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**Datasheet for the decision  
of 16 October 2023**

**Case Number:** T 1037/22 - 3.3.09

**Application Number:** 14761874.8

**Publication Number:** 3043659

**IPC:** A23D7/005, A23D9/05, A23L33/00,  
A23L35/00

**Language of the proceedings:** EN

**Title of invention:**  
IMPROVED PROCESS FOR PREPARING INFANT FORMULA USING A STATIC  
MIXER

**Patent Proprietor:**  
N.V. Nutricia

**Opponent:**  
Société des Produits Nestlé S.A.

**Headword:**  
Preparing an infant formula using a static mixer/NUTRICIA

**Relevant legal provisions:**  
EPC Art. 56, 100(a)  
RPBA 2020 Art. 13(2)

**Keyword:**

Inventive step - main request and auxiliary requests 1 to 3 -  
(no)

Amendment after summons - exceptional circumstances (no)

**Decisions cited:**

**Catchword:**



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Case Number: T 1037/22 - 3.3.09

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.09**  
**of 16 October 2023**

**Appellant:** Société des Produits Nestlé S.A.  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 3 January 2022  
rejecting the opposition filed against European  
patent No. 3043659 pursuant to Article 101(2)  
EPC.**

**Composition of the Board:**

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

## Summary of Facts and Submissions

- I. The opponent (appellant) lodged an appeal against the opposition division's decision rejecting the opposition.
- 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 that the subject-matter of claim 1 of the patent as granted involved an inventive step in view of D1 as the closest prior art.
- IV. Claim 1 of the patent as granted (main request) reads as follows:

"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, 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 a static mixer so as to obtain a lipid and protein component-containing composition comprising lipid globules, wherein the

lipid globules have a volume-weighted mode diameter of less than 15  $\mu\text{m}$ ."

- V. Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the feature "wherein the lipid globules have a volume-weighted mode diameter of less than 15  $\mu\text{m}$ " has been amended to read "wherein the lipid globules have a volume-weighted mode diameter of at least 1.0  $\mu\text{m}$  and less than 15  $\mu\text{m}$ " (emphasis added).
- VI. Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the feature "wherein the lipid globules have a volume-weighted mode diameter of less than 15  $\mu\text{m}$ " has been amended to read "wherein the lipid globules have a volume-weighted mode diameter of from 3 to 8  $\mu\text{m}$ " (emphasis added).
- VII. Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 1 in that the feature "wherein the static mixer is configured and operates so as to achieve a pressure drop of 2 to 30 bar (0.2 to 3 MPa) between inlet and outlet of the static mixer, and" has been inserted.
- VIII. Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 3 in that the feature "wherein the static mixer is configured and operates so as to achieve a pressure drop of 2 to 30 bar (0.2 to 3 MPa) between inlet and outlet of the static mixer" has been amended to read "wherein the static mixer is configured and operates so as to achieve a pressure drop of 2 to 12 bar (0.2 to 1.2 MPa) between inlet and outlet of the static mixer" (emphasis added).

IX. The following documents were cited in the present case:

D1: WO 2010/027258 A1

D5: R.K. Thakur et al., "Static Mixers In The Process Industries - A Review", Trans IChemE, 2003, volume 81, part A, pages 787 to 826

D7: E.L. Paul et al., "Handbook of Industrial Mixing", Science and Practice, John Wiley & Sons, Inc., Publication, 2004, pages 400 and 646

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

XI. Requests

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

The respondent (proprietor) requested that the appeal be dismissed (main request) or, as an auxiliary measure, that the patent be maintained on the basis of one of auxiliary requests 1 to 3, filed with the reply to the statement of grounds of appeal, or on the basis of auxiliary request 4, filed during the oral proceedings before the board.

