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**Datasheet for the decision
of 3 September 2015**

Case Number: T 0053/13 - 3.3.06

Application Number: 00929825.8

Publication Number: 1180545

IPC: C11C3/00, A23D7/00, A23D9/00

Language of the proceedings: EN

Title of invention:
Vegetable sterol-containing fat compositions and process for
producing the same

Patent Proprietor:
Adeka Corporation

Opponents:
AARHUSKARLSHAMN SWEDEN AB
KAO Corporation

Headword:
Fat composition / ADEKA

Relevant legal provisions:
EPC Art. 52(1), 56, 83, 84, 123(2)

Keyword:

Inventive step - main request (no)
Sufficiency of disclosure - first auxiliary request (no)
Amended claims - second auxiliary request -
compliant with Articles 123(2) and 84 EPC (yes)
Sufficiency of disclosure - second auxiliary request (yes)
Inventive step - second auxiliary request (yes)

Decisions cited:

Catchword:



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Case Number: T 0053/13 - 3.3.06

D E C I S I O N
of Technical Board of Appeal 3.3.06
of 3 September 2015

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 19 October 2012
revoking European patent No. 1180545 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman B. Czech
Members: L. Li Voti
 S. Fernández de Córdoba

Summary of Facts and Submissions

- I. The present appeal is from the decision of the Opposition Division to revoke the European patent no. 1 180 545.
- II. The two opponents had invoked grounds for opposition according to Articles 100(a), (b) and (c) EPC. They relied inter alia on the following prior art documents:
- D3: R.Ap. Ferrari et al.: "Alteration of Steryl Ester Content and Positional Distribution of Fatty Acids in Triacylglycerols by Chemical and Enzymatic Interesterification of Plant Oils" (JAOCS, Vol. 74, no.2 (1997), pages 93 to 96); and
- D9: GB 1 405 346.
- III. The independent process claims according to the requests that had ultimately been pending before the Opposition Division read as follows:
- Main request and First auxiliary request - Claim 7 (identical to claim 8 as granted)
- "7. A process for producing a plant sterol-containing fat composition, comprising: effecting the esterification reaction of 5 to 35% by weight of a plant sterol, and 95 to 65% by weight of a partial glyceride and/or a triglyceride under solventless conditions by using a lipase or an alkali as a catalyst."*
- Second auxiliary request
- Claim 1 is identical to claim 8 as granted except for the numbering.

Third auxiliary request

Claim 1 differs from claim 1 according to the said second auxiliary request only in that it contains, between "...fat composition," and "comprising..." the added wording

"comprising 5% by weight or more of a plant sterol fatty acid ester (A); and from 10 to 70% by weight of a partial glyceride (B),"

Fourth auxiliary request

Claim 1 according to the fourth auxiliary request differs from claim 1 according to said third auxiliary request in that its final clause, after "...under solventless conditions", is amended and reads as follows:

"by using a lipase as a catalyst, wherein the lipase is a lipase having no positional selectivity, and wherein the moisture content of the reaction system of the esterification reaction is 900 ppm or less."

IV. In the decision under appeal, the Opposition Division came *inter alia* to the following conclusions (Reasons, points 14, 16, 17 and 18):

- The replacement of the term "*clay*" by the expression "*activated clay*" in the examples of the patent in suit contravened the requirements of Article 123(2) EPC.
- Document D9 was admissible and considered despite its late filing.
- The subject-matter of the independent process claim 7

according to the then pending main request (*supra*) lacked an inventive step in the light of either of D3 or D9, which both disclosed processes for the preparation of plant sterol fatty acid esters similar to that of claim 7 at issue.

- Even though the amounts of reagents used in these known processes were different from those to be used according to process claim 7, it was "well within the ability of the skilled person to adjust these amounts in order to modify the reaction yield".

- The claimed subject-matter thus lacked an inventive step.

- The then pending first and second (*supra*) auxiliary requests were not allowable either, since they contained the same independent process claim as the then pending main request.

