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Datasheet for the decision of 30 September 2010

Case Number: T 0182/08 - 3.3.09

Application Number: 00916886.5

Publication Number: 1161152

IPC: A23J 3/34

Language of the proceedings: EN

Title of invention:
Nutritional composition intended for specific gastro-intestinal maturation in premature mammals

Patentee:
SOCIETE DES PRODUITS NESTLE S.A.

Opponent:
Numico Research B.V.

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 83, 123(2)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Sufficiency of disclosure (yes)"
"Compliance with Article 123(2) (yes)"
"Novelty, inventive step (yes)"

Decisions cited:
T 0246/91

Catchword:
-

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Case Number: T 0182/08 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 30 September 2010

Appellant: (Opponent)
Numico Research B.V.
P.O. Box 7005
NL-6700 CA WAGENINGEN (NL)

Representative:
Meekel, Arthur Augustinus P.
Nederlandsch Octrooibureau
P.O. Box 29720
NL-2502 LS Den Haag (NL)

Respondent: (Patent Proprietor)
SOCIETE DES PRODUITS NESTLE S.A.
Case postale 353
CH-1800 Vevey (CH)

Representative:
Rupp, Christian
Mitscherlich & Partner
Patent- und Rechtsanwälte
Sonnenstrasse 33
D-80331 München (DE)

Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 22 October 2007 concerning maintenance of European patent No. 1161152 in amended form.

Composition of the Board:

Chairman: W. Sieber
Members: W. Ehrenreich
W. Sekretaruk

Summary of Facts and Submissions

I. Mention of the grant of European patent No. 1 161 152 in respect of European patent application No. 00 916 886.5 filed on 1 March 2000 as international application PCT/EP2000/001744 in the name of Société des Produits Nestlé S.A. was announced on 13 October 2004 (Bulletin 2004/42).

The patent was granted with six claims, Claim 1 reading as follows:

"1. A nutritional enteral composition intended for favoring the growth and maturation of non-mature gastro-intestinal tracts of young mammals, which contains

- a mixture of dietary protein hydrolysates having a degree of hydrolysis in a range of from 10 % to less than 50 % and being in form of a mixture of different size peptides and free amino acids, the free amino acids being present in an amount of up to about 20 % by weight of the total protein content (each calculated as nitrogen x 6.25),
- intact proteins being partly in form of bioactive peptides, and

wherein the dietary protein hydrolysates contain at least about 5 % (by weight, of the total protein content calculated as nitrogen x 6.25) of hydrolysate having a degree of hydrolysis of about 40 % and at least about 5 % of hydrolysates having a lesser degree of hydrolysis."

Product Claims 2 to 5 were dependent claims and Claim 6 was directed to the use of the composition as defined

in any one of Claims 1 to 5 for the preparation of a nutritional enteral composition intended for favouring the growth and maturation of non-mature gastro-intestinal tracts of young mammals.

II. An opposition against the patent was filed by

Numico Research B.V. on 13 July 2005.

The opponent requested revocation of the patent on the grounds of

- Article 100(a) EPC (lack of novelty and lack of inventive step);
- Articles 100(b) and 100(c) EPC.

The opponent relied *inter alia* on the following documents:

D1 US-A 5 514 655;
D6 CA-A 2 163 379; and
D7 David B.A. Silk et al *"Relevance of Physiology of Nutrient Absorption to Formulation of Enteral Diets"* in Nutrition, vol. 8, No. 1 (1992).

III. With its interlocutory decision announced orally on 4 October 2007 and issued in writing on 22 October 2007 the opposition division decided that, account being taken of the amendments made by the patent proprietor during the oral proceedings, the patent and the invention to which it related met the requirements of the Convention.

Claim 1 of the main request reads as follows:

"1. A nutritional enteral composition intended for favoring the growth and maturation of non-mature gastro-intestinal tracts of young mammals, which contains

- a mixture of dietary protein hydrolysates having a degree of hydrolysis in a range of from 15 % to less than 50 % and being in form of a mixture of different size peptides and free amino acids, the free amino acids being present in an amount of up to about 20 % by weight of the total protein content (each calculated as nitrogen x 6.25),
- intact proteins being partly in form of bioactive peptides, and

wherein the dietary protein hydrolysates contain at least 5 % (by weight, of the total protein content calculated as nitrogen x 6.25) of hydrolysate having a degree of hydrolysis of about 40 % and at least 5 % of hydrolysates having a lesser degree of hydrolysis."

