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**Datasheet for the decision
of 4 April 2017**

Case Number: T 0697/14 - 3.3.09

Application Number: 02805966.5

Publication Number: 1455585

IPC: A23C9/15, A23C11/04, A23L1/305

Language of the proceedings: EN

Title of invention:
INFANT FORMULA COMPOSITIONS COMPRISING INCREASED AMOUNTS OF
ALPHA-LACTALBUMIN

Patent Proprietor:
Nestec S.A.

Opponents:
N.V. Nutricia
Friesland Brands B.V.

Headword:

Relevant legal provisions:
EPC Art. 100(b), 54, 56

Keyword:

Grounds for opposition - insufficiency of disclosure (no)

Novelty - (yes)

Inventive step - (yes)

Decisions cited:

Catchword:



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Case Number: T 0697/14 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 4 April 2017

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 21 January 2014 rejecting the opposition filed against European patent No. 1455585 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman W. Sieber
Members: M. O. Müller
 F. Blumer

Summary of Facts and Submissions

- I. This decision concerns the appeal filed by opponent 1 against the decision of the opposition division to reject the oppositions against European patent No. 1 455 585.
- II. With their notices of opposition, opponents 1 and 2 had requested revocation of the patent in its entirety on the grounds under Article 100(a) EPC (lack of novelty, lack of inventive step and non-patentability under Article 53(c) EPC) and Article 100(b) EPC.

The documents submitted during the opposition proceedings included:

- E1: J.M.K Timmer, "Whey protein concentrates with non-traditional compositions? - A new challenge for product developers", Eur. Dairy Magazine, volume 189(8), 1997, pages 47 to 49;
- E2: WO 02/28194 A1;
- E5: CA 1 243 887 A;
- E8: US 4,485,040 A;
- E9: EP 0 604 684 A1; and
- E11: Commission Directive 91/321/EEC of 14 May 1991 on infant formulae and follow-on formulae, 38 pages.

- III. The decision of the opposition division was based on the claims as granted, which comprised the following independent claims:

"1. An infant formula composition comprising a whey fraction wherein 40% or less of the total protein in said whey fraction is alpha-lactalbumin and more than 8% of the total protein in said whey fraction is beta-lactoglobulin, with the proviso that the percentage of alpha-lactalbumin in said whey fraction is greater than the percentage of beta-lactoglobulin in said whey fraction."

"2. An infant formula composition comprising an amount of bovine milk providing 1.0 to 1.2 grams of protein per 100 available kilocalories and an amount of a bovine whey material providing 1.0 to 1.2 grams of protein per 100 available kilocalories, said bovine whey material having an alpha-lactalbumin content of 28% to 40% and a beta-lactoglobulin content of 8% to 33% of total protein."

"10. A method of feeding an infant, comprising feeding a nutritionally sufficient amount of the infant formula of claim 1 to an infant less than one year of age."

IV. The opposition division rejected the oppositions essentially for the following reasons:

The invention as defined in the claims as granted was sufficiently disclosed. The documents cited during the opposition proceedings showed that the skilled person working in the dairy field had at his disposal a number of methods for making whey protein fractions in varying degrees of enrichment with respect to the proteins of interest. No exceptional effort was required to combine these available fractions in such a way as to obtain whey fractions with a content of alpha-lactalbumin and

beta-lactoglobulin as required by the claims as granted.

The subject-matter of the claims as granted was furthermore novel. With regard to E1 a twofold selection was necessary, namely the selection of (i) a specific WPI99 fraction having an alpha-lactalbumin and beta-lactoglobulin content as claimed and (ii) the use thereof in infant formulae. E2 disclosed a protein composition with an alpha-lactalbumin and beta-lactoglobulin content as claimed but did not disclose that this composition as such was used in an infant formula. E9 did not unambiguously disclose alpha-lactalbumin and beta-lactoglobulin contents as claimed, let alone an infant formula having these contents.

