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**Datasheet for the decision
of 24 June 2015**

Case Number: T 0254/10 - 3.3.01

Application Number: 99105497.4

Publication Number: 0950410

IPC: A61K31/20, C11C3/14,
C07C51/353, A23L1/30

Language of the proceedings: EN

Title of invention:

Conjugated linoleic acid compositions

Patent Proprietor:

Aker Biomarine ASA

Opponent:

Loders Croklaan Nutrition B.V.

Headword:

Low impurity CLA compositions/AKER

Relevant legal provisions:

EPC 1973 Art. 100(c), 84
EPC Art. 123(2), 123(3)

Keyword:

Main and first auxiliary request: amendments -
extension beyond the content of the application as filed (yes)
Second and third auxiliary requests: amendments -
extension of scope of protection (yes)
Fourth auxiliary request: clarity (no)

Decisions cited:

G 0002/88, G 0003/14, T 0113/86, T 0301/87, T 0307/05,
T 0560/09

Catchword:



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Case Number: T 0254/10 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 24 June 2015

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(Patent Proprietor)

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 22 December
2009 revoking European patent No. 0950410
pursuant to Article 101(3) (b) EPC.**

Composition of the Board:

Chairman C. M. Radke
Members: G. Seufert
L. Bühler

Summary of Facts and Submissions

I. The patent proprietor lodged an appeal against the decision of the opposition division revoking European patent No. 0 950 410.

II. Claims 1, 4 to 6 and 10 of the patent as granted read as follows:

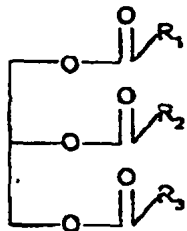
"1. A composition containing at least 50 percent conjugated linoleic acid said composition being characterized in having:

- (a) less than 1 percent total 11,13-octadecadienoic acid isomers,
- (b) less than 1 percent total 8,10-octadecadienoic acid isomers and
- (c) a total t9,t11-octadecadienoic acid and t10,t12-octadecadienoic acid level of less than 1 percent."

"4. A biologically active conjugated linoleic acid composition comprising: a mixture of free fatty acid conjugated linoleic acid isomers, said mixture containing at least 30% t10,c12-octadecadienoic acid, at least 30% c9,t11-octadecadienoic acid, and

- (a) less than 1 percent total 11,13-octadecadienoic acid isomers,
- (b) less than 1 percent total 8,10-octadecadienoic acid isomers and
- (c) a total t9,t11-octadecadienoic acid and t10,t12-octadecadienoic acid level of less than 1 percent."

"5. A biologically active acylglycerol composition comprising a plurality of acylglycerol molecules of the structure:



wherein R_1 , R_2 , and R_3 are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said composition characterized in containing at least 30% t10,c12-octadecadienoic acid, at least 30% c9,t11-octadecadienoic acid, and

- (a) less than 1 percent total 11,13-octadecadienoic acid isomers,
- (b) less than 1 percent total 8,10-octadecadienoic acid isomers and
- (c) a total t9,t11-octadecadienoic acid and t10,t12-octadecadienoic acid level of less than 1 percent

at positions R_1 , R_2 , and R_3 ."

"6. A biologically active conjugated linoleic acid composition comprising: a mixture of esters of conjugated linoleic acid isomers, said mixture containing at least 30% t10,c12 octadecadienoic acid, at least 30% c9,t11 octadecadienoic acid, and

- (a) less than 1 percent total 11,13-octadecadienoic acid isomers,
- (b) less than 1 percent total 8,10 octadecadienoic acid isomers and

(c) a total t9,t11-octadecadienoic acid and t10,t12-octadecadienoic acid level of less than 1 percent."

"10. A process for producing the conjugated linoleic acid of claim 1 comprising providing a linoleic acid containing seed oil, propylene glycol, and an alkali compatible with a non-aqueous medium; forming a blended reaction mix with said seed oil, said propylene glycol, and said alkali compatible with a non-aqueous medium; isomerizing said linoleic acid contained in said seed oil by heating to form conjugated linoleic acids; and aquefying to release glycerol."