## **Reasons for the Decision**

### MAIN REQUEST

#### 1. Inventive step

1.1 The respondent argued that the process in claim 1 involved an inventive step in view of D1 as the closest prior art. In its view, the effect resulting from using a static mixer (i.e. the distinguishing feature from D1) instead of the high-shear mixing device described in D1 was a more narrow lipid droplet size distribution, as shown in Figure 3 of the patent, so the objective technical problem was to provide a process for producing an improved infant or follow-on formula or a growing-up milk having a more narrow lipid droplet size distribution. None of the cited documents taught that this improvement could be achieved by using a static mixer. The common general knowledge of the skilled person did not include the use of static mixers for the homogenisation of an aqueous phase and a lipid phase so as to obtain lipid globules of the claimed size in an infant formula. Neither D5 nor D7 taught that a static mixer could be used for homogenisation in a process for preparing an infant formula or follow-on formula or growing-up milk. The closest prior art taught high-shear mixing devices, whereas D5 and D7 related to low-shear static mixers. A skilled person would derive from Table 12-1 of D7 that it is better not to use static mixers when a stable and non-creaming emulsion, such as an infant formula, was desired. Even when no technical effect could be attributed to the use of a static mixer for homogenisation instead of the homogenisation process disclosed in D1 and the

objective technical problem was to provide an alternative process, the solution to this problem was still not obvious to the skilled person. A skilled person starting from D1 (which teaches high-shear mixers) would not have contemplated that a low-shear static mixer was suitable for solving the objective technical problem, be it an ambitious problem or providing an alternative. In its view the claimed process was not obvious in view of D1 as the closest prior art in combination with the common general knowledge reflected by D5 and D7.

- 1.2 As outlined below, the board does not agree with the respondent.
  - 1.2.1 The parties agreed that D1 qualifies as closest prior art in the present case.
  - 1.2.2 D1 discloses a process for the preparation of a nutritional composition, in particular an infant formula, wherein an aqueous phase and an oil phase are mixed and then homogenised, preferably in a two-step process, at a pressure of 5 to 100 bar in a first step and 5 to 50 bar in a second step (see claim 21, page 18, lines 16 to 31, and Examples 1A and 1B of D1). The homogenisation can be performed with a variety of mixing equipment which is said to apply "high shear" to the product (see page 18, lines 18 and 19, of D1). As can be derived from Example 1A of D1, this process leads to a composition with lipid globules of a volume-weighted mode diameter of 7.3  $\mu\text{m}$ , wherein 71% of the lipid globules have a size between 2 and 12  $\mu\text{m}$  (see Table 1). Example 1B of D1 shows that this process leads to a composition with lipid globules of a volume-weighted mode diameter of 4.0, 5.0 or 4.3  $\mu\text{m}$ ,

wherein 72.2%, 74.8% or 70.3 % of the lipid globules have a size between 2 and 12 µm (see Table 1).

1.2.3 Furthermore, the parties agreed that the claimed process only differs from the process disclosed in D1 in that a static mixer is used in step c).

1.2.4 However, the parties had different views on whether there is an improvement resulting from this difference over the process according to D1.

1.2.5 The respondent submitted that paragraph [0009] and Figure 3 of the patent provided evidence that the claimed process led to a narrower particle size distribution.

1.2.6 As outlined below, the board is not convinced.

The relevant part of paragraph [0009] of the patent, referred to by the respondent, reads as follows:

"WO 2010/027258, WO 2010/027259, WO 2011/108918 and WO 2010/068105 disclose the preparation of nutritional compositions comprising a process step of mixing an aqueous phase with an oil blend using an Ultra-Turrax T50 batch mixer. In the mixing chamber of a batch mixer heterogeneous mixing conditions are present, resulting in a broad lipid droplet size distribution and the formation of partially very large lipid globules" (emphasis added).

While "WO 2010/027258" mentioned in paragraph [0009] of the patent relates to document D1, the above, rather vague, passage in paragraph [0009] alone is not sufficient for acknowledging an improved narrower particle size distribution over document D1. In the

absence of a comparison with the closest prior art, Figure 3 of the patent is not suitable for demonstrating an improved, narrower particle size distribution over D1 either. Therefore, there is no evidence on file which is suitable for demonstrating that the claimed process leads to a narrower particle size distribution over the process in D1. An improvement over the process in D1 cannot be acknowledged.

