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Case Number: T 2391/19 - 3.3.09

Application Number: 13709099.9

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Language of the proceedings: EN

Title of invention:
PROCESS FOR PREPARING INFANT FORMULA

Patent Proprietor:
N.V. Nutricia

Opponents:
Société des Produits Nestlé S.A.
FrieslandCampina Nederland B.V.

Headword:
Process for preparing infant formula/NUTRICIA

Relevant legal provisions:
EPC Art. 54(1), 56, 83

Keyword:
Novelty - (yes)
Inventive step - (yes)
Sufficiency of disclosure - (yes)

Decisions cited:

Catchword:

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Beschwerdekammern

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Case Number: T 2391/19 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 9 July 2021

Appellant: (Opponent 1)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
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Representative:	Schrell, Andreas Gleiss Große Schrell und Partner mbB Patentanwälte Rechtsanwälte Leitzstrasse 45 70469 Stuttgart (DE)
Party as of right: (Opponent 2)	FrieslandCampina Nederland B.V. Stationsplein 4 3818 LE Amersfoort (NL)
Representative:	FrieslandCampina Nederland B.V. IP Department Bronland 20 6708 WH Wageningen (NL)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 12 July 2019 concerning maintenance of the European Patent No. 2825062 in amended form.**

Composition of the Board:

Chairman	A. Haderlein
Members:	C. Meiners
	D. Rogers

Summary of Facts and Submissions

I. The appeal was filed by opponent 1 (appellant) against the interlocutory decision of the opposition division finding that European patent No. 2 825 062 as amended in the form of the main request filed under cover of a letter dated 4 July 2018 met the requirements of the EPC.

II. With their notices of opposition, opponents 1 and 2 had requested revocation of the patent in its entirety on the grounds for opposition under Article 100(a) EPC in combination with Articles 54 and 56 EPC (lack of novelty and lack of inventive step) and Article 100(b) EPC (sufficiency of disclosure).

III. The following documents cited by the parties in the opposition and appeal proceedings are relevant to the present decision:

D1 WO 2010/068105 A1

D3 WO 2009/064436 A1

D5 "Effect of Pasteurization, Freeze-drying and Spray Drying on the Fat Globule and Lipid Profile of Human Milk", A. Cavazos-Garduño et al., J. Food Nutr. Res. (2016), 4(5), 296-302

D6 D.-H. Montagne - Chapter 9: Infant Formulae-Powders and Liquids, in "Dairy Powders and Concentrated Products" (June 2009)

D11 WO 2012/080205 A1

D14 WO2010/068103 A1

D16 "High-Pressure Homogenization as a Process for Emulsion Formation", S. Schultz et al., Chem. Eng. Technol. (2004), 27(4), 361-368

D20 "The effect of high velocity steam injection on the colloidal stability of concentrated emulsions for the manufacture of infant formulations", E. G. Murphy et al., Procedia Food Science (2011), 1, 1309-1315

D22 Experiments on Effects of Spray Drying on particle size distribution in IMF formulations

D25 Internet excerpt, https://cavitron.de/wp-content/uploads/2018/05/Katalog_Maschinenbau_2018_ WEB.pdf

D26 Technical Product Specifications of CAVITRON® process engineering machines (publication year 2009)

D28 US 2007/0030322 Al

D30 "Relationship Between Surface Hydrophobicity and Structure of Soy Protein Isolate Subjected to Different Ionic Strength", L. Jiang et al., Int. J. Food Prop. (2015), 18(5), 1059-1074, DOI: 10.1080/10942912.2013.865057

IV. In the decision under appeal, the opposition division concluded that the subject-matter of the European patent as amended in the form of the main request met the requirements of the EPC.

V. With the reply to the grounds of appeal, the proprietor (respondent) filed a main request and auxiliary requests 1 to 8. The requests correspond to the main request and auxiliary requests 1 to 8 previously filed in the opposition proceedings.

