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Datasheet for the decision of 3 May 2024

Case Number: T 1571/22 - 3.3.09

Application Number: 14765917.1

Publication Number: 3043660

IPC: A23P10/40, A23L33/115, A23L33/17, A23L33/00

Language of the proceedings: EN

Title of invention:
IMPROVED PROCESS FOR PREPARING INFANT FORMULA USING A ROTARY ATOMIZER

Patent Proprietor:
N.V. Nutricia

Opponent:
Société des Produits Nestlé S.A.

Headword:
Infant formula/NUTRICIA

Relevant legal provisions:
EPC Art. 100(a), 56
RPBA 2020 Art. 12(6)

Keyword:
Documents filed with grounds of appeal - admitted (no)
Auxiliary request 1 - Inventive step - (no)
Auxiliary request 3 - Inventive step - (yes)
Adapted description consistent with the claims - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1571/22 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 3 May 2024

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Schrell, Andreas Gleiss Große Schrell und Partner mbB Patentanwälte Rechtsanwälte Leitzstrasse 45 70469 Stuttgart (DE)
Appellant: (Opponent)	Société des Produits Nestlé S.A. Avenue Nestlé 55 1800 Vevey (CH)
Representative:	Plougmann Vingtoft a/s Strandvejen 70 2900 Hellerup (DK)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 13 April 2022 concerning maintenance of the European Patent No. 3043660 in amended form.**

Composition of the Board:

Chairman	A. Haderlein
Members:	M. Ansorge
	A. Jimenez

Summary of Facts and Submissions

I. The proprietor and the opponent both lodged appeals against the opposition division's interlocutory decision holding the then auxiliary request 1 allowable.

II. With its notice of opposition, the opponent had requested that the patent be revoked on the ground for opposition under Article 100(a) EPC (lack of inventive step).

III. The opposition division decided *inter alia* that the subject-matter of claim 1 of the patent as granted did not involve an inventive step in view of D15 as the closest prior art.

IV. Claim 1 of auxiliary request 1, filed by letter of 12 December 2023, reads as follows (the differences from claim 1 of the patent as granted are indicated by underlining and striking-through):

"A process for preparing a spray-dried lipid and protein component-containing composition, which is a spray-dried infant or follow-on formula or growing up milk and comprises lipid globules, wherein a lipid and protein component-containing composition comprising lipid globules is spray-dried with an atomization system employing a rotary atomizer so as to obtain a spray-dried lipid and protein component-containing composition comprising lipid globules having a volume-weighted mode diameter ~~of at least 1.0 µm~~ from 2 to 12 µm, and/or lipid globules wherein at least 45% of said lipid globules have a diameter from 2 to 12 µm (% based on vol.-%) and wherein the lipid and protein

component-containing composition to be atomized has a dry matter content of 40 to 65 wt.-%."

V. Claim 1 of auxiliary request 3, filed by letter of 12 December 2023, reads as follows (the differences from claim 1 of the patent as granted are indicated by underlining and striking-through):

"A process for preparing a spray-dried lipid and protein component-containing composition, which is a spray-dried infant or follow-on formula or growing up milk and comprises lipid globules, comprising the steps of:

a) providing an aqueous phase with a dry matter content of 30 to 50 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 a static mixer or an inline mixer with at least one mixing head so as to obtain a lipid and protein component-containing composition comprising lipid globules,

wherein ~~a~~ the lipid and protein component-containing composition comprising lipid globules is spray-dried with an atomization system employing a rotary atomizer so as to obtain a spray-dried lipid and protein component-containing composition comprising lipid globules having a volume-weighted mode diameter of at least 1.0 µm, and/or lipid globules wherein at least 45% of said lipid globules have a diameter from 2 to 12 µm (% based on vol.-%) and wherein the lipid and

protein component-containing composition to be atomized has a dry matter content of 40 to 65 wt.-%."

Claims 2 to 15 of auxiliary request 3 are dependent claims.

VI. The following documents were cited in the case at hand:

D3: WO 2010/027258 A1
D4: G. Bylund, "Dairy processing handbook", Tetra Pak Processing Systems AB, 1995, Chapter 17 Milk powder, pages 361-73
D5: A.S. Mujumdar, "Handbook of Industrial Drying", third edition, CRC Press, 2006
D6: "Milk Powder Technology", Evaporation and Spray Drying, GEA Process Engineering, pages 99 and 295
D15: E.G. Murphy et al., "A high-solids steam injection process for the manufacture of powdered infant formula", Dairy Sci. & Technol. (2013) 93:463-75
D20: C.G.J. Baker, "Industrial Drying of Foods", Blackie Academic & Professional, 1997, pages 91 and 92
D21: B. Bhandari, "Handbook of food powders", Processes and properties, Woodhead Publishing, 2013, pages 475-8

VII. The parties' relevant arguments, submitted in writing and during the oral proceedings, are reflected in the reasons for the decision below.

