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Datasheet for the decision of 8 March 2019

Case Number: T 1381/15 - 3.3.09

Application Number: 09766866.9

Publication Number: 2296494

IPC: A23L1/29, A23L1/30

Language of the proceedings: EN

Title of invention:
INFANT MILK FORMULA WITH FAT GRADIENT

Patent Proprietor:
N.V. Nutricia

Opponents:
ABBOTT LABORATORIES
Nestec S.A.

Headword:

Relevant legal provisions:
EPC Art. 114(2), 54(2), 100(b), 56
RPBA Art. 12(4), 12(2), 13(1)

Keyword:
Novelty - main request (no) - auxiliary request (yes)
Sufficiency of disclosure - (yes)
Inventive step - auxiliary request (yes) - non-obvious alternative

Decisions cited:
T 1914/12

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 1381/15 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 8 March 2019

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Appellant: (Opponent 1)	ABBOTT LABORATORIES 100 Abbott Park Road Abbott Park IL 60064 (US)
Representative:	Boult Wade Tennant LLP 5th Floor, Salisbury Square House 8, Salisbury Square London EC4Y 8AP (GB)
Appellant: (Opponent 2)	Nestec 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 18 May 2015 concerning maintenance of the European Patent No. 2296494 in amended form.**

Composition of the Board:

Chairman	W. Sieber
Members:	F. Rinaldi
	F. Blumer

Summary of Facts and Submissions

I. This decision concerns the appeals filed by opponent 1, opponent 2 and the patent proprietor against the interlocutory decision of the opposition division that European patent No. 2 296 494 as amended met the requirements of the EPC.

II. With their respective notice of opposition, opponent 1 and opponent 2 had requested revocation of the patent based on Article 100(a) (lack of novelty and lack of inventive step) and Article 100(c) EPC, opponent 2 also based on Article 100(b) EPC.

The documents cited during opposition proceedings included:

E4: M.C. Michalski et al., "Size distribution of fat globules in human colostrum, breast milk and infant formula", Journal of Dairy Science, 88(6), 2005, 1927-1940

E6: US 2006/0188614 A1

E7: A. Durand et al., "Particle sizes and stability of UHT bovine, cereal and grain milks", Food Hydrocolloids, 17, 2003, 671-678

E8: G. E. Petrowski, "Emulsion stability and its relation to foods", Advances in food research, 1976, 309-359

E10: G. Favé et al., "Physicochemical properties of lipids: new strategies to manage fatty acid bioavailability", Cellular and Molecular Biology, 50(7), 2004, 815-831

E11: D. J. McClements "Food Emulsions - principles, practices, techniques", 2nd edn., Boca Raton,

London, New York, Washington D.C., 2005, (149 pages)

E19: "A Basic Guide to Particle Characterization", 2012, Malvern Instruments Limited, 1-26

E24: Declaration by T.J. Wooster.

III. The opposition division's decision was based on a main request (claims of the patent as granted) and auxiliary requests 1 and 2.

Claims 1, 9 and 10 of the granted patent read as follows:

"*1. Use of vegetable fat, protein and carbohydrate, for the preparation of a liquid infant milk formula wherein at least 15 wt.% of fat droplets have a diameter of 5-25 micrometer based on total weight of fat for feeding an infant.*"

"*9. Liquid infant milk formula comprising vegetable fat, carbohydrate and protein, comprising at least 15 wt.% fat droplets with a diameter of 5-25 micrometer based on total weight of fat.*"

"10. *Powder comprising vegetable fat, protein and carbohydrate, suitable for making a liquid infant milk formula, wherein at least 15 wt.% of the total amount of fat droplets have a diameter of 5-25 micrometer.*"

The claims as granted contained further independent claims relating to a container (claim 6) containing the liquid infant milk formula and a process (claim 7) for preparing the liquid infant milk formula according to claim 1 and the use (claim 8) of the liquid infant milk formula obtained by the process of claim 7. All these

claims encompassed (either in explicit terms or through their dependency) the feature relating to the size of the fat droplets and their amount.

The decision of the opposition division may be summarised as follows:

The claims as granted (main request) did not include added subject-matter and met the sufficiency requirements, but the subject-matter of claim 9 lacked novelty over E10. Claim 9 was deleted in auxiliary request 1. The opposition division decided that the subject-matter of claim 1 of this request lacked an inventive step over E10. The opposition division subsequently held that auxiliary request 2 complied with the requirements of the EPC, in particular, it involved an inventive step in view of the closest prior art, E4. Auxiliary request 2 was based on auxiliary request 1 from which dependent claim 2 was deleted, and all independent claims were amended to indicate (either explicitly or through their back reference to claim 1) that the upper limit of the amount of the fat droplets was "less than 50 wt.%".

IV. In their respective statement setting out the grounds of appeal, opponents 1 and 2 requested that the decision of the opposition division be set aside and that the patent be revoked. Furthermore, opponent 2 filed the following document:

E25: Experimental evidence.

