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Datasheet for the decision of 21 October 2019

Case Number: T 0442/15 - 3.3.08

Application Number: 06014355.9

Publication Number: 1748074

IPC: C12N15/54, C12N15/55, C12N9/10,

C12N9/18, A23L1/03, A23L1/035

Language of the proceedings: ΕN

Title of invention:

Method for the in situ production of an emulsifier in a foodstuff

Patent Proprietor:

DuPont Nutrition Biosciences ApS

Opponent:

Novozymes A/S

Headword:

Lipid acyltransferase egg-based dairy product/DUPONT NUTRITION BIOSCIENCES

Relevant legal provisions:

EPC Art. 100(c), 113(1), 114(2), 123(2) RPBA Art. 12(4), 13(1), 15(1)

Keyword:

Main request and auxiliary request 1 - added subject-matter (yes); Auxiliary requests 2 to 7 - admission (no);

Decisions cited:

G 0002/10, T 0217/15

Catchword:



Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 0442/15 - 3.3.08

DECISION
of Technical Board of Appeal 3.3.08
of 21 October 2019

Appellant I: DuPont Nutrition Biosciences ApS

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Appellant II: Novozymes A/S

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Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted on 23 December 2014 concerning maintenance of the European Patent No. 1748074 in amended form.

Composition of the Board:

Chairman B. Stolz
Members: P. Julià

R. Winkelhofer

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Summary of Facts and Submissions

- I. European patent no. 1 748 074 is based on European patent application no. 06 014 355.9 (hereinafter "the patent application"), a divisional application of the earlier European patent application no. 04 702 393.2, published under the PCT as International patent application WO 2004/064537. The patent was granted with 47 claims.
- II. An opposition was filed on the grounds as set forth in Articles 100(a), (b) and (c) EPC. The opposition division considered the main request (claims as granted) to extend beyond the content of the application as filed (Article 100(c) EPC) and auxiliary request 1 to fulfil the requirements of the EPC. Accordingly, the patent was maintained on the basis of this auxiliary request.
- III. Appeals were lodged by the patent proprietor and the opponent (appellants I and II, respectively). With the statement setting out the grounds of appeal, appellant I filed a main request (claims as granted) and auxiliary requests 1 to 7. As an auxiliary measure, oral proceedings were requested by both appellants.
- IV. The parties replied to their respective statements of grounds of appeal. In further submissions, appellant I filed additional experimental evidence (document (15)).
- V. The board summoned the parties to oral proceedings. In a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), they were informed of the board's provisional opinion on some of the issues of the case. The board stated *inter alia* that it considered the main request to contravene

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Article 123(2) EPC, that the admission of auxiliary requests 2 to 7 into the proceedings had to be discussed at the oral proceedings, and that all these auxiliary requests contravened Article 123(2) EPC.

- VI. In reply thereto and without making any substantive submissions, both appellants withdrew their requests for oral proceedings.
- VII. The oral proceedings were cancelled.
- VIII. Claims 1 and 25 of the <u>main request</u> (claims as granted) read as follows:
 - "1. Use of a lipid acyltransferase to prepare from a water containing food material comprising 10-98% water a food stuff selected from egg or an egg-based product or a dairy product comprising an emulsifier, wherein the emulsifier is generated from constituents of the food material by the lipid acyltransferase, wherein the lipid acyltransferase is one which when tested using the Transferase Assay in Buffered Substrate has at least 2% acyltransferase activity; said transferase assay comprising the steps of:
 - i) dissolving 450mg phosphatidylcholine and 50mg cholesterol in chloroform, evaporating to dryness under vacuum;
 - ii) transferring 300mg cholesterol/phosphatidylcholine mixture to a Wheaton glass, adding 15ml 50mM HEPES buffer pH 7 and dispersing the lipid in the buffer during agitation;
 - iii) heating the substrate to 35°C during mixing with a magnetic stirrer and adding 0.25ml enzyme solution;