In the opposition division's view none of the opposition grounds under Article 100(a), (b) and (c) EPC was prejudicial to the maintenance of the patent in amended form.

With regard to novelty it was held that neither D1 nor D6 contained an unambiguous disclosure of all the features in Claim 1 of the main request.
Concerning inventive step D1 was considered to be the closest prior art. The opposition division further argued that D7, relating inter alia to the improved absorptive capacity of protein hydrolysates containing mainly di- and tripeptides in the gastro-intestinal

tract, did not specify any degree of hydrolysis (hereinafter: DH) for the hydrolysates. Therefore, a combination of D1 with D7 would not lead to the claimed invention.

The opposition division also saw no insufficiency of disclosure of the invention with regard to the features in Claim 1 "mixture of different size peptides and free amino acids", "intact proteins being partly in form of bioactive peptides" and "at least 5% ... of hydrolysate having a degree of hydrolysis of about 40%". In its view, there was either sufficient explanation of the features in the description of the patent specification or a problem under Article 84 rather than 83 EPC.

With regard to the amended feature "15% to less than 50%" in Claim 1 the opposition division saw no non-compliance with Article 123(2) EPC.
The amendment in Claim 3 from "TGF-ß" into "TGF-ß2" was considered to be a correction under Rule 88 EPC 1973.

IV. Notice of appeal against the decision was filed by the opponent (hereinafter: appellant) on 21 December 2007. The prescribed fee was paid on the same day. The statement of the grounds of appeal was submitted on 29 February 2008.
The appellant maintained its objections of lack of novelty, lack of inventive step and added subject-matter raised in the opposition proceedings. As to insufficiency of disclosure, the objection that it was not possible to distinguish a mixture of hydrolysates from a single hydrolysate was maintained and reference was made in this respect to the notice of opposition.

V. In a reply dated 9 July 2008 the patent proprietor (hereinafter: the respondent) defended maintenance of the patent as allowed by the opposition division (main request). Further sets of claims according to auxiliary requests 1 to 5 were filed.

VI. On 30 September 2010 oral proceedings before the board took place in which the subject-matter of the claims according to the main request was discussed with regard to compliance with Article 123(2) EPC, sufficiency of disclosure, novelty and inventive step.

VII. The arguments of the appellant provided in writing and at the oral proceedings with regard to the main request may be summarised as follows:

(a) Article 123(2) EPC

The range "15% to less than 50%" in Claim 1 relating to "a mixture of dietary protein hydrolysates" was not disclosed in the application as filed. The broadest originally disclosed range of "5 % to about 50 %" related to protein hydrolysates in general, whereas the sub-ranges "10 % to about 15" and "15 % to about 25 %" related to specific functions of the protein hydrolysates in the liver and the jejunum. A combination of the broadest range with one of the above sub-ranges in order to create a new narrower range was therefore not in compliance with Article 123(2).

In addition, all disclosed ranges only related to the protein hydrolysates and excluded the free amino acids. This was in contrast to Claim 1, in

which the DH-range of "15% to less than 50%" included the free amino acids because it related to "a mixture of different size peptides and free amino acids".

(b) Article 83 EPC 1973

It was insufficiently disclosed how the skilled person could distinguish between a mixture of hydrolysates and a single hydrolysate. A protein hydrolysate having a certain degree of hydrolysis always consisted of a range of peptide fractions in varying sizes, each fraction having its own DH. Thus, a mixture of hydrolysates with a DH below 40 % and a hydrolysate with a DH of about 40 % and an overall DH between 15% and 50% were indistinguishable. Consequently, the skilled person intending to carry out the invention would not know whether he was working within or outside the claimed invention.