VI. Claim 1 of the main request read:

"A process for preparing a lipid and protein component-containing composition, which is an infant or follow-on formula or a growing up milk and comprises lipid

globules having a volume-weighted mode diameter of at least 1.0 µm, comprising the steps of:
a) providing an aqueous phase with a dry matter content of 10 to 60 wt.% (based on total weight of the aqueous phase), which comprises at least one protein component,
b) providing a liquid lipid phase, which comprises at least one lipid and
c) mixing the lipid phase with the aqueous phase in a ratio of 5 to 50 % (w/w) using an inline mixer with at least one mixing head mixing the lipid and aqueous phases with a tip rotor speed of 20 to 50 m/s so as to obtain a lipid and protein component-containing composition comprising the lipid globules."

VII. The appellant's arguments, where relevant to the decision, may be summarised as follows.

Claim 1 of the main request did not meet the requirement of sufficiency of disclosure firstly because the patent did not contain any guidance as to how to produce a stable oil-in-water emulsion over the whole range claimed. Secondly, no infant formula could be obtained over the entire range claimed. The scope of claim 1 encompassed a lipid content which far exceeded the fat values for infant formulations. Claim 1 lacked essential technical features for adjusting the fat concentration in the compositions. Thirdly, there was a lack of guidance as to the required operating parameters for a specific inline mixer to arrive at the desired lipid globule size. Moreover, there was no upper limit specified in claim 1 of the lipid particle size. However, it was not credible that high volume-weighted mode diameters of lipid globules could be obtained if no effectively working emulsifiers were added.

The subject-matter of claim 1 was not novel over document D11. The only technical feature of claim 1 not explicitly disclosed in D11 was a tip rotor speed of from 20 to 50 m/s. This feature was implicitly disclosed in D11 in view of the additional information provided in documents D25, D26 and D28 relating to the specifications of Cavitron rotor-stator inline mixers and rotor-stator inline mixers in general.

As to the requirement of inventive step, the subject-matter of claim 1 was obvious to a skilled person in view of either document D1 or D14 as closest prior art in combination with, in particular, document D3, D16 or D20 in view of the mere objective technical problem to provide alternative processes for the preparation of oil-in-water emulsions. Hence, the subject-matter of claim 1 of the main request was obvious to a skilled person in view of the prior art.

VIII. The respondent's arguments, where relevant to the decision, may be summarised as follows.

With regard to the requirement of sufficiency of disclosure, the appellant had not provided any evidence that the skilled person was not enabled to put the claimed invention into practice across the full breadth of claim 1 of the main request, especially in non-exemplified areas of it.

The appellant had also not provided any evidence that the presence of polar lipids in the prepared compositions was essential for carrying out the process of claim 1 over its full range. It was well-known that proteins could act as stabilisers/emulsifiers in oil-in-water emulsions.

As to the argument that infant formulae could not be obtained over the full breadth of claim 1, the respondent countered that the calculations of the appellant referred to ready-to-drink liquid formulae, i.e. to infant formulae after reconstitution with water. Claim 1, however, also included dry or concentrated infant formula compositions. The latter could comprise a considerably higher fat content than the reconstituted compositions. Likewise, a skilled person was put in the position to select a suitable inline mixer having a tip rotor speed as required by claim 1, thus being able to select suitable operating parameters without undue burden.
Finally, the intended purpose of the compositions as an infant or follow-on formula or a growing up milk inherently imposed an upper limit of the particle size of the lipid globules. Hence, the subject-matter of the claims of the main request was sufficiently disclosed.

The subject-matter of claim 1 of the main request was also novel in view of D11 since the tip rotor speed of the Cavitron mixer employed in example 1 of D11 was not directly and unambiguously derivable from the information provided in this document. D25 and D26 only taught that a Cavitron inline mixer was *suitable* for being operated in a tip rotor speed range of from 20 to 50 m/s. However, a direct correlation between the parameters "rpm" and "tip rotor speed" did not exist. It was not even derivable from the information provided in D11 that the Cavitron mixer used was one of the various Cavitron mixers described in D25 and D26.

