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**Datasheet for the decision
of 27 May 2009**

Case Number: T 1061/07 - 3.3.09

Application Number: 99108405.4

Publication Number: 1048226

IPC: A23L 1/29

Language of the proceedings: EN

Title of invention:

Infant formula containing sweet whey protein

Patentee:

Société des Produits Nestlé S.A.

Opponent:

N.V. Nutricia
Friesland Brands B.V.

Headword:

-

Relevant legal provisions:

EPC Art. 69, 123(3)

Relevant legal provisions (EPC 1973):

EPC Art. 54, 56

Keyword:

"Main request: Novelty - No"

"Auxiliary request 1: added subject-matter - yes"

"Auxiliary request 2: Novelty - yes, inventive step - no"

Decisions cited:

-

Catchword:

-



Case Number: T 1061/07 - 3.3.09

DECISION
of the Technical Board of Appeal 3.3.09
of 27 May 2009

Appellant: N.V. Nutricia
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Representative: Meekel, Arthur Augustinus P.
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Respondent: Soci t  des Produits Nestl  S.A.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
2 May 2007 concerning maintenance of European
patent No. 1048226 in amended form.

Composition of the Board:

Chairman: P. Kitzmantel
Members: J. Jard n  lvarez
W. Sekretaruk

Summary of Facts and Submissions

I. The grant of European patent No. 1 048 226 in respect of European patent application No 99108405.4 in the name of Société des Produits Nestlé S.A., which had been filed on 29 April 1999, was announced on 31 August 2005 (Bulletin 2005/35) on the basis of eight claims. Claim 1 read as follows:

"1. An infant formula which comprises a lipid source, a carbohydrate source, and a protein source which contains the free amino acids arginine, tyrosine, histidine and a hydrolysed sweet whey fraction from which caseino-glyco-macropptide has been removed."

Claims 2 to 8 were dependent claims.

II. Two Notices of Opposition requesting the revocation of the patent in its entirety on the grounds of Article 100(a) EPC, for lack of novelty and inventive step, and Article 100(b) EPC, for lack of sufficient disclosure, were filed on 31 May 2006 against this patent by:

N.V. Nutricia (Opponent 01), and by

Friesland Brands B.V. (Opponent 02)

The oppositions were supported *inter alia* by the following documents:

D2: DE - A - 43 44 342;

D4: M.M. Mullally *et al.* "Proteolytic and Peptidolytic Activities in Commercial Pancreatic Protease Preparations and Their Relationship to Some Whey Protein Hydrolysate Characteristics", *J. Agric. Food Chem.* 1994, 42, 2973-2981;

D5: M. Canciani *et al.* "Absorption of a New Semielemental Diet in Infants with Cystic Fibrosis", *Journal of Pediatric Gastroenterology and Nutrition* 4: 735-740, 1985;

D7: T. Kitagawa *et al.* "Treatment of Phenylketonuria with a Formula Consisting of Low-Phenylalanine Peptide", *Recent Adv. Inborn Errors of Metabolism. Proc. 4th Int. Congr., Sendai 1987. Enzyme* 38: 321-327 (1987);

D14: EP - A - 0 631 731; and

D19: EP - A - 0 421 309

III. By its interlocutory decision announced orally on 26 February 2007 and issued in writing on 2 May 2007, the Opposition Division held that the grounds for opposition raised by the Opponents did not prejudice the maintenance of the patent in the form as amended according to the then pending auxiliary request 2 submitted during the oral proceedings.

Claim 1 of this request reads as follows:

"1. An infant formula which comprises a lipid source, a carbohydrate source, and a protein source which contains a hydrolysed sweet whey fraction from which

caseino-glyco-macropptide has been removed supplemented with the free amino acids arginine, tyrosine, histidine."

With regard to the arguments of the Opponents in relation to Article 83 EPC, the Opposition Division found that they related to issues of clarity and not sufficiency of disclosure. In particular the Opposition Division noted that the claimed subject-matter defined an infant formula by means of precise ingredients, that the description indicated ways of preparing the claimed compositions and that the specification of the patent gave guidance as to which steps had to be applied to remove caseino-glyco-macropptide.

The Opposition Division acknowledged the novelty of the subject-matter of the second auxiliary request because D5 did not disclose the presence of further free amino acids in addition to those already present in the hydrolysed lactalbumin fraction of Formula B of D5.