(c) Novelty

Assuming that the range 15% to 50% indicated in Claim 1 represented an overall DH, D1 was of relevance for the assessment of novelty. When considering the molecular weight partition for the soy protein hydrolysate with an overall DH of 14 to 17, most preferably about 16, depicted in Table 3 of D1, it emerged undoubtedly therefrom that part of the fractions, in particular those with a molecular weight of <500, had a DH of about 40 %. This followed from the calculation provided in the grounds of appeal. Therefore, the protein

hydrolysate mixtures of batches 33, 34, 39, 40 according to Table 9 of D1 were novelty-destroying to the claimed subject-matter.

Similar considerations applied with respect to D6 disclosing a nutritional composition containing a protein source on the basis of a casein hydrolysate having a DH of from 25% to 35%, free amino acids and intact casein. In this context, it was known that casein was not a single protein species but represented different subclasses of casein including gamma- and kappa-casein. Thus, the term "hydrolyzed casein" in D6 already implied that a mixture of dietary protein hydrolysates was present.

(d) Inventive step

According to paragraph [0003] of the patent specification, faster absorption of nutritional compositions based upon protein hydrolysates was one of the problems to be solved by the claimed invention.
D6, dealing with the same problem and disclosing a nutritional enteral composition with improved digestion and absorption, could therefore be considered the closest prior art. The claimed enteral composition differed from the composition of D6 only in that it contained a second hydrolysate with a DH of about 40%. The effect of this difference was better absorption and digestion of protein in the intestinal tract in order to cover high nutrient needs (paragraph [0036] of the patent specification).

A skilled person starting from D6 and intending to further improve absorption of the enteral composition would be prompted by D7 to add protein hydrolysates with a high DH because it was indicated in Table III of D7 that short-chain protein hydrolysates having a high DH led to an improved digestion and jejunal absorption. In the section under "Conclusion and Perspectives" at page 5 of D7 it was concluded that absorption in the form of di- and tripeptides was of importance in infants where rapid growth occurred.

The claimed subject-matter was therefore rendered obvious from a combination of D6 with D7.

In its written submissions, the appellant started from D1 as the closest prior art.

VIII. The counter-arguments of the respondent were as follows:

(a) Article 123(2) EPC

It was disclosed in the application as filed that the enteral composition according to the invention was intended for specific gastro-intestinal maturation in pre-mature mammals. The broadest originally disclosed range for the DH of the protein hydrolysate of 5% to 50% was, however, not optimal for achieving this specific effect in the gastro-intestinal tract. The sub range of 10% to 15% had only a specific influence on the liver, and not the gut, whereas the DH-range for the desired specific influence of the protein

hydrolysate on the gastro-intestinal tract began at 15%.
In order to cope with this specific advantage of the hydrolysate with respect to the maturation of the gastro-intestinal tract of young mammals, it was necessary to limit the broadest range for the DH by increasing its lower limit to 15%.

As regards the appellant's argument that the originally disclosed ranges for the DH of the protein hydrolysates excluded free amino acids, it should be considered that the DH of a protein hydrolysate was a statistical single value representing the percentage of the cleaved peptide bonds out of all hydrolytically cleavable peptide bonds in an intact protein (the starting product). According to this technically established definition of the DH - which was determined by measuring the free alpha nitrogen and comparing it with the total nitrogen (see for instance J. Adler-Nielsen in J. Agric. Food Chem., 1979 27(6), pp. 1256-1262) - the DH of a specific protein hydrolysate was unchangeable, irrespective of the amount of free amino acids added to the mixture.

(b) Article 83 EPC 1973

Because, as stated above, the DH represented a single value resulting from a comparison of the fee alpha amino nitrogen with the total nitrogen, irrespective of whether or not free amino acids were present, it was of course possible for a skilled person to obtain single protein

hydrolysates with a DH within the claimed range of 15% to 50% and mix them afterwards.

(c) Novelty

The appellant's calculation on the DH of the soy protein hydrolysate according to Table 3 in D1 presented with the letter dated 29 February 2008 was incorrect. It could not be seen how the molecular weight fractions depicted in this table could be converted into peptide fractions of a certain length on the basis of the unproven assertion that the average molecular weight of the amino acids in soy protein was 135. No disclosure in this respect was found in D1. Therefore there was no unambiguous explicit or implicit disclosure in D1 that at least 5 % of the soy protein hydrolysate had a DH of about 40 %. This situation was not changed when considering samples 33, 34, 39, 40 in Table 9 of D1 which were merely related to soy protein hydrolysates in admixture with the protein hydrolysate FXP 720 of a DH below the claimed range.
D1 could therefore not anticipate the claimed subject-matter.

