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Datasheet for the decision of 15 January 2024

Case Number: T 1766/22 - 3.3.09

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Language of the proceedings: EN

Title of invention:
TWO-STEP EMULSIFICATION PROCESS FOR PREPARING INFANT FORMULA

Patent Proprietor:
N.V. Nutricia

Opponent:
Fresenius Kabi Deutschland GmbH

Headword:
Emulsification Process/NUTRICIA

Relevant legal provisions:
EPC Art. 56, 123(2)

Keyword:
Main Request: added-subject matter - (no); Inventive step - (yes)

Decisions cited:
T 1621/16, T 1937/17

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 1766/22 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 15 January 2024

Appellant: (Opponent)	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg (DE)
Representative:	Fresenius Kabi Deutschland GmbH Patent Department Pharmaceuticals Division Borkenberg 14 61440 Oberursel (DE)
Respondent: (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)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 4 May 2022 rejecting the opposition filed against European patent No. 3271056 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Haderlein
Members:	A. Veronese
	A. Jimenez

Summary of Facts and Submissions

I. The appeal was filed by the opponent (appellant) against the opposition division's decision rejecting the opposition filed against the European patent.

II. With its notice of opposition, the opponent requested revocation of the patent in its entirety on the ground under Article 100(a) EPC (lack of inventive step).

III. The documents submitted during the opposition proceedings included:

D1: WO 2013/135738 A1
D2: WO 2013/135739 A1
D3: EP 2 465 359 A1
D4: Experimental evidence filed by the proprietor by letter dated 27 January 2022

IV. In its decision, the opposition division found that the subject-matter claimed in the opposed patent involved an inventive step over the teaching of D1, the closest prior art, alone or in combination with that of D3.

V. With its reply to the statement setting out the grounds of appeal of the opponent (appellant), the patent proprietor (respondent) filed auxiliary requests 1 to 11. During the oral proceedings, it requested that auxiliary request 2 be considered the main request.

VI. Claim 1 of auxiliary request 2 reads:

1. "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 which comprises lipid globules, comprising the steps of:

a) providing an aqueous phase with a dry matter content of 5 to 75 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) carrying out a first homogenization step by homogenizing the lipid phase with the aqueous phase in a ratio of 3 to 50 % (w/w) lipid to aqueous phase so as to obtain a first lipid and protein component-containing composition comprising lipid globules, wherein at least 10 vol.-% of the lipid globules have a diameter of >12 µm and wherein the lipid globules have a volume-weighted mode diameter from 7 to 15 µm,

d) carrying out a second homogenization step by homogenizing the first lipid and protein component-containing composition obtained in step c) with an atomizer, wherein the particle size of the lipid globules obtained in step c) is reduced so as to obtain a second lipid and protein component-containing composition comprising lipid globules, wherein less than 10 vol.-% of the lipid globules have a diameter of >12 µm and wherein the lipid globules have a volume-weighted mode diameter from 3 to 6 µm.

VII. As far as relevant to the decision, the appellant's arguments can be summarised as follows.

- Claim 1 of the main request contained added subject-matter.

- The experimental report D4 was irrelevant and should not be admitted.

- The subject-matter of claim 1 lacked an inventive step over D2 (or, alternatively, D1), the closest prior art, alone or combined with D3.

- D2 disclosed a process for preparing an infant formula comprising lipid globules involving, as the claimed process, two homogenisation steps.

- The claimed process differed from that of D2 at most in the size of the globules obtained in the first homogenisation step. There was no evidence that this difference was associated with any effect, let alone an improvement of the controllability and reproducibility of the process.

- The underlying problem was the provision of an alternative process. Confronted with this problem, the skilled person would have provided the claimed method without the need of an inventive step. Thus, there would have been a one-way street situation leading to the claimed solution.

VIII. As far as relevant to the decision, the respondent's arguments can be summarised as follows.

- D4 was filed during the opposition proceedings within the period set under Rule 116 EPC, was relevant and should be admitted.