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- iv) taking samples of 2 ml at 0, 5, 10, 15, 25, 40 and 60 minutes reaction time and immediately stopping the enzyme reaction by the addition of $25\mu l$ 4M HCl to acidify the free fatty acid;
- v) adding 3ml chloroform and shaking vigorously for 30 seconds, centrifuging and isolating 2ml of the chloroform phase, filtering through a $0.45\mu m$ filter into a 10ml tared Dram glass;
- vii) evaporating the chloroform under a stream of nitrogen at 60°C, and scaling the samples;
- viii) analysing the extracted lipid by GLC.
- 25. A method of production of egg or an egg-based product or a dairy product comprising an emulsifier, wherein the method comprises the step of adding a lipid acyltransferase to egg or an egg-based product or a dairy product containing 10-98% water, wherein the lipid acyltransferase is one which when tested using the Transferase Assay in Buffered Substrate has at least 2% acyltransferase activity; said transferase assay comprising the steps of:
- [i) to viii) as in claim 1]."
- IX. Claims 1 and 25 of <u>auxiliary request 1</u> are identical to claims 1 and 25 of the main request, except for steps i) and v) which read as follows:
 - "... i) dissolving 450mg L-alpha-phosphatidylcholine 95% (Plant) Avanti no. 441601 and 50mg cholesterol in chloroform, evaporating to dryness under vacuum;

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... v) adding 3ml chloroform and shaking vigorously for 30 seconds on a Whirley, centrifuging and isolating 2ml of the chloroform phase, filtering through a $0.45\mu m$ filter into a 10ml tared Dram glass; ..."

- X. The following documents are cited in this decision:
 - (7): Product information "Avanti Polar Lipids", L-alpha-phosphatidylcholine (95%) (Soy), no. 441601;
 - (15): Technical Note; "Test of lipid acyl transferase variants according to EP 1 748 074".
- XI. Appellant I's (patent proprietor's) submissions, insofar as relevant to this decision, may be summarised as follows:

Main request - Article 123(2) EPC

According to the criteria set out in decision G 2/10 (OJ EPO 2012, 376), for an amendment to comply with Article 123(2) EPC it could not convey new technical information to the skilled person. The absence in steps i) and v) of claims 1 and 25 of the specific phosphatidylcholine (L-alpha-phosphatidylcholine 95% (Plant) Avanti no. 441601) and shaker (Whirley) disclosed in Example 12 of the patent application did not convey any new technical information to the skilled person. When reading the "Transferase Assay in Buffered Substrate" (TABS) as described in Example 12, a skilled person would have understood that the specific phosphatidylcholine used therein was only exemplary and that the assay could be performed with any suitable food grade phosphatidylcholine. Nothing was mentioned in Example 12 that could have led a skilled person to

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consider the exemplified phosphatidylcholine essential for performing the assay. Likewise, the skilled person would not have seen the use of a Whirley as an essential element of the mixing step. The essential feature was to perform that mixing to the required degree (vigorously).

Auxiliary request 1 - Article 123(2) EPC

The three features referred to in the preamble of claims 1 and 25, namely i) the class of lipid acyltransferases, ii) a food material comprising 10-98% water, and iii) a foodstuff selected from egg or an egg-based product or a dairy product, simply defined more preferred aspects of the same embodiment. A skilled person would have seriously contemplated that the patent application was directed to such subjectmatter which was directly and unambiguously derivable from its content.

Admission of auxiliary requests 2 to 7

No submissions were made in this respect.

XII. Appellant II's (opponent's) submissions, insofar as relevant to this decision, may be summarised as follows:

Main request - Article 123(2) EPC

The specific substrate used in the TABS of Example 12 of the patent application (L-alpha-phosphatidylcholine 95% (Plant) Aventi no. 441601) had specific properties, such as mixture, fatty acid composition, etc., that were not necessarily the same as those of a generic phosphatidylcholine as cited in step i) of claims 1 and

25. As a result thereof, a different class of lipid acyltransferases was defined by the assay mentioned in the claims and thereby, the technical information conveyed to a skilled person was changed. Moreover, the degree of dispersal of a lipid and thus, its effective concentration, depended on the degree of agitation used to disperse it. Whilst step v) of claims 1 and 25 only required vigorously shaking, this shaking was performed "on a Whirley" in Example 12. Thus, the generic term used in claims 1 and 25 added subject-matter by omitting a key technical feature of the assay disclosed in Example 12 of the patent application.