VIII. Requests

The proprietor requested that the decision be set aside and that the patent be maintained on the basis of auxiliary request 1 or, as an auxiliary measure, on the

basis of auxiliary request 3, both claim requests being filed by letter of 12 December 2023.

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

Reasons for the Decision

1. Admittance of D20 and D21

1.1 The opponent filed D20 with its statement setting out the grounds of appeal and D21 with its reply to the proprietor's statement setting out the grounds of appeal. The opponent submitted that D20 and D21 were filed as evidence of the skilled person's common general knowledge, and requested that these documents be admitted into the proceedings. In its view, D20 did not result in an amendment of the opponent's case, but merely reinforced the arguments already submitted during the first-instance proceedings. D21 was submitted in order to eliminate any doubt that, for infant formulas as well, it was part of the skilled person's common general knowledge to convey a liquid feed having a dry matter content of approximately 50 wt.-% to a spray dryer.

1.2 As outlined below, these documents are not admitted into the appeal proceedings.

1.3 The question of whether the use of dry matter contents of about 50 wt.-% during spray drying of infant formulas is conventional or not was already an issue during the opposition proceedings, as correctly pointed out by the proprietor. There is no action from the proprietor's side which could have triggered the filing

of D21. Thus D21 should have been filed earlier in order to be admitted into the proceedings. Regarding D20, it is not more relevant than documents D4 or D5 already on file as far as the wheel speed and tip speed of the rotary atomizer are concerned.

In view of the above, D20 and D21 are not admitted into the proceedings (Article 12(6) RPBA).

AUXILIARY REQUEST 1

2. Inventive step

2.1 The proprietor argued that D15 is not an appropriate closest prior-art document in the case at hand, but D3 is the only suitable one.

2.2 As outlined below, the board comes to a different conclusion.

2.2.1 The board shares the proprietor's view that the closest prior art for assessing inventive step should be a prior-art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common.

2.2.2 However, as outlined below, D15 meets these criteria to be applied in the selection of the closest prior art.

2.2.3 D15 relates to a process for producing a powdered infant milk formula comprising a spray drying step. Thus D15 relates to the same technical field as the patent. In the same way as the contested patent, D15 is also directed to a process being more energy-efficient than a conventional process. Thus the patent and D15

share a similar purpose of providing an energy-efficient process.

2.2.4 In this context, the proprietor argued that D15 was completely silent on the intention to prepare a composition comprising large lipid globules or to maintain a large lipid globule size during spray drying. In the proprietor's view, D15 was consequently far removed from the teaching underlying the contested patent.

2.2.5 The board disagrees. Although D15 is not explicitly directed to a process for producing a composition having large lipid globules, it is directed to a similar purpose as the patent. In addition, it is in the same technical field as the patent and has many relevant technical features in common with it. By no means is D15 so remote that a skilled person would not have considered it as appropriate closest prior art in the case at hand.

For the above reasons, the board concludes that D15 qualifies as an appropriate closest prior-art document in the case at hand and the question of inventive step is to be decided starting from D15.

2.3 D15 is a study on the use of an inline rotor-stator mixer followed by direct steam injection to disperse a heat-treated high-solids (60% w/w) formulation for the production of powdered infant milk formula in comparison with a typical preparation process as a control (see abstract of D15). The study reveals that prior to spray drying the volume-weighted mean particle size is about 2.04 µm and about 1.82 µm for the control and high-solids steam injection (HSSI) processes, respectively. The control and HSSI formulations to be

spray-dried both have a solids content of approximately 55% w/w and are spray-dried using a two-fluid nozzle atomiser. The reconstituted HSSI formulations show a D[4,3] (De Brouckere mean diameter) of about 1.44 µm.

2.4 The proprietor argued that D15 neither implicitly nor explicitly disclosed the lipid globule size distribution in the composition after spray drying; in particular, it did not allow any conclusion about the volume-weighted mode diameter of the lipid globules after spray drying (the first alternative in claim 1).

2.5 While the board agrees that D15 does not explicitly disclose measurements for the lipid globules' volume-weighted mode diameter, and thus D15 cannot be considered as unambiguously disclosing the feature "lipid globules having a volume-weighted mode diameter from 2 to 12 µm" (the first alternative in claim 1), it mentions a volume-weighted mean diameter (the second alternative in claim 1). Thus D15 also allows certain conclusions on the volume-weighted mean diameter after spray drying. Hereinafter, this mean diameter (second alternative in claim 1) is assessed in more detail.