- The claims of the main request did not contain originally undisclosed subject-matter.

- The claimed process involved an inventive step starting from D1 or D2. It differed from that disclosed in these documents in the size of the globules obtained in the first homogenisation step and in that the size of these globules was reduced in the second step.

- The gist of the invention was to significantly reduce the globule size in the second step. Starting from large globules in the atomisation step prevented the risk of undercutting and increased control and flexibility during atomisation.

- The problem was the provision of an improved process making it easier to control the atomisation step.

- Whether or not the problem was the provision of an improved or an alternative process, D1 and D2 pointed away from the claimed solution because they taught that the shear forces applied during the second homogenisation step should not exceed those used in the first step.

The requests

IX. The appellant requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

X. The respondent requested that the patent be maintained on the basis of the main request, which corresponds to auxiliary request 2 filed with the reply to the statement setting out the grounds of appeal.

Reasons for the Decision

Main request

1. *Allowability of the amendments*

1.1 The appellant argued that claim 1 of the main request contained originally undisclosed subject-matter.

1.2 Claim 1 was amended to indicate that the globules obtained:

- in step c) have a volume-weighted mode diameter of 7 to 15 µm

- in step d) have a volume-weighted mode diameter of 3 to 6 µm

1.3 It was not disputed that these ranges are disclosed on page 5, lines 2 to 5 and page 7, lines 16 and 31 of the application as filed.

1.4 However, according to the appellant, their combination resulted from a double selection from separate lists of ranges not disclosed in combination in the application as filed. In its opinion, there was also no pointer to this combination. Furthermore, D4 showed that the combination resulted in a new technical effect and provided an originally undisclosed technical contribution. Thus, the conditions set out in T 1621/16 for making multiple selections from lists of converging alternatives without creating new subject-matter were not fulfilled.

1.5 These arguments are not convincing.

1.6 Claim 1 of the originally filed application defines a process in which at least 10 vol.-% of the globules after step c) has a diameter of >12 µm and in which less than 10 vol.-% of the globules after step d) has a diameter of >12 µm.

1.7 These same requirements are found in the passage bridging pages 4 and 5 of the description of the application as filed, which characterises the size of the globules. This passage mentions, in addition, three progressively narrowing ranges defining the size of the globules obtained after steps c) and d), respectively. The two ranges 7 to 15 µm and 3 to 6 µm most narrowly define the volume-weighted mode diameter of the globules obtained in these steps.

1.8 Furthermore, the combination of these ranges excludes from claim 1 any overlap between the sizes of the globules obtained after steps c) and d). Thus, it reflects the gist of the invention disclosed in the original application, which is to prepare large globules in the first homogenising step, whose size is substantially reduced in the second homogenising step. This fact alone is a pointer to the claimed combination of ranges. Furthermore, the claimed ranges are not chosen among many in the aforementioned passages of the application as filed. The passages on page 7, lines 16 and 31 of the application as filed confirm the relevance of the selected ranges.

1.9 The respondent noted that the passage on page 5, lines 7 to 10 of the application disclosed even narrower ranges. However, this passage is less relevant because it does not define, as the preceding one and claim 1 as

filed do, the percentage of globules having a size larger than 12 µm.

1.10 The argument that the claimed combination of ranges provides an originally undisclosed technical contribution is not relevant either. This is at least because, in line with T 1937/17, in the current case, the "technical contribution" is of no relevance for deciding on the allowability of amendments under Article 123(2) EPC.

1.11 For these reasons, it is concluded that claim 1 does not contain added subject-matter. The same applies to claim 8, which contains the same amendments as claim 1.

2. *Inventive step*

2.1 The claimed invention relates to a process for preparing a nutritional composition for infants and follow-up formula which includes lipids and proteins. The composition comprises lipid globules similar in size to those in human milk.