V. In its statement setting out the grounds of appeal, the patent proprietor requested that the decision of the opposition division be set aside and that the patent be maintained as granted or alternatively, based on

auxiliary requests 1 filed together with it. It also submitted an allegedly retyped version of the claims as upheld by the opposition division as auxiliary request 2.

VI. Having regard to the fact that opponent 1, opponent 2 and the patent proprietor are appellants and respondents in these proceedings, for simplicity the board will continue to refer to them as opponent 1, opponent 2 and patent proprietor.

VII. Opponent 1 and opponent 2 replied to the patent proprietor's statement setting out the grounds of appeal, and opponent 1 filed the following document:

E26: "Message d'alerte" (Ministère des Solidarités, de la Santé et de la Famille (Paris, 17 December 2004).

VIII. By letter dated 12 February 2016, the patent proprietor filed auxiliary requests 3, 4 and 5, and requested that E25 not be admitted into the proceedings.

IX. The board summoned the parties to oral proceedings. In its communication, the board listed the documents which had been used and discussed on appeal and, based on these documents, set out its preliminary and non-binding opinion.

X. By letter dated 18 February 2019, the patent proprietor replaced auxiliary request 2 with a corrected version in which the dependency in claim 2 was corrected.

XI. Oral proceedings were held on 8 March 2019, during which the patent proprietor modified its request. It replaced auxiliary request 1 with a corrected auxiliary

request 1 in which the dependency in claim 2 was corrected.

XII. The final requests of the parties were:

Opponents 1 and 2 requested that the decision under appeal be set aside and that the patent be revoked. Opponent 1 further requested that auxiliary request 4 not be admitted into the proceedings.

The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or on the basis of any of the following:

- corrected auxiliary request 1, filed during oral proceedings before the board on 8 March 2019
- auxiliary request 2, filed by letter dated 18 February 2019 (which corresponds to the dismissal of the opponents' appeals)
- auxiliary requests 3 to 5, filed by letter dated 12 February 2016.

XIII. Relevant for the present decision are the main request (claims as granted) and auxiliary request 1. The claims of auxiliary request 1 are identical to the claims as upheld by the opposition division (where the upper limit of the amount of the fat droplets is less than 50 wt.), except that it includes a claim 8 directed to a liquid infant milk formula. Claim 8 of this request reads as follows:

> "8. *Liquid infant milk formula comprising vegetable fat, carbohydrate and protein, comprising 15 to less than 50 wt.% fat droplets with a diameter of 5-25 micrometer based on total weight of fat.*"

XIV. The arguments of opponent 1 and opponent 2 relevant to the present decision may be summarised as follows:

Admission of E25

Opponent 2 argued that E25 had been filed in reaction to the opposition division's decision.

Validity of priority and added subject-matter

The objections raised in the notice of opposition were reiterated and incorporated by reference.

Admissibility of new objection

Based on the comparison between the first and second priority with the opposed patent, opponent 2 concluded that the invention had changed, and it now concerned the production of unstable fat droplets. Nevertheless, the opposed patent did not disclose what had to be done to destabilise the fat droplets.

Novelty - main request

The opposition division's decision was correct regarding lack of novelty of claim 9 in view of E10 and declaration E24. The conclusions in E24 had not been contested by the patent proprietor. The difference between the mean and median fat droplet sizes shown in E10 was simply an indication of an asymmetric particle distribution. Although the patent proprietor had contested the validity of the data in E10 on Peptijunior 15%, it had not provided own data regarding the composition of the formula. The patent proprietor's argument that the formula had "turned" and was not safe for infants was merely an assertion. The publication date of E10 did not give any indication as to when the composition of the formula had been investigated.

Finally, the subject-matter of claim 1 also lacked novelty.

Novelty - auxiliary request 1

Opponent 1 argued that by simply visually inspecting the photo micrograph of figure 2 of E10 of the product Peptijunior 15% and in view of the size distribution of the fat droplets, it was highly likely that 15 to less than 50 wt.% of fat droplets had a diameter of 5 to 25 µm.

Sufficiency of disclosure - auxiliary request 1

Opponent 2 argued with reference to sample B of E25 that the fat gradient was not achieved over the whole scope of the claims and that it was not possible to produce a ready-to-use infant milk formula which maintained a fat gradient. Moreover, the homogenisation method of the opposed patent did not lead to particle size distributions within the ranges recited in the claims of the opposed patent. The particle size distribution depended also on the ingredients used in the composition. Moreover, the skilled person would not have been able to know whether they were working within the scope of claim 3 because no point in time was given at which the fat gradient had to be measured.

Inventive step - auxiliary request 1

Opponent 1 considered E6 as the closest prior art. A person skilled in the art wanting to mimic the different fat contents of human fore-milk and hind-milk would have provided a liquid infant formula composition having a larger proportion of fat at the top of the composition than at the bottom of the composition. Thus, the skilled person would have been directed to provide compositions that cream.