2.6 D15 discloses that prior to spray drying the volume mean particle size of the globules is about 1.82 µm for the HSSI formulation. Although no value is given for the composition after spray drying, the reconstituted HSSI formulation is indicated as having a D[4,3] of about 1.44 µm.

In this context, the opponent made an attempt to estimate the percentage of lipid globules having a diameter of from 2 to 12 µm, % based on vol.-%, based on an enlarged reproduction of Figure 1b of D15 (see

pages 29 and 30 of the opponent's reply to the proprietor's statement setting out the grounds of appeal). The opponent itself confirmed that the opposition division was correct in that it was not possible to conclude with certainty that the lipid globules in the spray-dried infant formula of D15 satisfied the feature "wherein at least 45% of said lipid globules have a diameter from 2 to 12 µm (% based on vol.-%)". However, it submitted that it was highly questionable whether the size of the lipid globules defined in claim 1 was different from that of those in the spray-dried or reconstituted HSSI formula of D15. In this context, the opponent also referred to Table 1 on page 28 of D3 (as technical background information) showing that in a standard infant milk formula having a volume-weighted mode diameter of 0.5 µm the volume % of lipid globules with a size between 2 and 12 µm was already 34%, which makes it likely that, for a larger volume-weighted mode diameter as in the reconstituted HSSI formula of D15, the volume % with a diameter of 2 to 12 µm should be even higher.

The board does not consider the opponent's above estimations sufficient evidence to prove that the feature "wherein at least 45% of said lipid globules have a diameter from 2 to 12 µm (% based on vol.-%)" is implicitly disclosed in D15. However, the board concludes that the mean diameter of the spray-dried product in D15 is rather close to the lower limit of 2 µm as required in claim 1. In view of the above, this also applies to the formulation after spray drying.

However, the board shares the opposition division's conclusion that D15 does not unambiguously disclose the feature "wherein at least 45% of said lipid globules

have a diameter from 2 to 12 µm (% based on vol.-%)" (the second alternative in claim 1), which is a feature characterising the final spray-dried product. There was also agreement among the parties that D15 fails to disclose an atomisation system employing a rotary atomizer.

2.7 In view of the above, the subject-matter of claim 1 of auxiliary request 1 differs from D15 in that

(i) the spray drying is performed with a rotary atomizer and

(ii) a spray-dried lipid and protein component-containing composition comprising lipid globules has a volume-weighted mode diameter from 2 to 12 µm (first alternative) and/or wherein at least 45% of the lipid globules have a diameter from 2 to 12 µm (% based on vol.-%) (second alternative).

2.8 In the proprietor's view, the technical effect that could be attributed to said differences was a more economic process for obtaining a spray-dried infant or follow-on formula or a growing up milk comprising large lipid globules having a particle size distribution similar as in human breast milk.

2.9 In the board's view, there is no evidence on file that the claimed process leads to a more economic process than that taught in D15. In the process of D15 the composition to be atomised also has a high dry matter content of about 55 wt.%, which falls within the feature "composition to be atomized has a dry matter content of 40 to 65 wt.-%" of claim 1. Consequently, in the process of D15 a low amount of water needs to be evaporated, which makes this process energy-efficient

as well. Thus this alleged improvement cannot be acknowledged over D15.

With respect to the question of whether the term "large lipid globules having a particle size distribution similar as in human breast milk" should be mentioned in the problem to be solved, it is noted that this, rather, relates to a claim feature and not to an improvement over the prior art. In this context, it is noted that, according to established case law, the technical problem addressed by an invention has to be formulated in such a way that it does not contain pointers to the solution or partially anticipate the solution, since including part of a solution offered by an invention in the statement of the problem necessarily results in an *ex post facto* view being taken of inventive step when the state of the art was assessed in terms of that problem (see Case Law of the Boards of Appeal, 10th edition, I.D.4.2.1).

Thus this aspect cannot be part of the problem to be solved.

2.10 The board shares the opposition division’s assessment that a synergistic effect resulting from the two distinguishing features was not demonstrated. However, in the board's view the absence of a synergistic effect does not necessarily result in two problems which are solved independently of each other (partial problems). In the case at hand, the two distinguishing features relate to or have an impact on the particle size distribution, and thus the board does not deem it appropriate to formulate two separate partial problems.

2.11 In view of the above, the objective technical problem to be solved is the provision of an alternative process

for producing a spray-dried lipid and protein-containing infant or follow-on formula or growing up milk.

