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**Datasheet for the decision  
of 10 July 2014**

**Case Number:** T 1565/12 - 3.3.09

**Application Number:** 01952255.6

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**IPC:** A23C9/14, A23K1/16, A23K1/18

**Language of the proceedings:** EN

**Title of invention:**  
IMPROVED METHODS OF INCORPORATING POLYUNSATURATED FATTY ACIDS  
IN MILK

**Patent Proprietor:**  
DSM IP Assets B.V.

**Opponent:**  
UNILEVER N.V./UNILEVER PLC

**Headword:**

**Relevant legal provisions:**  
EPC Art. 123(2), 111(1), 84, 83, 54, 56

**Keyword:**  
Main request: added subject-matter (yes)  
Auxiliary request 1: added subject-matter (no)  
Claims - clarity (yes)  
Sufficiency of disclosure - (yes)  
Novelty - (yes)  
Remittal - (no)  
Inventive step - (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
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Case Number: T 1565/12 - 3.3.09

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.09**  
**of 10 July 2014**

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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
2 May 2012 concerning maintenance of the  
European Patent No. 1299003 in amended form.**

**Composition of the Board:**

**Chairman** W. Sieber  
**Members:** J. Jardón Álvarez  
K. Garnett

## Summary of Facts and Submissions

- I. This decision concerns the appeals filed by the patent proprietor and the opponent against the interlocutory decision of the opposition division that European patent EP-B-1 299 003 in the name of MARTEK BIOSCIENCES CORPORATION (now DSM IP Assets B.V.) as amended meets the requirements of the EPC.
- II. A joint opposition had been filed by Unilever N.V. and Unilever PLC (hereafter "the opponent") requesting revocation of the patent in its entirety based on the grounds that the claims referred to essentially biological processes for the production of animals and to methods of therapy, both excluded from patentability under Article 52(4) EPC 1973 and Article 53(b) EPC, respectively, and that the claimed subject-matter was neither novel nor inventive (Article 100(a) EPC), that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC) and that the patent contained subject-matter which extended beyond the content of the application as filed (Article 100(c) EPC).

The documents cited during the opposition proceedings included:

D2: S.T. Franklin *et al.*, "Dietary Marine Algae (*Schizochytrium sp.*) Increases Concentrations of Conjugated Linoleic, Docosahexaenoic and Transvaccenic Acids in Milk of Dairy Cows", *Nutrient Metabolism*, 1999, pages 2048-2054;

D4: WO 97/37546 A1;

D7: WO 96/40106 A2; and

D8: EP 0 249 282 A1.

III. The decision of the opposition division announced orally on 13 December 2011 and issued in writing on 2 May 2012 was based on a main request, and a first and second auxiliary request.

The opposition division's view can be summarized as follows:

- The patent did not include non-patentable subject-matter.
- The main request did not fulfill the requirements of Article 123(2) EPC because the expression "effective amount" in the claimed compositions had no basis in the application as filed.
- The subject-matter of claim 1 of the first auxiliary request lacked novelty in view of example 1 of D4, example 7 of D7 and example 1 of D8. The term "encapsulated" had to be interpreted in the broadest possible way since no definition was provided by the claim. Moreover, the functional feature relating to the increase in polyunsaturated fatty acids (in the following: PUFAs) in milk was not considered as having any limiting effect on the scope of the claim.
- Lastly, the opposition division found that the subject-matter claimed in the then pending second auxiliary request fulfilled the requirements of Articles 123(2) EPC, 84 EPC and 83 EPC. Moreover, the subject-matter of claim 1 was novel over the

disclosure of D4 and involved an inventive step starting from D2 as the closest prior-art.

- IV. Appeals against this decision were filed on 2 July 2012 by the patent proprietor and the opponent. The respective appeal fees were paid in due time.

As the patent proprietor and the opponent are appellant and respondent in this appeal proceedings, for simplicity the board will continue to refer to them as the patent proprietor and the opponent.