The subject-matter of claim 1 of the main request was also not obvious in view of D1 or D14 as the closest prior art. The technical effect ascribable to the distinguishing features was a more economical and

controllable production process for the production of stable oil-in-water emulsions which avoid excessive creaming and had an improved particle size distribution. This effect was credibly observed across the full breadth of claim 1. Neither D3, D16 nor D20 provided the missing link.

IX. The requests

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

The respondent requested, as a main request, that the appeal be dismissed or, alternatively, that the decision under appeal be set aside and that the patent be maintained upon the basis of one of auxiliary requests 1 to 8, all filed with the reply to the grounds of appeal.

Reasons for the Decision

Main request

1. Sufficiency of disclosure (Article 83 EPC)

1.1 Alleged lack of guidance as to how to obtain stable oil-in-water emulsions over the entire range claimed

1.1.1 The appellant argued that there was no guidance in the patent in suit as to how to produce stable emulsions according to the claims over the whole range claimed. While the examples only exemplified lipid to aqueous phase ratios of from 15 to 30% (w/w), the claimed ratio ranged from 5 to 50% (w/w). However, a stable oil-in-water emulsion comprising a high lipid content close to

50% lipid content could only be obtained in the presence of a polar lipid. Document D30 corroborated that lipophilic segments had to be present on the protein surface in a certain ratio to polar amino acids. Polar and hydrophobic clusters on the surface of the proteins were necessary for the proteins to act as emulsifiers. Hence, not each and every protein was a suitable emulsifier. Moreover, the mode of operation of claim 2 was essential for obtaining an oil-in-water emulsion in such a case. In addition, the patent in suit did not suggest in any way that these features were required for high lipid proportions.

1.1.2 The board observes that the process defined in claim 1 of the main request does not require a particular stability of the prepared emulsions. However, not reaching a non-claimed technical effect is not objectionable under Article 83 EPC. Consequently, the appellant's argument on this point fails. Nor has the appellant demonstrated that it would not be possible for a skilled person using their common general knowledge to prepare oil-in-water emulsions having a high lipid content of, for instance, 50% (w./w.) without undue burden.

1.2 Alleged lack of essential features for arriving at an infant formula over the whole scope claimed

1.2.1 The appellant also argued that in view of D6, claim 1 lacked essential technical features that were needed to provide an infant formula that complied with the law on such formulations.

1.2.2 The board, however, concurs with the respondent that infant formulae obtained by the process called for in claim 1 need not necessarily meet the compositional

limitations referred to in D6. Even assuming that a skilled person would aim at obtaining an infant formula that complied with the law on such compositions, and as described in D6, the composition of the infant formulae of claim 1 could be adapted by adjustments of the content of other components of it, such as carbohydrates or lactose (see table 9.7 of D6). The respondent also set out that the calculations of the appellant related to ready-to-drink liquid formulae, which already had the required concentration of ingredients for direct administration. In contrast, the compositions prepared in claim 1 can also be dry or concentrated IMF compositions which have a considerably higher fat content than the ready-to-drink formulations. Consequently, a spray-drying and a reconstitution step are not, in the opinion of the board, essential technical features missing from claim 1 of the main request.

The board concludes that the corresponding objection of the appellant does not lead to an insufficient disclosure of the subject-matter of claim 1.

1.3 Alleged lack of guidance concerning the adjustment of the desired lipid globule size by suitable process parameters

1.3.1 According to the appellant, there was no guidance in the patent in suit as regards the necessary operating parameters for adjusting the particle size of the lipid droplets. Different parameter ranges, such as the tip rotor speed of the mixer, revolutions per minute of the rotor ("rpm"), dry matter content of the aqueous phase, and the lipid phase to aqueous phase ratio, had to be adjusted. In example 1, a volumetric mode diameter of 4.3 µm had been obtained, whereas a lipid globule

diameter of about 2 µm had been measured in example 2 of the patent under an atomisation pressure of 0.4 to 0.8 MPa versus 0.8 MPa in example 1. It was thus not clear how the process parameters influenced the lipid globule diameter.