2.12 With respect to the question of obviousness, the board comments as follows.

The board shares the opposition division's conclusion that spray drying processes using a rotary atomiser are common general knowledge in the field of dairy processing (see page 99, lines 1 to 6 of document D6). D6 discloses that in the dairy industry only pressure nozzles and rotary atomisers are used. In addition, D4 discloses the use of a rotating disc for atomising milk in the spray drying chamber (see section "Spray drying" on page 366, section "Milk atomising" on page 368 and Figure 17.6 of D4). In view of this teaching, it is obvious to a skilled person seeking a solution to the above problem to use a rotary atomiser instead of the two-fluid nozzle mentioned in D15.

In this context, the proprietor argued that there was no teaching in D15, or in D4 or D6, that the claimed particle size distribution could be achieved by a rotary atomiser.

In the board's view, it is common general knowledge in the present technical field that the lipid globule size can be varied over a certain range. As outlined above, as far as the mean diameter of the lipid globules is concerned, the respective mean diameter of the final spray-dried product of D15 is considered close to the lower limit of 2 µm given in claim 1. A skilled person would expect that the claimed particle size distribution can be achieved by using a rotary

atomiser. This is within the common knowledge of a skilled person.

In addition, it is a routine modification for a skilled person to vary the lipid globule size distribution within certain ranges. When starting from D15 as closest prior art, achieving lipid globules wherein at least 45% have a diameter from 2 to 12 µm, % based on vol.-% (the second alternative of claim 1) is obvious to the skilled person.

In view of the above, the subject-matter of claim 1 of auxiliary request 1 does not involve an inventive step in view of D15 as closest prior art in combination with D4 or D6.

For completeness, the board observes that the same result would also be arrived at even if the problem suggested by the proprietor, i.e. to provide a process for obtaining a spray-dried infant or follow-on formula or a growing up milk comprising large lipid globules having a particle size distribution similar as in human breast milk, were accepted.

AUXILIARY REQUEST 3

3. Claim interpretation

3.1 The process of claim 1 of auxiliary request 3 contains the following additional features a) to c):

a) providing an aqueous phase with a dry matter content of 30 to 50 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 a static mixer or an inline mixer with at least one mixing head so as to obtain a lipid and protein component-containing composition comprising lipid globules.

3.2 According to the wording of claim 1 the lipid and protein component-containing composition (obtained in step c)) is spray-dried with an atomization system employing a rotary atomizer (emphasis added).

3.3 While the process of claim 1 is defined in an open manner by the feature "comprising the steps of ... a), b), c)", due to the definite article "the" in the expression "wherein the lipid and protein component-containing composition comprising lipid globules is spray-dried with an atomization system", it is apparent from the wording of claim 1 that the mixture obtained in step c) is spray-dried. The board interprets claim 1 in such a way that no further ingredients are added after step c) and before spray drying. This however does not exclude a reheating step after step c) and before spray drying. This claim construction is in line with the description wherein no further ingredients are added after step c) and before spray drying, but in preferred embodiments the composition obtained after step c) is reheated in order to reduce pathogenic bacteria (see e.g. paragraph [0124]) or fed *via* a concentrate heater to the spray dryer (see e.g. paragraph [0147]).

4. Inventive step

4.1 The opponent argued that the subject-matter of claim 1 of auxiliary request 3 did not involve an inventive step in view of D15 as closest prior art.

4.2 For the following reasons, the board comes to a different conclusion.

4.3 The subject-matter of claim 1 of auxiliary request 3 essentially differs from claim 1 of auxiliary request 1 in that the following additional features, i.e. steps a) to c), are added:

a) providing an aqueous phase with a dry matter content of 30 to 50 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 a static mixer or an inline mixer with at least one mixing head so as to obtain a lipid and protein component-containing composition comprising lipid globules.

4.4 The opponent argued that these additional features were already known from D15 (Table 1), the only exception being that the dry matter content in the aqueous phase according to step a) was 53 wt.% in D15 instead of "30 to 50 wt.%" in claim 1.

4.5 As outlined below, the board does not agree with the opponent's analysis in this respect.

According to step c) of claim 1, the lipid phase provided in step b) is mixed with the aqueous phase according to step a) having a dry matter content of 30 to 50 wt.%. After step c) the lipid and protein component-containing composition is spray-dried (see point 3. above).