- III. Notice of opposition had been filed by the respondent (opponent), requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step, insufficiency of disclosure and added matter (Article 100(a), (b) and (c) EPC).
- IV. The opposition division decided that the subject-matter of claims 1 and 4 to 6 as granted had no basis in the application as filed. The same applied to the subject-matter of claims 4, 5, 9, 11 to 13, 16 and 17 of the first auxiliary request. The second auxiliary request was considered to comply with Article 123(3) EPC, but was held to contravene Articles 123(2) and 84 EPC. The subject-matter of the third to fifth auxiliary requests contravened the requirement of Article 83 EPC.
- V. With the statement of grounds of appeal, the appellant defended the maintenance of the patent in suit on the set of claims as granted as its main request and filed first to fourth auxiliary requests.

In the first auxiliary request, claims 4 and 5 are identical to claims 5 and 6 as granted (see point II above).

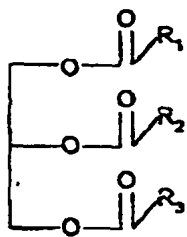
In the second auxiliary request, process claim 10 as granted, now claim 8, has been amended and reads as follows:

"8. A process for producing a conjugated linoleic acid having less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic and trans-trans octadecadienoic acid, said process comprising:
providing a linoleic acid containing seed oil, propylene glycol, and an alkali compatible with a non-aqueous medium;
forming a blended reaction mix with said seed oil, said propylene glycol, and said alkali compatible with a non-aqueous medium;
isomerizing said linoleic acid contained in said seed oil by heating to form conjugated linoleic acids; and
aquefying to release glycerol."

In the third auxiliary request, process claim 6 is identical to process claim 8 of the second auxiliary request except for the addition of the feature of dependent claim 14 as granted, namely the further step of **"and treating said free fatty acid conjugated linoleic acid with lipase to form triglyceride"** after the aquefying step.

The fourth auxiliary request consists of five claims, with claim 1 reading as follows:

"1. A biologically active acylglycerol composition comprising a plurality of acylglycerol molecules of the structure:



wherein R₁, R₂, and R₃ are selected from the group consisting of a hydroxyl group and an octadecadienoic acid, said composition characterized in containing at least 30% t10,c12 octadecadienoic acid, at least 30% c9,t11 octadecadienoic acid, and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic and trans-trans octadecadienoic acid at positions R₁, R₂, and R₃."

- VI. In a communication accompanying the summons to oral proceedings the board expressed its preliminary opinion. In particular, it indicated that the subject-matter of claim 1 as granted had no basis in the application as originally filed. The same applied to the claims of the first auxiliary request referring to features (a) to (c). The board also indicated the reasons for its objections under Article 123(3) EPC against claim 8 of the second auxiliary request and claim 6 of the third auxiliary request, under Article 84 EPC against claims 3 and 4 of the second auxiliary request and claims 1 and 2 of the third and fourth auxiliary requests, and under Article 83 EPC against all requests.
- VII. With letter dated 21 May 2015, the appellant informed the board that it would not be attending the oral proceedings scheduled for 24 June 2015. No observations or comments with respect to the issues raised in the board's communication accompanying the summons were provided.

VIII. The appellant's arguments submitted in writing as far as they concern the relevant issues can be summarised as follows:

Claim 1 as granted had an adequate basis in the passages on page 4, lines 5 to 7 (hereinafter denoted as the first passage on page 4), and page 4, lines 15 to 24 (hereinafter denoted as the second passage on page 4), in particular lines 17 to 19, of the application as filed. The first passage disclosed a composition containing at least 50% conjugated linoleic acid. The second passage disclosed features (a) to (c). The limitations according to features (a) to (c) were product features and as such clearly separable from the process features mentioned in the second passage. Hence, the 90% linoleic acid conversion was not tied-in with the limits of the undesired isomers. The 1% limit on total unidentified linoleic acid species was not essential to the invention. Its introduction was therefore not necessary to satisfy Article 123(2) EPC.

