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## Datasheet for the decision of 4 August 2015

Case Number: T 1016/13 - 3.3.09

00906735.6 Application Number:

Publication Number: 1166652

IPC: A23L1/30, A61K31/20, A61K31/23,

A23K1/16

Language of the proceedings: ΕN

Title of invention:

UTILIZATION OF MATERIAL CONTAINING DOCOSAPENTAENOIC ACID

### Patent Proprietor:

Suntory Holdings Limited

### Opponent:

DSM Nutritional Products, LLC

Headword:

### Relevant legal provisions:

EPC Art. 100(c), 123(2), 84, 123(3), 54, 56

### Keyword:

Amendments - correction of errors (yes) broadening of claim (no) Claims - clarity after amendment (yes) Novelty - (yes) Inventive step - (yes)

#### Decisions cited:

### Catchword:



## Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 1016/13 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 4 August 2015

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Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 11 February 2013 revoking European patent No. 1166652

pursuant to Article 101(3)(b) EPC.

Composition of the Board:

Chairman W. Sieber Members: M. O. Müller

F. Blumer

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### Summary of Facts and Submissions

- This decision concerns the appeal filed by the proprietor of European patent No. 1 166 652 against the decision of the opposition division to revoke it.
- II. The opponent had requested revocation of the patent in its entirety on the grounds of Article 100(a) (lack of novelty and inventive step, as well as non-patentable subject-matter under Article 52(4) EPC 1973), Article 100(b) and Article 100(c) EPC.
- III. The documents submitted during the opposition proceedings included:
  - D8: B. Verdino et al, J. Nutrition, volume 83, 1964, pages 234 to 238;
  - D12: W. Barclay et al, Journal of the World Aquaculture Society, volume 27(3), 1996, pages 314 to 322;
  - D15: WO 98/03671 A1; and
  - D19: Ph.S.Y. Tam et al, Lipids, volume 35(1), 2000, pages 71 to 75.
- IV. The decision of the opposition division was based on a main request and first to fifth auxiliary requests. The main request, which is also the main request in the present appeal proceedings, contained five independent claims, namely claims 1, 4, 8, 9 and 14, which read as follows:
  - "1. Use of material containing 4, 7, 10, 13, 16-docosapentaenoic acid (DPA) in the manufacture of a

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composition for relieving arachidonic acid deficient conditions and maintaining a good fatty acid balance in mammals."

- "4. Use of DPA-containing material in the manufacture of a composition for preventing decrease of arachidonic acid levels caused by intake of  $\omega 3$  unsaturated fatty acids."
- "8. A method for the production of composition that prevents the decrease of arachidonic acid levels caused by intake of  $\omega$ 3 unsaturated fatty acids, comprising:

preparing a unit dose of said composition containing DPA-containing material based on an average intake of  $\omega 3$  unsaturated fatty acids determined during a set period of time in a subject and an estimate of the decrease of arachidonic acid levels brought forth by intake of said  $\omega 3$  fatty acids in the subject."

"9. A method for the production of composition that prevents the decrease of arachidonic acid levels caused by intake of  $\omega 3$  unsaturated fatty acids, comprising:

preparing a unit dose of said composition containing DPA-containing material and  $\omega 3$  unsaturated fatty acid-containing material based on an estimate of arachidonic acid levels caused by intake of a pre-determined amount of  $\omega 3$  unsaturated fatty acids, wherein the predetermined amount of  $\omega 3$  unsaturated fatty acids is an amount of  $\omega 3$  unsaturated fatty acids to be included per unit dose in said composition."

"14. A lipid containing arachidonic acid (ARA), DPA, and DHA, in which:

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ARA/DHA (weight ratio) is 0.03-0.4; DPA/DHA (weight ratio) is not less than 0.07; and EPA/DHA (weight ratio) is not more than 0.03."