1.3.2 Firstly, the board concurs with the respondent that a skilled person would be in a position to calculate the circumferential speed (tip rotor speed) of the required rotor from the diameter/radius of the rotor and the revolutions per minute of the rotor. A skilled person can thus adjust the tip rotor speed as needed to obtain the desired lipid globules.

In relation to the argument of the appellant that the patent did not disclose how the volume-weighted mode diameter could be adjusted, especially in the range between 1 and 2 micrometres volumetric mode particle diameter, the board takes the view that the appellant has not substantiated that a skilled person using their common technical knowledge would not be in a position to adjust the particle diameter by appropriate measures, such as by adjusting the exerted shear forces as described in paragraph [0068] of the patent and/or the shear time. Thus, the board sees no plausible line of argument that insufficiency of disclosure would arise from an alleged lack of a teaching in the patent as to how a particle size of the lipid globules of specifically between 1 and 2 micrometres should be reduced to practice.

With regard to the argument of the appellant that no upper limit of the particle diameter of the lipid globules was specified in claim 1, the board concurs with the respondent's argument that a skilled person would rule out any embodiment not consistent with the

teaching of the patent. In this case, the composition to be prepared is an infant or follow-on formula or a growing up milk. Thus, a skilled person would rule out absurd embodiments (including infinitely large lipid globules) not suitable for this purpose and also be aware that there might be a factual upper limit of attainable lipid globule particle sizes. In this context, the appellant has not shown that a sufficiently large globule size which the skilled person would consider to be encompassed by claim 1 could not be obtained using the claimed process.

The experiments described in document D22 demonstrate that suitable oil-in-water emulsions, having a volume-weighted mode diameter of at least 1.0 µm, can also be obtained without a spray-drying and reconstitution step. Consequently, the conclusion of the appellant that in view of the diverging particle sizes obtained in example 1 and 2 of the patent, the pressure applied for atomisation appeared to be an essential feature for adapting the lipid particle size is not convincing.

Consequently, the board does not see that the required adaptation by the skilled person of the process parameters, the lack of an upper end-point and of an exemplified lipid particle diameter between 1 and 2 µm could render the subject-matter of claim 1 insufficiently disclosed.

1.3.3 Finally, the appellant argued that the volume-weighted mode diameter of the lipid globules after preparation of the emulsions differed from those obtained after spray drying and reconstitution. In line with this, document D5 stated that spray drying of human milk led to a marked reduction of the lipid globules' sizes. What is more, the lipid globule diameters of the

compositions prepared in D22 significantly differed from those of example 1 in the patent, despite the fact that the same composition and exactly the same parameters for the tip rotor speed of 20 to 50 m/s had been used.

However, the board does not see insufficiency of disclosure in relation to the claimed subject-matter resulting from these arguments. The appellant has not demonstrated that such fluctuations of the lipid particle diameter (assuming in favour of the appellant that indeed the compositions of D22 and example 1 do not differ in the chemical constitution of the components) could not be compensated by a skilled person using their common general knowledge without undue burden. In contrast, Figure 4 of the patent supports that the process of claim 1 can be run with a rather constant particle size distribution. Moreover, the IMF formulations of D22 do not exhibit a significant reduction of the lipid globule size after spray drying and reconstitution.

1.4 Therefore, the board concludes that the invention claimed in the main request is sufficiently disclosed and meets the requirements of Article 83 EPC.

2. Novelty (Article 54 EPC)

2.1 The appellant cited document D11 against the novelty of claim 1 of the main request. The opposition division found that D11 forms part of the prior art under Article 54(3) EPC, this finding not being contested. This document discloses a process for the manufacture of an infant formula in which a carbohydrate source, a protein source and a lipid source are mixed in appropriate amounts in a high shear rotor-stator mixer.