The subject-matter of the granted claims was also inventive. It differed from the closest prior-art document E5 by a lower content of alpha-lactalbumin. The problem to be solved was to provide an infant formula which met the standards laid down in the relevant legislation, was well tolerated and promoted proper growth in infants, required no or only limited amino acid supplementation and, lastly, could be manufactured in a cost-effective manner. On the basis of example 4 of the patent, and in the absence of any evidence to the contrary, it was credible that this problem was solved. The skilled person would not obtain any hint from the prior art to reduce the content of alpha-lactalbumin in order to solve this problem.

V. This decision was appealed by opponent 1 (hereinafter the appellant). The statement setting out the grounds of appeal included

E21: R. Jost et al., International Journal of Food

Science and Technology, volume 34, 1999,
pages 533 to 542; and

E22: A.L. Zydney, Int. Dairy Journal, volume 8,
1998, pages 243 to 250.

VI. With letter dated 2 October 2014, the proprietor (hereinafter the respondent) filed auxiliary requests 1 to 6 and requested as a main request that the appeal be dismissed, i.e. that the patent be maintained as granted (for the independent claims, see point III above). Furthermore, the respondent requested that new documents E21 and E22 and the appellant's inventive-step attack based on E1 as the closest prior art not be admitted.

VII. With letter dated 24 March 2015, the appellant filed

E23: "Technology of Cheesemaking", B.A. Law et al. (ed.), second edition, 2010, pages 94 and 95;

E24: J.N. de Wit, "Lecturer's Handbook on whey and whey products", first edition, 2001, 89 pages; and

E25: "Lehrbuch der Ernährungstherapie", K. Huth et al., 1986, 28 pages.

VIII. With letter dated 2 September 2015, the respondent filed a new auxiliary request 6 and requested that new documents E23 to E25 not be admitted.

IX. By its communication dated 4 October 2016, the board communicated its preliminary opinion to the parties.

X. With its letter dated 14 February 2017, the respondent filed

E26: E.L. Lien et al., Journal of Pediatric Gastroenterology and Nutrition, volume 38, 2004, pages 170 to 176.

XI. On 4 April 2017, oral proceedings were held before the board. The appellant maintained its requests made during the written proceedings. The respondent withdrew its requests that E21, E24 and the appellant's inventive-step attack based on E1 not be admitted.

XII. Opponent 2 did not file any submissions in substance during the written appeal proceedings.

XIII. So far as relevant to the present decision, the appellant's and opponent 2's arguments presented during the written and oral proceedings can be summarised as follows:

The alpha-lactalbumin (hereinafter "ALA") and beta-lactoglobulin (hereinafter "BLG") content in claim 1 of the main request referred to the percentages of these two components in a whey fraction (i.e. more than one whey fraction may be present) but not necessarily to the ALA and BLG content of the total whey in the complete formula. The ALA and BLG contents in claim 2 of the main request referred to the percentages in the bovine whey material. From this, the contents in the final infant formula could be calculated, but the respondent's calculation resulted in ranges for these contents which were too narrow.

The invention as defined in the main request was insufficiently disclosed, since the skilled person was

not able to prepare whey fractions with an ALA and BLG content as defined in claims 1 and 2 (argument presented during the written proceedings only).

The subject-matter of claim 1 of the main request lacked novelty over E1, E2 and E9. All documents disclosed whey fractions with contents as claimed and their use in infant formulae. No double selection would be needed in the disclosures of these documents to arrive at the claimed subject-matter.

The subject-matter of claim 1 of the main request was not inventive. It differed from the closest prior-art document E5 in terms of the ALA content. Since no effect had been shown to be linked to this content, the objective technical problem was the provision of an alternative infant formula composition. The solution to this problem was already known from E1 and E21. Furthermore, the subject-matter of claim 1 lacked inventive step starting from any of E1, E2, E8 or E9 as the closest prior art (argument presented in the written proceedings only).

The subject-matter of claim 2 of the main request was not inventive either. It differed from the closest prior-art document E5 in terms of the ALA content. The objective technical problem was the provision of an alternative, and the solution as claimed was already suggested by E1 and E21.