2.2 As explained in the opposed patent, the known processes for preparing infant and follow-up formulae involve homogenisation of the fat phase. This leads to the formation of lipid globules which are significantly smaller than those in unprocessed human milk (paragraph [0004]).

2.3 The aim of the claimed invention is to produce globules of a size closer to that of the globules in unprocessed human raw milk (paragraphs [0005], [0009] and [0010]). According to the patent, globules of the desired size can be obtained carrying out a two-step emulsification process which involves:

- a first homogenisation step of an aqueous phase comprising at least one protein and a lipid phase comprising at least one lipid, providing a lipid globule composition in which at least 10 vol.-% of the globules has a diameter of >12 µm and the lipid globules have a volume-weighted mode diameter from 7 to 15 µm

- a second homogenisation step in which the emulsion obtained in the first step is passed through an atomiser and in which the size of the globules is reduced so that less than 10 vol.-% of the globules has a diameter of >12 µm and the lipid globules have a volume-weighted mode diameter from 3 to 6 µm

2.4 The patent explains that the first homogenisation step must be carried out in very mild conditions to obtain globules which are significantly larger than those obtained in the second homogenisation step. In this manner, the second step serves as a final step to determine and control the size distribution of the globules in the final composition (paragraphs [0018] to [0020]). Harsher shear forces sufficient to induce a drop in the size of the globules can thus be applied in the second step.

The closest prior art

2.5 The opposition division and the parties agreed that D1 or D2 (cited in the patent as WO 2013/1355738 and WO 2013/135739) could be considered the closest prior art. Like the opposed patent, D1 and D2 aim at the preparation of an infant formula comprising globules similar in size to those of human raw milk (see D1: page 1, line 3 to page 2, line 23; page 4, lines 14 to

18; page 9, lines 5 to 9; D2: page 1, line 3 to page 2, line 24; page 4, lines 15 to 19; examples 1 and 2; and the claims).

2.6 According to certain disclosed embodiments, D1 and D2 describe a two-step process which comprises, like the claimed one:

- a first homogenisation step carried out by mixing an aqueous phase containing proteins with a lipid phase comprising lipids, followed by

- a second homogenisation step of the obtained mixture in which the homogenisation is carried out using a spray-drying system, i.e. an atomiser

2.7 According to D1, the first step is optional (see claims 1 and 4), whereas according to D2, the second step is optional (see claims 1 and 15). The process disclosed in example 1 of D1 and D2 comprises both steps.

2.8 Furthermore, like the claimed patent, D1 and D2 teach to carry out the homogenising steps, and in particular the first one, under low shear conditions. An in-line homogeniser is preferred to minimise the shear force applied in the first step (D1: page 11, lines 4 to 21; page 11, line 27 to page 12, line 4; page 25, lines 3 to 16 and D2: page 5, lines 12 to 28; page 6, line 23 to page 7, line 2).

2.9 There are no reasons to deviate from the opposition division's finding that these documents represent the closest prior art for assessing inventive step. Since during the proceedings the parties focused on D2 and the teaching of D1 does not go beyond that of D2, this

latter document will be considered the starting point for discussing inventive step.

Distinguishing features

2.10 It was not disputed that D2 discloses a two-step homogenisation process producing globules of a size within the claimed range. The globules obtained by atomisation in the second homogenisation step of example 1 of D2 have, in fact:

- a volume-weighted mode diameter of 4.3 µm, i.e. within the claimed range of from 3 to 6 µm (example 1 on page 38, line 18 of D2)

- less than 10% of these globules have a diameter of more than 12 µm (Figure 4 of D2)

2.11 Example 1 does not, however, disclose the size of the globules after the first homogenisation step. Thus, the claimed process differs from that described in D2 in that the size of the globules obtained in the first homogenisation step is defined so that:

- at least 10 vol.-% of the lipid globules have a diameter of > 12 µm **and**

- the lipid globules have a volume mode diameter from 7 to 15 µm

2.12 The appellant drew attention to the two passages in the description on page 24, line 13 to page 25, line 2 and on page 31, lines 7 to 19 of D2, which read:

"at least 1 µm, preferably 2 and more preferably 3 µm, most preferred of at least 3.5 µm even more preferably about 4 µm..." and "...most preferably 4 to 7 µm"

2.13 In its opinion, these passages characterised the size of the globules obtained after both the first and the second homogenisation steps of a process involving two homogenisation steps.