- The amended process claims 1 according to the third and fourth auxiliary requests (*supra*) lacked clarity (Article 84 EPC) since they both required (as pointed out by Opponent 1) "the reaction of 5-35% weight of plant sterol with 95-65% weight of a partial glyceride and/or a triglyceride to produce a composition which comprises at least 5% by weight or more of a plant sterol fatty acid ester and 10-70% by weight of a partial glyceride". These claims were thus directed to subject-matter of which "some embodiments appear to be impossible, in particular when starting with 5% plant sterol and/or using only triglycerides. The exact scope of the claim is therefore shrouded in doubt, contrary to the requirement of Art. 84 EPC."

V. With its statement of grounds of appeal of 14 February

2013 the Appellant (Patent Proprietor) filed seven amended sets of claims as main request and first to sixth auxiliary requests, the claims according to the new main, first and second auxiliary requests corresponding to those according to the second to fourth auxiliary requests that had been pending before the Opposition Division (wording of independent claims 1: see III, *supra*).

It also filed amended pages 8 and 9 of the description of the patent specification.

It submitted that the claims according to all requests were clear and that their subject-matter was novel and inventive over the cited prior art.

VI. In its letter of 18 January 2013, Respondent II (Opponent 2) requested that the appeal be rejected. In its reply (to the Appellant's statement of grounds) of 19 June 2013, it submitted that no comments/arguments were filed with regard to the patentability of the process claims according to the new main request as well as of the (process) claims according to the first, second and fourth auxiliary requests. However, it argued that the process claims according to the third, fifth and sixth auxiliary requests did not comply with the requirements of Articles 123(2) EPC.

Respondent I (Opponent 1) did not reply at all to the Appellant's statement of grounds.

VII. The Parties were summoned to oral proceedings. In its communication pursuant to Article 15(1) RPBA dated 20 April 2015, the Board indicated issues possibly to be addressed at the forthcoming oral proceedings including inventive step (all requests), clarity of the claims

according to the auxiliary requests, insufficiency and compliance of the amendments with the requirements of Article 123(2) EPC.

VIII. By letters of 8 June 2015 and 3 August 2015, respectively, Respondent I and Respondent II merely indicated that they did not intend to attend the oral proceedings and did not comment on the substance of the case or filed further requests.

IX. Oral proceedings were held on 3 September 2015 in the absence of the duly summoned Respondents (Article 15(3) RPBA).

X. Requests

At the oral proceedings the Appellant confirmed that it requested that the decision under appeal be set aside and the patent be maintained on the basis of the claims according to the main request or, in the alternative, on the basis of the claims according to any of the first to sixth auxiliary requests, all requests filed with letter of 14 February 2013.

Respondent II had requested in writing that the appeal be dismissed.

Respondent I did not submit any request in the appeal proceedings.

XI. The Appellant's arguments of relevance here, submitted in writing and orally, can be summarised as follows:

Article 123(2) EPC

- In description pages 8 and 9, filed with the statement

of grounds, the term "*activated clay*" was replaced with the term "*clay*" as appearing in the description of the application as filed.

- The deficiencies under Article 123(2) EPC identified in the decision under appeal were thus overcome.

Main request - Inventive step - Claim 1

- The object of the invention was the provision of a process for producing a plant sterol-containing fat composition capable of providing a cholesterol absorption inhibiting effect and having improved flavour characteristics. In particular, the plant-sterol containing fat composition obtained by means of the claimed process needed no, or only a reduced, addition of an emulsifier in the production of emulsified fat foods. Hence, the emulsified product had no, or at least less, flavour characteristics of the emulsifier.

- Therefore, document D9, rather than document D3, was the most appropriate starting point for the evaluation of inventive step. Whereas D9 also concerned the preparation of a plant-sterol containing fat composition capable of providing a cholesterol absorption inhibiting effect, D3 did not concern the preparation of this type of products.

- Document D9/example 2 disclosed a process differing from that according to the main request only in that the relative amount of plant sterol used in the esterification process was 4.578% by weight, instead of at least 5% by weight as required by claim 1 at issue. D9 concerned only the preparation of fat compositions practically free of undesired partial glycerides, considered to have disadvantageous properties in the

context of various end uses.