The mixture is subsequently subjected to homogenisation at a pressure between 0 and 60 bar to provide a composition with a monomodal fat particle size as covered by claim 1 of D11.

2.2 The appellant mentioned example 1 of D11 and argued that all the features of claim 1, other than the tip rotor speed of 20 to 50 m/s, were explicitly disclosed in the passage of D11 relating to example 1. According to the appellant, the tip rotor speed was implicitly disclosed in this example. On page 7, lines 14 to 18, D11 referred to a continuous high shear homogeniser sold under the name "Cavitron®". There was thus no doubt that the "Cavitron mixer" used in example 1 of D11 was an inline mixer of the manufacturer "Cavitron". It could be inferred from D26, a technical datasheet of "Cavitron" inline mixers published in 2009, that these mixers were operated at a tip rotor speed of from 3 to 50 m/s (see page 7, left-hand column, section designated "Leistungsübersicht" relating to the mixer designated "CD 1000"). D26 had been published before the priority date of the patent in suit (unlike the post-published document D25), and the information in D25 and D26 on Cavitron rotor-stator mixers was similar. Moreover, it was mentioned in D26 that all the Cavitron rotor-stator mixers were operated at a tip rotor speed of up to 50 m/s, and the mixer "CD 1000" was operated at 50 Hz, as in example 1 of D11. In example 1 of D11, a rotor speed of 12000 rpm had been applied, which corresponded to the preferred range of from 6500 to 12000 rpm disclosed in paragraph [0067] of the patent in suit. In example 1 of D11, a lipid droplet size D(4.3) of 2.225 µm was disclosed. The mixer "Ystral Z80" used in the examples of the opposed patent corresponded to a rotational speed of 12000 rpm and had clearly not been run in the lower range of the

rotational-speed range disclosed in the patent in suit (ranging from 4000 to 15000 rpm, see paragraph [0067]).

2.3 Furthermore, the appellant put forward that the opposition division had concluded that the invention was sufficiently disclosed in view of the guidance provided in independent claim 1 by means of the indication of the tip rotor speed of 20 to 50 m/s. Also, the respondent had submitted that the claimed lipid droplet size could only be achieved if the tip rotor speed was selected from the claimed range. Therefore, in example 1 of D11, the tip rotor speed had to have been within the claimed range. Otherwise, the claimed droplet size would not have been achieved, as had been confirmed by the patentee and the opposition division.

With regard to this argument of the appellant that it was impossible that the process of D11 had been carried out at tip rotor speeds of less than 20 m/s, the board concludes that this allegation has not been corroborated by pertinent evidence. There is no corroborated information on hand that a volume-weighted mode diameter of at least 1.0 µm of the lipid globules would not be obtainable when applying tip rotor speeds of less than 20 m/s. While claim 1 limits the tip rotor speed to 20 to 50 m/s, it is not derivable from the patent in suit that lipid globule sizes of at least 1.0 µm (volume-weighted mode diameter) would be only obtainable when operating in this range. While the opposition division held that when working within this range the desired lipid globule sizes can be obtained (see the paragraph bridging pages 5 and 6 of its decision), in the view of the board, this does not imply that the sought particle size could not be obtained at tip rotor speeds of, for example, 19 m/s or

lower (with D26 disclosing a lower end-point of 3 m/s on page 7 in the section "Leistungsübersicht" for the model "CD 1000" and generally "up to 50 m/s" on page 5). In D11, the particle size was adjusted by repeated homogenisation in a Cavitron rotor-stator mixer, in which in the second homogenisation step (in example 1 on a second head), the pressure can be varied to adjust the particle size of the lipid globules (see example 1 and reference to Figure 2 plus claim 1). Also according to claim 1 of the patent in suit, the inline mixer comprises *at least* one mixing head, and mixing time and pressure in the rotor-stator inline mixer can be adjusted.

