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Datasheet for the decision of 19 October 2010

Case Number: T 0470/08 - 3.3.09

Application Number: 00991317.9

Publication Number: 1237419

IPC: A23D 9/00

Language of the proceedings: EN

Title of invention:
Infant formula with improved protein content

Patentee:
N.V. Nutricia

Opponent:
NESTEC S.A.
Friesland Brands B.V.

Headword:
-

Relevant legal provisions:
EPC Art. 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"Inventive step: Main request and auxiliary requests 1-6 - no, Auxiliary request 7 - yes"

Decisions cited:
T 0197/86

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0470/08 **-** 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 19 October 2010

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office announced orally on 18 December 2007 and posted 10 January 2008 concerning maintenance of the European patent No. 1237419 in amended form.**

Composition of the Board:

Chairman: W. Sieber
Members: J. Jardón Álvarez
K. Garnett

Summary of Facts and Submissions

I. European patent No. 1 237 419 was granted in respect of European patent application No. 00991317.9, which was filed in the name of N.V. Nutricia on 13 December 2000 as International application PCT/NL2000/000913 (WO 2001/041581). The mention of grant was published on 9 March 2005 in Bulletin 2005/10. The patent was granted with 21 claims, Claims 1 and 15 reading as follows:

"1. Infant formula, comprising

a) a protein component having a phosphorus content of less than 0.75 g P/100 g protein; and

b) a lipid component that can be easily digested by an infant, comprising fatty acid triglycerides, in which palmitic acid residues make up more than 10% (w/w) of all fatty acid residues present in the triglycerides, at least 30 % of the palmitic acid residues in the triglycerides being in the Sn2 position of the triglycerides."

"15. A process for preparing a protein hydrolysate, comprising hydrolysing a protein starting material having a phosphorus content of les than 0.75 g P/100 g protein with a combination of at least one endo- and at least one exoproteinase, the starting material further containing a suspension of yeast cells in an amount of 1 to 8 g dry mass of yeast cells per 100 g protein."

Claims 19-21 were independent claims directed to a protein hydrolysate obtainable by the process of Claim 15, an infant formula comprising the protein

hydrolysate and the use thereof in the preparation of an infant formula, respectively.

Claims 2 to 14 and 16 to 18 were dependent claims.

II. Notices of opposition were filed by:

NESTEC S.A. (opponent 01) on 8 December 2005, and

Friesland Brands B.V. (opponent 02) on 9 December 2005.

Both opponents requested the revocation of the patent in its entirety on the grounds that the claimed subject-matter lacked novelty and did not involve an inventive step (Article 100(a) EPC). Opponent 02 further invoked the grounds pursuant to Article 100(b) and (c) EPC.

During the opposition proceedings *inter alia* the following documents were cited:

D4: V.P. Carnielli *et al.*, "Structural Position and Amount of Palmitic Acid in Infant Formulas: Effects on Fat, Fatty Acid, and Mineral Balance", Journal of Pediatric Gastroenterology & Nutrition, 23, 1996, pages 553-560;

D5: EP 0 671 126 A1;

D11: Frisopep. De volgende generatie peptidevoeding. Product sheet concerning the products Frisopep® 1 and Frisopep® 2, handwritten dated 26.11.92;

D15: G.R. Gibson *et al.*, "Dietary Modulation of the Human Colonic Microbiota: Introducing the Concept of Prebiotics", J. Nutr. 125, 1995, pages 1401 to 1412;

D36a H. Schmelzle *et al.*,"Randomized Double-Blind Study of the Nutritional Efficacy and Bifidogenicity of a New Infant formula Containing Partially Hydrolyzed Protein, a High ß-Palmitic Acid Level, and Nondigestible Oligosaccharides", Journal of Pediatric Gastroenterology and Nutrition, 36, 2003, pages 343-351; and

D36b: M.E. Bongers *et al.*, "The clinical effect of a new infant formula in term infants with constipation: a double-blind, randomized cross-over trial", Nutrition Journal, 6:8, 2007, pages 1-7.

III. Taking into account the amendments made by the proprietor during the opposition proceedings, the opposition division found that the patent and the invention to which it related met the requirements of the EPC. The interlocutory decision was announced orally on 18 December 2007 and issued in writing on 10 January 2008.