Opponent 2 argued that the technical problem was not solved over the entire scope. The claims had an open wording, and stabilisers might be included which prevent creaming of the fat droplets. Therefore, it was not credible that an appropriate fat gradient formed. Moreover, the claims were not limited to fat droplets having a size below 25 µm, and so the invention might not work. Also, based on the results of E25, it was not possible to provide a ready-to-use liquid formula having a fat gradient.

The closest prior art for opponent 2 was document E4. The only technical problem solved was to mimic the fat droplet size distribution of human milk. The skilled person would have found the solution in E4 in combination with E10.

XV. The arguments of the patent proprietor relevant to the present decision may be summarised as follows:

Admissibility of documents
Document E25 should have been filed during the opposition proceedings.

Validity of priority and added subject-matter
Reference was made to the opposition division's decision which in this respect was correct.

Admissibility of new objection
The fresh objection should not be admitted, because the patent proprietor had no means to rebut it at the oral proceedings.

Novelty - main request
E10 did not anticipate the subject-matter of claims 1 and 9. Firstly, there was no explicit disclosure in the

prior art of a composition comprising at least 15 wt.% fat droplets with a diameter of 5 to 25 µm based on total weight of fat, and it was not excluded that a considerable amount of fat droplets had a diameter above 25 µm. Moreover, because in E10 the median sizes were all very low values, even for those formulas which had a relatively large droplet mean size, the skilled person would have considered these values to be incorrect. Finally, the skilled person would have recognised that the composition had "turned" both because of the values given in E10 and because Peptijunior 15% contained extensively hydrolysed whey protein. The fact that E10 was published in 2004, whereas the data in E10 related to a formula from 2000, confirmed this.

Novelty - auxiliary request 1

The information provided in E10 was not sufficient to allow the conclusion that 15 to 50 wt.% of the fat droplets of the formula had a diameter of 5 to 25 µm.

Sufficiency of disclosure - auxiliary request 1

The opposed patent provided guidance on how to prepare compositions according to claim 1 and on how to carry out the invention. The opposed patent also contained sufficient indication as to the point in time at which the fat gradient between the upper and lower volumes should be in place. The results in E25 concerning sample B were aberrant, and no conclusion could be drawn from them.

Inventive step - auxiliary request 1:

E6 was the closest prior art. It related to providing to infants a non-human milk that mimics breast fore- and hind-milk feeding. The distinguishing feature was responsible for providing a fat gradient in the

appropriate time frame. Thus, the technical problem was the provision of an alternative solution to E6. However, the solution found was not suggested by the prior art. E4 and E10 were not the closest prior art because the technical problem was not to mimic human milk. It was not possible to derive any conclusion from E25 and sample B regarding whether the technical problem had been solved.

Reasons for the Decision

1. Admission of E25

1.1 Opponent 2 filed experimental report E25 with its statement setting out the grounds of appeal to demonstrate that the invention was not enabled over the entire scope claimed. The patent proprietor objected to the filing of this evidence, saying it could and should have been filed during the opposition proceedings.

1.2 The filing of E25 at the earliest possible stage of the appeal proceedings is in the board's view an acceptable reaction of opponent 2 to reinforce its attack on sufficiency. In fact, the filing of E25 may be seen to be occasioned by the opposition division's decision, in which it was highlighted that doubts regarding sufficiency of disclosure had not been substantiated by verifiable facts. Thus, the board decided not to exclude E25 from the appeal proceedings under Rule 12(4) RPBA.

2. *Objections of opponent 2 regarding the validity of the priority and added subject-matter*

2.1 In its statement setting out the grounds of appeal (page 2), opponent 2 "reiterated and incorporated by reference" the objections with regard to the validity of the priority and to added subject-matter which it had raised in its notice of opposition. However, it did not address the opposition division's decision on these two points.

2.2 According to Article 12(2) RPBA, the appellant "shall set out clearly and concisely the reasons why it is requested that the decision under appeal be reversed, amended or upheld". Opponent 2 has not explained why it considered the decision of the opposition division on validity of the priority and added subject-matter to be incorrect. A plain reference to written submissions made in opposition proceedings does not satisfy the above-mentioned requirement. Therefore, these objections are not admissible.

3. *Admissibility of new objection*

3.1 At the oral proceedings, opponent 2 presented a new objection of lack of sufficiency of disclosure based on a comparison of (i) the disclosure of selected passages of the opposed patent concerning the homogenisation process and the lipid composition of the formula (*inter alia*, paragraph [0027], lines 41 and 42 and 45 to 47) with (ii) sections of the first priority document (EP 08158336.1, page 8, lines 4 and 5) and of the second priority document (EP 08163478.4, in particular, page 13, lines 25 to 27; page 8, line 19 to 21; page 9, line 1 to 3; and page 14, line 7 to 9). From this comparison, it concluded that the invention described

in the priority documents was to produce stable fat droplets, whereas the one of the opposed patent was to produce unstable fat droplets. Nevertheless, according to opponent 2, the opposed patent did not disclose what had to be done to destabilise the fat droplets.