The subject-matter of claim 2 of the main request was furthermore not inventive in view of E1 as the closest prior art. This document already disclosed the ALA and BLG contents as claimed and the addition of bovine milk was known from e.g. E24.

XIV. So far as relevant to the present decision, the respondent's arguments as presented during the written and oral proceedings can be summarised as follows:

The percentages for ALA and BLG in claim 1 of the main request referred to the contents in the total whey of the final (complete) infant formula composition. The percentages in claim 2 of the main request referred to those present in the bovine whey material. From these, the percentages for ALA and BLG in the (final) infant formula of claim 2 could be calculated to be 22% to 32% and 16% to 36%, respectively.

The invention defined in the claims of the main request was sufficiently disclosed. It was not impossible for the skilled person, using the patent, to obtain ALA and BLG contents as claimed. In fact the skilled person could obtain infant formula compositions with these contents on the basis of his common general knowledge as represented e.g. by E1.

The subject-matter of claim 1 of the main request was novel over E1, E2 and E9. These documents disclosed contents for ALA and BLG in whey fractions as such but were silent about their contents in the final infant formulae containing these fractions. These documents could thus not anticipate the ALA and BLG content of the infant formula composition as defined in claim 1.

The subject-matter of claim 1 of the main request was inventive. Unlike E1, E2, E8 and E9, E5 focused on improved infant formulae and thus constituted the closest prior art. This document differed from the subject-matter of claim 1 by an excessive ALA content. As demonstrated by examples 2 to 4 of the opposed patent and the appellant's calculation as regards the

amino acid contents of the infant formula of E5, a lower ALA content solved the problem of providing a further infant formula composition which was well tolerated by infants while not needing any amino acid supplementation. The claimed solution was not obvious in view of E1 or E21, since neither document disclosed infant formulae with ALA and BLG contents as claimed, let alone suggested these contents in order to obtain an infant formula that was well tolerated by infants without the need for amino acid supplementation.

For essentially the same reasons, the subject-matter of claim 2 of the main request was inventive as well.

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

The appellant furthermore requested that auxiliary requests 1 to 5 filed with letter dated 2 October 2014 and auxiliary request 6 filed with letter dated 2 September 2015 not be admitted into the proceedings.

XVI. Opponent 2 (party as of right) did not file any request.

XVII. The respondent requested that the appeal be dismissed or, alternatively, that the patent be maintained on the basis of the claims of any of auxiliary requests 1 to 5, filed with letter dated 2 October 2014, or those of auxiliary request 6, filed with letter dated 2 September 2015.

The respondent further requested that E22, E23 and E25 not be admitted into the proceedings and that E26 be admitted into the proceedings.

Reasons for the Decision

Main request (claims as granted)

1. Interpretation of independent claims 1 and 2
 - 1.1 Independent claim 1 is directed to "An infant formula composition comprising a whey fraction wherein 40% or less of the total protein in said whey fraction is alpha-lactalbumin and more than 8% of the total protein in said whey fraction is beta-lactoglobulin, with the proviso that the percentage of alpha-lactalbumin in said whey fraction is greater than the percentage of beta-lactoglobulin."

It was a matter of dispute between the parties how the percentages cited in claim 1 had to be interpreted.

- 1.1.1 The appellant argued that "a whey fraction" in claim 1 referred to one particular whey fraction in the infant formula composition. However, apart from this particular whey fraction, further whey fractions could be present, which, in turn, contained ALA and BLG. Hence, the contents of ALA and BLG in the total whey of the complete infant formula composition could be different from the content cited in claim 1 for the particular whey fraction.
- 1.1.2 The respondent argued that the term "a whey fraction" in claim 1 referred to the total whey present in the infant formula composition. The ALA and BLG percentages cited in claim 1 were thus those of the total whey, i.e. the ALA and BLG of the total whey in the complete infant formula composition.