- V. In its statement of grounds of appeal filed on 31 August 2012 the opponent requested that the decision under appeal be set aside and the patent be revoked. It also filed the following documents:

D12: Wikipedia excerpt 'Omega-3 fatty acid', non-dated;

D13: Wikipedia excerpt 'Algae fuel', non-dated; and

D14: J.D. Sutton, "Altering Milk Composition by Feeding" J. Dairy Sci., 1989, 72, pages 2801-2814.

- VI. In its statement of grounds of appeal filed on 12 September 2012 the patent proprietor requested maintenance of the patent on the basis of a main request, corresponding to the first auxiliary request in the opposition proceedings or, alternatively on the basis of newly filed auxiliary requests I to III.

- VII. Further submissions were filed:

- By the patent proprietor on 28 January 2013, including auxiliary requests IV and V and the following document:

D15: W. Banks *et al.*, "Effect of inclusion of different forms of dietary fatty acid on the yield and composition of cow's milk." *Journal of Dairy Research*, 1984, 51, pages 387-395;

- By the opponent on 11 April 2013; and
- By the patent proprietor on 3 May 2013.

VIII. In response to the board's communication, issued on 22 November 2103 in preparation for the oral proceedings, the patent proprietor filed on 15 May 2014 auxiliary requests 1 to 11 to replace its previous auxiliary requests.

IX. During the oral proceedings held on 10 July 2014, the proprietor withdrew its auxiliary requests 2 to 11 and maintained as its only requests the main request and auxiliary request 1.

Claim 15 of the main request, the only claim relevant to the decision, reads as follows:

"15. A method of making a composition comprising a PUFA and a protective fat, comprising the steps of:

- (a) obtaining the PUFA and protective fat to increase PUFA content of milk produced by a milk-producing animal, wherein said PUFA comprises omega-3 PUFA, omega-6 PUFA, or a combination thereof; and
- (b) combining the protective fat with the PUFA to produce the composition, and wherein the protective fat is a triacylglycerol containing at least two saturated fatty acids, or a functional

derivative thereof, and wherein the protective fat is encapsulating the PUFA."

The independent claims of auxiliary request 1, namely claims 1, 12, 13, 16, 18, 19, and 25 to 27, read as follows:

"1. A composition comprising a microorganism in a whole cell form or a lipid extracted therefrom comprising a polyunsaturated fatty acid (PUFA) and a protective fat encapsulating the whole cell or lipid to increase PUFA content of milk produced by a milk-producing animal, wherein said PUFA comprises an omega-3 PUFA, omega-6 PUFA or a combination thereof, and wherein the protective fat is a triacylglycerol containing at least two saturated fatty acids, or a functional derivative thereof."

"12. A method of making a composition comprising a PUFA and a protective fat to increase PUFA content of milk produced by a milk-producing animal, comprising the steps of:

- (a) obtaining the PUFA and protective fat, wherein said PUFA comprises omega-3 PUFA, omega-6 PUFA, or a combination thereof; and
- (b) combining the protective fat with the PUFA to produce the composition, and wherein the protective fat is a triacylglycerol containing at least two saturated fatty acids, or a functional derivative thereof, and wherein the protective fat is encapsulating the PUFA."

"13. A method of producing milk enriched with omega-3 PUFA, omega-6 PUFA or a combination thereof in an animal capable of producing milk, comprising feeding



the animal the composition as claimed in any of claims 1 to 11 in an amount effective to produce the enriched milk."

"16. A method of obtaining milk enriched with omega-3 PUFA, omega-6 PUFA or a combination thereof in an animal capable of producing milk, comprising the steps of:

- (a) producing said milk as claimed in any of claims 13 to 15; and
- (b) extracting milk from the animal to obtain the enriched milk."

"18. A method of obtaining milk enriched with omega-3 PUFA, omega-6 PUFA or a combination thereof in an animal capable of producing milk, comprising the steps of:

- (a) obtaining a PUFA, wherein said PUFA comprises omega-3 PUFA, omega-6 PUFA, or the combination thereof;
- (b) combining a protective fat with the PUFA to produce a mixture thereof and wherein the protective fat is a triacylglycerol containing at least two saturated fatty acids, or a functional derivative thereof;
- (c) feeding the animal said mixture in an amount effective to produce enriched milk; and
- (d) extracting milk from the animal to obtain said enriched milk."