2.14 This argument is not convincing. Reading the description of D2 as a whole, it is evident that the aforementioned passages on pages 24 and 31 refer to the globules obtained in the final product, irrespective of whether the process involved one or two steps. From these passages, no assumptions can be made as to the size of the globules obtained in the first step of a two-step homogenisation process. D2 does not directly and unambiguously disclose a two-step process where the size of the particles after the first step is that according to step c) of claim 1 and that after the second step is that according to step d) of that claim.

Technical effect

2.15 The respondent submitted that by applying very low shear forces and producing globules of the claimed size in the first homogenisation step, higher shear forces could be applied in the second homogenisation step, this being carried out in an atomiser, without the risk of the globules breaking down below the desired size. During the oral proceedings, it noted that this was shown in the table in paragraph [0169] of the patent. Increasing the difference in the size of the globules between the first and the second step decreased the amount of undesired very small particles of 1 to 2 µm (compare processes A and B in the table).

2.16 In other words, if the globules obtained in the first homogenisation step were significantly larger than the globules in the final product, it was easier to control the working conditions during atomisation and prevent the formation of very small particles. The claimed process allowed a higher control and flexibility of the operating conditions.

2.17 Thus, according to the respondent, when the size of the globules obtained in the two homogenisation steps was within the ranges in claim 1, the process was improved in terms of control and reproducibility. These advantages could not be obtained if the size of the lipid globules obtained in the first homogenisation step was substantially the same as that of the globules contained in the final product, which was obtained during the second homogenisation step, by atomisation.

2.18 In the process of D2, the final size of the globules was obtained in the first homogenisation step. D2 taught, in fact, that the shear forces applied during the spray-drying step should not exceed those applied during the first homogenisation step (D2: page 27, last paragraph). The shear conditions being the same, the size of the globules did not change substantially during the second step.

2.19 The respondent further submitted that the experimental report D4 showed that by conducting the first homogenisation step to obtain globules having a size within the claimed range, it was possible to maximise the size of the globules obtained in the second homogenisation step. This provided evidence that the selection of the sizes specified in claim 1 resulted in an optimised process.

2.20 The appellant disputed the relevance of the results in D4 and the opposed patent.

2.21 The board agrees with the appellant that no conclusions can be drawn from the information provided in D4. Figure 1, on which the respondent relies, defines neither the units of the x- and the y-axis nor the origin of the coordinates. It is also not clear what the curves represent and how they relate to the diameter of the globules defined in claim 1. The explanation of the results of Figure 1 given in D4 is also inadequate for understanding the results in the table. In the absence of a scale, it is impossible to determine which points on the x-axis in the figure correspond to the diameters of about 16 and 32 µm mentioned in the explanatory text. When challenged by the appellant and asked by the board to provide explanations on the significance of D4 during the oral proceedings, the respondent's representative conceded that he had received this document without further explanations and that he could not provide any either. For this reason, it is concluded that D4 does not provide relevant evidence and will be disregarded.

2.22 According to the appellant, the tests in the patent were also insignificant because no "true 1:1 comparison" with the process of D2 was presented. The homogeniser used in D2 was not produced by the same company as that used in comparative example B of the patent, and only one test had been performed. It also noted that the amount of particles within the range of 3 to 6 µm was higher in the composition obtained carrying out the process according to the invention than in the comparative example.