Concerning the issue of inventive step, the Opposition Division identified the infant formula disclosed in D2 comprising predominantly whey proteins as closest prior art and considered the objective technical problem as the provision of an infant formula with a nutritionally balanced amino acid profile. In the Opposition Division's view, the solution to this problem, namely the use of a hydrolysed sweet whey protein fraction from which caseino-glyco-macropptide was removed and which was supplemented with the free amino acids arginine, histidine and tyrosine, was not suggested by the cited prior art.

IV. On 2 July 2007 Opponent 01 (Appellant) lodged an appeal against the decision of the Opposition Division and paid the appeal fee on the same day.

In the Statement of Grounds of Appeal filed on 7 September 2009, the Appellant requested the revocation of the patent as a whole on the grounds that the claimed subject-matter was not sufficiently disclosed (Article 83 EPC), not clear (Article 84 EPC), not new (Article 54 EPC) and lacked inventive step (Article 56 EPC).

The Appellant also filed a new document:

D23: S-J. Ge *et al.* "Continuous production of high degree casein hydrolysates by immobilized proteases in column reactor", *Journal of Biotechnology* 50 (1996) 161 - 170.

V. With letter dated 10 January 2008 the Patent Proprietor (Respondent) requested that the appeal be dismissed and the patent be maintained with the claims in accordance with the decision of the Opposition Division. It also filed a set of claims for an auxiliary request.

Claim 1 of this auxiliary request 1 reads:

"1. An infant formula which comprises a lipid source, a carbohydrate source, and a protein source which contains about 98.5% to about 97% by weight of hydrolysed sweet whey fraction from which caseinoglyco-macropptide has been removed and about 1.5% to about 3% by weight of arginine, tyrosine, and histidine."

VI. On 14 January 2009 the Board dispatched a summons to attend oral proceedings on 27 May 2009. In the annexed communication the Board gave its preliminary opinion on the file.

VII. By letter dated 24 April 2009 Opponent 02 (Party as of Right) filed substantial comments on the case and requested that the appeal be allowed and the patent be revoked in its entirety.

VIII. By letter dated 24 April 2009 the Appellant submitted further comments and filed a new document:

D24: P. Walstra and R. Jenness, "Dairy Chemistry and Physics" John Wiley & Sons, 1984, Chapter 10, Heating, pages 162 - 185.

IX. During the oral proceedings held on 27 May 2009, the Respondent filed a second auxiliary request.

Claim 1 of this auxiliary request 2 is identical to Claim 1 of the auxiliary request 1 (see point V above) but for the addition of the words "the free amino acids" before the word arginine.

X. The arguments presented by the Appellant in its written submission and at the oral proceedings may be summarized as follows:

- The Appellant contended that the patent was not sufficiently disclosed because:

- it failed to describe how to arrive at a sweet whey fraction from which caseino-glyco-macropptide has been [completely] removed;
 - the skilled person could not determine whether the hydrolysed sweet whey fraction used was lactose-free (Claim 2); and
 - the specification did not disclose how to obtain infant formulas with the claimed percentages of arginine, histidine and tyrosine (Claims 4, 5 and 7).
-
- The Appellant further contended that Claim 1 lacked clarity as there were serious doubts as to what products were covered by the claim.
 - Furthermore the subject-matter of all the requests lacked novelty in view of the composition of Formula B of table 2 of D5 and example 24 of D19.
 - Concerning inventive step, the Appellant argued that the subject-matter of the claims lacked inventive step starting from D2 or D7 as closest prior art document.
 - Finally the Appellant argued that the absence of the term "free amino acids" in Claim 1 of the first auxiliary request led to an extension of the scope of the claims as granted (cf. Article 123(3) EPC).

XI. The arguments presented by Opponent 02 can be summarized as follows:

- Opponent 02 essentially supported the arguments of the Appellant and further pointed out that:

- the requirements of Article 83 EPC were not fulfilled because the patent did not specify the precise circumstances allowing the skilled person to decide whether "the protein source has an amino acid profile which is close to that of human milk", and
- that the claimed subject-matter lacked inventive step when combining the disclosure of D2 with document D14, which suggested adding certain amino acids to provide a nutritionally balanced amino acid content.