"19. A method of producing PUFA-enriched milk, comprising the steps of:

- (a) adding a layer comprising omega-3 PUFA, omega-6 PUFA, or a combination thereof on top of feed to

form a layered feed, wherein the PUFA layer contains an effective amount of PUFA to produce PUFA-enriched milk; and

(b) feeding said layered feed to a milk-producing animal."

"25. A composition comprising a polyunsaturated fatty acid (PUFA) and a protective fat, wherein said PUFA comprises an omega-3 PUFA, omega-6 PUFA or a combination thereof, wherein the protective fat is mixed with the PUFA in a ratio of about 1:10 to about 10:1 (protective fat:PUFA) and wherein the protective fat encapsulates the PUFA."

"26. A composition comprising a polyunsaturated fatty acid (PUFA) and a protective fat, wherein said PUFA comprises an omega-3 PUFA, omega-6 PUFA or a combination thereof, wherein the protective fat is mixed with the PUFA in a ratio of about 1:5 to about 5:1 (protective fat:PUFA) and wherein the protective fat encapsulates the PUFA."

"27. A composition comprising a polyunsaturated fatty acid (PUFA) and a protective fat, wherein said PUFA comprises an omega-3 PUFA, omega-6 PUFA or a combination thereof, wherein the protective fat is mixed with the PUFA in a ratio of about 1:1 to about 3:1 (protective fat:PUFA) and wherein the protective fat encapsulates the PUFA."

Claims 2 to 11, 14, 15, 17, 20 to 24 and 28 are dependent claims.

X. The arguments presented by the patent proprietor in its written submissions and at the oral proceedings,

insofar as they are relevant for the present decision, may be summarised as follows:

- Documents D12 to D14 should not be admitted into the proceedings. There were no new issues in the appeal proceedings and thus they could have been filed with the notice of opposition. Moreover they were less relevant than the documents already in the proceedings.
- In the event that the board decided to admit D14 into the proceedings, the case should be remitted to the opposition division for a discussion of inventive step. A decision by the board not to remit would prejudice its right to be heard.
- The subject-matter of the claims of the main and the first auxiliary requests was supported by the disclosure of the application as filed. The wording "encapsulating the PUFA" was supported by the disclosure in paragraphs 2 and 3 of page 5 of the application as filed. The feature "to increase PUFA content of milk produced by a milk-producing animal" was supported by the general teaching of the application as filed, for instance by page 2, lines 2 to 4.
- The term "milk-producing animal" was clear. It referred to an animal which produces milk.
- The opposition division correctly decided that the requirements of sufficiency of disclosure were met.
- The subject-matter of claim 1 required that the protective fat encapsulated the PUFA such that the

PUFA content of milk produced by a milk-producing animal was increased, a feature not disclosed in none of D4, D7 or D8.

- Lastly, the claimed subject-matter involved an inventive step when starting from D2 as closest prior art. Compared to the disclosure of D2, the protected compositions of the invention provided a quite good increase of omega-3 and omega-6 PUFAs in milk while maintaining good milk production levels. D2 used xylose as protective agent and did not give any hint to the claimed invention using a protective fat. Also in D14 there was no teaching to encapsulate unsaturated fatty acids. The combination of D2 with D14 did not suggest the claimed invention.

XI. The relevant written and oral arguments of the opponent may be summarised as follows:

- There was no support in the application as filed for the wording "encapsulating the PUFA" or "to increase PUFA content of milk produced by a milk-producing animal" in claim 1 of the main request. There was also no support for a "protective fat to increase PUFA content of milk produced by a milk-producing animal" in claim 15 of the main request. Also the wording "a lipid extracted therefrom" in claim 1 of auxiliary request 1 was not supported by the application as filed.
- It was not clear what animals were encompassed by the term "milk-producing animal". According to the patent specification the claimed method worked only for ruminants, as the encapsulation was said

to allow the PUFAs to pass relatively undamaged through the ruminant's first stomach.