1.1.3 The board concurs with the respondent's interpretation of claim 1. It is common general knowledge that a milk-based infant formula contains broadly speaking two groups of proteins, namely caseins and whey proteins. In other words, the proteins are grouped in a casein fraction and a whey fraction. Thus, normally the skilled reader would understand that "a whey fraction" in claim 1 denotes the total whey proteins present in the infant formula. This is in line with the teaching of the patent, in particular paragraph [0021] and table 1, from which it can be derived that it is the ALA and BLG contents in the infant formula composition (rather than one particular whey fraction thereof) that matter. This is also supported by the fact that, if one were to follow the appellant's rather than the respondent's interpretation, the contents of ALA and BLG of the total whey in the complete infant formula composition, i.e. the decisive feature, would be undefined. Therefore, the board's and the respondent's interpretation of claim 1 is the only technically meaningful one.

Actually, throughout the opposition proceedings, the appellant took exactly the position outlined above by the board (see page 5 of opponent 2's letter dated 4 April 2013, where opponent 2 had stated that opponent 1 (the present appellant) shared its interpretation of claim 1 that the percentages cited therein could only refer to the ALA and BLG contents of the total whey in the complete formula).

1.2 Independent claim 2 is directed to "An infant formula composition comprising an amount of bovine milk providing 1.0 to 1.2 grams of protein per 100 available kilocalories and an amount of a bovine whey material providing 1.0 to 1.2 grams of protein per 100 available

kilocalories, said bovine whey material having an alpha-lactalbumin content of 28% to 40% and a beta-lactoglobulin content of 8% to 33% of total protein." Thus the infant formula of claim 2 comprises two components, namely bovine milk and (additional) bovine whey material.

It was common ground between all parties, and it is clearly reflected by the language of claim 2, that the percentages cited in this claim refer to the content of ALA and BLG in the bovine whey material only. It was also common ground that the additional bovine milk provides further ALA and BLG as part of its whey fraction, so that their content had to be added to those present in the bovine whey material to obtain the ALA and BLG content of the complete infant formula composition of claim 2. The respondent explained in this respect that with standard bovine milk and an amount of bovine milk and bovine whey material providing 1.0 g/100kcal each, the ALA and BLG contents in the infant formula composition of claim 2 were 22% to 32% and 16% to 36%, respectively. While the validity of this calculation as such was not disputed by the appellant, it argued that the ranges for the ALA and BLG contents in the final infant formula composition of claim 2 were in fact broader than those calculated by the respondent, since the amounts of bovine milk and bovine whey material were not necessarily 1.0 g/kcal, but varied between 1.0 to 1.2 g/kcal. The board concurs with this view. This has however no implications for novelty (no novelty objections were raised against claim 2) or inventive step (see point 5.1. below).

2. Sufficiency of disclosure

2.1 The appellant argued that according to paragraph [0008] of the patent, methods to obtain whey fractions with ALA and BLG contents as defined in claims 1 and 2 were not available in the prior art and that the patent did not disclose how to prepare such whey fractions.

The board does not agree with this argument. What paragraph [0008] of the patent discloses is that

"Dairy technology has focused on whey protein fractionation processes to selectively remove substantially all the beta-lactoglobulin from whey or to isolate enriched alpha-lactalbumin fractions substantially free of beta-lactoglobulin, for use in foods, including infant formula.

US patent No 5,455,331 describes a process using undefatted ultrafiltered whey to produce a material with a high alpha-lactalbumin content, and on a total precipitable protein basis, less than 5% of beta-lactoglobulin. [...] U.S. Patent No. 5,420,249 discloses the use of defatted whey and calcium-binding resin to prepare whey for separation and a preferred alpha-lactalbumin fraction comprising at least 60% of the protein as alpha-lactalbumin and at most 10% of the protein as beta-lactoglobulin. They describe an alpha-lactalbumin-enriched fraction containing 13% of the protein as beta-lactoglobulin. However, this fraction contained 74% of the protein as alpha-lactalbumin, with a beta-lactoglobulin to alpha-lactalbumin ratio of 1:6. Other alpha-lactalbumin-enriched fractions had beta-lactoglobulin to alpha-lactalbumin ratios of 1:4 to 1:7".