- D9 would thus lead the skilled person away from modifications of the process of example 2 resulting in the obtention of a fat composition containing an amount of partial glycerides of at least 10% by weight, which required no, or only a reduced amount of, added emulsifier in its further processing to a fat food in emulsified form, with a consequent improvement of the flavour characteristics of the final product.

- Therefore, even though the wording of claim 1 according to the main request did not require that the fat composition resulting from the claimed process had to contain a specific relative amount of partial glycerides, the skilled person, seeking to solve the technical problem posed, would not have modified the process of D9/example 2 in a way leading to such a composition.

- The subject-matter of claim 1 according to the main request thus involved an inventive step.

First auxiliary request - Clarity of claim 1

- The finding, in the decision under appeal, that it would be impossible to obtain a fat composition comprising only 5% by weight of a plant sterol fatty acid ester, as encompassed by claim 1 at issue, by using only 5% by weight of plant sterol in the esterification reaction, was based on the assumption that the esterification reaction was carried out at a 100% conversion rate. However, it would be clear to the skilled person that at a lower conversion rate of e.g. 60%, not excluded by the wording of claim 1, the concentration amount of plant sterol esters in the final

product would necessarily be lower and could also amount to 5% by weight.

- Moreover, the argument that it would be impossible to obtain a fat composition comprising at least 10% by weight of partial glycerides by reacting 95% by weight triglycerides with 5% by weight plant sterol, does not consider that the amount of partial glycerides in the final product of claim 1 depends on the constitution of the triglyceride used in the esterification reaction and on that of the diglyceride formed. Therefore, by using a triglyceride of appropriate molecular weight and a sufficient conversion rate, it was possible to obtain a product having at least 10% by weight of partial glycerides even starting from a reactant mixture containing 95% by weight of triglyceride.

- Claim 1 at issue thus did not encompass "impossible" embodiments and was clear (Article 84 EPC).

First auxiliary request - Sufficiency of the disclosure

- The description and the examples of the patent in suit clearly illustrated how to carry out the esterification reaction according to claim 1 at issue.

- Moreover, even though document D3 appeared to suggest that the use of some lipases having a particular positional specificity in the esterification of plant sterols with triglycerides results in a reduced amount of plant steryl esters compared to the use of other lipases having no positional specificity, it was nevertheless clear from D3 that such lipases were also able to promote the esterification of plant sterols. Therefore, as disclosed in the patent suit, it was possible to carry out the process of claim 1 using any

type of lipases.

- The invention was thus sufficiently disclosed.

Second auxiliary request - sufficiency of disclosure and inventive step

- Claim 1 according to the second auxiliary request was limited to a process involving an esterification reaction catalyzed by a lipase having no positional selectivity. Lipase of such type was used in all the examples of the patent in suit and was also known from document D3 to lead to a good esterification of plant sterol. Therefore, the claimed invention was clearly sufficiently disclosed.

- Document D9 did not suggest to use a lipase as a catalyst in the esterification reaction of example 2. Moreover, the teaching of D9 led the skilled person away from even trying to modify the reaction of example 2 in a manner that would result in an increased concentration of partial glycerides in the final product.

- Moreover, even if the skilled person, seeking to solve the technical problem posed, knew from D3 that lipases having no positional selectivity were able to esterify plant sterol, there would have been no incentive to modify the reaction described in example 2 of D9, against the teaching of this document, in a way resulting in an increased amount of partial glycerides in the fat composition produced.

- The subject-matter of claim 1 at issue thus involved an inventive step.

Reasons for the Decision

Admissibility of Appellant's claim requests

1. The Appellant's main, first and second auxiliary claim requests correspond to the second, third and fourth auxiliary requests, respectively, considered by the Opposition Division in its decision. Their admissibility into the proceedings was not at stake.