Auxiliary request 1 - Article 123(2) EPC

The subject-matter of claims 1 and 25 was characterized by three specific features selected from three different lists, namely i) a selection of a particular class of lipid acyltransferases having at least 2% acyltransferase activity tested using the TABS, ii) a selection of a food material comprising 10-98% water, and iii) a selection of a foodstuff (egg or egg-based product or a dairy product). There was however no pointer in the patent application linking these three selections; their combination resulted in an embodiment that was not directly and unambiguously derived from the patent application.

Admission of auxiliary requests 2 to 7 into the appeal proceedings

No submissions were made in this respect.

XIII. Appellant I (patent proprietor) requests, as its main request that the decision under appeal be set aside and the patent be maintained as granted or, in the

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alternative, that the patent be maintained on the basis of any of auxiliary requests 1 to 7 filed with the statement of grounds of appeal.

XIV. Appellant II (opponent) requests that the decision under appeal be set aside and the patent be revoked.

Reasons for the Decision

Article 113(1) EPC

- 1. By their decision to withdraw their requests for oral proceedings and not to file substantive arguments in reply to the issues raised in the board's communication pursuant to Article 15(1) RPBA, all parties have chosen not to make use of the opportunity to comment on the board's provisional, non-binding opinion, either in writing or at the oral proceedings, in particular not the appellant I to whom this opinion was unfavourable.
- 2. In the light thereof, the present decision is based on the same grounds, arguments and evidence on which the provisional, non-binding opinion of the board was based.

Main request (claims as granted) and auxiliary request 1

3. The main request (claims as granted) and the auxiliary request 1 filed by appellant I with its statement of grounds of appeal are identical to the main request and the auxiliary request 1 underlying the decision under appeal; therefore, they already form part of the appeal proceedings.

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Main request - Article 123(2) EPC

- 4. In the decision under appeal, the opposition division considered the transferase assay cited in claims 1 and 25 to include features of the "Transferase Assay in Buffered Substrate" (TABS) disclosed in Example 12 of the patent application, but to omit other features, such as the specific phosphatidylcholine and the type of mixing, thereby resulting in added subject-matter.
- 5. It is undisputed that an essential feature of claims 1 and 25 is the lipid acyltransferase which is defined in these claims by the level (at least 2%) of its acyltransferase activity "when tested using the Transferase Assay in Buffered Substrate" (TABS); an assay described in Example 12 of the patent application.
- 5.1 Indeed, there are three different alternative assays described in the patent application for identifying the lipid acyltransferase by its acyltransferase activity (cf. paragraph [0238] of the published patent application): i) the TABS described in Example 12 "in which there is a very high water content approximately 95%" (underlined by the board) (cf. paragraphs [0223] and [0224]; see last sentences in paragraphs [0614] and [0627]), ii) the transferase assay in high water egg yolk described in Example 11 (cf. paragraphs [0225] to [0234]), and iii) the transferase assay in a low water environment described in Example 22 (cf. paragraphs [0235] to [0237]). The relevance of the water content to the enzymatic activity is conveyed to the skilled person in paragraph [0226], wherein reference is made to the percentages of high water egg yolk (54%) and egg yolk with enriched water content (73% or 89% water). In

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paragraph [0236], a content of 6% water in the low water (oily) environment is disclosed.