XII. The Respondent essentially argued as follows:

- The Respondent disagreed with the interpretation of the word "removed" by the Appellant. It noted that it was not limited to complete removal, and submitted that a method for separating caseino-glyco-macropptide from sweet whey hydrolysate was proposed in the patent specification. Concerning the further objections in relation to Article 83 EPC, it pointed out that they were based on a misunderstanding of the claimed subject-matter.
- As to the argument that it was not possible to know whether a whey hydrolysate based infant formula contained free arginine, tyrosine and histidine in excess of the amounts imported with the hydrolysed sweet whey, the Respondent submitted that this could be easily established by comparison with the theoretical amounts of these amino acids comprised by the whey hydrolysate.

- As to novelty, the Respondent argued that the disclosure of D5 was not novelty destroying because the product Alfaré was not supplemented with free amino acids. Neither was Example 24 of D19 novelty destroying because according to this example caseino-glyco-macropptide had not been removed in the sense of the invention since it and its hydrolysis products were not physically separated from the hydrolysed composition, with the consequence that the threonine and tryptophan contents remained the same as in the starting material.

- Concerning inventive step, the Respondent considered D2 as the closest prior art document and the technical problem to be solved as the provision of an infant formula close to human milk for infants in need of special nourishment. The novel features of the claimed formula, namely (i) the selection of the three specific amino acids arginine, tyrosine and histidine, (ii) the supplementation of the known whey, and (iii) the specific amounts used were not obvious in view of the cited prior art. It pointed out that there was no information in the prior art about how to fill the nutritional gap between the known protein source and the claimed invention. It noted that the arguments of the Appellant were mainly based on hindsight with knowledge of the invention.

XIII. The Appellant requested that the decision under appeal be set aside and that the European patent No. 1 048 226 be revoked.

Opponent 02 requested that the appeal be allowed and the patent be revoked in its entirety.

The Respondent requested that the appeal be dismissed or the European patent be maintained on the basis of auxiliary request 1 filed with letter dated 10 January 2008 or on the basis of auxiliary request 2 filed on 27 May 2009 during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.
2. *Preliminary remark.*

As stated above under points X and XI, several objections under the provisions of Articles 83 and 84 EPC have been raised by the Appellant and by Opponent 02 against all the requests. The Board is not convinced by these objections but sees no need to give detailed reasons for its position since, as set out below (points 3.6, 4.4 and 7.4), the patent is to be revoked for other reasons.

MAIN REQUEST

3. *Novelty (Article 54 EPC 1973).*

3.1 Claim 1 of the main request is directed to an infant formula which comprises:

(a) a lipid source,

(b) a carbohydrate source, and

(c) a protein source which contains

(c1) a hydrolysed sweet whey fraction from which caseino-glyco-macropptide has been removed,

(c2) supplemented with the amino acids arginine, tyrosine, and histidine.

3.2 The Appellant has contested the novelty of the subject-matter of Claim 1 of the main request having regard to the disclosure of Formula B of Table 2 of D5 and example 24 of D19.

3.3 Document D5 discloses the use of the semi-elemental Formula B (Alfaré-Nestlé) that could help obviate the main digestive abnormalities in cystic fibrosis patients. According to Table 2, Formula B contains a lipid source (medium-chain triglycerides, butterfat, corn oil - feature (a)), a carbohydrate source (dextrine-maltose, starch, lactose - feature (b)) and a protein source (lactalbumin hydrolysate - comprising 10-20% free amino acids, 60-70% two-three peptides and 10-20% oligopeptides - feature (c1)). Although not specified in D5, it is not disputed that the lactalbumin hydrolysate contains the free amino acids arginine, tyrosine, and histidine (cf. Table 3 of D4) according to feature (c2).

Thus, Formula B of D5 comprises all the components of Claim 1 of the main request.

- 3.4 The Respondent did not dispute this fact but denied a novelty destroying character of this disclosure on the basis of allegedly higher amounts of free arginine, tyrosine and histidine in the compositions of the claimed invention. It pointed out that the amount of free amino acids imported from the sweet whey hydrolysate would be known and that Claim 1 - owing to feature (c2) - required the presence of further amounts of the specified amino acids in excess of those contained in the whey hydrolysate fraction. The presence of supplemented amounts of arginine, tyrosine and histidine was thus easily detectable and represented a feature distinguishing the claimed infant formula over Formula B of D5.
- 3.5 The Board finds this argument unconvincing, since it starts from the wrong assumption that the amino acid profile of a sweet whey hydrolysate is invariable and always comprising the same amounts of the free amino acids arginine, tyrosine and histidine. However, depending on the whey used and to a very large extent on its degree of hydrolysis, the amount of these amino acids in the hydrolysate varies to a significant degree. The definition of the protein source according to present Claim 1 - allegedly requiring supplementation with the free amino acids arginine, tyrosine and histidine - is therefore not distinguished from the infant Formula B according to D5 according to which the same free amino acids are derived from the whey hydrolysate.