3.2 This objection was neither mentioned in the appealed decision nor in the written submissions of opponent 2 on appeal. In fact, opponent 2 did not contest that the objection was raised late. In its view, it constituted an argument based on a ground of opposition in the proceedings (Article 100(b) EPC), and, for this reason, it had to be considered by the board. In this context, reference was made to T 1914/12.

3.3 According to the headnote of T 1914/12, the boards of appeal do not have any discretion as to the admissibility of arguments submitted late which are based on facts already in the proceedings. However, the board does not consider the specific objection raised by opponent 2 an argument based on facts already in the proceedings.

3.4 Firstly, this objection relies on pieces of evidence (the first and the second priority document) which had not been discussed in the context of sufficiency of disclosure. In fact, the priority documents were not at all discussed on appeal (see also point 2 above). Moreover, the board had listed in its communication (point 1.2) the documents that it considered "used and discussed on appeal". The first and second priority documents were not in that list, and opponent 2 did not indicate until the oral proceedings that it wished to rely on these documents.

3.5 Secondly, the facts relied upon by opponent 2, namely, the stability of the fat droplets and the contribution of the polar lipids to this effect, had not been mentioned on appeal, let alone in the context of sufficiency of disclosure. However, it is this factual disclosure of the evidence that provides the starting point for the proposition developed by opponent 2.

3.6 In summary, in the present case, the board identifies a bundle of new (pieces of) evidence and new (allegations of) facts which are used to formulate a new objection (a new attack). However, the board fails to see that this specific objection raised by opponent 2 is based on facts already in the proceedings. The newly raised objection based on the alleged discrepancies between the present application and the priority documents is therefore not a mere argument which can be made at any time. Thus, its admission into the proceedings is subject to the board's discretion.

3.7 In view of the extremely late state of the proceedings and the complexity of the new objection, the board exercised its discretion under Article 13(1) RPBA and Article 114(2) EPC to not admit this new objection into the proceedings.

Main request (claims as granted)

4. *Novelty*

4.1 Claim 9 of the main request (point III) relates to a liquid infant milk formula comprising vegetable fat, carbohydrate and protein, with at least 15 wt.% fat droplets having a diameter of 5 to 25 µm based on total weight of fat.

4.2 In the appealed decision, the opposition division concluded that the infant formula Peptijunior 15% disclosed in table 1 of E10 implicitly anticipated the subject-matter of claim 9 of the main request. E10 disclosed for this formula a mean fat droplet size of 15.04 $\pm$ 1.10 µm and a median size of 9.35 $\pm$ 0.25 µm. Relying on declaration E24, the opposition division held that it was physically impossible for the product Peptijunior 15% not to have at least 15% of fat droplets between 5 and 25 µm.

4.3 The patent proprietor contested this finding for the following reasons:

- There was no explicit disclosure in the prior art of a composition comprising at least 15 wt.% fat droplets with a diameter of 5 to 25 µm based on total weight of fat. It could not be excluded that a considerable amount of fat droplets had a diameter above 25 µm.
- The disclosure of E10 was ambiguous because the values for the median size were very low, even for formulas having a relatively large droplet mean size. The skilled person would have considered these values to be incorrect.
- Peptijunior 15% was a paediatric formula based on extensively hydrolysed whey protein for infants suffering from severe digestive disorders. Due to the extensively hydrolysed whey protein, the formula lacked the emulsion-stabilising properties of normal protein, and thus it was unstable as an emulsion. With this knowledge in mind and assuming the skilled person would have accepted the reported values as they were, the skilled person would have realised that this formula had "turned" and as such was not suitable for administering to infants. This

was corroborated by the fact that E10 was published in 2004, whereas the data disclosed in it related to a formula from 2000.

4.4 The board cannot agree:

4.4.1 It is true that E10 does not explicitly disclose the required particle distribution of fat droplets. However, the decisive point is whether Peptijunior 15% inherently had the required amount of fat droplets having a diameter of 5-25 µm.

The board has no reason to doubt the analysis provided in E24, namely, that it is physically impossible that an infant milk formula in which the mean fat droplet size is 15.04 µm and the median size is 9.35 µm does not have at least 15% of fat droplets between 5 and 25 µm. Nor has the patent proprietor provided any evidence to the contrary.

The appellant's further argument that Peptijunior 15% could have contained (a considerable amount of) fat droplets having a diameter above 25 µm is also not convincing because the fat droplet sizes for all formulas described in E10 vary only within a range of 0.3 to 20 µm (page 817, left column).