The subject-matter of claim 4 of the first auxiliary request was based on claim 11 as originally filed, the second paragraph on page 6 and page 4, lines 17 to 19 and 21 to 22. The term "conjugated linoleic acid" in the second passage on page 4 had to be understood as including all forms, such as free acid, alkylesters and acylglycerols. Hence, the second passage on page 4, and consequently the limits of undesired isomers, applied to all forms of conjugated linoleic acids and formulations thereof.

Claim 10 as granted referred to the conjugated linoleic acids defined in claim 1. This reference did not apply to the 50% limit of the conjugated linoleic acid, but

had to be understood as a reference to the limits of the undesired isomers. The limits introduced into claim 8 of the second auxiliary request were narrower than those in claim 10 as granted. Thus Article 123(3) EPC was complied with.

IX. The respondent's arguments as far as they concern the relevant issues can be summarised as follows:

The composition of claim 1 as granted had no basis in the application as filed. None of the claims as originally filed contained the features (a) to (c). Instead, they referred to a limit of less than 1% of non-naturally occurring isomers, more specifically to a limit of less than 1% total of 8,10-, 11,13- and trans-trans isomers. The second passage on page 4 was in the context of a process, was linked to a yield of greater than 90% of the isomers and disclosed an additional purity-related feature. Moreover, the basis for the limits of the undesired isomers was not at all clear. It could not be deduced that these limits related to the final product.

The second passage on page 4 did not apply to all forms of conjugated linoleic acid. The product of the process mentioned in said passage was the salt of the fatty acid form of the conjugated linoleic acid. A further esterification step was required to convert the acid to esters or acylglycerols, with a likely change in the levels of isomers. Therefore the second passage on page 4 could not serve as a basis for the acylglycerol or ester composition of claims 4 and 5 of the first auxiliary request.

The second and third auxiliary requests contravened Article 123(3) EPC. The omission of the reference back

to claim 1 in claims 8 and 6 of the respective requests had the effect that they now covered processes which produced compositions having less than 50% conjugated linoleic acid. The opposition division had obviously doubts about whether the scope of protection had been changed by this amendment. In these circumstances, the division should not have allowed this amendment.

The fourth auxiliary request did not meet the requirement of Article 84 EPC. The use of the term "about" rendered the scope of claim 1 unclear.

- X. The appellant had requested in writing that the decision under appeal be set aside and the patent be maintained as granted (main request), or, alternatively, on the basis of one of the first to fourth auxiliary requests filed with the statement of grounds of appeal of 29 April 2010.
- XI. The respondent requested that the appeal be dismissed. It also requested that the case not be remitted to the department of first instance for consideration of novelty and inventive step.
- XII. At the end of the oral proceedings, which took place as scheduled on 24 June 2015 in the absence of the appellant, the decision of the board was announced.

Reasons for the Decision

- 1. The appeal is admissible.
- 2. Non-appearance at the oral proceedings before the board

- 2.1 As announced (see point VII above), the appellant did not attend the oral proceedings before the board to which it had been duly summoned.
- 2.2 According to Rule 115(2) EPC, oral proceedings may continue in the absence of a duly summoned party. Furthermore, pursuant to Article 15(3) of the Rules of Procedure of the Boards of Appeal (RPBA), the board is not obliged to delay any step, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned. Such party may then be treated as relying only on its written case.
- 2.3 The appellant had been informed, in the board's communication accompanying the summons to oral proceedings, about the issues which the board would consider and decide on during the oral proceedings. In deciding not to attend oral proceedings, the appellant chose not to avail itself of the opportunity to present additional observations and comments orally. It had therefore had an opportunity to present its observations and comments on the grounds and evidence on which the board's decision is based.
- 2.4 The board was therefore in a position to take a final decision at the oral proceedings, despite the absence of the appellant.

Main request (claims as granted)

3. Article 100(c) EPC 1973
 - 3.1 Claim 1 of the patent as granted relates to a composition containing at least 50% conjugated linoleic acid and small amounts of specific octadecadienoic acid isomers, namely

- (a) less than 1 percent total 11,13 octadecadienoic acid isomers,
- (b) less than 1 percent total 8,10 octadecadienoic acid isomers and
- (c) a total t9,t11 octadecadienoic acid and t10,t12 octadecadienoic acid level of less than 1 percent.