Likewise, the reference in D6 to a hydrolysed casein with a DH of 25% to 35% did not provide an unambiguous disclosure that this hydrolysate contained a product of hydrolysis with a DH of about 40 %.
Therefore, D6 was not novelty-destroying either.

(d) Inventive step

Contrary to the appellant's opinion, the present invention was not simply concerned with the absorption of amino acids in the gut. As was apparent from the paragraphs [0014, 0018, 0021] of the patent specification, the invention was particularly related to an optimum protein synthesis in the jejunum and the duodenum, with the aim to promote gut maturation of young mammals. In addition, optimal digestion and utilisation of the protein source for tissue accretion was intended.
Document D6 focused on nitrogen absorption for metabolically stressed patients and did not deal with the above problem and therefore did not represent the closest prior art. The same applied to D7 dealing with improved jejunal absorption of short-chain protein hydrolysates.

Rather, US-A 4 977 137 cited in paragraph [0004] of the patent specification and relating to the promotion of the growth of the gastro-intestinal tract of infants by the use of milk lactoferrin represented the closest prior art. This document, however, did not teach the use of lactoferrin, which was an intact protein, in combination with a protein hydrolysate. The skilled person was therefore not induced by the US document to add protein hydrolysates according to D6 or D7 in order to solve the posed problem.

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

X. The respondent requested that the appeal be dismissed or the patent maintained on the basis of any of auxiliary requests 1 to 5 filed by letter dated 9 July 2008.

Reasons for the Decision

1. The appeal is admissible.

2. Interpretation of Claim 1

Claim 1 defines the protein source of the claimed enteral composition. With respect to the degree of hydrolysis (hereinafter: DH) of the protein hydrolysates present in the protein source, the claim indicates two essential requirements:

(i) the DH of the hydrolysates is in the range of from 15% to less than 50%;

(ii) the hydrolysates (i) contain at least 5% of hydrolysates having a DH of about 40% and at least 5% of hydrolysates having a lesser DH.

The meaning of these definitions (i) and (ii) was discussed by the parties at some length.

In the appellant's understanding, a DH in the range of from "15% to less than 50%" as set out in Claim 1 represents an "overall DH", meaning that the "overall DH" of a mixture of two or more dietary protein hydrolysates is the average of the DHs of the individual hydrolysates. Thus, the "overall DH" of a mixture of two dietary protein hydrolysates as

disclosed in D1 (one hydrolysate having a DH of 14% to 17% and the other a DH of 10%) could be calculated to range from 13.5% to 16%, with a preference for 15.3% (taking into account the weight percentages of the protein hydrolysates). Since, furthermore, a protein hydrolysate generally consists of a mixture of hydrolysate fractions this implies that a portion of these fractions has a DH of about 40%. This interpretation further means that external influences, e.g. the addition of free amino acids (with a DH of 100%), would have an influence on the DH of a protein hydrolysate by shifting it to a higher value.

In the respondent's view, the DH of a protein hydrolysate represents the percentage of the cleaved peptide bonds out of all cleavable peptide bonds in the intact starting protein. For instance, a DH of 50% means that 50% of the peptide bonds out of all available bonds of the starting protein have been cleaved during the course of a hydrolysis. This definition is consistent with the definition given at page 3, lines 16-19 of the application as filed that *"degree of hydrolysis means the percentage of nitrogen in the form of free alpha-amino nitrogen as compared to total nitrogen". It is a measure of the extent to which the protein has been hydrolysed"*. From this definition of the DH, the question as to whether free amino acids have to be taken into account for calculating the DH value became irrelevant.