So all that the skilled reader learns from this passage is that the prior-art dairy technology focused on compositions with high ALA content and substantially no BLG, i.e. compositions which were not necessarily as defined in claims 1 or 2. Contrary to the appellant's assertion, however, this does not imply that it was not possible to prepare compositions with ALA and BLG content as claimed. It could simply mean that the prior art did not consider these compositions to be interesting.

In fact, processes to prepare whey fractions with ALA and BLG contents as defined in claims 1 and 2 were part of the skilled person's common general knowledge before the priority date of the patent. For instance, E1 describes the results obtained in an EU-funded project in 1997, in which processes were developed by eight laboratories and institutes in France, Spain and the Netherlands for ALA and BLG enrichment by way of ultra- and microfiltration. It is concluded in E1 that "It is obvious that the manufacture of highly enriched β -lg and α -lac fractions is feasible from a technological point of view". Examples of these enriched BLG and enriched ALA fractions are disclosed in figures 1 and 2 of E1. Having these fractions at hand, it would have been trivial for the skilled person to mix them in such proportions as to obtain infant formulae with ALA and BLG contents as claimed.

Therefore, the skilled person was able to carry out the claimed invention in view of the information in the patent together with his common general knowledge at the priority date of the patent. The invention as defined in the claims as granted is thus sufficiently disclosed.

3. Novelty

3.1 The appellant contested novelty of the subject-matter of claim 1 on the basis of E1, E2 and, during the written appeal proceedings, E9. No novelty objections were raised against claim 2.

3.2 As set out above when discussing sufficiency of disclosure, E1 discloses processes for ALA and BLG enrichment by way of ultra- and microfiltration. The document in particular discloses the fractionation of a liquid acid casein whey protein concentrate ACW-WPC75 (figure 1) and of a Gouda cheese whey GCW (figure 2). These fractionations result in eight different product streams (figures 1 and 2) of which one is whey protein isolate WPI99 with 26% ALA and 32% BLG (figure 2), which percentages are within the ranges as defined in claim 1. E1 ("Opportunities for product-developers and process engineers" on page 49) furthermore discloses that the whey fractions described therein can be used in food texturising, infant formulations and pharmaceuticals.

However, the whey protein isolate WPI99 of E1 is not necessarily the only whey fraction present in an infant formula as referred to in this document. The infant formula could contain further components, such as bovine milk, the whey of which contains further ALA and BLG. Therefore, depending on the nature and amount of further components, the ALA and BLG content disclosed for WPI99 is not that present in the rather generically disclosed infant formula of E1 as a whole. Since E1 is silent about the nature and amount of any further components, the content of ALA and BLG in the infant formulation of E1 cannot be derived from this document.

The infant formula composition of claim 1, which, as has been set out above, is defined by a specific content of ALA and BLG, is thus novel over E1.

- 3.3 It was common ground between the parties that E2, which was published after the priority but before the filing date of the opposed patent, is prior art under Article 54(2) EPC for claim 1, since this claim does not enjoy the claimed priority.

E2 (example 7c) refers to the preparation of a whey protein concentrate WPC, which is enriched in sialic acid and ALA, and which contains 34% ALA and 18% BLG (table 9, entry "Final"). These percentages are within the ranges defined in claim 1.

Referring to this whey protein concentrate WPC, E2 discloses that:

"It was then ultrafiltered to produce a WPC enriched in sialic acid and α -lactalbumin, as shown in Table 9, both useful ingredients for an infant formula".

However, in the same way as for E1, the whey protein concentrate is not necessarily the only component present in the infant formula of E2 which contributes to its ALA and BLG content. Again in the same way as for E1, E2 is silent about the amounts and nature of any further components, so that the content of ALA and BLG in the infant formula cannot be derived from E2. Therefore, the infant formula composition of claim 1 is also novel over E2.

- 3.4 With regard to E9, the appellant referred in particular to example 4. This example discloses whey protein

concentrates WPC-35, WPC-60, WPC-70 and WPC-80. E9 does not disclose that these whey protein concentrates are part of an infant formula, let alone give the composition of the entire infant formula.