The statement of the respondent that the tip rotor speed was an essential technical feature to obtain a volume-weighted mode lipid globule diameter of at least 1.0 µm was made in relation to the technical disclosure content of the patent in suit in the context of sufficiency of disclosure of the patent and not in relation to the technical disclosure content of document D11 and processes and process conditions described in it (such as in example 1, including a particle size adjustment step after the first homogenisation at 20, 40 or 60 bar on a second head).

2.4 The appellant also argued that, as the speed of 12000 rpm applied in example 1 of D11 fell within the preferred range indicated in paragraph [0067] of the patent of between 6500 and 12000 rpm, this confirmed that a tip rotor speed falling within the claimed range had been used in example 1 of D11. What is more, D28 disclosed in paragraph [0047] that the tip rotor speed for rotor-stator type inline homogenisers was typically 4000 to 10000 fpm (20 to 51 m/s). However, a tip rotor speed of 51 m/s did not apply to the Cavitron-type

mixers mentioned in paragraph [0041] of D28 which had only tip rotor speeds of up to 50 m/s.

The board concurs with the respondent that D26 discloses that rotors and stators can be exchanged at least for the type CD 1000 featured on page 7 of D26. As put forward by the respondent, D26 states that the intensity can be varied by the exchange of rotors and stators and by stepless speed adjustment. As argued by the respondent in the oral proceedings, the diameter of the rotor is a necessary input for calculating the tip rotor speed. Hence, the board concludes that it cannot be inferred from the rotational speed of 6500 to 12000 rpm indicated in paragraph [0067] of the patent in suit and the corresponding indication of 12000 rpm in example 1 of D11 that a tip rotor speed falling within the claimed range of claim 1 of the main request has been used in example 1 of D11.

In the view of the board, the alleged requirement of a tip rotor speed of 20 to 50 m/s for arriving at lipid globule sizes of at least 1 µm in D11 can neither be inferred from the statement in paragraph [0047] of D28 that "the tip speed for rotor-stator type in-line homogenizers is typically 4,000-10,000 fpm (20-51 m/s)". The opposition division found that the wording "typically" indicated that the corresponding feature (20-51 m/s) was not mandatory. As further outlined in the decision under appeal, D28 relates to a different purpose, namely a process for preparing phase-change inks, comprising mixing the dispersion of colouring material in an inline homogeniser until the particle size of the colouring material is less than 0.2 µm. In addition, this passage of D28 does not specifically refer to Cavitron inline mixers but to rotor-stator mixers in general and pertains to the context of

typical process parameters and equipment specifications for the XRCC pilot plant carbon black solid ink process. The board thus concurs with the conclusion of the opposition division that the statement in paragraph [0047] of D28 cannot be read into the disclosure of document D11.

2.5 Finally, the appellant argued that even if the claimed tip rotor speed was not considered to be inherently disclosed in example 1 of D11, the claimed range of from 20 m/s to 50 m/s would not qualify as a selection invention as there was at least an overlap with the end-point of "50".

As to the latter argument, the board observes that D11 does not disclose a numerical range of tip rotor speeds of "up to 50 m/s" (mentioned on page 5 of D26) but specific examples in which a Cavitron mixer not further specified by a type designation (such as "CD 1000") was employed for mixing the components. In general terms, D11 teaches to use in step b) (see step c) of claim 1 of the patent in suit) a continuous high shear homogeniser mixer as the preferred rotor-stator system and that such mixers may be a rotor-stator mixer sold under the name "Cavitron". While mixers generically sold under the brand "Cavitron" have the potential to be used at tip rotor speeds of up to 50 m/s, this does not, in the opinion of the board, imply that they have been operated in D11 at such tip rotor speeds of 20 m/s to 50 m/s, for instance, in example 1.