- The skilled person was not in a position to carry out the claimed method because there was no definition in the patent of the "control milk" to be used to obtain the claimed "enriched milk". Moreover, there was no information of how to carry out the claimed invention for animals other than ruminants.
- The subject-matter of claims 1 and 12 of the first auxiliary request was anticipated by documents D4, D7 and D8 and the subject-matter of claim 18 was not novel in view of D2.
- The subject-matter of claims 1, 12, 13, 16 and 18 of the first auxiliary request lacked inventive step in view of the combined teaching of documents D2 and D14.

XII. The patent proprietor requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request as filed with the statement of the grounds of appeal dated 12 September 2012, alternatively on the basis of auxiliary request 1 as filed with the letter dated 15 May 2014.

The opponent requested that the decision under appeal be set aside and the patent be revoked.

## **Reasons for the Decision**

1. The appeals are admissible.
2. *Procedural matters*
  - 2.1 Admissibility of D12 to D14
    - 2.1.1 Documents D12 to D14 constitute new evidence, cited for the first time in the opponent's statement of grounds of appeal. The patent proprietor requested that these documents be not admitted into the appeal proceedings for the reason that they were late-filed and not relevant.
    - 2.1.2 Documents D12 and D13 are non-dated excerpts from Wikipedia, and were filed by the opponent in order to support its novelty objections. They aim to show that fish do not synthesize omega-3 fatty acids (cf. D12) and that algae are naturally encapsulated and comprise protective fat (cf. D13). This was, however, not disputed by the patent proprietor and in any event is not relevant for the present decision.
    - 2.1.3 Under these circumstances the board exercised its discretionary power to not admit these documents.
    - 2.1.4 Document D14 is a review article that was filed to further support the opponent's previous inventive step attack starting from D2 as closest prior art. D14 was filed as a reaction to the opposition division's decision and with the statement of grounds of appeal. The board sees no reason to hold D14 inadmissible under Article 12(4) RPBA.

2.1.5 Hence, D14 is to be taken into consideration in the appeal proceedings.

2.2 Remittal

2.2.1 The patent proprietor requested that in the event that D14 is admitted, the case be remitted back to the opposition division for discussion of inventive step, since D14 had not been taken into consideration by the opposition division. In its view a decision by the board not to remit would prejudice its right to be heard.

2.2.2 It is established case law that there is no absolute right to have an issue decided by two instances and that the decision to remit the case to the opposition division is within the discretion of the board (see Case Law of the Boards of Appeal of the EPO 7<sup>th</sup> edition 2013, Chapter IV.E.7.6). In the present case the patent proprietor had had plenty of time to study D14 and to comment on it and it duly did so.

2.2.3 The board, therefore, decided to exercise the power of the opposition division without remittal of the case, pursuant to Article 111(1) EPC.

## MAIN REQUEST

### 3. *Amendments*

3.1 The only claim which it is necessary to consider for the decision on the main request is claim 15.

3.2 Granted claim 15 was based on claim 20 of the application as filed (basically combining the PUFA with the protective fat), whereby it was now further

specified that the protective fat "is a triacylglycerol containing at least two saturated fatty acids, or a functional derivative thereof". This amendment is supported by claim 12 as filed.

3.3 Claim 15 was further amended during opposition proceedings, such that claim 15 of the main request now contains the further features:

- in step (a): [obtaining the PUFA] "and protective fat to increase PUFA content of milk produced by a milk-producing animal"; and
- in step (b): "wherein the protective fat is encapsulating the PUFA".

3.4 There is no support for the first of these amendments (in step (a)) in the application as filed. The passages on page 5, lines 13 to 16 and on page 6, lines 14 to 19, on which the patent proprietor relied, link the increase in polyunsaturated fatty acid (PUFA) content of the milk to the coating or encapsulating of the PUFA with the protective fat, but not to the step of "obtaining the PUFA and protective fat" as now required by step (a) of claim 15.

3.5 Consequently, claim 15 of the main request does not fulfil the requirements of Article 123(2) EPC and the main request is not allowable.