- 3.6 For these reasons - and furthermore considering that the process feature "supplemented" in product Claim 1 has no bearing on the interpretation of this claim other than with regard to the result imparted to the product - the Board concludes that the disclosure of D5 anticipates the subject-matter of Claim 1 of the main request, which is therefore not novel.

AUXILIARY REQUEST 1

4. *Amendments (Article 123 EPC).*

4.1 Claim 1 of auxiliary request 1 is essentially based on Claim 1 of the main request but with the specific amounts of the components of the protein source now specified in accordance with granted Claim 4.

4.2 With this amendment the words "free amino acids" have not been retained in the claim wording. Because of this, the subject-matter of this amended Claim 1 is no longer limited to a composition that contains free amino acids, but embraces also infant formulas including the amino acids only as part of peptides or proteins. This omission therefore extends the protection compared with the granted claims.

4.3 The Board cannot accept the argument of the Respondent that, as is clear from the description (for instance [0018]), the subject-matter of the amended claims is in fact limited to the free amino acids even if not explicitly mentioned in the claim. In this context the Board considers that the meaning of a claim is essentially to be determined by its language - as it

would be understood by a skilled person - and reliance for interpretation on Article 69 EPC is ruled out in the present situation of an amended wording.

- 4.4 Claim 1 of auxiliary request 1 therefore does not fulfil the requirements of Article 123(3) EPC.

AUXILIARY REQUEST 2

5. *Admittance*

- 5.1 According to Article 13 (1) of the Rules of Procedure of the Boards of Appeal any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion. The discretion has to be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.
- 5.2 Although auxiliary request 2 was filed during the oral proceedings before the Board, i.e. at a very late stage, it takes account of the deficiencies discussed in relation to auxiliary request 1. The amendment does not substantially change the claimed subject-matter as it only reintroduces a feature which was already present in the main request and whose reinsertion does not increase the complexity of the case or give rise to any conflict with the need for procedural economy.
- 5.3 The set of claims according to auxiliary request 2 is therefore admitted into the proceedings.

6. *Novelty (Article 54 EPC 1973)*

6.1 Compared to the main request the subject-matter of Claim 1 of auxiliary request 2 quantifies the amount of free amino acids. It specifies that the protein source contains from about 98.5% to about 97% by weight of hydrolysed sweet whey fraction from which caseino-glyco-macropptide has been removed and from about 1.5% to about 3% by weight of the free amino acids arginine, tyrosine, and histidine.

There is no disclosure of the amount of free amino acids either in D5 or in D19 cited by the Appellant as novelty destroying for the subject-matter of Claim 1 of this request.

6.2 The Appellant admitted during the oral proceedings that there was no clear and unambiguous teaching of the values specified in Claim 1 in these documents but nevertheless maintained that their disclosures were still novelty destroying. It argued that the claimed range of 1.5% to 3% of free amino acids represented a selection from the disclosures of D5 and D19 and that such a selection did not fulfil the criteria for the novelty of selection inventions.

6.3 This argument of the Appellant is erroneous. It is essentially based on the assumption that since the disclosure of D5 does not specify the amount of amino acids included in formula B, any amount of amino acids is embraced by such formula. However, even if not specified, the composition of Formula B must comprise a definite amount of amino acids, not a broad range. Consequently the subject-matter of Claim 1 does not

relate to a selection within the teaching of D5 and the criteria for selection inventions do not apply.

6.4 Concerning example 24 of D19 the theoretical maximum amount of free amino acids histidine, arginine and tyrosine is ca. 0.35%, that is to say, well below the lower limit of the now claimed range.

6.5 The subject-matter of the claims of the auxiliary request 2 is therefore novel.

7. *Inventive step (Article 56 EPC 1973).*

7.1 Closest prior art.

7.1.1 The Board considers, in agreement with the parties to the proceedings, that document D2 represents the closest prior art document.

7.1.2 D2 relates, like the patent in suit, to a milk-type baby food containing hydrolysed whey protein with reduced content in threonine as a result of the removal of caseino-glyco-macropeptide (see Claim 1). Example 2 further discloses the presence of a lipid and a carbohydrate source.