- V. The requests before the opposition division that are relevant to the present appeal proceedings are the main request (see point IV above) and the first to third and fifth auxiliary requests. According to the opposition division, the main request was not allowable since the amendment of the EPA/DHA ratio to not more than 0.03 in claim 14 infringed Article 123(2) in conjunction with Rule 139 EPC. The first auxiliary request was not allowable in view of Article 84 EPC. The second auxiliary request was not allowable since claim 1, which is identical to claim 1 of the present main request, lacked novelty over D8. The regulatory type of mechanism disclosed therein anticipated the claimed therapeutic effect of maintaining a good fatty acid balance. The third auxiliary request was not allowable since claim 11, which differs from claim 14 of the present main request only in that the EPA/DHA ratio is not more than 0.05 (rather than 0.03), lacked novelty over D12. This document disclosed the claimed fatty acid ratios to be present in rotifers, which were used as a lipid even though they were not a pure lipid. The fifth auxiliary request was not allowable since claim 1, which corresponds to claim 4 of the present main request, lacked inventive step in view of D8.
- VI. On 19 April 2013, the proprietor (hereinafter: "the appellant") filed an appeal. The statement setting out the grounds of appeal was filed on 21 June 2013 together with auxiliary requests I to XII, and
  - D28: O. Suzuki et al, Oleo Chemistry, volume 30(12), 1981, pages 854 to 862;

D28a: English translation of D28;

D29: A. Fernandez-Casalderrey et al, Comp. Biochem. Physiol., volume 100C(1/2), 1991, pages 61 to 63;

D30: M. Kainz et al, Environmental Pollution, volume 155, 2008, pages 262 to 270; and

D31: E.N. Siguel et al, Clin. Chem., volume 33(10), 1987, pages 1869 to 1873.

- VII. The opponent filed a response with letter of 8 November 2013.
- VIII. On 23 February 2015, the board issued its preliminary opinion, in which it *inter alia* observed that the amendment of "*in vivo*" to "in mammals" in claim 1 was based on the application as filed and did not violate Article 123(3) EPC.
- IX. With its letter dated 28 May 2015, the appellant withdrew auxiliary requests I, III, V, IX, X, XI and XII and filed
  - D32: Declaration I of Prof. Sugano, signed on 21 May 2015;
  - D33: Declaration II of Prof. Sugano, signed on 21 May 2015;
  - D34: W.-H. Kunau, FEBS Letters, volume 16(1), 1971, pages 54 to 56; and
  - D35: H. Sprecher, Biochimica et Biophysica Acta,

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volume 1486, 2000, pages 219 to 231.

- X. By its letter dated 3 August 2015, the opponent withdrew its opposition. The opponent thereby ceased to be a party to the proceedings and will therefore be referred to hereinafter as "the former opponent".
- XI. On 4 August 2015, oral proceedings were held before the board. The appellant, the only party present, maintained its requests filed during the written proceedings and did not file any new requests. After the board had announced its opinion that the main request was allowable, the appellant filed five description pages adapted to the claims of the main request.
- XII. In so far as relevant to the present decision, the former opponent's arguments can be summarised as follows:

The replacement of the term "in vivo" in granted claim 1 by "in mammals" in claim 1 of the main request did not meet the requirements of Article 123(2) EPC since there was no basis in the application as filed for the embodiments covered by claim 1 pertaining to the use in relation to human mammals. This replacement also infringed Article 123(3) EPC, since the material could now be used to prepare a composition for the treatment of ex vivo conditions. Finally, the subjectmatter of claim 1 of the main request lacked novelty over D8 and D15.

The subject-matter of claim 4 of the main request lacked novelty over D8 and D15.

The subject-matter of claims 8 and 9 of the main request lacked novelty in view of D15.

The feature of claim 14 of the main request that the EPA/DHA ratio was not more than 0.03 was not based on the application as filed. The corresponding passage in the description referred to "0.03%", which could not be corrected to "0.03" (Rule 139 EPC). Claim 14 also lacked clarity, since the skilled person did not know how to interpret the value of 0.03 in claim 14 in the light of the corresponding passage in the description where 0.03% was disclosed. Furthermore, there was no basis in the application as filed for the combination of the three weight ratios contained in claim 14. Lastly, the subject-matter of claim 14 lacked novelty over D12 and inventive step in view of D15.

XIII. In so far as relevant to the present decision, the appellant's arguments presented during the written and oral proceedings can be summarised as follows:

The subject-matter of claim 1 of the main request was novel over D8 since this document did not disclose the maintenance of a normal ARA level. This maintenance of a normal ARA level was achieved in claim 1 due to the fact that the DPA to be used according to claim 1 was converted into ARA only until a normal ARA level was achieved. This mechanism was not only mentioned in the patent but experimentally confirmed by D19. The subject-matter of claim 1 was also novel over D15 since this document did not disclose the therapeutic effect required by this claim at all.