3.2 According to the appellant, claim 1 had its basis in the passages on page 4, lines 5 to 7, and page 4, lines 15 to 24, of the application as originally filed (see point VIII above).

3.3 The first passage on page 4, lines 5 to 7, states that during isomerisation 9,12 octadecadienoic acid (linoleic acid) is converted to a mixture of other isomers to form a composition having at least **50% conjugated** linoleic acid. This passage is silent on the type and amount of the isomers formed. The conjugated linoleic acid is not defined and therefore includes all positional and steric isomers of linoleic acid with two conjugated carbon-carbon double bonds anywhere in the molecule. This understanding is consistent with the disclosure on page 8, lines 24 to 26, of the application as originally filed.

The second passage on page 4, lines 15 to 24, discloses a composition in terms of a process, in which a high percentage of linoleic acid is converted in a carefully controlled reaction yielding **90% of two specific conjugated linoleic acids** (i. e. the c9,t11 and t10,c12 isomers) and a certain amount of undesired isomers. This amount is defined not only by features (a) to (c), but also by the feature that "less than 1 percent total unidentified linoleic acid species" (hereinafter feature (d)) is present.

It is immediately obvious that the specific context in which features (a) to (c) are disclosed on page 4 is not reflected in claim 1 as granted.

- The claimed composition is not defined as the result of a particular process (i. e. the conversion/isomerisation of linoleic acid). However, in the board's judgment, the type of process and the process conditions have a major impact on the composition, in particular on the type of conjugated linoleic acids that will in fact be obtained.
- The conjugated linoleic acid in the claimed composition is not limited to the specific isomers disclosed on page 4.
- Feature (d) is missing.

Although the exact scope of the latter is unclear - feature (d) could therefore not be introduced into claim 1 without contravening Article 84 EPC - it nevertheless represents an additional purity requirement. In the context of the application as originally filed, in which only the starting material (linoleic acid) and certain conjugated linoleic acid isomers (i. e. 9,11, 10,12, 11,13, 8,10 isomers) were identified, feature (d), for example, excludes the presence of other conjugated or unconjugated, positional or steric isomers of linoleic acids in an amount of more than 1%. In claim 1 as granted, no such limitation exists.

Furthermore, the board concurs with the respondent that it is not clear whether or not the levels of the undesired isomers (features (a) to (c)) in the second passage on page 4 are based on the total composition as

presently claimed. It is also conceivable that they are based on the total amount of conjugated linoleic acid in the composition.

- 3.4 The second passage on page 4 of the application as filed cannot, therefore, serve as a clear and unambiguous basis for the subject-matter of claim 1 as granted, either alone or in combination with the first passage on the same page.
- 3.5 The appellant's argument that the product and process features can be considered separately is not convincing, as the second passage on page 4 clearly links the purity of the product to the process by which it is obtained (cf. the wording "in a carefully controlled reaction yielding greater than 90 percent of these isomers, **so that** less than a combined 1 percent.... is present"). The argument that feature (d) is not essential is equally unconvincing, since the provision of a conjugated linoleic acid containing composition with low amounts of unknown fatty acid species and unusual isomers is the aim of the present invention (see page 3, lines 26 to 27 and 35 to 39, of the patent in suit, which corresponds to page 3, lines 31 to 33, and page 4, lines 9 to 14, of the application as filed).
- 3.6 For the aforementioned reasons, the board concludes that the subject-matter of claim 1 of the main request has no basis in the application as filed. Grounds under Article 100(c) EPC 1973 therefore prejudice the maintenance of the patent as granted.

First auxiliary request

4. Article 123(2) EPC

4.1 Claim 4 of the first auxiliary request relates to a biologically active acylglycerol composition which contains **at least 30%** t10,c12 octadecadienoic acid and **at least 30%** c9,t11 octadecadienoic acid (see point II above). The composition is further characterised by features (a) to (c) mentioned in point 3.1 above.