In the board's view, the respondent's interpretation of DH would be understood by a skilled person as being the correct one. Not only is it consistent with the disclosure given on page 3, lines 16 to 19 of the

application as filed (paragraph [0016] of the patent specification), it is also supported by the disclosure in J. Agric. Food Chem., 1979 27(6), pp. 1256-1262 (cited by the respondent, see point VIII(a) above). Accordingly, the DH of a certain protein hydrolysate is determined by

(a) measuring the total protein nitrogen;

(b) determining the amount of primary amino groups/free alpha amino groups formed during the hydrolysis reaction;

(c) forming the quotient (b)/(a) multiplied by 100.

Thus, the DH value of a certain protein hydrolysate represents a product-specific single value which is unchangeable, irrespective of external influences, e.g. by subsequent addition of free amino acids or other short-chain protein hydrolysates.

This is also corroborated by the three single values of 14%, 17.3% and 35%, each defining the DH of the separate Hydrolysates 1, 2 and 3 prepared in Example 1 of the patent specification. In Example 2, mixtures of hydrolysates 2 and 3 are formed after the determination of their respective DH. A new average ("overall") DH value for this two-component mixture is not given.

Nevertheless, it is true that a DH of a protein hydrolysate within the claimed range of from 15% to less than 50%, feature (i) of Claim 1, is a statistical value. This means that the hydrolysis reaction of a protein yields hydrolysate fractions where the protein has been hydrolysed to a lesser or a higher degree than the statistical value, for example fractions with a DH of 100% (i.e. free amino acids, completely hydrolysed protein) or with a DH of 0% (intact proteins, no hydrolysis at all), and fractions with a DH of about

40%. Feature (ii) of Claim 1 takes the significance of the DH being a statistical value into account by requiring a certain amount of a particular fraction.

3. Sufficiency of disclosure - Article 100(b) EPC 1973

In the light of the above, each hydrolysate has its own specific DH. For instance, when cleaving half of the peptide bonds of a certain protein by hydrolysis, a DH of 50% is reached, i.e. the quotient of alpha amino groups/total nitrogen is 0.5. The statistical distribution of fragments of different chain-length is irrelevant.

The board has no doubts, in particular with regard to Example 1 of the patent specification, that a skilled person is able to vary a conventional hydrolysis reaction (e.g. by adjusting certain reaction conditions) in such a manner that a protein hydrolysate with a certain DH within the claimed range of from 15% to 50% results. The provision of a mixture of two or more of such hydrolysates is merely a matter of routine.

The invention is therefore sufficiently disclosed within the meaning of Article 83 EPC 1973.

4. Compliance with Article 123(2) EPC

Claim 1 of the main request contains the feature that the mixture of dietary protein hydrolysates has a degree of hydrolysis of from 15% to less than 50%. This range results from a combination of the broadest range of "5% to about 50%" disclosed at page 3, lines 27 to 30 of the application as filed relating to the protein

hydrolysates in general, and the lower limit of the range "15% to about 25%" disclosed at page 4, lines 23 to 25 in relation to an increase of the concentration of protein in the jejunum.

According to the appellant the combination of the lower limit "15%" of the narrower range with the upper limit "50%" of the broader range infringes Article 123(2) EPC, because the lower limit is associated with a specific effect in the jejunum.

It is, however, conspicuous to the board that original Claim 1 does not specify any range for the DH of the protein hydrolysate but indicates that the nutritional enteral composition is *"intended for favoring the growth and maturation of non-mature gastro-intestinal tracts of young mammals"*. Thus, already the originally claimed and broadly defined enteral composition is directed to affect the gastro-intestinal tract, the jejunum being a part thereof. Furthermore, page 4, lines 25-29 refers to a DH of greater than 25%, more preferably greater than 35% in connection with an increase of the rate of protein synthesis in the jejunum and the duodenum. Consequently, it is clearly and unambiguously derivable from the application as filed that DH ranges at 15% or higher make the hydrolysate suitable for positively influencing the jejunum in the gastro-intestinal tract. Under this aspect, the limitation of the broadest possible range of from "5% to about 50%" to 15% to 50% in Claim 1 of the main request is in compliance with Article 123(2) EPC.