In this respect, the board is not convinced by the appellant's argument that column 1, lines 14 to 19 of E9 discloses the use of ALA and BLG in humanised milk and thus in an infant formula. This passage belongs to the introductory section of E9 and merely states that ALA is largely used in the preparation of humanised milk. This does not however directly and unambiguously disclose that the whey protein concentrates of E9, let alone the specific ones of example 4, are part of an infant formula. Furthermore, since the composition of the infant formula in its entirety is not disclosed in E9, in the same way as for E1 and E2, its ALA and BLG contents cannot be derived. Therefore, the subject-matter of claim 1 is also novel over E9.

3.5 Claim 10 refers to a method of feeding an infant with the infant formula of claim 1. Claim 11 is dependent on claim 1. Consequently, novelty of the subject-matter of claim 1 implies novelty of the subject-matter of claims 10 and 11.

4. Inventive step of the subject-matter of claims 1, 10 and 11

4.1 The opposed patent is directed to infant formula compositions comprising a modified whey protein concentrate comprising specific amounts of ALA and BLG (paragraph [0001]). It aims at infant formula compositions that do not require the addition of essential amino acids and that in terms of their

protein concentration and ALA and BLG content are closer to human milk (paragraph [0019]).

4.2 In the same way as the opposed patent, E5 relates to whey protein concentrates for infant formulae with low BLG content that are closer to the composition of human milk (page 1, lines 15 to 20). Therefore, in line with the arguments of all parties, E5 can be considered to represent the closest prior art.

4.3 E5 discloses the preparation of an infant formula which contains a total whey content of 65%, an ALA content of 36.4% and a BLG content of 5.7%, based on the total formula (page 7, lines 8 to 15 in conjunction with table 3). Recalculated to amounts based on the total whey content, these are 56% for ALA and 8.8% for BLG.

As acknowledged by the appellant, the composition of E5 differs from that of claim 1 in that the content of ALA is too high, namely 56%, compared to 40% or less as required by claim 1.

4.4 The respondent argued that this difference solved the problem of providing a further infant formula composition which was well tolerated by infants but which did not need any supplementation in the form of additional amino acids. This is also the problem referred to in the opposed patent (paragraphs [0011] and [0019]).

4.5 It needs to be examined whether this problem has been credibly solved.

4.5.1 In example 2 of the patent, four batches of an "improved infant formula", also denoted "Standard Infant Formula of the Invention" (table 3), were

prepared. These four batches contained 26% to 29% ALA and 15% to 25% BLG (calculated from the values given in table 3) and thus were all in accordance with claim 1.

In example 3, the amino acid contents of the four batches of the improved infant formula were determined and the average of these contents is reported for each amino acid in table 8. As follows from this table, the average values of the amino acid contents of the improved infant formula are close to the values stipulated for human milk by EU directive 91/321/EEC (annex V of E11). Hence, no supplementation of amino acids is needed for the improved infant formula.

This is different from the infant formula disclosed in E5, which, as calculated by the appellant (page 9 of the appellant's letter dated 2 June 2014), has an arginine content of only 65.9 mg/100kcal, compared to a minimum value of 69 mg/100kcal required by the EU directive. In fact it is plausible that the arginine content of the infant formula in E5 is too low, since it has a very high content of ALA. ALA contains very little arginine (see table 1 of E5), so the higher the ALA content the lower the amount of arginine. Consequently, unlike the infant formula composition defined in claim 1, the infant formula of E5 needs arginine supplementation.

The appellant argued in this respect that the respondent had stated during the opposition proceedings that the amount of arginine of 66 mg/100kcal compared to 69 mg/kcal in the EU directive was no problem since the two values were very close. Therefore, no amino acid supplementation was needed for the infant formula of E5. However, all that the respondent stated in this letter was that a value of 66 mg/100 kcal was very

close to 69 mg/100 kcal (see the discussion of sufficiency of disclosure in the last sentence of point 6.2.10 on page 7 of the respondent's letter of 21 December 2010). While the board acknowledges that this is true, it fails to see how one can deduce from this that no amino acid supplementation, even though it may be small, is needed for the infant formula of E5.