2.23 These arguments are not convincing. In the first place, the appellant has not provided evidence that by using a homogeniser from another manufacturer or repeating the test shown in the patent, the results would have been different. Second, the results in the table show that by increasing the difference in the size of the globules obtained in the first and the second step, it is possible to affect size distribution and, in particular, to decrease the amount of very small globules.

2.24 The appellant has further submitted that the respondent's argument that it was advantageous to increase the size of the globules in the first step was in contradiction with an earlier statement during the opposition proceedings that the production of large lipid globules was challenging due to instability.

2.25 This argument is not convincing either because, as shown in the patent, it is possible to prepare globules of the desired size, preventing the formation of the very small undesired ones, by carrying out a process involving the preparation of intermediate globules of the claimed larger size. Also, the earlier statement related to a request in which the size of the globules in the first step was considerably larger than that specified in current claim 1.

3. For these reasons, the board considers that on the basis of the results and the explanations given in the patent and by the respondent during the proceedings, it is credible that by producing intermediate globules having the size indicated in step c) of claim 1, higher shear forces can be applied in the second homogenisation step, increasing control and flexibility

during the process and preventing the risk of formation of very small globules.

Underlying problem

3.1 For these reasons, the underlying problem can be considered, as suggested by the respondent, as the provision of an improved process for the preparation of lipid globules of a size similar to those of human milk in which the final size of the globules is easier to control and the formation of very small globules is minimised.

Non-obviousness of the proposed solution

3.2 The appellant has argued that, for reasons of economy, the skilled person would have considered reducing as much as possible the shear force applied during the first homogenisation step described in D2. By doing this, larger globules would have been obtained in the first step. Thus, there would have been a one-way street situation leading the skilled person to the claimed solution.

3.3 Furthermore, in its opinion, D3 would have provided a pointer to the solution. D3 disclosed a process for manufacturing an infant formula comprising lipid globules having a size similar to those of human milk. The process involved two homogenisation steps in which the second was adjusted to obtain the desired globule size (paragraph [0026] and the examples). Thus, D3 disclosed the basic principle underlying the claimed invention.

3.4 None of these arguments is persuasive.

3.5 The argument that a one-way street situation existed that would have led to the claimed solution ignores the effect and the technical problem mentioned above and is therefore tainted by hindsight. As noted by the respondent, the size of the globules obtained in the first homogenisation step described in D3 (2.225 µm in example 1 and 2.573 µm in example 2) is considerably lower than that specified in step c) of claim 1. Furthermore, the second homogenisation step is carried out using a rotor-stator rather than an atomisation system as in step d) of claim 1. Thus, D3 does not provide a pointer to the claimed solution.

3.6 Furthermore, the claimed solution, which implies that the shear forces applied in the second homogenisation step are substantially higher than those applied during the first step, is contrary to the underlying teaching of D2, which explicitly states (page 27, last paragraph) that the shear forces applied during the second homogenisation step (by atomisation) should not exceed those applied during the first homogenisation step.

3.7 Moreover, the atomisation step described in D2, which is conducted by spray drying, aims at increasing the total solid content of the composition and possibly obtaining a composition in powder form. It does not aim, as step d) of the invention does, at controlling the globule size (see D2: page 26, lines 9 and 10 and page 29, lines 25 to 27).

3.8 For these reasons, it is concluded that the subject-matter of claim 1, as well as that of the following claims, which is more limited in scope, involves an inventive step.

4. *Adaptation of the description*

4.1 The respondent adapted the description to the claims of the main request. No objections were raised against the amendments.

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:

Claims: No. 1 to 24 according to the main request filed as auxiliary request 2 with the reply to the statement of grounds of appeal

Description: paragraphs 1 to 171 as filed during the oral proceeding before the board

Figures: the sole figure of the patent specification

The Registrar: The Chairman:

K. Götz-Wein A. Haderlein

Decision electronically authenticated