The opposition division found that the patent in suit was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, that the subject-matter of the claims did not extend beyond the content of the application as filed and that the claimed subject-matter was novel, and in particular that, based on the documents on file,

there was no prior use in view of the product "Frisopep"®.

The opposition division rejected the main request and auxiliary requests 1 to 5 because the subject-matter of Claim 1 of these requests lacked inventive step having regard to the combined teaching of documents D4 and D5.

Finally, the opposition division held that the subject-matter of Claims 1 to 19 of auxiliary request 6, filed on 18 December 2007 during the oral proceedings, met the requirements of the EPC. Claim 1 of the sixth auxiliary request read as follows:

"1. Infant formula, comprising

a) a protein component having a phosphorus content of less than 0.75 g P/100 g protein in which the protein component a) comprises a hydrolysate obtained by hydrolysing a protein with a combination of at least one endo- and at least one exoproteinase, and characterised by a content of free amino acids, derived from the protein hydrolysate a), of less than 7 g per 100 g protein equivalent; and

b) a lipid component that can be easily digested by an infant, comprising fatty acid triglycerides, in which palmitic acid residues make up more than 10% (w/w) of all fatty acid residues present in the triglycerides, at least 30 % of the palmitic acid residues in the triglycerides being in the Sn2 position of the triglycerides."

IV. On 6 March 2008 opponent 01 (appellant 01) filed an appeal against the interlocutory decision of the

opposition division and paid the prescribed fee on the same day. With the statement setting out the grounds of appeal filed on 9 May 2008, appellant 01 requested that Claims 1 to 12 of the request maintained by the opposition division be revoked for lack of inventive step. It also filed three new documents in support of its arguments.

V. Also on 6 March 2008 opponent 02 (appellant 02) lodged an appeal and paid the prescribed fee on the same day. With the statement setting out the grounds of appeal filed on 20 May 2008, appellant 02 requested to set aside the decision under appeal, because the subject-matter of Claim 1 of the sixth auxiliary request lacked inventive step. Appellant 02 submitted further evidence (7 documents labelled Annexes 1 to 7) relating to the alleged public prior use (Frisopep®). In addition, the following document was filed:

D42: EP - 0 946 106 B1;

VI. On 7 March 2008 the patent proprietor (appellant 03) filed an appeal and paid the prescribed fee on the same day. A statement setting out the grounds of appeal was filed on 19 May 2008 requesting that the decision of the opposition division be set aside and the patent be maintained as granted or according to any of the auxiliary requests 1 to 6 before the opposition division.

VII. Replies to the respective statement of grounds of appeal were filed on 6 October 2008 (appellant 01), on 5 December 2008 (appellant 02) and on 16 February 2009 (appellant 03).

With its reply appellant 01 also filed two further documents. Appellant 03 submitted with its reply an amended auxiliary request 5 and a seventh auxiliary request.

VIII. On 12 May 2010 the board dispatched a summons to attend oral proceedings on 19 October 2010. In a communication dated 1 July 2010 the board drew the attention of the parties to the points to be discussed during the oral proceedings.

IX. With letter dated 17 September 2010 appellant 03 filed a set of claims for an eighth auxiliary request.

X. With letter dated 17 September 2010 appellant 02 filed a copy of the application document corresponding to the patent document D42:

D42a:WO 98/27827 A1.

XI. On 19 October 2010 oral proceedings were held before the board. In the course of the oral proceedings, appellant 03 withdrew the third and fourth auxiliary requests and filed a set of claims for an amended auxiliary request 7.

Claim 1 of the main request is Claim 1 as granted (see above point I).

Claim 1 of auxiliary request 1 is based on Claim 1 of the main request including the further feature:

"c) one or more trans-galacto-oligosaccharides, one or more fructo-oligosaccharides, or mixtures thereof."

Claim 1 of auxiliary request 2 is based on Claim 1 of the main request including the further feature:

"c) one or more trans-galacto-oligosaccharides and one or more fructo-oligosaccharides."