The subject-matter of claim 4 of the main request was novel over D8 since this document did not disclose the administration of  $\omega 3$  unsaturated fatty acids, let alone

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a resulting decrease in ARA levels. The subject-matter of claim 4 was also novel over D15 since this document did not disclose the therapeutic effect required by this claim at all.

The subject-matter of claims 8 and 9 of the main request was novel over D15, since this document did not disclose the preparation of a unit dose as required by these claims.

The amendment of the EPA/DHA ratio in claim 14 of the main request to not more than 0.03 was based on page 22, lines 9 to 19 of the application as filed. It would have been evident to the skilled person that the value of 0.03% disclosed in this passage was wrong and the only possible correction was the deletion of the reference to a percentage. Furthermore, contrary to the former opponent's assertion, in view of claim 22 and page 22, lines 9 to 19 of the application as filed no multiple but only a single selection was needed to arrive at the subject-matter of claim 14. The subjectmatter of claim 14 was novel over D12, since this document did not disclose the claimed fatty acid ratios to be present in a lipid. Finally, the subject-matter of claim 14 was inventive in view of D15 as the closest prior art, from which it differed in that the claimed ARA/DHA ratio was higher. The problem solved by this higher ARA/DHA ratio was the provision of an improved lipid composition in the sense that it provided more efficient immediate relief of ARA-deficient conditions. There was no indication in D15 that this problem could be solved by a higher ARA/DHA ratio. In fact, the skilled person would not have been inclined to increase this ratio e.g. by increasing the amount of administered ARA since he would expect that to lead to excessive ARA in the organism.

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XIV. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of the main request or, alternatively, on that of the claims of any of auxiliary requests II, IV and VI to VIII, all filed with the statement setting out the grounds of appeal on 21 June 2013.

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### Reasons for the Decision

Main request

- 1. Claim 1
- 1.1 General remarks

Claim 1 refers to the use of a material containing docosapentaenoic acid (DPA) in the manufacture of a composition for relieving arachidonic acid (ARA) deficient conditions and maintaining a good fatty acid balance in mammals. The mechanism by which DPA leads to the relief of ARA-deficient conditions and the maintenance of a good fatty acid balance is explained in the patent as follows:

The administration of docosahexaenoic acid (DHA) decreases ARA levels in mammals since it inhibits the conversion of various ARA precursors to ARA (paragraph [0007]). This is confirmed by example 2 of the patent, where the administration of a diet containing 40.0% DHA (DHA group) reduces the ARA level in the liver of rats from 24.1 in a control group fed a DHA free diet to 6.18 in the DHA group.

DPA, the fatty acid to be used according to claim 1, functions as a prodrug, which is converted to ARA in the organism. Thus the administration of DPA relieves ARA-deficient conditions. This is confirmed by example 3 of the patent. More specifically, if a diet containing 34.9% DHA and 10.3% DPA is fed instead of the diet of example 2, which contains only 40.0% DHA, the ARA level in the liver of the rats increases to 22.4.

ARA-deficient conditions can in principle also be relieved by direct administration of ARA. However, even if the administration takes into account the biologically required amount, that amount varies among individuals and may therefore, in certain cases, cause excessive intake. Excessive ARA is disadvantageous since ARA is the direct precursor of eicosanoids which may be harmful to the body (paragraph [0038] of the patent).

Unlike the direct administration of ARA, the administration of DPA avoids excessive ARA amounts in the organism and maintains the ARA content at a normal level (expressed in claim 1 by the feature "maintaining a good fatty acid balance"). As set out in paragraph [0038] of the patent, this effect is achieved with DPA since once a normal ARA level is achieved, DPA conversion to ARA stops and any additional DPA will be stored in the mammal as an effective source of ARA. As soon as the ARA level drops again (e.g. due to an additional administration of DHA), it will be brought back to normal by conversion of this stored DPA. This is confirmed experimentally by post-published document D19, where it was found in experiment 2 that the conversion of DPA to ARA is active when the ARA content

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is decreased by administration of DHA and is not active when the ARA content is at the normal level.

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- 1.2 Amendments Article 123(2) and 123(3) EPC
- 1.2.1 The therapeutic effect defined in claim 1 differs from that of claim 1 as granted (and as filed) in that this effect is to be obtained "in mammals" rather than "in vivo". The same therapeutic effect is disclosed in the description as filed (see e.g. page 6, lines 10 to 17) for "mammals excluding humans". The former opponent argued that there was no basis in the application as filed for the patient group as defined in claim 1, i.e. mammals in general, which includes humans.