- 4.5.2 In example 4 of the opposed patent, the improved infant formula and a control formula which, as acknowledged by the appellant during the oral proceedings, contained a low ALA and a high BLG content, were fed to two groups of healthy term infants. It was found that feeding the improved infant formula instead of the control formula decreased the number of infants with formula-related vomiting from 14 to 12 and of infants with formula-related diarrhea from 8 to 4.

Thus, example 4 of the patent shows that compared to the control formula, the infant formula composition as defined in claim 1 leads to improved tolerance by infants without any need for amino acid supplementation.

- 4.5.3 In view of the above, the onus would have been on the appellant or opponent 2 to prove that the above problem was not solved. In the absence of any such proof, the board considers it credible that this problem, i.e. the provision of a further infant formula composition which is well tolerated by infants but which does not need any supplementation by additional amino acids, has been solved. This problem thus constitutes the objective technical problem.

- 4.6 It remains to be examined whether the solution as defined in claim 1 is obvious.

4.6.1 According to the appellant, the solution as defined in claim 1 was obvious in view of E21. This document taught the skilled person to increase the content of ALA (last sentence of the abstract on page 533). It disclosed two formulae with ALA percentages of 20% and 42% (last paragraph on page 538) and it stated that these two formulae provided essential amino acids in amounts equal to or superior to average breast milk (last sentence on page 539).

The board does not find this argument convincing. The infant formula of E21 does not solve the problem of avoiding any amino acid supplementation. On the contrary, it directly follows from table 6 of this document that the arginine amounts in the two formulae of E21 are significantly lower, namely 209 and 190, compared to 255 in breast milk (all values expressed as mg/gram of protein nitrogen). In fact, both formulae in table 6 of E21 have been supplemented with arginine to increase its amount to 287 and 288, respectively (see the entries "with added Arg" in the table). Consequently, the skilled person looking for a further infant formula composition that avoids the need for amino acid supplementation would not have been inclined to use the one disclosed in E21. Furthermore, even if he had done so, he would not necessarily have arrived at the subject-matter of claim 1. More specifically, E21 is silent about the content of BLG, so this is not necessarily within the range of claim 1.

4.6.2 The appellant furthermore argued that the content of ALA and BLG as defined in claim 1 was already known in view of whey fraction WPI99 in E1. First of all however, this is not correct, as set out above when discussing novelty over E1. Secondly, E1 does not

provide any motivation to the skilled person to replace the infant formula of E5 with that of E1 in order to solve the objective technical problem, i.e. to obtain a further infant formula composition which is well tolerated by infants but which does not need any supplementation by additional amino acids.

4.6.3 Therefore, the subject-matter of claim 1, and by the same token of claims 10 and 11, is inventive over E5 as the closest prior art.

4.7 During the written proceedings, the appellant had also presented inventive-step attacks starting from E1, E2, E8 and E9 as the closest prior art (points C.1, C.2, C.3 and C.5 of the appellant's letter dated 2 June 2014).

E1 focuses on the development of processes for the preparation of ALA- and BLG-enriched whey fractions (second paragraph on page 47) and mentions infant formulae only in passing as one of several possible uses (second full paragraph on page 49).

E2 is directed to processes for recovering acidic peptide fractions such as CMP and BLG from whey protein containing feedstocks using anion exchangers (page 1, lines 8 to 10). It mentions the use in infant formulae among several other different uses (page 15, lines 8 to 14).

E8 is directed to the treatment of whey with a view to extracting valuable products, in particular to obtain an ALA-enriched product (column 1, lines 8 to 9 and column 2, lines 5 to 7). Apart from the use as a replacement for human milk (example 3), many other uses

are disclosed (see e.g. example 4 and column 9, lines 8 to 19).

