, one or more fatty acids and St. John's Wort; thus indeed compositions comprising several components different to those disclosed in D6. However, this is the very reason why the skilled person, in their search for further means to treat depression, would have taken this document into consideration: they would have expected to find useful alternative components. Accordingly, argument (a) must fail.

4.13.2 Argument (b) is also not found to be persuasive. If, as in the present case, the objective technical problem to be solved lies merely in the provision of further means to treat depression in a subject, no incentive or pointer is required to select the particular solution claimed from a host of equally possible solutions (see Case Law of the Boards of Appeal, 9th edition 2019, section I.D.9.19.8). Accordingly, the selection of methyl folate and a combination of EPA and DHA in a ratio of 2:1 from suitable alternatives, and the addition of these two components to the SAME disclosed

in D6, constitutes an arbitrary choice of one of several obvious solutions. The board acknowledges that the conclusion regarding inventive step might have been different if the skilled person had had reason to expect that methyl folate and the combination of EPA and DHA in a ratio of 2:1 would abrogate the antidepressant properties of SAME. However, no such reason is apparent in the present case nor has one been invoked by the appellant. Furthermore, this view is supported by the teaching of D2, which discloses combinations containing *inter alia* methylating agents, such as SAME and methyl folate, and fatty acids.

Conclusion regarding inventive step

- 4.14 In light of the above considerations, the board concludes that the subject-matter of claim 1 does not involve an inventive step (Article 56 EPC).

Overall conclusion

- 4.15 Since the appellant's main request is not allowable owing to lack of inventive step and there are no other requests on file, it follows that the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

J. Molina de Alba

Decision electronically authenticated