However, the application as filed also envisages the patient group of humans. This is confirmed by the sentence bridging pages 1 and 2 of the application as filed which refers to humans and page 12, line 13 of the application as filed which refers to "humans or other mammals".

In fact, the application as filed mentions an exclusion of humans for purely legal reasons to take account of restrictions in certain national patent laws (see page 12, line 30 to page 13, line 7 of the application as filed: "Utilization of DPA-containing material of this invention and administration of compositions comprising DPA-containing material may exclude the utilization and administration carried out according to medical prescription by a medical doctor in cases where the patent law applied to applications made by this description includes such limitations").

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Therefore, the former opponent's objection under Article 123(2) EPC against the feature "in mammals" in claim 1 must fail.

1.2.2 The former opponent argued that the amendment of "in vivo" to "in mammals" extended the scope of protection of claim 1, since claim 1 now covered the use to prepare a composition for the treatment of ex vivo conditions (Article 123(3) EPC).

This argument is not convincing. The term "in vivo" in claim 1 as granted means "in a living organism" and mammals are one sub-group of such organisms. Contrary to the former opponent's assertion, the use in mammals therefore does not cover the use in ex vivo conditions. Amended claim 1 thus meets the requirements of Article 123(3) EPC.

### 1.3 Novelty

1.3.1 The opposition division had held that the subjectmatter of claim 1 lacked novelty over D8 (in the context of the identical claim 1 of the second auxiliary request before the opposition division). This objection was maintained by the former opponent in the present appeal proceedings.

D8 describes a study in which four groups of rats showing severe symptoms of essential fatty acid deficiency were fed for 52 days with ARA (in the form of ethyl arachinodate), DPA (in the form of methyl docosapentaenoate), safflower oil (containing linolenic acid, which is a precursor of ARA) and a fat-free diet, respectively. On the 52nd day, the rats were killed and the following ARA amounts were found in their livers:

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- 13.9 (group fed the safflower oil),
- 18.5 (group fed the ARA),
- 8.6 (group fed the DPA), and
- 1.3 (surviving animal of the group fed the fatfree diet).

It is thus clearly and unambiguously derivable from table 2 of D8 that ARA-deficient conditions, such as present in the rat fed the fat-free diet (ARA amount of 1.3), can be relieved by the administration of DPA (ARA amount of 8.6). It is in fact explicitly stated several times in D8 that DPA is converted to ARA (abstract, second paragraph on the left-hand column on page 234, first full paragraph on the right-hand column of page 236 and last paragraph on the left-hand column of page 237).

However, there is no disclosure in D8 that by feeding DPA the ARA level can be brought to and maintained at a normal level as required by claim 1 (feature: "maintaining a good fatty acid balance"). In fact it is impossible to draw any conclusion from D8 about the maintenance of normal ARA levels. In order to observe such maintenance, the ARA level would have to be brought back by DPA administration to the normal level, since it is only then that conversion of DPA to ARA stops and DPA is stored in the mammal. In D8, however, the experiment was stopped before any normal level of ARA was achieved. This is apparent from e.g. the last paragraph of the left-hand column on page 236 of D8 stating that DPA was not as efficient as ARA for correcting essential fatty acid deficiency. This implies that correction has not been complete and in fact the DPA administration led to an ARA amount in the liver of only 8.6%, compared to 18.5% obtained with ARA administration (see table 2 of D8). The same follows

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from the statement in the first paragraph of the righthand column on page 235 that the dermal symptoms of essential fatty acid deficiency were not completely cured in the experiment.

The opposition division had reasoned in its decision that the disclosure of a regulatory-type mechanism between many fatty acids in the left-hand column of page 237 of D8 was equivalent in scope to the requirement in claim 1 of maintaining a good fatty acid balance. The board does not find this argument convincing. D8 is silent about how fatty acid levels are regulated, and in particular does not disclose that the regulation is such that conversion of DPA stops when normal ARA levels are obtained and additional DPA is stored in the mammal so that it is available for further conversion to ARA if the ARA level drops later on. Therefore the regulatory-type of mechanism as defined in claim 1, namely the maintenance of a good fatty acid balance, is not disclosed in D8. The board agrees with the appellant that the very speculative unexplained "regulatory mechanism" referred to in D8 can only with hindsight be considered to be equivalent to the therapeutic effect referred to in claim 1. The public was provided with the knowledge of the selfcontrolled conversion and storage of DPA to correctly maintain a good fatty acid balance for the first time with the publication of the opposed patent.