Claim 1 of auxiliary request 5 reads as follows:

"Infant formula, comprising

a) a protein component having a phosphorus content of less than 0.75 g P/100 g protein, in which the protein component a) comprises a hydrolysate obtained by hydrolysing milk protein with a combination of at least one endo- and at least one exoproteinase, characterised by a content of free amino acids, derived from the protein hydrolysate a), of less than 10 g per 100 g protein equivalent; and

b) a lipid component that can be easily digested by an infant, comprising fatty acid triglycerides, in which palmitic acid residues make up more than 10% (w/w) of all fatty acid residues present in the triglycerides, at least 30 % of the palmitic acid residues in the triglycerides being in the Sn2 position of the triglycerides."

Claim 1 of auxiliary request 6 is Claim 1 as maintained by the opposition division (see point III above).

Claim 1 of auxiliary request 7 reads as follows:

"Infant formula, comprising

a) a protein component having a phosphorus content of less than 0.75 g P/100 g protein, in which the protein component a) comprises a hydrolysate obtained by hydrolysing milk protein with a combination of at least one endo- and at least one exoproteinase, characterised by a content of free amino acids, derived from the protein hydrolysate a) of less than 10 g per 100 g protein equivalent; and

b) a lipid component that can be easily digested by an infant, comprising fatty acid triglycerides, in which palmitic acid residues make up more than 10% (w/w) of all fatty acid residues present in the triglycerides, at least 30 % of the palmitic acid residues in the triglycerides being in the Sn2 position of the triglycerides; and

c) one or more trans-galacto-oligosaccharides, one or more fructo-oligosaccharides, or mixtures thereof."

XII. The arguments presented by appellants 01 and 02 in its written submissions and at the oral proceedings may be summarized as follows:

– Appellants 01 and 02 maintained that the claim language did not exclude the presence of additional protein and/or lipid components not fulfilling the criteria set forth in Claim 1, thus embracing embodiments not solving the technical problem and consequently lacking inventive step.

– They argued further that starting from the disclosure of D4 as closest prior art document, the

claimed subject-matter lacked inventive step. The skilled person aimed at providing an infant formula would have chosen a low phosphorus protein which was generally available in the art, as evidenced by D5. Also the preference for a protein hydrolysate was already well established in view of the reduced antigenicity of hydrolyzed proteins as evidenced by the newly cited document D42a.

– Appellant 02 further maintained that the subject-matter of Claim 1 of the main request lacked novelty having regard to the product Frisopep® (D11).

XIII. The arguments of appellant 03 may be summarised as follows:

– Appellant 03 maintained that the word "comprising" on Claim 1 indicated that further components might be present into the infant formula, but that these components could not be further proteins or further lipids. The assumption that it would be the case would result in the definitions given for these components under (a) and (b) being meaningless.

– Appellant 03 argued that the further evidence provided by appellant 02 concerning the product Frisopep® was not conclusive as to the publication date of D11 or its precise content.

– Concerning inventive step, appellant 03, starting from the disclosure of D4 as representing the closest prior art document, saw the problem to be solved by the patent in suit as being to provide for improved bioavailability of calcium ions in bottle-

fed infants, while ensuring good stool consistency by avoiding calcium soaps. The solution to this problem as claimed in Claim 1 of the main request was not obvious in view of the cited prior art. Taking account that D4 was silent about any effect of the nature of the protein, the skilled person would not modify the protein in order to solve the problem of the patent. D5 gave also no hint to this solution as it was not related to the stool problems.

– As to the question whether the problem was credibly solved by the measures taken, appellant 03 maintained that the newly filed documents D36a and D36b showed the improvement of the claimed formulas. Although it admitted that the formulas of D36a and D36b differed from those of D4 by further features, al least part of the improvement was due to the protein component.

– The same reasoning applied for the subject-matter of the claims of the auxiliary requests which were limited to formulas closer to the formula used in the examples of D36a/D36b.

XIV. Appellants 01 and 02 (opponents) requested that the decision under appeal be set aside and that the European patent No. 1 237 419 be revoked.