#### AUXILIARY REQUEST 1

#### 4. *Amendments*

4.1 Claim 1 as granted refers to "a composition comprising a polyunsaturated fatty acid (PUFA) and a protective fat, wherein said PUFA comprises an omega-3 PUFA,



omega-6 PUFA or a combination thereof, and wherein the protective fat is a triacylglycerol containing at least two saturated fatty acids, or a functional derivative thereof." It resulted from the combination of claims 1 and 12 (the alternative "at least two saturated fatty acids") as filed. Compared to claim 1 as granted claim 1 of auxiliary request 1 has then been further amended:

- to indicate that the composition comprises "a microorganism in a whole cell form or a lipid extracted therefrom" [comprising the PUFA]; and
- to specify the protective fat as "encapsulating the whole cell or lipid to increase PUFA content of milk produced by a milk-producing animal".

4.1.1 The first amendment is supported by the disclosure on page 2, lines 8 to 11 of the application as filed wherein is stated that a preferred source of the PUFA is a microorganism, particularly algae, and that it "**can be used in a whole cell form or as lipid extracted from the microorganism.**" (emphasis by the board).

4.1.2 The second amendment is supported by the disclosure on page 5, lines 12 to 18 of the application as filed that reads:

"While not wishing to be bound by any theory, it is believed that the PUFAs can be "protected" by coating or **encapsulating the lipids or whole cells** allowing the fatty acids to pass relatively undamaged through the ruminant's first stomach. **As a result**, milk is produced at a substantially normal rate and the resulting **milk is enriched in polyunsaturated fatty acids**, has substantially normal fat and protein content, no

significant increases in trans-fatty acids, and/or has excellent organoleptic qualities." (emphasis by the board).

Moreover in the first sentence of the immediately following paragraph (page 5, lines 19 to 22) it is stated that "the terms "protective fat" also commonly called "by-pass fat" includes any suitable fat that can **encapsulate**, coat or otherwise **protect the PUFAs** from significant degradation or saturation, while allowing the PUFAs to be easily absorbed by the animal". (emphasis by the board).

- 4.1.3 It is evident from the above cited paragraphs that the application as filed discloses a microorganism in a whole cell form or a lipid extracted therefrom comprising the PUFA and the encapsulation thereof with a protective fat. But these passages also make it clear that the encapsulation of the whole cells or lipids protects the PUFA from degradation, thus increasing its content in the milk produced as required in amended claim 1.

Therefore the board cannot accept the objection of the opponent that there is no support for the feature "to increase PUFA content of milk produced by a milk-producing animal".

- 4.2 As regards claim 12 (corresponding to claim 15 of the main request), the wording of the claim has been amended to overcome the objections against claim 15 of the main request (see point 3.4 above). By the rewording of the claim, the feature "to increase PUFA content of milk produced by a milk-producing animal" now clearly relates to the protective fat which encapsulates the PUFA.

It is noted that claim 12 more generally refers to "encapsulating the PUFA" rather than "encapsulating the whole cell or lipid" as claim 1. However, it is evident from the above cited passage on page 5, lines 19 to 22 of the application as filed that the concept of encapsulating applies to PUFAs in a more general aspect. Apart from that, the same considerations as for claim 1 apply.

4.3 Hence the subject-matter of amended claims 1 and 12 fulfils the requirements of Article 123(2) EPC.

4.4 In this context it is noted that also the independent product claims 25, 26 and 27 contain the feature "wherein the protective fat encapsulates the PUFA". Again the basis for this amendment can be found in the passage on page 5, lines 19 to 22 of the application as filed.

## 5. *Clarity*

5.1 The opponent argued that the term "milk-producing animal" in claim 1 was not clear since it could be deduced from paragraph [0026] of the patent specification that this term referred to ruminants, while on paragraph [0030] also non-ruminant animals and humans appeared to be covered.

5.2 The board is not convinced by this argument of the opponent. The term "milk-producing animal" is clear in itself in that it refers to all milk-producing animals. Therefore there is no need to look into the description to understand the term. In any case, the passage in paragraph [0026] which allegedly restricts this term to ruminants merely refers to a certain advantage obtained

in the case of ruminants. It can not be deduced from this paragraph that the milk-producing animal of claim 1 should be restricted to ruminants.