Hence, the subject-matter of claim 1 is novel over D8.

1.3.2 The former opponent furthermore argued that the subject-matter of claim 1 lacked novelty over D15.

D15 refers to a process for preparing lipids containing DHA and DPA by cultivating microorganisms (page 1,

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lines 8 to 12). The only (therapeutic) effects disclosed in D15 are the growth of babies, in particular in height and brain development (page 14, lines 25 to 30), the maintenance of health (page 15, line 17), and recovery from, or prevention of, reduced functioning of the body (page 16, lines 5 to 7).

The therapeutic effect required by claim 1 is not disclosed in D15 at all.

Therefore, the former opponent's novelty attacks against claim 1 must fail.

- 2. Claim 4
- 2.1 General remark

Claim 4 refers to the use of DPA-containing material in the manufacture of a composition for preventing a decrease in ARA levels caused by the intake of  $\omega 3$  unsaturated fatty acids such as DHA.

As set out above (point 1.1), the intake of DHA reduces the ARA level and this can be prevented by the intake of DPA.

- 2.2 Novelty and inventive step
- 2.2.1 According to the former opponent, the subject-matter of claim 4 lacks novelty over D8, and, according to the opposition division, lacks inventive step over D8.

However, D8 nowhere discloses or suggests the  $\frac{\text{prevention}}{\text{prevention}} \text{ of any decrease in ARA levels by the} \\ \text{administration of DPA, let alone the prevention of a} \\ \text{decrease caused by the administration of } \omega 3 \text{ unsaturated}$ 

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fatty acids. In fact, the decrease in ARA levels in D8 is caused by a completely different means, namely the administration of a fat-free diet, and DPA is administered in D8 to relieve rather than to prevent this decrease. D8 therefore cannot take away the novelty or inventive step of the subject-matter of claim 4.

2.2.2 According to the former opponent, the subject-matter of claim 4 lacks novelty over D15.

As set out above (point 1.3.2), the only (therapeutic) effects disclosed in D15 are the growth of babies, the maintenance of health, and recovery from, or prevention of, reduced functioning of the body. These therapeutic effects are completely different from that of claim 4.

- 2.2.3 Therefore, novelty of the subject-matter of claim 4 over D15 must be acknowledged.
- 3. Claims 8 and 9
- 3.1 General remark

Claims 8 and 9 refer to a method for the production of a composition containing DPA and  $\omega 3$  unsaturated fatty acids that is suitable to prevent the decrease in ARA levels caused by the intake of the  $\omega 3$  unsaturated fatty acids, with the method comprising the step of preparing a unit dose of said composition, this unit dose being based on an estimate of the decrease in ARA levels caused by the intake of  $\omega 3$  fatty acids (for the exact wording of claims 8 and 9, see point IV above). Even though the exact amount of the unit dose is not specified in claims 8 and 9, the step of preparing a unit dose implies at least some limitation of the

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amount of the composition present in this unit dose and thus restricts claims 8 and 9.

### 3.2 Novelty

The only objection on file against claims 8 and 9 is the former opponent's assertion that the subject-matter of claim 8 and 9 lacks novelty over D15. This document however does not disclose the preparation of a unit dose as defined in claims 8 and 9 or an amount corresponding thereto.

Therefore, the former opponent's novelty attack against claims 8 and 9 must fail.

- 4. Claim 14
- 4.1 General remark
- 4.2 Claim 14 refers to a lipid containing ARA, DPA and DHA in which the ARA/DHA weight ratio is 0.03 to 0.4, the DPA/DHA weight ratio is not less than 0.07 and the EPA/DHA weight ratio is not more than 0.03.
- 4.3 Amendments Articles 123(2) and 84 EPC
- 4.3.1 Claim 14 of the main request is identical to claim 14 as granted (claim 22 as filed) except that the EPA/DHA weight ratio is defined as not more than 0.03 rather than 0.05. According to the former opponent, as well as the opposition division, this amendment was not allowable. However, the board disagrees for the following reasons:

This amendment is derived from page 22, lines 9 to 19 of the application as filed, which reads as follows:

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"This invention introduces novel lipids that may be utilized favorably as DPA-containing lipids. These lipids contain ARA, DPA, and DHA (and optionally EPA), and are characterized by the combination of three ratios, ARA/DHA, DPA/DHA, and EPA/DHA (each expressed by their weight ratio). Typically the ARA/DHA ratio is 0.03~0.4, preferably 0.05~0.4, and more preferably 0.1~0.4. Typically the DPA/DHA ratio is not less than 0.07, preferably 0.07~5.0, more preferably 0.07~3.0, and even more preferably 0.07~0.5. The EPA/DHA ratio is typically not more than 0.05, preferably not more than 0.04%, and more preferably not more than 0.03%." (emphasis added)

Unlike amended claim 14, this passage defines the EPA/DHA ratio by an upper limit of 0.03% rather than 0.03.