Appellant 03 (proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted, alternatively on the basis of the first or second auxiliary requests filed with the letter of 12 December 2007, alternatively the fifth auxiliary request filed with the letter dated

16 February 2009, alternatively the sixth auxiliary request filed during the oral proceedings on 8 December 2007, alternatively the new seventh auxiliary request filed during the oral proceedings on 19 October 2010, alternatively the eighth auxiliary request filed with the letter dated 17 September 2010.

Reasons for the Decision

1. The appeals are admissible.

2. *Extent of the appeal*

2.1 The claim sets of the main request and the first to seventh auxiliary requests include claims directed to an infant formula (eg Claims 1 to 14 in the main request) and claims directed to a process for preparing a protein hydrolysate, the protein hydrolysate obtainable by that process, an infant formula comprising the protein hydrolysate and the use thereof in the preparation of an infant formula (eg Claims 15 to 21 in the main request).

2.2 The opposition division in its decision acknowledged novelty and inventive step for the subject-matter of the second group of claims (points 7 and 13 to 15 of the opposition division's decision).

2.3 In the written procedure appellants 01 and 02 raised no objections to the subject-matter of Claims 15 to 21 of the main request and the corresponding claims in the auxiliary requests. At the oral proceedings they

confirmed that they did not appeal the opposition's division decision to this extent.

2.4 Thus, the patentability of these claims (eg Claims 12 to 18 of the seventh auxiliary request) is not at issue in these appeal proceedings.

MAIN REQUEST

3. *Interpretation of the claims*

3.1 Claim 1 is directed to an infant formula, **comprising**

a) a protein component having a phosphorus content of less than 0.75 g phosphorus/100 g protein;
and
b) a lipid component that can be easily digested by an infant, comprising fatty acid triglycerides, in which palmitic acid residues make up more than 10% w/w) of all fatty acid residues present in the triglycerides, at least 30% of the palmitic acid residues in the triglycerides being in the Sn2 position of the triglycerides.

3.2 Appellants 01 and 02 maintained that the claim, due to the use of the word "comprising", did not require that the complete protein fraction and/or the complete lipid fraction of the infant formula had to comply with the definitions given in Claim 1. Thus, the claim would encompass infant formulas where, for example, the protein component was a mixture of different protein fractions but only one protein fraction thereof satisfied the definition of the claim.

3.3 In the board's view a claim has to be interpreted in the proper context. This is in line with EPO jurisprudence that a skilled reader, in order to arrive at an interpretation which is technically sensible and takes account of the whole disclosure of the patent, should rule out interpretations of a claim which are illogical or which do not make technical sense (Case Law of the boards of appeal 6th edition 2010, Chapter II.B. 5.1).

3.4 It is true that the word "comprising" does not limit the infant formula to components (a) and (b) and allows the presence of further components in the infant formula, eg further components usually present in infant formulas such as carbohydrates, vitamins, minerals, further nutrients, etc. This does not mean by implication that the protein component (a) itself is defined in an "open" manner. As submitted by appellant 03, a person skilled in the art would understand that the term "protein component" refers to the complete protein fraction in the infant formula, because he would know that an infant formula may comprise more than one protein. All the proteins present in the infant formula form the protein component. The use of the indefinite article **"a"** in relation to the protein component (a) does not mean that the formula comprises **one** protein component having the phosphorus content required by the claim, but that it may comprise other protein fractions not satisfying this requirement. It is in fact the complete protein fraction that has to meet this requirement.

3.5 This interpretation is also supported by the patent specification. It is, for example, stated in

paragraph [0024] that "The protein component may comprise whole proteins and/or a protein hydrolysate, or a mixture thereof, and is most preferably low in phosphorus, …". This clearly supports the position of appellant 03 that the protein component relates to the complete protein fraction.

Furthermore, it is clear from the patent specification that, *inter alia*, the use of a low amount of phosphorus in the infant formula and the use of specific triglycerides (see [0019] and [0016]) are essential features of the infant formula in order to solve the problems of the prior art formulas.

3.6 The interpretation of appellants 01 and 02 that the claim wording would allow the presence of further proteins having a higher phosphorus content would result in infant formulas against the teaching of the patent specification which limits the amount of phosphorus in the protein component and requires a certain amount of palmitic acid in the Sn2 position. In fact, such an interpretation would render Claim 1 meaningless.