5.3 For this reason the board concludes that amended claim 1 fulfils the requirements of clarity.

6. *Sufficiency*

6.1 The patent relates to methods of incorporating PUFAs in milk with increased efficiency. More particularly, the methods include protecting the PUFAs with a protective agent prior to feeding the supplement to a milk-producing animal. The patent specification discloses how to make the compositions (see paragraphs [0028] to [0029]) and how to produce milk enriched with PUFAs (see paragraphs [0030] to [0033]). It further includes two working examples, examples 1 and 2, showing the effect in cows fed the compositions of the invention.

6.2 The opponent considered the disclosure of the patent insufficient essentially because in its view:

(a) there is no information on how to carry out the invention for non-ruminants; and

(b) the patent lacks information as to which milk was the reference point for milk with an increased PUFA content.

6.3 The board finds these objections not convincing for the following reasons:

6.3.1 Concerning the first objection, the opponent did not show that the examples of the patent could not be reproduced or that the invention could not be carried

out for non-ruminants. The argument that the invention cannot work for ruminants in the same manner as it works for non-ruminants does not permit the conclusion that the invention would not work for ruminants at all. The onus on proof in this respect lies with the opponent.

6.3.2 Concerning the second objection, the opposition division decided that "the "control" milk is adequately defined in paragraph 3 of the contested patent in terms of the nature of the ingredients present in it; thus, the "control" is what is fed without the addition of any supplement" (point 15 of the decision). The opponent has not provided any technical reasons why the opposition division erred in its decision, nor has it provided any evidence to support its objection. Thus, for this reason alone, the objection must fail.

6.4 Consequently, the board concludes that the requirements of sufficiency of disclosure are met.

## 7. *Novelty*

7.1 Claim 1 is directed to a composition comprising:

- (a) a microorganism in a whole cell form or a lipid extracted therefrom comprising a polyunsaturated fatty acid (PUFA) comprising an omega-3 PUFA, omega-6 PUFA or a combination thereof; and
- (b) a protective fat that is a triacylglycerol containing at least two saturated fatty acids, or a functional derivative thereof, wherein
- (c) the protective fat encapsulates the whole cell or lipid,
- (d) to increase PUFA content of milk produced by a milk-producing animal.

7.2 Interpretation of claim 1

7.2.1 Features (a) and (b) are the compositional features; feature (c) requires that the fat encapsulates the PUFA, that is to say, the fat completely surrounds the PUFA; and feature (d) indicates the effect obtained by the composition, namely an increased PUFA content in the milk produced by a milk-producing animal. In other words, feature (d) refers to the intended use of the composition.

7.2.2 While granted claim 1 merely required the presence of a PUFA and a protective fat, claim 1 now under examination requires that the fat encapsulates the PUFA, a preferred embodiment disclosed in the patent in suit (see paragraphs [0027], [0029] and example 1 wherein *Schizochytrium sp.* ATCC 20888 has been encapsulated in tristearine). Concerning the encapsulation, i.e. feature (c), the opposition division in its decision interpreted it in the broadest way possible, since no precise definition was provided in the claim. According to this, even physical mixtures of PUFA and protective fat would be considered as containing "encapsulated" PUFA.

The board disagrees because, as stated above, encapsulation requires, per definition, that the fat completely surrounds the PUFA, otherwise the fat would not encapsulate it. Therefore, it cannot be interpreted as including the simple mixing of the fat and the PUFA.