4.2 According to the appellant, this claim is based on claim 11, page 6, second paragraph, and page 4, lines 17 to 19 and 21 and 22, of the application as originally filed.

4.3 However, claim 11 as originally filed does not characterise the acylglycerol composition by features (a) to (c). Instead, it refers to the feature "about less than **1% total** of 8,10-octadecadienoic acid, 11,13-octadecadienoic and trans-trans octadecadienoic acid". The same disclosure is found in the second paragraph on page 6, in particular lines 22 to 23. The passage on page 4 cannot serve as a clear and unambiguous basis for claim 4 of the first auxiliary request, even if the board adopts the appellant's view that the reference to the conjugated linoleic acid on page 4 should be understood as encompassing all forms of said acid, including free acid, acylglycerols or alkylesters. The reasons are essentially the same as explained in point 3.3 above. The board notes that the specific c9,t11 and t10,c12 isomers mentioned on page 4 are cited in claim 4. However, the amount of at least 30% for each individual isomer is not referred to on page 4.

The subject-matter of claim 4 of the first auxiliary request is therefore the result of an arbitrary combination of selected features from different parts of the application as filed, which, in addition, have been taken out of their respective context. This creates subject-matter that is not directly and unambiguously derivable from the application as filed.

4.4 Hence, the board concludes that claim 4 of the first auxiliary request contravenes Article 123(2) EPC.

Second auxiliary request

5. Article 123(3) EPC

5.1 Claim 10 as granted relates to a process for producing the conjugated linoleic acid **of claim 1**, comprising the steps of providing the starting materials, including linoleic acid containing seed oil, forming a blended reaction mix, isomerising the linoleic acid contained in the seed oil and aquefying to release glycerol (see point II above). The corresponding claim 8 of the second auxiliary request has been amended by replacing the reference to the conjugated linoleic acid of claim 1 with the feature "having less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic acid and trans-trans octadecadienoic acid" (see point II above).

5.2 The appellant argued that the reference to the conjugated linoleic acid of claim 1 in claim 10 as granted concerned features (a) to (c) only and was not related to the 50% limit of claim 1 (see point VIII above). Thus, claim 8 of the second auxiliary request did not contravene Article 123(3) EPC.

5.3 The board has a different understanding of claim 10 as granted. It is clear from the wording of claim 1 that features (a) to (c), and the requirement that the composition is to contain **at least 50 percent conjugated linoleic acid**, are features of the composition and not of the linoleic acid (cf. "**said composition** being characterised in having: (a)..., (b)..., and (c)..."). Hence, in the board's judgement, the only technically meaningful understanding of granted claim 10 is that it is directed to the preparation of the conjugated linoleic acid **composition** of claim 1. Reading the appellant's interpretation into granted claim 10 would require the skilled person to completely ignore the wording of granted claims 1 and 10, which were not per se technically meaningless. The board cannot accept this approach.

Since claim 1 as granted relates to a composition with a content of at least 50% of conjugated linoleic acid and since claim 10 as granted in the board's judgement relates to the preparation of such a composition, deletion of the reference to claim 1 has the effect that amended claim 8 of the second auxiliary request now covers a process for the preparation of any composition with less than 50% conjugated linoleic acid and, by virtue of Article 64 EPC, the products directly obtained by such a process. Such compositions were not covered by claim 1 as granted or any of the other product claims as granted (i.e. claims 4, 5, 6, 17, 18 and 20). Hence, the amendment in claim 8 of the second auxiliary request extends the scope of protection conferred by the claims as granted.

5.4 In the decision under appeal, the opposition division considered that the boundaries of granted claim 10 were not clear, in view of the reference in granted claim 10

to a conjugated linoleic acid of claim 1 and the fact that claim 1 did not relate to conjugated linoleic acid as such. Without providing any further reasons, the division concluded that it could not be determined beyond reasonable doubt that the amendment made to process claim 10 as granted extended the scope of protection conferred by the claims as granted. Accordingly, it considered Article 123(3) EPC to be complied with.