Main request - Inventive step - Claim 1

2. The invention
 - 2.1 The present invention concerns a process for producing a plant sterol-containing fat composition (see wording of claim 1 under III, *supra*, and paragraph [0001] of the patent in suit).
 - 2.2 In the description of the patent in suit (paragraphs [0002] and [0003]) it is first indicated that it was known that plant sterol has a cholesterol absorption inhibiting effect. Subsequently, the following is stated (paragraphs [0009] and [0010]): "... *plant sterol is little used for fat foods because of its low solubility in an oil or fat. On the other hand, there is another example in which a plant sterol is used for fat foods by being changed into a plant sterol fatty acid ester to enhance the solubility thereof in a fat or oil.*"
 - 2.3 Moreover, it is stated in paragraph [0013] that "... *it is an object of the present invention to provide a plant sterol-containing fat composition capable of providing a cholesterol absorption inhibiting effect, and capable of ensuring no addition of an emulsifier or a reduction in amount of the emulsifier to be added when utilized for*

production of fat foods in the emulsion product form such as margarines, fat spreads, and whip creams, whereby an emulsion product having no or reduced flavor characteristic of the emulsifier can be obtained."

3. Closest prior art

3.1 Documents D3 and D9 were both cited during the proceedings as conceivable starting points in the evaluation of inventive step.

3.2 In the application of the so-called problem-solution approach, the closest prior art is normally a prior art document disclosing similar subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention. In identifying the closest prior art, the Board considered the following.

3.2.1 On the one hand, it is undisputed that document D3, addressing *inter alia* (page 93, right hand column, lines 9 to 11) the "*formation of steryl esters during chemical interesterification and enzymatic interesterification of rapeseed oil*", is a scientific study investigating "*the effect of chemical and enzymatic esterification on the sterol esters content and composition of plant oils*" (See title and page 94, section "RESULTS AND DISCUSSION", first paragraph, last sentence).

However, D3 does not concern, at least not explicitly, the provision of a plant sterol-containing fat composition to be used for the production of fat food products in the form of an emulsion.

3.2.2 On the other hand, document D9 (page 1, line 72 to page 2, line 18; page 2, lines 42 to 49 as well as page 3, line 50 to 68) concerns explicitly the provision of a

plant-sterol containing fat composition capable of providing a cholesterol absorption inhibiting effect, to be used *inter alia* for manufacturing fat food products in the form of emulsions, like margarine or mayonnaise.

Therefore, document D9, in contrast to document D3, discloses subject-matter explicitly conceived for the same purpose and aiming at a similar objective as the claimed invention.

Moreover, as acknowledged by the Opposition Division (Reasons, point 16, page 7) and not disputed by the Appellant, example 2 of D9 discloses a process with all the features of claim 1 at issue except for the required minimum relative amount (of at least 5 % by weight) of the plant sterol to be reacted.

3.3 Thus, for the Board, it is D9 (example 2), and not D3, that represents the most appropriate starting point for the evaluation of inventive step.

4. Technical problem according to the Appellant

According to the Appellant the technical problem solved by the invention in the light of the closest prior art consisted in the provision of a process for producing a plant-sterol containing fat composition capable of providing a cholesterol absorption inhibiting effect and having improved flavour characteristics.

5. Solution

As the solution to this problem, the patent in suit proposed a process for producing a plant sterol-containing fat composition of the type disclosed in D9, which process is, according to claim 1 at issue,

characterised in that it comprises the step of *"effecting the esterification reaction of **5 to 35%** by weight of a plant sterol, and 95 to 65% by weight of a partial glyceride and/or a triglyceride under solventless conditions by using a lipase or an alkali as a catalyst"* (emphasis added).

6. Alleged success of the solution

6.1 It was pointed out by the Board during oral proceedings and not disputed by the Appellant that, according to the patent in suit, the presence in the fat composition obtained by esterification of at least 10% weight of partial glycerides contributes to obtaining the desired improved flavour characteristics. In fact, as also remarked by the Appellant on page 6 of its statement of grounds, the description of the patent in suit states (paragraph [0023]) that *"...If the content of the partial glyceride (B) is less than 10% by weight, undesirably, the amount of an emulsifier to be added cannot be reduced when the composition is used for an emulsion product, so that the flavor of the emulsion product cannot be improved..."*.

6.2 However, claim 1 at issue does not require that the plant sterol-containing fat composition produced by the claimed process has to comprise a specific minimum amount of partial glycerides or plant sterol fatty acid ester.