2.6 For these reasons, the board is not convinced that the disclosure of lipid globule diameters of at least 1.0 µm (volume-weighted mode diameter) as called for in claim 1 of the main request would imply a tip rotor speed as claimed in the main request. The lack of a

demonstrated requirement of a tip rotor speed of from 20 to 50 m/s for arriving at lipid globule sizes of at least 1 µm (volume-weighted mode diameter) in D11, such as in example 1 of the document, also leads to the conclusion that example 1 of D11 does not directly and unambiguously disclose an inherent tip rotor speed of 20 to 50 m/s of the inline mixer used.

2.7 The board therefore concludes that the subject-matter of claim 1 of the main request is not directly and unambiguously derivable from document D11 and is consequently novel. It thus meets the requirements of Article 54(1) EPC.

3. Inventive Step (Article 56 EPC)

3.1 The closest prior art

The appellant cited documents D1 and D14 as equivalent suitable closest prior art documents in the statement setting out the grounds of appeal. Therefore, in the following, the analysis of inventive step is based on D1 as the starting point. The conclusions made apply *mutatis mutandis* to document D14. D1 relates to a process for the preparation of a lipid and protein-containing composition which is an infant milk formula or a growing up milk comprising lipids with a lipid globule size larger than that of standard infant formulae. Since this posed technical problem is also addressed in the patent in suit, the board concurs with the appellant that document D1 can be taken as the closest prior art.

3.2 Distinguishing technical features

The appellant referred to the statement in the opposition division's decision according to which the differences between the subject-matter of claim 1 and D1 resides in i) a ratio of lipid phase to aqueous phase of 5 to 50 weight% and in that ii) the lipid phase and aqueous phase were mixed using an inline mixer with at least one mixing head with a tip rotor speed of 20 to 50 m/s.

The board agrees with the opposition division on this point.

3.3 Technical effect ascribable to distinguishing features

The board concurs with the appellant that the first difference, i.e. the ratio of lipid to aqueous phase as specified in step c) of claim 1, is not associated with a substantiated technical effect. As argued by the appellant, D1 discloses a nutritional composition comprising 10 to 50 wt.% vegetable lipids based on the dry weight of the composition.

With regard to the second difference, the board takes the view that this feature leads to a simplified process for the preparation of lipid- and protein-containing infant nutritional compositions having a lipid globule size of at least 1.0 µm (volume-weighted mode diameter). According to the patent in suit, the emulsification of the lipid phase in the aqueous phase can be accomplished by means of mixing both phases in a (rotor-stator-type) inline mixer having at least one mixing head at a tip rotor speed of 20 to 50 m/s, *so as to obtain* a lipid and protein component-containing

composition comprising *the* lipid globules.

In D1, *inter alia,* infant formulae and growing up milks are provided which comprise lipid globules with a volume-weighted mode diameter above 1.0 µm. Consequently, the board agrees with the appellant that this technical effect had already been accomplished in D1. However, the process of D1 involves two separate process steps, first, a mixing step (typically in an Ultra-Turrax® batch mixer) and second, a subsequent homogenisation step at high pressure.
While the appellant argued in the oral proceedings that already in the mixing step in the Ultra-Turrax mixer (which was according to D16 also a rotor-stator mixer) particle sizes of the lipid globules above 1 µm were obtained, the board observes that the separate homogenisation step is presented as essential in the process of D1. D1 does not suggest that this step of homogenisation could be omitted. There was no dispute between the parties that the Ultra-Turrax used in D1 is a batch and not an inline mixer.

The board holds that the appellant has not convincingly demonstrated that the sought lipid globule particle size of at least 1 µm could not be obtained across the full breadth of claim 1, i.e. that the effect of a simplified process leading to similar globule particle sizes compared to those of D1 could not be obtained across the full breadth of claim 1. As set out under section 1.3.2 above, it is plausible that by adjusting the process parameters of the mixing step in the inline mixer in step c) of claim 1, a skilled person could adjust the particle size of the lipid globules using an inline mixer with at least one mixing head. Likewise, a skilled person would be aware of an implicit upper limit of suitable lipid globule particle sizes

encompassed by the scope of claim 1 in view of the intended use in infant or follow-on formulae or growing up milk and exclude absurd embodiments like infinitely large lipid particles. Furthermore, claim 1 does not require any degree of stability of emulsions prepared in process step c) of claim 1.