3.7 The objection of appellants 01 and 02 was based in part on the fact that some passages in the patent specification were said to be ambiguous (paragraphs [0023], [0052], [0119], etc) and cast doubts on the above reached interpretation of Claim 1. While it is true that the redaction of some paragraphs of the specification is not ideal, none of them conclusively supports the interpretation of appellants 01 and 02. Thus, for instance, paragraph [0119] mentions polyunsaturated long chain fatty acids

as further components of the infant formula, but in the examples these poly-unsaturated are ascribed to the fat (lipid) part of the composition, thus implying that all the components of the fat must fulfil the requirement of feature (b) of the claim.

3.8 In summary, Claim 1 is to be interpreted as directed to an infant formula wherein the protein component (as a whole) must have a phosphorus content of less than 0.75 g per 100 g of protein and the lipid component (as a whole) has the specified amount of palmitic acid. The infant formula may comprise other components not specified in the claim but these components cannot be further proteins or further lipids.

4. *Novelty*

4.1 The novelty of the subject-matter of Claim 1 was contested by appellant 02 having regard to the public prior use alleged to have occurred with the sale of Frisopep® (D11). The availability of document D11 to the public was not accepted by the opposition division and remained in issue during the appeal proceedings.

4.2 There is, however, no need for the board to investigate whether D11 was made available to the public and whether its disclosure is novelty destroying for the subject-matter of Claim 1 since, as set out below, the main request is not allowable for lack of inventive step.

5. *Inventive step*

The patent in suit relates to infant formulas containing a specified easily digestible lipid component and a specified protein component. The infant formula aims to prevent, alleviate and/or reduce undesired processes in the gastrointestinal tract, namely undesirable constitution of faeces, high local gas production, decreased bioavailability of divalent cations, etc. (see paragraphs [0005] - [0008]).

5.1 Closest prior art

5.1.1 Document D4 was agreed as the closest prior art document. D4 is a clinical study where the effect of structural position and amount of palmitic acid in infant formulas on the intestinal fat absorption in healthy term infants was studied. It concludes that formulas containing palmitic acid predominantly at the ß-position (the Sn2 position in the terminology of the patent) have significant beneficial effects on the intestinal absorption of fat and calcium (see abstract, last sentence; the last paragraph of "Discussion").

5.1.2 The infant formula "beta" of D4, having 24% palmitic acid, 66% esterified to ß-position, and the formula "intermediate", having 24% palmitic acid, 39% esterified to ß-position (see D4, section "Study Feedings"), fulfil the requirements of the lipid component of Claim 1 of the main request.

There is, however, no information in D4 (see Table 1) as regards the nature of the protein component used.

5.1.3 The subject-matter of Claim 1 thus differs from the disclosure of D4 in that it specifies that the content of phosphorus in the protein component is less than 0.75 g per 100 g of protein.

5.2 Problem to be solved and its solution

5.2.1 According to appellant 03 this difference results in an improvement in the stool constitution due to better calcium absorption rates. Therefore, the problem to be solved had to be seen in the provision of infant formulas with improved calcium bioavailability, ensuring good (soft) stool constitution by reducing the formation of calcium fatty acid soaps and of insoluble calcium phosphates.

5.2.2 The question whether or not this problem has been credibly solved was hotly disputed during the proceedings and constitutes the key issue in the present decision.

In order to show that the infant formula as defined in Claim 1 of the main request actually solves this problem, appellant 03 relied on the comparative study according to Example 5 in the patent and on the evidence as described in documents D36a and D36b, both documents having been filed during the opposition proceedings.

5.2.3 According to the established jurisprudence of the boards of appeal, when comparative tests are chosen to demonstrate an inventive step on the basis of an improved effect, the nature of the comparison with the closest state of the art must be such that the alleged

advantage or effect is convincingly shown to have its origin in the distinguishing feature of the invention compared with the closest prior art (see T 197/86 OJ EPO 1989, 371, Headnote and point 6.1.3 of the reasons).

5.2.4 Thus in the present case it is necessary to investigate whether the evidence provided by appellant 03 shows that the improvement of the infant formula is due to the distinguishing feature, namely to the phosphorus content of the protein component.