4.4.2 Next, the argument that the spread between the mean and median fat droplet sizes indicated that the values cannot be correct remains an allegation. Instead, the divergence might simply be a consequence of the fact that the fat droplet size distribution was not symmetrical. In these cases, the mean and median particle sizes do not give equivalent values as confirmed by E19, page 8.

4.4.3 The argument that the composition had "turned" and was not suitable for administration to infants is also not convincing. The board agrees with opponent 1 that "Peptijunior was a commercially available infant formula considered by the authors of E10. The notes at the end of page 818 of E10 indicate that it was a product of the current Patentee. It is noted that the Patentee submits that there is ambiguity in the disclosure of E10, but has not provided its own data concerning Peptijunior 15%" (letter of opponent 1 dated 21 January 2016, page 2). Furthermore, the fact that E10 was published in 2004 whereas the data concerned a formula from 2000 (footnote 4 of table 1) is in itself not an indication that the formula has "turned". Other scenarios might explain this time difference, as pointed out by opponent 2.

4.5 It follows from these considerations that the formula Peptijunior 15% described in table 1 of E10 discloses all features of claim 9 of the main request, including the particle size distribution and the corresponding amounts. Therefore, the subject-matter of claim 9 lacks novelty, Article 54 EPC.

4.6 In addition, the disclosure of E10 relating to Peptijunior 15% implicitly anticipates the use of milk formula ingredients for the preparation of a liquid infant milk formula in which at least 15 wt.% of fat droplets have a diameter of 5 to 25 µm, based on total weight of fat. In view of this, the subject-matter of claim 1 of the main request also lacks novelty.

Auxiliary request 1

5. *Novelty*

5.1 In auxiliary request 1, all independent claims were amended to indicate, either in explicit terms or through their dependency, that the amount of fat droplets having a diameter of 5 to 25 µm was 15 to less than 50 wt.% based on total weight of fat/fat droplets. As pointed out in the decision under appeal, the introduction of the upper limit is based on page 7, first paragraph, of the application as filed. This was not contested by the opponents.

5.2 Opponent 1 argued that by simply visually inspecting the photo micrograph of figure 2 of E10 of the product Peptijunior 15%, it was likely that 15 to less than 50 wt.% of fat droplets had a diameter of 5 to 25 µm. Moreover, in view of the broad fat droplet size distribution described in E10 for this formula, it was highly likely that more than 50% of the fat droplets were outside the claimed range.

5.3 However, "[a]ccording to established case law, it is a prerequisite for the acceptance of lack of novelty that the claimed subject-matter is 'directly and unambiguously derivable from the prior art'". (Case Law of the Boards of Appeal of the European Patent Office, 8th edition, 2016 ["Case Law"], Chapter I.C.4.1, fourth paragraph). This means that it has to be beyond doubt, and not merely probable, that the claimed subject-matter is directly and unambiguously disclosed in a prior-art document.

5.4 However, the amount of fat droplets described in claim 8 cannot be identified directly and unambiguously

in E10. Consequently, the subject-matter claimed in auxiliary request 1 is novel (Article 54 EPC).

6. *The subject-matter of the opposed patent*

6.1 The opposed patent aims to mimic the concentration difference in fat which occurs when an infant is breastfed (paragraph [0001]). When being breast fed, infants receive human milk in which the fat concentration gradually increases during the feeding event. The fore-milk, which the infant receives at the beginning of the feeding event, has a lower fat concentration as compared to the hind-milk, i.e. the milk received towards the end of the feeding event (paragraph [0002]). The composition of the opposed patent "*contains fat droplets with an increased diameter compared to standard infant milk formula. The fat droplets will 'cream' due to the differences in densities between the fat and water. This will result in an increased fat concentration in the upper part of the container compared to the lower part of the container. Hence, within the present liquid composition, the fat concentration will differ in the vertical direction of the container. Keeping the container, e.g. bottle 'upside down' (teat down), the fat concentration in the upper part of the container will be higher than in the lower part. Consequently, when drinking, the infant will first ingest the part of the formula with a lower concentration of fat. Towards the end of feeding, the fat concentration will increase, thereby mimicking the concentration differences, in particular of fat, which occur when the infant is breast fed*" (paragraph [0010], lines 3 to 9).

6.2 In short, the invention aims to imitate the physiological aspect occurring during breastfeeding,

which implies that the infant ingests low-fat fore-milk at the beginning of a feeding event and the fat-rich hind-milk towards the end of the feeding event, making use of the physical phenomenon of creaming, which occurs in a composition having fat droplets of a certain size range. In the context of the opposed patent, this phenomenon is also referred to as the provision of a fat gradient.