- 5.2 In view thereof, a skilled person would not change the specific conditions of the exemplified enzymatic assays and certainly not the water content which is, directly and unambiquously, identified as an essential feature of the three methods described in the patent application. In line therewith, a skilled person would also not replace the specific substrates described in these examples, in particular not the egg yolk that gives name to the exemplified transferase assay in a high water environment. This specific (egg yolk) substrate of the high water assay is directly compared to that used in the very high water (TABS) assay; thereby, the relevance of the "artificial substrate based on purified phosphatidylcholine" (underlined by the board) is also clearly acknowledged in the patent application (cf. paragraphs [0627] and [0628]).
- 5.3 Whilst the skilled person knows that the fatty acid composition of the phosphatidylcholine (16:0 and 18:1 in egg yolk; 18:2 in soy-bean, see document (7)) used in these assays may lead to the identification of different lipid acyltransferases (substrate specificity) as argued by appellant II, the relevance of the type of phosphatidylcholine used in the very high water (TABS) assay is also clearly stated in the patent application and directly conveyed to the skilled person. In fact, appellant I itself referred to the possible replacement of the specific phosphatidylcholine from soybean used in Example 12 by "any suitable food grade phosphatidylcholine" (underlined by the board). None of these features (pure or purified, food grade, >95% from soybean, etc.) are necessarily inherent features of the generically

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defined phosphatidylcholine used in step i) of claims 1 and 25. Therefore, the subject-matter of these claims extends beyond the content of the patent application and thus contravenes Article 123(2) EPC.

6. In the communication pursuant to Article 15(1) RPBA, the board drew the parties' attention furthermore to its view that the arguments put forward in the statement of grounds of appeal by appellant II under Article 123(2) EPC against the auxiliary request upheld by the opposition division (auxiliary request 1), equally apply to the main request. Since no reply in substance was submitted, the board has no reason to change its provisional view. Therefore, the subject matter of the main request also extends beyond the content of the application as filed for the reasons given below with regard to auxiliary request 1.

Auxiliary request 1 - Article 123(2) EPC

- 7. In the decision under appeal, the opposition division considered that the introduction of the two features referred to above for the main request, namely the specific phosphatidylcholine used in the TABS of Example 12 and the "on a Whirley" (cf. point IX supra), overcame the objection raised under Article 123(2) EPC.
- 8. In appeal proceedings, the parties' arguments under Article 123(2) EPC on claims 1 and 25 of auxiliary request 1 relate to the combination of three specific features or selections, namely i) a class of lipid acyltransferases having at least 2% acyltransferase activity "when tested using the TABS", ii) a food material comprising 10-98% water, and iii) a foodstuff selected from egg or an egg-based product or a dairy product.

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- It is common ground between the parties that there is a 9. basis in the patent application for each of the three specific features or selections in isolation. Example 12 and the general disclosure on page 18, paragraphs [0223] and [0224] of the published patent application provide a basis for the subject-matter of the first selection; page 17, paragraph [0205] for the second selection; and pages 16 and 23, paragraphs [0195], [0199] and [0280], [0281], respectively, for the third selection (see Examples 7, 13 and other examples relating to margarine, mayonnaise and ice cream production). It is however disputed whether or not there is a basis in the patent application for the specific combination of these three features.
- 10. In the communication pursuant to Article 15(1) RPBA, the board considered the case law cited by the parties in support of their arguments relevant, in particular the case law precluding the use of the patent application as a "reservoir" (cf. "Case Law of the Boards of Appeal of the EPO", 9th edition 2019, II.E.1.6.1, 459), defining the criteria for allowing selections from several lists (cf. "Case Law", supra, II.E.1.6.2, 460) and, more particularly, the definition of the gold standard for assessing compliance with Article 123(2) EPC (cf. "Case Law", supra, II.E.1.3.1, 436; G 2/10, OJ EPO 2012, 376).
- 11. It is directly and unambiguously derivable from the patent application that lipase acyltransferases identified by the (TABS) method as described in Example 12 may be used to prepare from a food material a foodstuff comprising an emulsifier; this being one of the broadest disclosures of the patent

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application. Preferred acyltransferases identified by the (TABS) method of Example 12 for use in the compositions and methods disclosed are defined on page 18, paragraph [0224] of the published patent application. They have at least 2% relative acyltransferase activity, the lowest relative activity on a long list of possible values of relative acyltransferase activities.