5.2.5 In the comparative study of Example 5 in the patent, a formula according to Claim 1 is said to be compared with "a standard commercial product not containing beta palmitate and no adapted calcium to phosphorus ratio". Although the exact composition of the formulas used for the comparison is not given, it is evident that the commercial product used was not a product resembling the closest prior art products described in D4 because it does not contain beta palmitate. Consequently, this example in principle cannot provide evidence that the improvement stems from the specific phosphorus content of the protein component, ie the only distinguishing feature over the closest prior art D4.

5.2.6 The same considerations apply to document D36b. The infant formulas compared in this study differ *inter alia* in the amount of palmitic acid esterified at the Sn2 position, the standard formula having only 11.5% palmitic acid at the Sn2 position (see Table I) and therefore not being according to the closest prior art D4.

5.2.7 Finally, the infant formulas compared in D36a show similar content of palmitic acid (see Table 1A) as the closest prior art and could, in principle, be regarded as an appropriate comparison against the closest prior art.

However, the infant formulas of D36a differ not only in the protein component used, they also differ in other components (cf. Table 1A, in particular the prebiotic oligosaccharides). It is further noted that according to D36a the achievement of the softer stools is said to be due to the high proportion of ß-palmitic acid, the presence of nondigestible oligosaccharides and the use of hydrolyzed protein (see page 343, "Abstract" and pages 347-350 under "Discussion", in particular page 350, paragraph bridging both columns).

D36a shows therefore that an improvement is achieved using infant formulas according to the patent, but it also shows that this improvement is not only due to the use of a protein component with a low phosphorus content, but to the combination of several features in the infant formulas, namely:

- the use of partially hydrolyzed protein having a low phosphorus content,
- a lipid with high ß-palmitic acid content, and
- nondigestible oligosaccharides.

5.2.8 The board thus concludes that an improvement of the calcium bioavailability relating to the distinguishing feature of the invention as claimed in Claim 1 of the main request is not derivable from the evidence presented by appellant 03.

5.2.9 The board can also not accept the argument of appellant 03 that the effect of the formula "must be partly due to the combination of the lipid component and protein component". There is no information on file supporting this affirmation. The evidence on file shows that the effect is due to the combination of features indicated above and does not permit the conclusion that "part" of the effect is due to the protein component.

5.3 Reformulation of the problem and its solution

5.3.1 In view of the above, an improvement of the calcium bioavailability cannot be taken as the objective technical problem underlying the invention as claimed in the main request. As a consequence, the problem has to be reformulated in a less ambitious manner, not involving such improvement.

5.3.2 The objective problem can thus be reformulated as the provision of further infant formulas to be used to feed infants.

5.3.3 It was not disputed that this less ambitious problem is solved by the claimed infant formulas.

5.4 Obviousness

5.4.1 The question which remains to be decided is whether the solution proposed by Claim 1 of the main request is obvious from the prior art.

5.4.2 In the absence of an improvement for the infant formula as claimed in Claim 1, the use of a protein component

having a phosphorus content of less than 0.75 g per 100 g of protein is an obvious alternative protein component for the skilled person and therefore lacks an inventive step. The reason for this finding is that it is undisputed that protein components with low phosphorus content as required by feature (a) were already known for the preparation of infant formulas (see, for instance, D5, Claim 1 and page 15, lines 14-15 read in the light of page 3, line 21).

5.4.3 Appellant 03 did not dispute that D5 disclosed protein components with low phosphorus content for use in infant formulas. It only argued that it was not obvious to combine D5 with D4 in order to arrive at an improved infant formula. However, this argument would only be valid if an improvement for the claimed formula over the closest prior art were demonstrated, which is not the case here for the reasons given above.

5.5 In summary. the subject-matter of Claim 1 of the main request lacks inventive step.

AUXILIARY REQUESTS 1, 2, 5 and 6.

6. *Inventive step*

6.1 The subject-matter of Claim 1 of these requests is directed to infant formulas having the features of Claim 1 of the main request and further requiring the presence of a carbohydrate component (auxiliary requests 1 and 2) or requiring a protein component comprising a specific hydrolysate (auxiliary requests 5 and 6).