5.5 The board concurs with the respondent that the opposition division applied the wrong standard when considering Article 123(3) EPC. It is established jurisprudence of the boards of appeal that a very rigorous standard, namely that of beyond any reasonable doubt, is to be applied when examining the allowability of amendments under Article 123(2) and (3) EPC. If there is the slightest doubt that the unamended patent could be construed more narrowly than the patent as amended, and apparently the opposition division had such doubts, the amendments should not be allowed (cf. T 113/86 of 28 October 1987, point 2.2 of the Reasons; T 307/05 of 27 February 2007, points 3.3.1 and 3.3.2 of the Reasons).

5.6 For the aforementioned reasons, the board concludes that the amendments in claim 8 of the second auxiliary request do not comply with Article 123(3) EPC.

Third auxiliary request

6. Article 123(3) EPC

6.1 In claim 6 of the third auxiliary request the same amendment has been made as in claim 8 of the second auxiliary request, namely the replacement of the

reference to the conjugated linoleic acid of claim 1 with the feature "having less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic and trans-trans octadecadienoic acid". In addition, the feature of granted claim 14, which was dependent on granted claim 10, has been included. This has no influence on the board's observations and conclusion set out in point 5 above, which equally apply to claim 6 of the third auxiliary request. Hence, the third auxiliary request must also be refused for contravening Article 123(3) EPC.

Fourth auxiliary request

7. Article 84 EPC 1973

7.1 Claim 1 of auxiliary request 4 differs from claim 4 as granted in that features (a) to (c) have been replaced by the feature "and about less than 1% total of 8,10 octadecadienoic acid, 11,13 octadecadienoic and trans-trans octadecadienoic acid". In these circumstances, the board has the power under Article 101(3) EPC to examine whether the amendment introduces any contravention of requirements of the EPC, including Article 84 EPC 1973 (cf. T 301/87, OJ EPO 1990, 335, point 3.8 of the Reasons, confirmed in G 3/14 of 25 March 2015, paragraph 87 of the Reasons).

7.2 Article 84 EPC 1973 in combination with Rule 29(1) EPC 1973 requires that the claims must be clear and define the matter for which protection is sought in terms of the technical features of the invention. These requirements serve the purpose of ensuring that the public is not left in any doubt as to which subject-matter is covered by a claim and which is not. A claim cannot be considered clear in the sense of

Article 84 EPC if it does not unambiguously allow this distinction to be made (cf. G 2/88, OJ EPO 1990, 93, point 2.5 of the Reasons). A claim comprising an unclear technical feature therefore entails doubts as to the subject-matter that the claim covers. This applies all the more if the unclear feature is essential with respect to the invention in the sense that it is intended to delimit the claimed subject-matter from the prior art, thereby giving rise to uncertainty as to whether or not the claimed subject-matter is anticipated (cf. T 560/09 of 20 January 2010, point 2 of the Reasons).

7.3 In the present case, the level of undesired isomers is essential to the invention, which aims at providing a safe and defined product suitable for consumption by animals and humans. This level also distinguishes the claimed compositions from those of the prior art (see page 3, paragraph [0010], of the patent in suit). It is therefore essential that this level is clearly defined.

However, claim 1 of auxiliary request 4 lacks a clear boundary in this respect, due to the use of the vague expression "about less than 1%", with the consequence that the skilled person is not able to establish with certainty which subject-matter is covered by claim 1 and which is not. Merely to illustrate this point, the board notes that it is not at all clear whether a composition with, for example, 1.4% total of undesired isomers falls within the scope of claim 1 or not.

7.4 The appellant, who had been made aware of this objection in the board's communication accompanying the summons to oral proceedings, did not provide any arguments in this respect.

7.5 For the above reasons, the board concludes that claim 1 of auxiliary request 4 does not comply with Article 84 EPC 1973.

8. Remittal

Since the board has come to the conclusion that the patent as granted cannot be maintained pursuant to Article 100(c) EPC 1973 and that the first to fourth auxiliary requests are not allowable under Article 123(2) or (3) or Article 84 EPC, there is no room for a decision on remittal of the case to the department of first instance.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

C. M. Radke

Decision electronically authenticated