Moreover, it emanates from the description of the patent in suit (see, for example, paragraphs [0036] and [0050] to [0051]) that additional reactants, like for example fatty acid esters of lower alcohols, can be present in the esterification reaction according to claim 1. Therefore, as also accepted by the Appellant during oral

proceedings, the wording of claim 1 reading
"*...effecting the esterification reaction of 5 to 35% by weight of a plant sterol, and 95 to 65% by weight of a partial glyceride and/or a triglyceride*" has to be understood as encompassing also the possibility of carrying out the reaction with amounts of plant sterol and partial glycerides and/or triglycerides falling within the ranges indicated in the claim, in the (additional) presence of up to 30% by weight of other reactants, such as fatty acid lower alkyl esters.

- 6.3 The Board remarks in this respect that document D9 discloses in its example 2 a process comprising the solventless esterification, catalyzed by alkali, of plant sterol (β -sitosterol), sunflower oil fatty acid ethyl ester (fatty acid lower alkyl ester) and sunflower oil (triglyceride), which process is thus of the same type of that of claim 1 at issue and differs only in that the amount of plant sterol used in the esterification reaction is 4.578% by weight instead of at least 5% by weight. This esterification reaction is carried out in the presence of an amount of fatty acid lower alkyl ester nearly equivalent (1.1 equivalents) to that of plant sterol (see also claim 1 of D9).

D9 also teaches explicitly (page 2, lines 63 to 68) that "*the products of the processes are **practically free of partial glycerides**, especially diglycerides, which are produced in amount equivalent to the free sterol content **if fatty acid monoesters are not used...***". In fact, the product of the "transesterification" process of example 2 of D9, carried out in the presence of fatty acid monoesters, contains a calculated amount of only 0.7% by weight diglycerides (page 5, lines 38 to 41).

6.4 D9 thus clearly shows that by carrying out a process like that of claim 1 at issue, catalyzed by alkali, in the presence of fatty acid lower alkyl esters in an amount equivalent to the amount of plant sterol, the formation of partial glycerides is practically inhibited.

Therefore, it is not credible for the Board that the process of claim 1 at issue, which also allows for the presence, as reactants, of fatty acid lower alkyl esters in an amount equivalent to the amount of the plant sterol, leads necessarily to a product having at least 10% by weight of partial glycerides. The Board remarks in this respect that none of the reaction mixtures used according to the examples of patent in suit actually contains a fatty acid lower alcohol ester (see table 4).

6.5 The Board, taking into account that the aimed-for improvement of the flavour characteristics is linked to the presence, in the final product, of at least 10% by weight partial glycerides as explained in point 6.1, *supra*, thus concludes that the technical problem formulated by the Appellant (point 4, *supra*), is not solved throughout the whole ambit of claim 1 at issue.

7. Reformulation of the technical problem

7.1 In view of the above finding, the technical problem actually solved by the invention must be reformulated in less ambitious terms.

7.2 For the Board, it can thus be seen in providing an alternative process for producing a plant-sterol containing fat composition capable of providing a cholesterol absorption inhibiting effect.

8. The success of the claimed solution

It is not in dispute, and the Board has no reason to doubt in the light of the description of the patent in suit, that the esterification reaction according to claim 1 leads to a plant sterol-containing fat composition containing plant sterol fatty acid esters, which are known to have a cholesterol absorption inhibiting effect (see paragraph [0010] of the patent in suit). Therefore, the Board accepts that the less ambitious technical problem posed is indeed successfully solved by the process of claim 1.

9. Obviousness of the solution

9.1 It remains to be decided whether the claimed solution was obvious to the skilled person having regard to the state of the art.

9.2 It is undisputed that the process of example 2 of D9, which also concerns the production of a fat composition capable of providing a cholesterol absorption inhibiting effect (see 3.2.2, *supra*), differs from the process of claim 1 at issue only in that the esterification reaction is carried out using 4.578% by weight plant sterol instead of 5% by weight or more.

9.3 The Board notes that the amount of plant triglycerides to be used is not subjected to any limits according to claim 1 and the description of D9. Moreover, nothing in D9 suggests that decreasing slightly the relative amount of triglyceride (sunflower oil) used in the reaction and, correspondingly, slightly increasing the relative amount of plant sterol (β -sitosterol) used to a value of at least 5%, would lead to some substantial change in

terms of the properties of the fat composition so obtained.