Hence, amended claim 14 results from the incorporation of the upper limit disclosed on page 22 of the application as filed into claim 22 as filed after correcting this upper limit from 0.03% to 0.03.

It was argued that this correction was not allowable since it was not immediately apparent that there was an error on page 22 of the application as filed, let alone what any correction should be.

The board does not share this view. Firstly, the skilled person would not be able to differentiate with certainty by analytical means between the two preferred values of 0.04% and 0.03%, i.e. 0.0004 and 0.0003, and thus would realise that these values were meaningless from a technical point of view. Secondly, weight ratios are ratios between two numbers and thus are expressed as absolute values rather than a percentage. The

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specification of a ratio by a percentage is thus clearly wrong. Thirdly, a percentage refers to a particular percentage of something. On page 22 of the application as filed, there is however no definition of what the percentage of 0.03% is referring to. Fourthly, the only composition disclosed in the examples of the application as filed that contains both EPA and DHA has a EPA/DHA ratio of 0.003 (table 8, EPA content of 0.1% and DHA content of 36.6%). This is an order of magnitude higher than the upper limit of 0.03% taken at face value (0.0003).

The skilled person would thus consider the specification of the EPA/DHA ratio by an upper limit of 0.03% (and 0.04%) to be erroneous.

The only correction of this error that makes technical sense is the one made in claim 14 of the main request, i.e. the deletion of "%". More specifically, apart from the two values of 0.04% and 0.03% on page 22, line 19, all other fatty acid ratios are given in the application as filed without the percentage sign (see in particular page 8, lines 26 to 30 and page 22, lines 14 to 18, as well as claims 22 and 23). Hence, the immediately apparent correction would be to delete the percentage signs also from "0.03%" on page 22. Furthermore, by way of this correction, all the problems discussed above would be removed. No other correction was provided by the former opponent for which the same would hold true.

Therefore, the correction of the value of 0.03% to 0.03 meets the requirements of Rule 139 EPC and thus the amended upper limit of the EPA/DHA ratio in claim 14 is allowable under Article 123(2) EPC.

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4.3.2 Furthermore, the former opponent argued that the ratios in claim 14 represented a multiple selection out of page 22, lines 9 to 19 of the application as filed (Article 123(2) EPC).

However, this amendment represents only a single selection, namely that of the preferred range for the EPA/DHA ratio (after its correction by the deletion of %), as disclosed on page 22, lines 9 to 19 of the application as filed for the broader range required for this ratio in claim 14 as granted (claim 22 as filed). The former opponent's argument must thus fail.

4.3.3 The former opponent argued that due to the amended upper limit of the EPA/DHA ratio (which was not present in claim 14 as granted), claim 14 lacked clarity. More specifically, in view of the fact that the description of the patent referred to 0.03%, it was not clear how the value of 0.03 in claim 14 had to be interpreted.

This discrepancy between the value of 0.03% in the description and 0.03 in claim 14 has been removed by amending "0.03%" in the description to "0.03". The former opponent's objection is thereby rendered moot.

- 4.4 Novelty
- 4.4.1 The former opponent and the opposition division argued that the subject-matter of claim 14 lacked novelty over D12.

D12 discloses a study in which rotifers and Artemia nauplii were enriched with long-chain fatty acids using spray-dried heterotrophic strains of microalgae rich in both  $\omega 3$  and  $\omega 6$  long-chain fatty acids (second full paragraph on the right-hand side of page 315). In

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table 4, the mean fatty acid contents of enriched rotifers are given, namely 1.4% ARA (20:4(n-6), 0.3% EPA (20:5(n-3), 7.4% DPA (22:5(n-6)) and 18.3% DHA (22:6(n-3)). To determine the fatty acid contents in D12, the fatty acids in the whole cells were methylated and the resulting fatty acid esters were then separated and quantified by gas-liquid chromatography (first paragraph on the left-hand column of page 316).