As can be gathered from section "2.2 Batch formulation" of D15, the composition to be inducted into the rotor-stator mixer comprises water (aqueous phase), sunflower oil (as the lipid phase), lactose, demineralised whey protein and skim milk powder (as solid ingredients). In this batch-wise process according to D15 water is provided before the other ingredients are added. A rotor-stator mixer was used for ingredient induction, and powders and sunflower oil are inducted into the rotor-stator mixer, which is connected to a mixing tank *via* a closed loop. The order of ingredient addition in this process is (1) lactose, (2) demineralised whey protein, (3) sunflower oil followed by (4) skim milk powder. Accordingly, sunflower oil is added to an aqueous phase comprising lactose and demineralised whey protein as solid ingredients and skim milk powder is added after the sunflower oil.

As a consequence, the dry matter content of the aqueous phase comprising lactose and demineralised whey protein is 47 wt.% (calculated from the values of the HSSI formula (60% w/w) shown in Table 1 of D15), which is within the range of "30 to 50 wt.%" of step a). Consequently, the process described in D15 complies with step a) of claim 1.

However, in view of the interpretation of claim 1 of auxiliary request 3 as outlined under point 3. above, the further addition of skim milk powder, which takes

place after the addition of sunflower oil in D15, is not in line with claim 1, since according to claim 1 no further ingredients are added after step c) and before spray drying.

4.6 In view of the above, the claimed process differs from the process of D15 not only by the two distinguishing features set out at point 2.7 above, but also in that no further ingredients are added after step c) and before spray drying, whereas in the process of D15 skim milk powder is added after the step of mixing the lipid phase with the aqueous phase.

4.7 In the absence of any effect resulting from said difference from D15, the same objective problem as outlined above for auxiliary request 1 is to be applied in the assessment of the claimed process of auxiliary request 3 (the provision of an alternative process).

4.8 With respect to the question of obviousness, it is noted that D15 fails to teach or suggest that the skim milk powder may be added before the addition of the sunflower oil (which would lead to the further distinguishing feature set out above at point 4.6 being met). Even if a skilled person were to consider this change of sequence of the ingredients, the consequence would be that the aqueous phase before addition of the sunflower oil would have a dry matter content of 53 wt. %, being outside the claimed range of "30 to 50 wt.%" in step a) of claim 1. There is no incentive or prompt in D15 or the other documents cited by the opponent to change the order of the addition of the ingredient and, at the same time, lower the dry matter content of the aqueous phase of the composition to be spray-dried.

4.9 The claimed process is consequently a non-obvious alternative to D15 as closest prior art.

In view of the above, the subject-matter of claim 1 of auxiliary request 3 involves an inventive step in view of D15 as closest prior art. The same applies to the dependent claims.

5. Adaptation of the description

5.1 The opponent argued that paragraphs [0059], [0085] and [0124] required further adaptation. In addition, it contested that, when following the board's interpretation of claim 1 of auxiliary request 3, the example of the patent fell within the scope of claim 1.

5.2 As outlined below, the board considers the adapted description to meet the requirement of consistency with the claims in accordance with auxiliary request 3.

5.2.1 Paragraph [0059] refers to an embodiment in which an evaporation step may be performed on the mixture of the aqueous phase and the lipid phase. Such an evaporation step is not excluded by the process of claim 1 and is not in contradiction with the interpretation of claim 1 (see point 3 above).

5.2.2 Paragraph [0085] relates to an embodiment according to which the liquid lipid phase provided in step b) is fed into the aqueous phase provided in step a) prior to or during the mixing step c). The alternative of feeding the liquid lipid phase provided in step b) into the aqueous phase provided in step a) during the mixing step c) simply relates to the mixing step c). The feeding of the liquid lipid phase provided in step b) into the aqueous phase provided in step a) prior to the

mixing step c) relates to a pre-mixing step which is not excluded by claim 1 either.

5.2.3 Paragraph [0124] relates to an embodiment in which the lipid and protein component-containing composition obtained in step c) is reheated to 75 to 85°C, preferably 78 to 80°C, to further reduce, preferably completely eliminate, pathogenic bacteria. This reheating is not excluded by the wording of claim 1 either.

5.2.4 In a similar manner to that outlined in paragraph [0124], in the example of the patent the oil-in-water mixture is fed *via* a concentrate heater to the spray dryer (see paragraph [0147]). For the same reason as outlined above, this heating is not excluded by the wording of claim 1 either. The same applies to Figure 1 of the patent, which relates to a flow chart with respect to the process applied in the example.

In view of the above, the requirement of consistency between the claims and the description is met.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:

Description:
Pages 2, 4, 7, 10-13 of the patent specification
Pages 3, 5, 6, 8, 9 filed during the oral proceedings before the board

Claims:
No. 1 to 15 in accordance with auxiliary request 3 filed by letter of 12 December 2023.

Drawings:
Figures 1 and 2 of the patent specification.

The Registrar: The Chairman:

K. Götz-Wein A. Haderlein

Decision electronically authenticated