- 9.4 Hence, for the skilled person seeking to solve the technical problem of providing a similar alternative process for producing a plant-sterol containing fat composition capable of providing a cholesterol absorption inhibiting effect, proceeding accordingly would be one solution readily available to him.
- 9.5 More particularly, by reducing slightly the amount of triglyceride used in example 2 of D9, thereby increasing correspondingly the relative amounts of plant sterol (from 4.578 to 5% by weight) and that of the sunflower oil fatty acid ethyl ester, the skilled person would arrive, without ingeniousness and without having to expect a substantial change in properties, at a process falling within the ambit of claim 1 at issue and leading to a fat composition having similar properties as that obtained in example 2 of D9.
- 9.6 Therefore, in the Board's judgement, the subject-matter of claim 1 at issue does not involve an inventive step (Articles 52(1) and 56 EPC).
- 9.7 The main request is thus not allowable.

First Auxiliary request - Sufficiency of disclosure

10. Claim 1 according to the first auxiliary request differs from claim 1 according to the main request in that it additionally requires that the fat composition obtained by the process comprises specified amounts of plant sterol fatty acid ester and partial glycerides, namely "5% by weight or more of a plant sterol fatty acid ester (A); and from 10 to 70% by weight of a partial glyceride

(B)" (see point III, *supra*).

- 10.1 As regards sufficiency of disclosure the Appellant submitted that the description of the patent in suit comprised clear indications regarding the process conditions to be used, as well as examples of the process leading to a fat composition as defined in claim 1 at issue.
- 10.2 The Board accepts that the description of the patent (for example, paragraphs [0046] to [0056]) indeed comprises indications regarding the process conditions to be used when catalyzing the esterification reaction by means of a lipase or an alkali.
- 10.3 However, it is to be noted that the examples of the patent in suit exclusively describe reactions catalyzed by a lipase having no positional selectivity (see paragraphs [0072], [0078] and [0084]), although according to the patent in suit (paragraph [0043]) "*the lipase to be used as a catalyst in the production process of the present invention has no particular restriction*". Therefore, the claimed process includes the use of any type of lipase, including a lipase having positional specificity like Lipozyme.
- 10.4 In this connection, the information content of document D3 is of relevance.
 - 10.4.1 D3 is a study investigating *inter alia* the formation of plant steryl fatty acid esters in the esterification reaction of triglycerides and plant sterols catalyzed by lipases such as "Lipozyme" or a lipase powder preparation from *C. cylindracea* (see page 93, right hand column, lines 9 to 15; page 94, left hand column, lines 11 to 16; page 95, right hand column, line 13, to page

96, left hand column, line 11), i.e. an esterification reaction of a type encompassed by claim 1 at issue.

- 10.4.2 In D3 (page 94, section "RESULTS AND DISCUSSION", first paragraph, last sentence) it is stated that "*Little is known so far on the effect of chemical and enzymatic esterification on the sterol esters content and composition of plant oils*".
- 10.4.3 The following is further explained in D3 (page 95, right-hand column, first full paragraph, to page 96, left-hand column, line 11): "*... the formation of steryl esters during ... enzymatic interesterification was examined by using [4-¹⁴C]β-sitosterol as radioactive marker, added to refined rapeseed oil before interesterification, and measuring the radioactive steryl esters formed. The results given in Table 5 show that ... enzymatic interesterification of the oil, catalyzed by Lipozyme, led to very little formation of radioactive β-sitosterol esters [*]. ... With the lipase from *C. cylindracea* as biocatalyst high proportions (> 90% of total radioactivity) of ¹⁴C-labeled β-sitosterol esters were formed in the course of time (Table 5). Obviously, randomization of the triacylglycerols caused by ... enzymatic interesterification, catalyzed by the non-specific lipase from *C. cylindracea*, results in measurable formation of steryl esters, whereas little steryl esters is formed by enzymatic interesterification catalyzed by the sn-1,3-specific Lipozyme (Table 5).*"

*: See Table 5: < 1% of total radioactivity

- 10.5 It emanates thus from the content D3, that the type of esterification according to the process of claim 1 at issue, when catalyzed by a lipase having positional

specificity like Lipozyme, may lead to a very low degree of esterification of the plant sterol, in contrast to the results achievable using a non-specific lipase as the catalyst. Hence, the Board is not convinced that the use of lipase with positional specificity as the catalyst in an esterification reaction according to the process of claim 1 necessarily leads to a fat composition comprising an amount of at least 5% by weight of plant sterol fatty acid esters as prescribed by the claim.