E9 is directed to a process for the recovery of ALA- and/or BLG-enriched whey protein concentrates from whey protein products (column 1, lines 1 to 4). As set out above when discussing novelty over E9, it mentions the use in humanised milk only in relation to the prior art.

Consequently, unlike in E5, the focus in E1, E2, E8 and E9 is not on improved infant formula. Therefore, the skilled person would not have started from any of these documents as the closest prior art. Furthermore, these documents are silent about the content of ALA and BLG in the infant formulae they disclose. Consequently, even if the skilled person had started from any of these documents, he would not have arrived at the content as defined in claim 1. Lastly, none of these documents suggests that by selecting amounts as defined in claim 1, infant formulae could be obtained which solve the objective technical problem, i.e. which are well tolerated by infants without the need for any amino acid supplementation.

Therefore, the subject-matter of claims 1, 10 and 11 is also inventive in view of any of E1, E2, E8 and E9.

5. Inventive step of the subject-matter of claims 2 to 9
- 5.1 As set out above when discussing the interpretation of claims 1 and 2, claim 2 is directed to an infant formula composition which comprises bovine milk and bovine whey material and contains roughly 22% to 32% of ALA and 16% to 36% BLG, based on the total protein amount. As agreed by all parties, and for the reason

given above with regard to claim 1, E5 constitutes the closest prior art.

As acknowledged by the appellant, the infant formula of claim 2 differs from that disclosed in E5 by a lower ALA content. This is true even if one takes into account that the actual range of the ALA content in claim 2 is to some extent broader than that calculated by the respondent (point 1.2 above). More specifically, the appellant mentioned a variation of 20% between the actual and calculated values. This means that the upper limit for the ALA content might actually be 38.4% instead of the calculated value of 32%. This is still way below the ALA content in E5 (56%, see point 4.3 above).

Hence, the distinguishing feature is the same as that present with regard to claim 1. Therefore the objective technical problem remains the same, namely the provision of a further infant formula composition which is well tolerated by infants but does not need any amino acid supplementation. In this respect, the board is not convinced by the appellant's argument that since the content of BLG in claim 2 could exceed that of ALA, this problem was not solved over the entire scope of claim 2. More specifically, the ALA and BLG content of the improved infant formula in the examples of the opposed patent (26% to 29% ALA and 15% to 25% BLG) is still within the ranges defined by claim 2. Therefore, in view of these examples, and in the absence of any proof to the contrary, it is still credible that the problem of providing a further infant formula composition which is well tolerated by infants but does not need any amino acid supplementation has been solved.

Since the objective technical problem does not change, the board's considerations on obviousness set out above with regard to claim 1 likewise stay the same, i.e. the subject-matter of claim 2, and by the same token of claims 3 to 9, is not obvious starting from E5 as the closest prior art.

- 5.2 The appellant argued that E1 could also be considered to represent the closest prior art. However, as set out above with regard to claim 1, the board does not concur. Furthermore, in the same way as for claim 1, E1 does not disclose an infant formula composition with a content of ALA or BLG as defined in claim 2, let alone that by choosing this content, infant formula compositions could be obtained which are well tolerated by infants without the need for any supplementation by additional amino acids.

In this respect the appellant's argument that it would have been known on the basis of E24 to add bovine milk to the whey protein concentrate WPI99 of E1 is not convincing, since the content of ALA and BLG of the resulting infant formula would still not necessarily have been as required by claim 2.

Therefore, the subject-matter of claim 2, and by the same token of claims 3 to 9, is also inventive in view of E1 as the closest prior art.

6. Further issues

- 6.1 Since documents E22, E23 and E25 are not relevant to the present decision, the board does not need to decide on the respondent's request that they not be admitted into the proceedings, Furthermore, since E26 is not relevant to the present decision either, the board does

not need to decide on the respondent's request that this document be admitted into the proceedings.

6.2 Since the present decision is based on the main request, there is no need to decide on the appellant's request that auxiliary requests 1 to 6 not be admitted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Cañueto Carbajo

W. Sieber

Decision electronically authenticated