- 1.2.7 Under these circumstances, the board cannot agree with the respondent that the technical problem to be solved in light of D1 is that of providing an improved process for preparing an infant formula composition with a lipid globule size distribution similar to that of human breast milk. As outlined under point 1.2.6 above, no improvement was demonstrated over D1. In addition, claim 1 is defined so broadly that it encompasses much broader lipid globule size distributions than those similar to human breast milk.
- 1.2.8 Consequently, the objective technical problem is to provide an alternative process for preparing an infant formula or follow-on formula or a growing-up milk.
- 1.2.9 With respect to the question of obviousness, the board concludes as follows.

While D5 teaches that "good mixing at low shear rates" is an advantage of static mixers, they may also locally generate high shear rates. In addition, D5 teaches that static mixers may be used in the food industry in numerous applications, e.g. for producing milk drinks (see page 799, left-hand column, line 6 from the bottom, to page 799, right-hand column, line 2 of D5). From Table 4 of D5 it can be derived that static mixers

may be used in food processing for liquid blending and emulsification. Therefore, D5 demonstrates that static mixers can be used in numerous food applications, so a skilled person looking for a solution to the problem posed above would consult D5, which is considered to reflect the common general knowledge of a skilled person.

While D5 does not contain specific information concerning the lipid globule size which is achieved after passing a mixture through a static mixer, it teaches that an increase in flow rate tends to decrease the Sauter drop diameter ( $d_{32}$ ) (see page 796, lines 13 to 16 from the bottom of D5). Further guidance concerning the lipid droplet size typically achieved by using a static mixer can be found in D7, which is a handbook of industrial mixing and mentions that a droplet size ( $d_{32}$ ) of 0.5  $\mu\text{m}$  to 3  $\mu\text{m}$  or above 3  $\mu\text{m}$  can be achieved with a static mixer. Although a droplet size ( $d_{32}$ ) is not identical to the volume-weighted mode diameter required in claim 1, it is at least in the same order of magnitude. It is again emphasised that the lipid globule diameter defined in claim 1 is defined broadly and is much broader than that of typical human breast milk. Moreover, claim 1 does not mention anything regarding the actual droplet size distribution.

The respondent argued that D7 would prompt a skilled person wishing to produce a stable emulsion to use high pressure homogenisation (see Table 12-1 of D7) and not a static mixer. Since Table 12-1 of D7 indicates that a static mixer leads to marginally stable or usually unstable emulsions, a skilled person would not consider a static mixer as an alternative mixing device in view of that described in D1. Instead, the teaching of D7

would discourage a skilled person from contemplating a static mixer.

The board does not agree.

First, D1 does not disclose the use of typical high pressure homogenisation, but one which applies a lower pressure in the preparation of an infant formula in order to obtain large lipid globules (as intended in the claimed process as well) and not the typically small lipid globules obtained when applying typical high pressure homogenisation, while maintaining a sufficiently stable emulsion (see page 17, lines 1 and 2 of D1). Second, the presence of some creaming was found in the patent to even be advantageous in the claimed process, since it mimics the situation during breastfeeding (see paragraph [0085] of the patent). Therefore, although infant formulas produced according to the claimed process are intended to be rather stable, some creaming is allowed and even advantageous. Third, the droplet size achieved in D1 and the patent are comparable and are preferably in the range of what is required for large globules in the present technical field. Therefore, a skilled person looking for an alternative process for producing infant formulas would not consider typical high pressure homogenisation, which would lead to smaller particles, but instead a static mixer, which leads to larger particles having a globule size similar to those described in D1 as well as in the opposed patent.

Based on their common general knowledge, reflected by D5 and D7, a skilled person confronted with the above objective technical problem would consider a static mixer as an alternative to the mixing device described in D1.

In view of the above, the subject-matter of claim 1 of the main request does not involve an inventive step in view of D1 as the closest prior art in combination with the common general knowledge reflected by D5 and D7.