7. *Sufficiency of disclosure*

7.1 Opponent 2 considered that the invention was not sufficiently disclosed for the following reasons.

- Based on the evidence provided in sample B of E25, the skilled person would not have been in a position to prepare (ready-to-use) infant milk formula which provided the fat gradient.
- There was no guidance in the description that would have allowed preparation of the claimed compositions over the whole range of the claims without undue experimentation.
- The skilled person would not have known when they were working within the scope of claim 3 since no time frame was indicated for when the fat gradient had to be in place.

7.2 Objections based on sample B of E25

7.2.1 The invention aims, as described above in point 6, to establish the fat gradient. The physical principle according to which creaming occurs is well investigated in the field of food emulsions and is governed by Stokes' law (E7, page 677; E8, page 315; and E11, equation 7.9). As explained in declaration E24, a document submitted by opponent 2 during the opposition

proceedings, "*[t]here is a direct link between the fat droplet size in the composition and the fat gradient that is generated in the product within a specific time frame. It is known that increasing an emulsion[']s droplet size will cause it to create a cream layer at the top of the product. The Stokes['] equation (E11, equation 7.9) gives speed of creaming as [a] function of the droplet size. It indicates that creaming speed is proportional to fat droplet diameter to the power 2. ... In reality, things may be more complex and Stokes['] equation does not take into account, for example, polydispersity, interaction between the particles which may hinder their move. However, combination of theoretical calculations and simple trial and error experimentation of different particle size distributions leads to determination of appropriate droplet sizes for a defined target fat gradient.*"

7.2.2 Nevertheless, opponent 2 objected that there was no evidence demonstrating that it was possible to produce a (stable) ready-to-use infant milk formula which provided a fat gradient. In this context, it referred to sample B of E25.

7.2.3 Sample B was prepared from UHT-treated composition including vegetable oil, carbohydrate and protein. The sample was homogenised twice at 20°C, at 0 bar and at 30 bar. The particle size distribution was measured immediately after homogenisation and 19% of the fat droplets had a diameter between 5 and 25 µm. The sample was then stored for two weeks at 4°C, and it was heated to 50°C. In this sample, the 10% top volume fraction had a much lower fat content (1.53 wt%) compared to the 10% bottom volume fraction (5.38 wt%) as shown on table 2 of E25. Thus, in sample B, the fat particles

did not naturally move to the upper fraction to form a gradient with a higher concentration of fat on the top. The authors of E25 provided an explanation of what might have occurred, i.e. "visually undetectable serum had been released from the bulk, diluting the top fraction and leading to a more concentrated product at the bottom". Based on these results, it was argued that the fat gradient was not achieved over the whole scope of the claims and that it was not possible to produce a (stable) ready-to-use infant milk formula which maintained a fat gradient.

7.2.4 The patent proprietor considered that the storage of sample B "for 2 weeks at 4°C followed by heating to 50°C is not representative for a standard handling of infant formula and cannot result in an infant formula that is suitable for use" (letter of 12 February 2016, page 4, last full paragraph). This is at least, not the handling of liquid milk formula suggested in the specification of the opposed patent. More importantly, serum release is not considered to be a desired property in infant milk formula, and the formula shows an unexpected concentration of fat at the 10% bottom volume fraction.

7.2.5 In view of all these aspects, the board is not convinced that the single experiment carried out with sample B provides sufficient evidence demonstrating that the fat gradient cannot be achieved or that it is not possible to prepare a ready-to-use liquid infant milk formula which provides the fat gradient of claim 3. As also explained in E24, the effect is straightforwardly achievable according to well-established physical principles. Thus, no conclusions regarding sufficiency of disclosure can be drawn from sample B of E25.

7.3 Objection regarding the preparation of the claimed compositions

7.3.1 Opponent 2 referred to the experimental results regarding sample A and C of E25. These two compositions had been prepared in the same way, from an UHT-treated composition including vegetable oil, carbohydrate and protein. Sample A included lactose as the only carbohydrate, whereas in sample C part of the lactose was replaced by starch. The samples were homogenised twice at 40°C, both times at 50 bar, and stored in a separation funnel at ambient temperature for 30 minutes immediately after homogenisation. After the storage period, the upper and lower 10vol% fractions were collected. In sample A, which contained only starch, only between 0.3 and 0.6% of the fat particles had a diameter between 5 and 25 µm. In addition, the fat droplet distribution differed significantly between samples A and C. Opponent 2 concluded that the homogenisation method in the opposed patent did not necessarily lead to particle size distributions within the ranges recited in the claims of the opposed patent, and the particle size distribution obtained depended also on the ingredients used in the composition.

7.3.2 However, in the patent specification there is sufficient information on how to provide the compositions claimed. A process for obtaining the fat droplets is described in paragraph [0027] and following, the homogenisation is described in paragraph [0032], and a specific preparation method is described in paragraph [0044].