- 10.6 In this respect the patent in suit neither discloses any particular process conditions to be adopted when using lipases having a positional specificity like Lipozyme, nor any particular conditions to be applied or steps to be carried out in order to ensure that an esterification catalyzed by a lipase having a specificity like Lipozyme would lead, in contrast to the teaching of D3, to a more pronounced esterification of the plant sterol and, in particular, to a product having at least 5% by weight of plant sterol fatty acid esters.
- 10.7 Based on the above considerations, the Board concludes that the patent in suit does not contain information sufficiently clear and complete to enable the skilled person, even taking into account common general knowledge, to carry out the invention as defined in claim 1 at issue across the whole breadth thereof without undue burden.
- 10.8 Hence, in the Board's judgement, the claimed invention is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC).
- 10.9 The first auxiliary request is thus not allowable

either.

Second Auxiliary request

11. The second auxiliary request consists of a single claim, which differs from claim 1 according to the first auxiliary request (see point III, *supra*) in that it additionally specifies that the esterification is to be carried out **"by using a lipase as a catalyst, wherein the lipase is a lipase having no positional selectivity, and wherein the moisture content of the reaction system of the esterification reaction is 900 ppm or less."**

12. Amendments

12.1 Compliance with Article 123(2) EPC

12.1.1 Claim 1 is a combination of claims 8, 9 and 10 of the application as filed.

Therefore, the Board is satisfied that claim 1 meets the requirements of Article 123(2) EPC.

12.1.2 For the sake of completeness, the Board notes that the amendments to pages 8 and 9 of the description, filed with the statement of grounds, reinstate the wording used in the application as filed, whereby the deficiencies under Article 123(2) EPC identified in the decision under appeal (see also points V and XI above) are overcome.

13. Clarity (Article 84 EPC)

13.1 The Opposition Division found that Claim 1 at issue lacked clarity (see point IV *supra*).

13.2 Regarding this objection, the Appellant submitted in substance the following (statement of grounds, part C.II, pages 9 and 10):

- Claim 1 in its present wording did not require carrying out the esterification reaction at a conversion rate of 100%, which would indeed lead to a product having at least 8% by weight of plant sterol fatty acid esters (considering the conversion of β -sitosterol to the oleic acid ester thereof). According to claim 1, the reaction could also be carried out at a lower conversion rate like of e.g. 60%, leading to an amount of 5% by weight of plant sterol fatty acid ester in the final product, in accordance with the lower limit of claim 1 at issue.

- The amount of partial glycerides resulting from the esterification reaction depended *inter alia* on the constitution of the starting triglyceride and of the obtained diglyceride. Therefore, as exemplified in the statement of grounds, by using a triglyceride having an appropriate molecular weight and by carrying out the reaction at a sufficient conversion rate, it was perfectly possible to arrive at a composition containing at least 10% by weight of partial glycerides, even in case 95% by weight of triglyceride were used as starting reactant.

13.3 The Respondents did not contest the Appellant's arguments. Moreover, the Board sees no reason for calling their validity into question.

13.4 Therefore, in the Board's judgement, the wording of claim 1 does not encompass "impossible embodiments" making the ambit of the claims unclear.

13.5 In the Board's judgement, claim 1 thus complies with the clarity requirement of Article 84 EPC.

14. Sufficiency of disclosure

14.1 The invention as defined in claim 1 at issue is further limited to the use of a lipase having no positional selectivity as a catalyst for the esterification reaction.

14.2 On the one hand, a reaction making use of a catalyst having a particular positional specificity, like Lipozyme, is, therefore, no longer part of the claimed subject-matter.

Hence, the objection regarding insufficiency considered with regard to claim 1 of the first auxiliary request (points 10.3 to 10.7, *supra*) does no longer apply to the more limited claim 1 at issue.