#### AUXILIARY REQUESTS 1 TO 3

2. For the same reasons as outlined above for the main request, the subject-matter claimed in auxiliary requests 1 to 3 also lacks an inventive step in view of D1 as the closest prior art.

2.1 With respect to auxiliary requests 1 and 2, no additional arguments were submitted by the respondent. Limiting the volume-weighted mode diameter of the lipid globules in claim 1 of auxiliary requests 1 and 2 does not lead to a further difference from D1, since D1 already discloses lipid globules falling within this further restricted range. Therefore, the board cannot see that the process claimed in auxiliary requests 1 and 2 could be judged differently compared with the main request. Consequently, auxiliary requests 1 and 2 are not allowable.

2.2 With respect to auxiliary request 3, the respondent argued that none of the cited prior-art documents teaches a pressure drop of 2 to 30 bar, as now required in claim 1. As can be derived from the table on page 13 of the patent, the lower limit of 2 bar led to a volume-weighted mode diameter of 12.0  $\mu\text{m}$  and higher pressures of 4.5 bar or 5.0 bar led to a volume-weighted mode diameter of 10.0  $\mu\text{m}$  or 7.1  $\mu\text{m}$ . In the respondent's view, no such teaching concerning the importance of the lower limit of the pressure drop in a

static mixer could be found in the prior art, so the claimed process involved an inventive step.

As outlined below, the board is not convinced.

First, the pressure drop range in claim 1 is rather broad. Second, it was concluded for the main request that finding an alternative mixing device, i.e. a static mixer as taught in D5 and D7, for producing an infant formula having the required volume-weighted mode diameter was obvious to a skilled person. Although none of the cited documents explicitly disclosed a pressure drop value in the claimed range, it is considered a routine measure for a skilled person to find pressure drop values for a static mixer in the claimed range, given the fact that D1 also discloses a volume-weighted mode diameter in the claimed range.

The board cannot see that the process claimed in auxiliary request 3 could be judged differently compared with the higher-ranking auxiliary requests, so auxiliary request 3 is not allowable either.

In view of the above, the subject-matter of claim 1 of each of auxiliary requests 1 to 3 does not involve an inventive step in view of D1 as the closest prior art in combination with the common general knowledge reflected by D5 and D7 either.

AUXILIARY REQUEST 4

3. Article 13(2) RPBA

3.1 During the oral proceedings, the respondent filed auxiliary request 4 and requested that it be admitted into the proceedings. As the reasons in favour of admitting it, it mentioned that the preliminary opinion outlined in the board's communication was positive for the respondent as far as the main request was concerned and no opinion was given by the board on the merits with respect to auxiliary request 3, which was the basis for auxiliary request 4, except for a further limitation directed to the pressure drop range. In its view, the process claimed in auxiliary request 4 was *prima facie* allowable, so it should be admitted to the proceedings.

3.2 For the following reasons, the board is not convinced.

As already stipulated in Article 12(3) RPBA the statement of grounds of appeal and the reply shall contain a party's complete appeal case, including all the claim requests. In this context, it is noted that the board essentially only assessed the appellant's arguments and came to the conclusion that they were convincing, and this led to the conclusion that the process claimed in the main request and auxiliary requests 1 to 3 did not involve an inventive step. A change in the board's opinion between the time of drafting the communication and the oral proceedings is not considered as being exceptional in the sense of Article 13(2) RPBA. In addition, the fact that no preliminary opinion was given in the board's communication for the auxiliary requests is not in favour of admitting a new auxiliary request either. As

outlined above, the board essentially only assessed the appellant's inventive-step objection submitted in writing and came to the conclusion that it was convincing. Moreover, the feature newly introduced into claim 1 (i.e. the limitation of the upper limit of the pressure drop) was taken from the description. The board cannot see why the process claimed in auxiliary request 4 could be considered as being *prima facie* allowable, since the range of the pressure drop was still rather large.

Under these circumstances, auxiliary request 4 is not taken into account (Article 13(2) RPBA).

**Order**

**For these reasons it is decided that:**

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

The Registrar:

The Chairman:



H. Jenney

A. Haderlein

Decision electronically authenticated