7.3.3 As regards the specific results of sample A, the homogenisation of this composition was carried out at

50 bar, which is the highest pressure described in the opposed patent (paragraph [0032], line 31). The fact that opponent 2 chose to repeat the teaching of the opposed patent using values at the upper limit of the range taught in the patent does not necessarily mean that the invention is not enabled. In such a case, a higher amount of trial and error might be required, and the skilled person would also have found in the opposed patent an indication as to what would have to be done in case of failure, namely, to reduce the homogenisation pressure.

7.3.4 Thus, the board is not convinced that from the samples A and C of E25 it can be concluded that the invention is not enabled over the entire scope of the claims.

7.4 Objection regarding the time frame within which the gradient claimed in claim 3 had to be established

7.4.1 Claim 3 relates to setting up a concentration ratio of fat in the upper 10 volume% : lower 10 volume% of the liquid infant milk formula above 1. Opponent 2 argued that the skilled person would not have known when they would be working within the scope of claim 3 because no time frame was defined for assessing the presence of the claimed concentration ratio, i.e. the fat gradient.

7.4.2 However, according to recent decisions, the concept of "forbidden area" is associated with the scope of the claims, i.e. Article 84 EPC, rather than with sufficiency of disclosure (Case Law, Chapter II.C. 5.6.5).

7.4.3 More importantly, a time range when the fat gradient should be in place is in fact indicated in several

paragraphs of the patent in suit, namely, that the fat gradient should be established "at the start of or during the feeding event" (paragraph [0019]), that a feeding event usually lasts for about 5 to 30 minutes (paragraph [0020]), and that the fat gradient in the infant nutrition is preferably prepared in a single container by pouring the liquid infant formula with the larger fat droplets in a single container and leaving it undisturbed for at least 5 minutes (paragraph [0040]). Any imprecision that may be found for this feature is regarded as a potential issue of lack of clarity, which, however, is outside the scope of examination.

7.4.4 Thus, this objection of lack of sufficiency of disclosure also fails.

7.5 Therefore, the ground under Article 100(b) EPC does not prejudice the maintenance of the patent in the form of auxiliary request 1.

8. *Inventive step*

8.1 The set of claims of the auxiliary request 1 comprises six independent claims. All independent claims require (either in explicit terms or through their dependency) that the amount of fat droplets having a diameter of 5 to 25 µm is 15 to less than 50 wt.% based on total weight of fat/fat droplets. At the oral proceedings, it was common ground that the conclusions arrived at for the subject-matter of a single claim (such as claim 8) applied to the other five independent claims as well. In view of this, the board will discuss inventive step in relation to claim 8 (point XIII), which relates to a liquid infant milk formula comprising vegetable fat, carbohydrate and protein, comprising 15 to less than

50 wt.% fat droplets with a diameter of 5 to 25 µm based on total weight of fat.

8.2 The closest prior art

8.2.1 In its written submissions, the patent proprietor considered E6 to be the closest prior art, and the board indicated in its communication that it tended to agree with this choice. At the oral proceedings, opponent 1 too used E6 as the closest prior art. However, opponent 2 maintained that E4 was the closest prior art.

8.2.2 E6 aims to administer to infants a non-human milk that mimics breast fore- and hind-milk feeding (paragraph [0001]). E6 describes two alternative solutions to address this problem: (i) the feeding is performed using two bottles, one filled with the fore-milk equivalent and one filled with the hind-milk equivalent, and the contents of the bottles are fed to the infant one after the other (paragraph [0013]); or (ii) the feeding is performed with a bottle which is divided into two compartments, one filled with the fore-milk equivalent and the other with the hind-milk equivalent, and the bottle is designed in such a manner enabling the infant to consume the fore-milk equivalent first and then the fore-milk equivalent gradually admixed with the hind-milk equivalent (paragraph [0014]). The bottle's special design is shown in figures 1 or 2 and requires the presence of non-return diaphragm valves (paragraphs [0037] and [0038]).

8.2.3 E4 is a scientific article analysing the size distribution of fat globules in human colostrum, breast milk and in infant formula (title). It describes in the

abstract that fat droplets in infant formula (diameter on average: 0.4 µm) are smaller than in human milk (diameter on average: 4 µm). Further data relative to the fat droplet size of human milk and infant milk formula is given, *inter alia*, in figures 2 and 7.

8.2.4 It is evident from the above analysis that only E6 relates to the phenomenon of a fat gradient in the context of an infant's feeding event. Since the disclosure of E6 relates to the same technical problem as the patent in suit, the board considers this document to be indeed the closest prior art, in line with established case law (Case Law, Chapter I.D.3.3).

8.2.5 In its statement setting out the grounds of appeal, opponent 1 used also E10 as the closest prior art. This document discusses the fat droplet size in human milk and infant formula. Like E4, this document also does not address fore- or hind-milk or how to mimic the breastfeeding event. Therefore, it cannot be considered the closest prior art.

8.3 Distinguishing feature

The subject-matter of claim 8 differs from E6 in that at least 15 wt.% to less than 50 wt.% of fat droplets have a diameter of 5 to 25 µm, based on total weight of fat.