7.2.3 Concerning feature (d) it is noted that, according to EPO practice, in a composition claim the intended use does not limit the claim. Thus if a prior-art composition is known in a form in which it is in fact

- suitable for that use, though it has never been described for that use, it will be novelty-destroying.
- 7.3 The opponent maintained that the subject-matter of claim 1 lacked novelty over any of D4, D7 and D8.
- 7.3.1 Example I of D4 discloses a composition obtained by mixing semi-refined tuna oil containing omega-3 PUFAs and a hard fat, namely hardened soybean oil with a melting point of 65°C with an equal weight amount of solid carbon dioxide and milling the resulting blend in a turmix-blender. Example 7 of D7 discloses a composition prepared by dilution of a crude microbial oil, enriched in docosahexaenoic acid and arachidonic acid, with at least one part per ten parts of cocoa butter. Lastly, example 7 of D8 discloses a margarine produced from a fat blend consisting of 10% of stearin and 90% sunflower oil.
- 7.3.2 However, none of D4, D7 or D8 discloses the encapsulation of the PUFA by the protective fat. In these documents the PUFA and the fat are mixed, diluted or blended but no encapsulation is disclosed.
- 7.3.3 Thus, for this reason alone, the subject-matter of claim 1 is novel over the cited prior art.
- 7.4 The same considerations apply to the subject-matter of claim 12, which relates to a method of making a composition comprising a PUFA and a protective fat, wherein the protective fat encapsulates the PUFA.
- 7.5 Claim 18 is directed to a method of obtaining milk enriched with omega-3 PUFA, omega-6 PUFA or a combination thereof in an animal capable of producing milk, comprising the features of:

( $\alpha$ ) obtaining a PUFA, wherein said PUFA comprises omega-3 PUFA, omega-6 PUFA, or the combination thereof;  
( $\beta$ ) combining a protective fat with the PUFA to produce a mixture thereof and wherein the protective fat is a triacylglycerol containing at least two saturated fatty acids, or a functional derivative thereof;  
( $\gamma$ ) feeding the animal said mixture in an amount effective to produce enriched milk; and  
( $\delta$ ) extracting milk from the animal to obtain said enriched milk.

7.6 The novelty of claim 18 has been contested by the opponent in view of the disclosure of D2.

7.6.1 There is, however, no disclosure of feature ( $\beta$ ) in document D2. D2 describes a study concerning the modification of milk fat to contain long-chain omega-3 fatty acids and increased concentrations of conjugated linoleic acid using, *inter alia*, a diet containing algae protected against ruminal biohydrogenation (see abstract). The algae were protected by coating them with xylose (page 2050, paragraph entitled "Animals and diets").

7.6.2 The use of a triacylglycerol containing at least two saturated fatty acids to protect the PUFAs is not disclosed in D2. The subject-matter of claim 18 is therefore novel over D2.

8. *Inventive step*

8.1 The present invention relates to methods of incorporating PUFAs, such as omega-3 and omega-6 fatty acids into milk (see paragraph [0001]). It aims to reduce some of the drawbacks of prior-art methods of



incorporating PUFAs into milk, such as reduced milk output, decreased fat content in the milk, decreased protein content in the milk, and/or increased trans-fatty acid content in the milk (see paragraph [0003]).

Auxiliary request 1 includes nine independent claims which are directed to methods of producing milk enriched with omega-3 and omega-6 PUFAs and to specific compositions used in such methods. During the appeal proceedings the opponent contested the inventive step of the subject-matter of claims 1, 12, 13, 16 and 18. These claims relate to the embodiments using a triacylglycerol containing at least two saturated fatty acids that encapsulates the PUFA (claims 1, 12, 13 and 16) and to embodiments wherein the triacylglycerol containing at least two saturated fatty acids and the PUFA are combined to produce a mixture (claim 18).

## 8.2 Closest prior art

8.2.1 Document D2 was agreed as representing the closest prior art document for all objected claims.

8.2.2 D2 describes a study in which cows were fed a control diet, a diet containing unprotected algae, or a diet containing algae protected against ruminal biohydrogenation (abstract). The algae are of the species *Schizochytrium* and contain long chain omega-3 fatty acids. The protection is achieved by coating the algae with xylose (paragraph "Animals and diets" in the left-hand column on page 2049). While the overall performance of the dairy cows was not greatly affected by feeding the algae, the proportion of omega-3 PUFA in the milk of cows fed with the protected algae was increased compared to that of cows fed the unprotected algae (first full paragraph of the right-hand column on

page 2050 and last paragraph of the left-hand column on page 2051). It is concluded in D2 that the protection of the algae prevents ruminal biohydrogenation of the omega-3 fatty acid DHA to an extent and allows for more efficient incorporation of this fatty acid into milk fat (sentence bridging the left- and right-hand columns on page 2051).