Document D2 is silent about the presence of the free amino acids arginine, tyrosine, and histidine. The Respondent affirmed during the oral proceedings that the amount of free amino acids, if present, would be well below the range now claimed. Taking into account that the main products of the hydrolysis of whey are oligopeptides, not free amino acids (see for instance

D19), the Board has no reason to question this affirmation of the Respondent.

- 7.1.3 The subject-matter of Claim 1 of auxiliary request 2 thus differs from the disclosure of D2 by the presence of the three amino acids arginine, tyrosine, and histidine in an amount of about 1.5% to about 3% by weight.

- 7.2 Problem to be solved and its solution.
 - 7.2.1 Having regard to this prior art, the objective technical problem to be solved by the patent can be seen as the provision of an infant formula having an amino acid profile close to that of human milk (see [0007]), human milk being usually known as the "golden standard" in the field.
 - 7.2.2 This problem is solved by the claimed infant formula wherein the protein source, in addition to the hydrolysed whey with low threonine content, includes a higher amount of the above mentioned three amino acids.
 - 7.2.3 By this measure infant formulas having a balanced amino acid profile (see [0040]) suitable for pre-term infants and/or for full term, hypoallergenic infants are obtained.
 - 7.2.4 The Board is thus satisfied that the above mentioned problem has been credibly solved. This was not challenged by the Appellant or by Opponent 02.

7.3 *Obviousness.*

7.3.1 The question which remains to be decided is whether this solution involves an inventive step.

7.3.2 As acknowledged at paragraph [0002] of the patent, infant formulas made to replace mother's milk should provide an amino acid profile as close as possible to that of mother's milk.

It is common for the skilled person in this field (as was explicitly confirmed by the Respondent) to adapt compositions of infant formulas using protein sources whose amino acid profile is different from that of human milk to the amino acid profile of human milk. This is actually the gist of the invention of D2, which focuses on the reduction of the high content of threonine of the whey protein source in order to make it similar to human milk (D2, column 1, lines 16 - 46).

On the other hand, the addition of amino acids to a nutritionally balanced infant formula is also known and disclosed for instance in D14. The partial (whey and casein) protein hydrolysate of D14 may be supplemented with various free amino acids. D14 mentions as possible amino acids to be added to infant formulas tryptophan, methionine, cystine, tyrosine and arginine (see page 5, lines 6 - 10).

In view of this teaching of the prior art, the Board considers it obvious to modify the protein source of an infant formula (here the protein source of D2) by addition of further amino acids, insofar as these amino acids are amino acids already known to be present in

human milk. The selection of the three specific amino acids arginine, tyrosine and histidine now claimed and the amount of them to be added to the protein source (1.5% to 3% by weight) cannot, in the absence of an unexpected effect due to their addition, contribute to an inventive step.

- 7.3.3 It follows that the subject-matter of Claim 1 of auxiliary request 2 is obvious in view of the teaching of documents D2 and D14.
- 7.3.4 It was argued by the Respondent that although at first sight the supplementation with the three amino acids might appear obvious, actually there was no information in the cited documents allowing the skilled person to fill the nutritional gap between the compositions of D2 and the patent. In its opinion arriving at the selection of the three specific amino acids and the amount to be used could only be done on the basis of an *ex post facto analysis* with knowledge of the patent.
- 7.3.5 The Board finds these arguments unconvincing. As pointed out above, the addition of amino acids normally present in human milk in order to supplement an infant formula designed to meet the nutritional needs of a human infant is already described in D14 (cf. page 4, lines 39-40; page 5, lines 6-9). Furthermore, while D14 specifically mentions *inter alia* only two (arginine and tyrosine) of the three amino acids specified in present Claim 1, the additional supplementation with histidine - included by the term "free amino acids" to be supplemented according to D14 and equally known to be part of human milk - cannot as such provide an inventive step unless this particular selection of

amino acids gives rise to an unexpected technical effect, something for which there is no evidence in this case. In these circumstances the Board regards the choice of the amino acids as arbitrary and not involving an inventive step.

Analogous considerations apply to the selected amount of 1.5% to 3% by weight of the amino acids for which no unexpected technical effect has been shown.

7.4 Hence, the Board concludes that, in the light of the cited prior art D2 and D14, it is obvious to a person skilled in the art to arrive at the claimed infant formulas.

8. In summary, none of the requests of the respondent relates to patentable subject-matter.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The European patent is revoked.

The Registrar

The Chairman

G. Röhn

P. Kitzmantel