14.3 On the other hand, the description of the patent in suit (see, for example, paragraphs [0046] to [0052] and [0054] to [0056]) contains ample indications regarding the process conditions to be used when catalyzing the esterification reaction with a lipase. Moreover, all the examples of the patent (paragraphs [0072] to [0089]) concern an esterification reaction carried out with a starting composition of reactants according to claim 1 and a lipase having no positional selectivity as the catalyst, and wherein the moisture content of the reaction system is 900 ppm or less, as required by claim 1 at issue. All the esterification reactions described in the examples lead to a fat composition comprising at least 5% by weight or more of a plant sterol fatty acid ester and 10 to 70% by weight of a partial glyceride (see table 6).

14.4 The Board is thus satisfied that the claimed invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC).

15. Inventive step

15.1 The indications/considerations concerning the invention and the closest prior art, exposed in points 2 and 3, *supra*, apply also to claim 1 at issue.

15.2 Technical problem

15.2.1 The Appellant submitted that the technical problem, seen in the light of the closest prior art represented by D9/example 2, consisted in providing a process for producing a plant-sterol containing fat composition capable of providing a cholesterol absorption inhibiting effect and having improved flavour characteristics.

15.3 The solution

As the solution to this technical problem the patent in suit proposes the process of claim 1, which is characterised in that the esterification is carried out using "*a lipase having no positional selectivity*" as the catalyst, and in that "*the moisture content of the reaction system of the esterification reaction is 900 ppm or less*", and in that the fat composition produced comprises "*5% by weight or more of a plant sterol fatty acid ester (A); and from 10 to 70% by weight of a partial glyceride (B)*".

15.4 Success of the solution

15.4.1 The examples of the patent in suit show that the fat

compositions obtained by processes in accordance with claim 1 at issue (paragraphs [0072] to [0089]) can be further processed into fat foods in the form of emulsions having very good flavour characteristics (Table 9), also because the addition of a further emulsifier is not needed (paragraphs [0090] to [0103]).

15.4.2 Hence, the Board is convinced that the process of claim 1 effectively solves the technical problem posed.

15.5 Non-obviousness of the solution

15.5.1 Absent any argument of the Respondents in this respect, the Board sees no reason to call into question the Appellant's view that the skilled person, starting from D9/example 2, would not arrive in an obvious way at a process with all the features of claim 1 at issue.

15.5.2 In this connection, the Board notes in particular that in document D9 (page 2, lines 60 to 71) it is expressly indicated that *"A particular advantage of the process of this invention...is that the products of the processes are practically free of partial glycerides, especially diglycerides, which are produced in amount equivalent to the free sterol content if fatty acid monoesters are not used...oils and fats containing partial glycerides are known to have disadvantageous properties for various end uses."*

The Board holds that these indications would dissuade the skilled person from trying to modify the process of example 2 of D9 in a way leading to an increased amount of partial glycerides in the so-obtained fat composition.

15.5.3 Assuming, for the sake of argument only, that the skilled person would nevertheless envisage replacing the alkali used as a catalyst in the esterification reaction described in example 2 of D9 with a non-specific lipase, i.e. a lipase having no positional selectivity, as described in document D3 (see point 10.5, *supra*), he would not find in the cited prior art any suggestion to use such a modified reaction to produce a fat composition comprising at least 10% by weight of partial glycerides, which can be further processed to fat food products in emulsion form requiring no or only reduced addition of a further emulsifier, thereby improving the flavour characteristics of said fat food products.

15.5.4 Therefore, the Board concludes that the prior art did not contain any pointer leading to the claimed solution of the technical problem posed.

15.5.5 In the board's judgement the subject-matter of claim 1 at issue thus involves an inventive step (Articles 52(1) and 56 EPC).

Conclusion

16. The claim according to the second auxiliary request is allowable.

Order

For these reasons it is decided that:

- The decision under appeal is set aside.
- The case is remitted to the department of first instance with the order to maintain the patent with claim 1 according to the second auxiliary request filed with the letter of 14 February 2013 and a description to be adapted where appropriate.

The Registrar:

The Chairman:



D. Magliano

B. Czech

Decision electronically authenticated