8.3 The problem to be solved and its solution

8.3.1 The claimed subject-matter differs from that of D2 in that the PUFA contained in the microorganism is encapsulated in (claims 1, 12, 13 and 16) or mixed with (claim 18) a protective fat which is a triacylglycerol containing at least two saturated fatty acids, rather than a coating made of the sugar xylose used in D2.

8.3.2 The patent proprietor argued, by comparing the results in D2 with those in example 1 of the patent, that the use of the compositions of the invention resulted in improved properties of the obtained milk, at least in relation to the omega-6 PUFAs and the protein content in the milk and defined the problem to be solved by the patent in suit as to improve the compositions used in D2 to obtain good balance and consistent levels of omega-6 and omega-3 PUFAs while maintaining milk production levels.

8.3.3 The board disagrees. The results of example 1 of the patent are not directly comparable with those of D2 as they have not been carried out under the same conditions. Moreover in example 1 of the patent the PUFAs are encapsulated in the protective fat, while the subject-matter of claim 18 does not require such encapsulation. It is therefore not established that for the embodiments covered by the claims an improvement

compared to the use of the compositions of D2 is achieved.

- 8.3.4 Taking account these considerations the problem underlying the subject-matter of claims 1, 12, 13, 16 and 18 of the patent in the light of D2 can be seen in the provision of alternative compositions that also leads to increased amount of PUFAs in milk produced by milk-producing animals.
- 8.3.5 In view of the examples and comparative examples in the patent the board is satisfied that this problem has been credibly solved. The use of the compositions according to the invention, compared to a control feed ration without the protective fat, are effective in increasing omega-3 and omega-6 fatty acid content of the milk (see Table 1) while maintaining milk production, milk fat and milk protein (Table 2). This finding was not contested by the opponent.
- 8.4 Obviousness
- 8.4.1 It remains to be decided whether the above solution is obvious in view of the cited state of the art.
- 8.4.2 D2 does not contain any indication to coat (or to combine) the PUFAs containing algae with a protective fat which is triacylglycerol containing at least two saturated fatty acids or a functional derivative thereof. Such fatty acids are not mentioned at all in D2.
- 8.4.3 The opponent filed D14 during the appeal proceedings and argued that D14 hinted at the claimed method and compositions, essentially because it discloses on page 2806, left hand column, last full paragraph that

unsaturated lipids cause milk fat to fall, but that saturated fats tend to increase milk fat concentration.

- 8.4.4 D14 is a review article relating to ways of altering milk composition by feeding (see abstract). According to D14 "the effects of dietary fats on milk fat synthesis are complex and are mediated within the gut, particularly the rumen, as well as within the body and udder of the cow." (page 2806, left-hand column, lines 3 to 6). D14 mentions the feeding of protected fats, the protection being achieved by formaldehyde-treated proteins (page 2806, right-hand column, lines 4 to 6) but not by the protective fat now used.

The passage cited by the opponent is not linked at all to the protection of PUFAs and does not suggest encapsulating or mixing PUFAs: it is simply a comment on the differences between saturated and unsaturated fats. It therefore does not suggest the replacement of the xylose in D2 by a triacylglycerol containing at least two saturated fatty acids.

- 8.4.5 For these reasons the subject-matter of claims 1, 12, 13, 16 and 18 of auxiliary request 1 involves an inventive step as required by Article 56 EPC.
9. During the oral proceedings the patent proprietor filed a description adapted to the amended claims. The amendments were discussed with the opponent, who did not raise any objection to them.

## 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:
  - Claims 1 to 28 according to auxiliary request 1 as filed with the letter dated 15 May 2014;
  - The amended description pages numbered 2 to 7 as filed during the oral proceedings on 10 July 2014; and
  - Figure 1 as granted.

The Registrar:

The Chairman:



K. Götz

W. Sieber

Decision electronically authenticated