Therefore, the board is convinced that the aforementioned effect, i.e. the provision of a simplified production process of lipid and protein-containing nutrient compositions having lipid globule diameters of at least 1.0 µm in terms of volume-weighted mode diameter, has been obtained essentially across the full breadth of claim 1.

3.4 Objective technical problem

It follows from these considerations that the objective technical problem underlying the subject-matter of claim 1 of the main request can be formulated as to provide a simplified process for the preparation of lipid and protein-containing nutrient compositions (infant formulae and growing up milks) comprising lipid globules having a volume-weighted mode diameter of at least 1.0 µm.

3.5 Obviousness

3.5.1 According to the appellant, the subject-matter of claim 1 was obvious in view of, in particular, documents D3, D16 and D20 considering that the problem to be solved was merely to provide an alternative process. As the problem to be solved is not a mere alternative process (see above), this argument must fail.

3.5.2 Moreover, the skilled person would not have arrived at the subject-matter claimed when combining D1 with these documents, or they would have had to depart from the core teaching of D1 to arrive at the claimed subject-matter. The reasons for this are as follows.

3.5.3 The appellant argued that claim 1 of the main request was not restricted to any pressure values. Therefore, claim 1 did not require "low-pressure homogenisation". Thus, the wording of claim 1 did not exclude a further step carried out at "high-pressure".

The board does not share the appellant's view that an additional high-pressure homogenisation step was not excluded by the wording of claim 1. In step c) of claim 1, it is explicitly stated that the lipid and aqueous phases are mixed using an inline mixer with at least one mixing head "*so as to obtain* a lipid and protein component-containing composition comprising *the* lipid globules". "*The* lipid globules" are those comprised in the nutrient compositions prepared in amended claim 1 of the main request, i.e. the lipid globules referred to in the preamble of claim 1. Hence, the board sees no room for additional high-pressure homogenisation steps after step c) and prior to the optional spray-drying step in claim 1 as it stands. Thus, when not departing from the core teaching of D1, i.e. by keeping the high-pressure homogenisation step, and adding feature ii) of 3.2 above (e.g. by substituting the Ultra-Turrax batch mixer used for the pre-mixing step with an inline rotor-stator mixer), the skilled person would not have arrived at the claimed process.

3.5.4 Moreover, the primary object of D1 is to provide nutritional compositions having larger lipid globules for improving bone health. D1 does not mention the aim

of providing a more efficient process for the preparation of such compositions. D1 focuses on the preparations of emulsions using a blending step (typically an Ultra-Turrax high shear *batch* mixer), followed by homogenisation using a high-pressure emulsification system, as put forward by the respondent. Furthermore, this high-pressure emulsification device is employed in the exemplary embodiments of D1 (see example 1 and page 18, lines 1-5). There is no suggestion or prompt in D1 to substitute these "core" steps, i.e. the mentioned blending step followed by homogenisation in a high-pressure homogeniser, with a single process step involving an inline rotor-stator mixer with at least one mixing head under process conditions as claimed in claim 1 of the patent in suit. Such a modification would essentially imply the entire substitution of the central technical teaching of D1 relating to the emulsification process featured in this document. Therefore, the board concludes that a skilled person would not be motivated to depart from the teaching of D1 and apply the teachings of secondary references such as D3, D16 and D20 to create an entirely new preparation process for infant formulae and growing up milks to solve the problem posed and, thus, would not have arrived at a process in accordance with claim 1 of the main request.

Thus, the subject-matter of claim 1 of the main request is not obvious to a skilled person in view of D1 as closest prior art.

3.6 It is for these reasons that the board concludes that the subject-matter of claim 1 is not obvious to a skilled person and therefore meets the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Nielsen-Hannerup A. Haderlein

Decision electronically authenticated