From the fatty acid contents in table 4, an ARA/DHA ratio of 0.076, a DPA/DHA ratio of 0.404, and an EPA/DHA ratio of 0.016 can be calculated. All these ratios are within the ranges of claim 14.

These ratios are present in the cells of the rotifers or, after the methylation of these cells to determine the fatty acid contents, in the mixture of cell components including the fatty acids. Neither rotifer cells, which are cells of living organisms, nor a mixture of cell components of these organisms represent lipids. In this respect, the opposition division's argument that rotifers were used as lipids is not supported by the disclosure of D12, and in fact is irrelevant since what matters is whether rotifers are lipids rather than whether they are used as lipids.

Consequently, novelty of the subject-matter of claim 14 can be acknowledged.

- 4.5 Inventive step
- 4.5.1 According to the former opponent, the subject-matter of claim 14 lacks inventive step in view of D15.
- 4.5.2 Like the invention defined in claim 14, D15 is directed to lipids containing DHA and DPA (page 1, lines 8 to 15

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- of D15). Therefore, in line with the former opponent's argument, D15 can be considered to represent the closest prior art for the subject-matter of claim 14.
- 4.5.3 Example 2 of D15 discloses the extraction of lipids from the microorganism Ulkenia sp. SAM 2179. The lipids contain 0.7 ARA, 0.7 EPA, 12.4 DPA and 45.8 DHA (table 4), implying an ARA/DHA ratio of 0.015 (claim 14: 0.03-0.4), a DPA/DHA ratio of 0.27 (claim 14: not less than 0.07) and an EPA/DHA ratio of 0.015 (claim 14: not more than 0.03). Consequently, as acknowledged by the former opponent, the subjectmatter of claim 14 differs from D15 in that the claimed ARA/DHA ratio is higher than in D15.
- 4.5.4 According to the appellant, the problem solved by this higher ARA/DHA ratio is the provision of an improved lipid composition, which leads to more efficient immediate relief of ARA-deficient conditions.
- 4.5.5 The higher ARA/DHA ratio required by claim 14 implies a higher amount of ARA and/or a lower amount of DHA. The administration of a higher ARA amount increases the amount of ARA in the organism. The administration of a lower DHA amount implies that the ARA level in the organism is decreased less (see point 1.1 above). Hence, the higher ARA/DHA ratio required by claim 14 leads to a higher initial ARA level in the organism. By the further requirement in claim 14 that the DPA/DHA ratio is above a certain lower limit, this ARA level is brought to a normal ARA level by conversion of the administered DPA to ARA (see point 1.1 above). While the latter can be assumed to be also achieved in D15, since the DPA/DHA ratio disclosed therein is as required by claim 14, the initial ARA level achieved by the lipid of D15 will be lower due to the lower ARA/DHA

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ratio. Therefore, it is credible that the lipid composition as defined in claim 14 is indeed improved over that of D15 in that it achieves a higher initial ARA level in the organism, which translates into a more efficient immediate relief of ARA-deficient conditions.

- 4.5.6 There is no suggestion in D15 to increase the ARA content and/or to decrease the DHA content of the lipid in order to obtain such a more efficient immediate relief of ARA-deficient conditions. Not knowing that the conversion of the DPA contained in the lipid of D15 to ARA stops when normal ARA levels are obtained, the skilled person would assume that the DPA in D15 is fully converted to ARA, already leading to a rather high ARA level. Since a further increase in the ARA level might lead to excessive ARA in the organism, the skilled person would try to avoid such a further increase and hence would not increase the amount of ARA or decrease the amount of DHA in the lipid.
- 4.5.7 The former opponent's inventive-step attack on the basis of D15, which was the only such attack raised in the present appeal proceedings, must thus fail.

### 5. Summary

It follows from the above that none of the objections of the opposition division and former opponent is persuasive. The main request is thus allowable.

6. The amendments in the description pages submitted during the oral proceedings before the board meet the requirements of the EPC.

### 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 on the basis of the following documents:
  - Claims 1 to 21 filed as main request with the statement setting out the grounds of appeal of 21 June 2013;
  - Description:
    - pages 2, 7, 9 to 13 as published;
    - pages 3 to 6 and 8 as filed during the oral proceedings on 4 August 2015.

The Registrar:

The Chairman:



M. Cañueto Carbajo

W. Sieber

Decision electronically authenticated