8.4 The objective technical problem

8.4.1 The technical problem addressed in the opposed patent is mimicking the concentration differences in fat which occur when an infant is breastfed (paragraph [0001]). This problem is allegedly solved due to the specified fat droplet size in the composition and in the

specified amount, which allows the generation of a fat gradient within a certain time frame.

8.4.2 However, opponent 2 contested that the technical problem set out in the opposed patent was solved over the entire scope of the claims.

- The open wording of the claim ("comprising") allowed for the presence of stabilisers which prevented creaming of the fat droplets. Thus, it was not credible that an appropriate fat gradient formed in this case.
- The claim encompassed the presence of fat droplets having a size above 25 µm, for instance in an amount of up to 85 wt.% based on total weight of fat.
- It was not possible to provide a ready-to-use liquid formula.

8.4.3 In theory, infant milk formula compositions according to claim 8 are conceivable in which the fat droplets do not behave according to Stokes' law, for example, due to the presence of unsuitable stabilisers. However, opponent 2 appears to "tear down" the claimed invention by construing non-working embodiments. Neither the description nor the claims describe embodiments containing, for example, detrimental stabilisers, which would operate against the invention. Therefore, there would have been no reason for the person skilled in the art to deliberately have read into the claim features which undo or cancel the effects of the invention.

8.4.4 As to the argument that claim 8 encompassed compositions having many very large fat droplets, it is true that such fat droplets are not excluded by the feature "15 to less than 50 wt.% fat droplets with a

diameter of 5-25 micrometer based on total weight of fat". However, as pointed out by the patent proprietor, a vast amount of large fat droplets is excluded by the feature "liquid infant milk formula". A skilled person would not have regarded a composition including a high amount of fat droplets having a diameter above 25 µm as suitable for use as a liquid infant milk formula.

8.4.5 Based on the results of sample B, opponent 2 also argued that the patent proprietor had not demonstrated that it was possible to produce a ready-to-use liquid infant milk formula which provided the required fat gradient. However, as discussed in detail above (point 7.2), sample B cannot be used to draw any conclusion on the effects achievable by the invention, and consequently on the technical problem it solves. Therefore, this argument of opponent 2 also fails.

8.4.6 Thus, it can be concluded that the technical problem addressed in the patent in suit is indeed solved by the features of the claim. However, in view of the fact that the same technical problem was already solved by the closest prior art E6 in a different way, the objective technical problem has to be reformulated as the provision of an alternative to the solution provided in E6.

8.4.7 It is self-evident from the above discussion that this problem has been solved.

8.5 Obviousness

8.5.1 Opponent 1 argued that it was well known that bottle feeding of an infant was routinely conducted using an inverted (baby) bottle and that formula was taken out of the bottle via the teat from the lower part of "the

liquid column". Therefore, the person skilled in the art wishing to mimic the different fat contents of human fore- and hind-milk would have known that it was necessary to have a liquid infant formula composition in which there was a larger proportion of fat at the top of the composition than at the bottom of the composition. This was, in fact, the well-studied phenomenon known as "creaming", based on Stokes' law (discussed in E7, E8, E11 and E24). Thus, the skilled person faced with the objective problem would have modified the teaching of E6 by using an ordinary single (baby) bottle including the application of the known creaming effect.

8.5.2 However, the disclosure of E6 requires the presence of two different compositions which are kept separate from each other. As described above, either the two compositions are provided in two different bottles or the bottle is designed in such a way that during consumption, the fore-milk equivalent is gradually admixed with the hind-milk equivalent using specific diaphragm valves. There is no suggestion in E6 to abandon the concept of providing two different compositions that are maintained separate up to the start of the feeding session. Moreover, in E6 the (micro)structure of the two compositions is not discussed, and the document is entirely silent on the size of the fat droplets and their distribution in the two compositions. Thus, the person skilled in the art would have had no motivation to look into the formulation aspects of the two separate compositions of E6, and even less to modify them.

8.5.3 Although it is true that the effect of creaming of fat droplets is well known in the art, opponent 1's approach of making use of this effect to modify the

teaching of E6 to mimic the breastfeeding event is in the board's view tainted with hindsight.

8.6 In view of this, the subject-matter of claim 8 of auxiliary request 1 involves an inventive step (Article 56 EPC). The same applies also to the remaining claims of this request. This is due to the fact that all independent claims encompass (either in explicit terms or through their dependency) the same feature regarding the fat droplet diameter and amount of claim 8.

9. As this request of the patent proprietor is allowable, it is not necessary to deal with the lower-ranking auxiliary requests.

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 on the basis of the following claims and a description to be adapted thereto:

   Claims 1 to 9, filed as corrected auxiliary request 1 during oral proceedings before the board on 8 March 2019.

The Registrar: The Chairman:

M. Cañueto Carbajo W. Sieber

Decision electronically authenticated