6.2 Problem to be solved and its solution - obviousness

6.2.1 The question to be decided in relation to the subject-matter of the claims of these auxiliary requests is whether or not the added feature(s) ensure(s) that the alleged improvement in calcium bioavailability is indeed achieved by the features of Claim 1 of the respective auxiliary requests.

6.2.2 This is not the case, essentially for the reasons already given for the main request. As discussed in paragraphs 5.2.5 to 5.2.7 the evidence provided by appellant 03, in particular D36a, demonstrates that an improved calcium bioavailability is achieved when using compositions having a specific combination of features.

6.2.3 The subject-matter of Claim 1 of auxiliary requests 1, 2, 5 or 6 in no case includes the combination of all the features responsible for the improvement demonstrated in D36a. Therefore, in the absence of an improvement of the claimed formulas, the problem has to be seen, as for the main request, as being to provide alternative infant formulas.

6.2.4 The solutions proposed by the subject-matter of Claim 1 of auxiliary requests 1, 2, 5 and 6 lack inventive step essentially for the same reasons as given for the main request. The further components of the formulas specified in each of these respective auxiliary requests were undisputedly known for use in food products before the priority date of the patent. For oligosaccharides see, for instance, D15 (Abstract) and also [0108]-[0109] of the patent specification. For

protein hydrolysates see, for instance, D42a, page 1, lines 15-31.

Concerning the sixth auxiliary request, the opposition division acknowledged an improvement because the patent specification indicated that the protein hydrolysates of the invention assisted in providing such an improvement. However, the board cannot follow this reasoning because the evidence on file only shows the improvement for formulas also including nondigestible oligosaccharides.

6.2.5 For these reasons the subject-matter of Claim 1 of auxiliary requests 1, 2, 5 and 6 in each case lacks inventive step.

AUXILIARY REQUEST 7

7. *Novelty*

7.1 The novelty of the subject-matter of Claim 1 of auxiliary request 7 was not contested during the appeal proceedings. Moreover appellants 01 and 02 stated during the oral proceedings that they did not have any novelty objection having regard to the prior art product Frisopep® (D11). The board sees no reason to raise an objection on its own.

8. *Inventive step*

8.1 The subject-matter of Claim 1 of auxiliary request 7 includes now, in addition to a lipid component with high palmitic acid in Sn2 position, a protein component comprising partially hydrolysed protein with low

phosphorus content and nondigestible oligosaccharides, the features which according to D36a were responsible for the achievement of softer stools (improved calcium bioavailability) in infant formulas.

8.2 The board is therefore satisfied that the problem as defined above under 5.2.1 has now been credibly solved by the subject-matter of Claim 1 of auxiliary request 7.

8.3 Appellants 01 and 02 maintained that in the formula exemplified in D36a a specific protein component and specific oligosaccharides were used and that such a specific formula meant that the problem was not actually solved for the whole scope of the claim including infant formulas with a very different composition.

This argument is not accepted by the board. Appellant 03 has shown that an embodiment covered by the claims actually solves the problem underlying the patent in suit. Appellants 01 and 02 did not provide any experimental evidence or any argument that contradicted that finding. The mere statement that the claim is broad cannot bring into question a finding that the problem has been actually solved.

8.4 Obviousness

The solution to the above problem by the amended patent also clearly involves an inventive step. Although the components used in the claimed formula were already known per se, their combination was not described in relation to calcium bioavailability or the improvement of stool constitution. There is therefore no hint in

the cited prior art that the use of an infant formula as now claimed would improve the calcium bioavailability of the infant formulas resulting in softer stool.

8.5 For these reasons the subject-matter of Claim 1 of auxiliary request 7 and, by the same token, the subject-matter of dependent Claims 2 to 11 involve an inventive step.

9. The subject-matter of Claims 12 to 18 of auxiliary request 7 is not in issue (see point 2. above).

10. As auxiliary request 7 of appellant 03 is allowed, there is no need for the board to deal with auxiliary request 8.

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 Claims 1 to 18 according to the seventh auxiliary request filed on 19 October 2010 during the oral proceedings and after any necessary consequential adaptation of the description.

The Registrar The Chairman

G. Röhn W. Sieber