- 11.1 There is however no indication in the patent application that a lipid acyltransferase having a specific lipid acyltransferase activity of (as little as) at least 2% (identified by the TABS method of Example 12) may be suitable/appropriate to prepare a foodstuff selected from egg or an egg-based product or a dairy product, let alone that any of these products can be prepared using a lipid acyltransferase having at least 2% relative acyltransferase activity from a water containing food material comprising (as little as) 10% to (as much as) 98% water.
- In this context, it is worth noting that paragraph [0223] of the published patent application describes the "Transferase Assay in Buffered Substrate" as an assay "in which there is a very high water content approximately 95%" (underlined by the board). The use of a lipid acyltransferase identified by an (TABS) assay with a very high water content (approximately 95%) in a food material with a low content of water (as little as 10%) is not directly and unambiguously derivable from the patent application, let alone when such a food material is the basis for preparing a foodstuff selected from egg or an egg-based product or a dairy product.

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- 11.3 Therefore, in the absence of a clear hint or indication to the skilled person, the combination of the specific relative acyltransferase activity of at least 2%, selected from a list of thirteen values, with a particular range of water content, selected from a list of eight ranges (cf. page 17, paragraph [0205] of the published patent application), and three specific products (egg, egg-based or dairy product) selected from a long list of products (cf. page 16, paragraph [0195] et seq.), cannot be directly and unambiguously derived from the patent application. The specific combination of the selected parameters does not satisfy the criteria developed in the established case law for allowing combinations of features or parameters selected from several lists.
- 12. It follows that the subject-matter of auxiliary request 1 extends beyond the content of the patent application and contravenes Article 123(2) EPC.

<u>Auxiliary requests 2 to 7 - Admission into the appeal</u> proceedings

13. In the communication pursuant to Article 15(1) RPBA, the board drew the parties' attention to the established case law defining the function of an appeal. According thereto, the function of an appeal is to give a judicial decision upon the correctness of a separate earlier decision taken by an examining or opposition division. Appeal proceedings are not an opportunity to re-run or re-open proceedings before any of these divisions. The admission of new claim requests into the appeal proceedings is at the board's discretion (Article 114(2) EPC and Articles 12(4) and 13(1) RPBA; see "Case Law", supra, V.A.1, 1133 and V.A.4, 1206).

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- 14. In the board's communication, the parties were also informed that, although auxiliary requests 2 to 7 are identical to auxiliary requests 2 to 7 filed already at first instance, the mere fact of filing auxiliary requests at first instance cannot serve as a justification for automatically admitting them into the appeal proceedings, especially when their admission has not even been examined at first instance (cf. T 217/15 of 14 March 2019, point 39.2 of the Reasons). Thus, the parties were informed that the admission of auxiliary requests 2 to 7 into the appeal proceedings is at the board's discretion.
- 15. The board further stated that the objection raised under Article 123(2) EPC against auxiliary request 1 equally applied to auxiliary requests 2 to 7 since the specific combination of the three features or selections referred to above is found in all of them.
- 16. Appellant I, for whom the provisional opinion of the board was negative, made no substantive submissions in reply to the board's communication. Thus, the board has no reason to change its position and, in the exercise of its discretion, does not admit auxiliary requests 2 to 7 into the appeal proceedings.

Admission of document (15)

17. Since none of the claim requests is allowable, the admission of appellant I's late-filed experimental evidence (document (15)) into the appeal proceedings is not relevant anymore and thus, there is no need to decide thereupon.

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Conclusion

18. Since there is no allowable claim request, the patent must be revoked.

Order

For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The patent is revoked.

The Registrar:

The Chairman:



L. Malécot-Grob

B. Stolz

Decision electronically authenticated