According to the respondent, the limitation is not only formally allowable but also necessary in view of the

technical background of the invention. As is apparent from the application as filed, the lower part of the broadest originally disclosed range for the DH is not optimal for achieving the desired benefits in the gastro-intestinal tract. As disclosed on page 4, lines 21 to 29 of the application as filed, the sub-range of 10% to 15% has only a specific influence on the liver, and not on the gut, whereas the DH-range for the desired specific influence of the protein hydrolysate on the gastro-intestinal tract begins at 15%. In order to better reflect the specific advantages of the hydrolysate with respect to the maturation of the gastro-intestinal tract of young mammals, it was, according to the respondent, necessary to limit the broadest range for the DH by increasing its lower limit to 15%.

The finding with respect to Article 123(2) EPC is not changed by the fact that the DH ranges are originally disclosed in direct relation to the protein hydrolysates, whereas Claim 1 of the main request indicates that the protein hydrolysates are *"in a form of a mixture of different size peptides and free amino acids ..."*. As mentioned under point 2 above, external addition of free amino acids does not change the DH value of a given protein hydrolysate. Furthermore, it is very likely that the protein hydrolysate itself contains a portion of free amino acids, owing to the splitting of single amino acids from the peptide chain during the hydrolysis reaction.

The amendment to Claim 1 of the main request therefore complies with Article 123(2) EPC.

5. Novelty

According to Claim 1 of the main request the hydrolysate mixture of the nutritional enteral composition has a DH of from 15% to less than 50% (feature (i) above) and further has to contain a hydrolysate (fraction) having a DH of about 40% in an amount of at least 5% by weight of the total protein content (feature (ii) above).

Neither D1 nor D6, cited by the appellant with respect to novelty, explicitly and unambiguously describe protein hydrolysates in the form of a mixture of hydrolysates with a DH of from 15% to 50%, wherein at least one portion of 5% represents a hydrolysate having a DH of about 40%.

D1 relates to a liquid enteral nutritional product which contains a protein system of, by weight, about 50-90% of soy protein hydrolysate (SPH) having a DH in the range of 14-17% and at leat 10% intact protein (Claim 1). Optionally, a small portion of the SPH may be substituted by a less hydrolysed protein. A protein investigated was, for example, FXP 720 having a DH of 10 (column 9, lines 17 to 22). Table 9 shows the evaluation of various protein combinations in experimental formulations, including mixtures of SPH and FXP 720 in Batch Nos. 33, 34, 39 and 40.
Firstly, it is conspicuous to the board that the SPH described in D1 (DH=14-17%) may or may not meet the requirement of feature (i) of Claim 1. It is not clearly and unambiguously derivable from the disclosure of D1 what the actual DH of the SPH used was. Secondly,

FXP 720 with a DH of 10% does not in any case meet the requirement of feature (i) of Claim 1.

As regards feature (ii) of Claim 1, Table 3 of D1 depicts a molecular weight partition for SPH. This partition results from a fractionation of a single hydrolysate with a DH value of 16 (column 1, lines 56 to 60) via chromatography. The purpose of such a fractionation, however, is merely the analysis of the molecular weight of hydrolysate fractions contained in a single hydrolysate and apparently does not aim at determining the DH of the respective fractions. Furthermore, the appellant's calculation based on Table 3 as presented with the grounds of appeal (point VII(c), whose correctness was contested by the respondent, cannot unambiguously show that a hydrolysate fraction with a DH of about 40% is present in the hydrolysate of D1, nor is it derivable therefrom that such a fraction is contained in an amount of at least 5%.

In view of the above, D1 cannot therefore anticipate the claimed composition.

In a similar manner, no disclosure can be derived from D6 that the hydrolysed casein with a DH of 35% (page 7 first paragraph) contains a hydrolysate portion with a DH of about 40%.
Similar considerations also apply to the other cited documents.

The claimed subject-matter is therefore novel over the prior art.

6. Inventive Step

6.1 The claimed invention relates to nutritional enteral compositions containing peptides in an adapted profile size, bioactive peptides, intact proteins, and free amino acids intended for specific gastro-intestinal maturation in pre-mature mammals (paragraph [0001] of the patent specification).

The board agrees with the respondent that neither D1 nor D6 (i.e. the documents relied upon by the appellant in the statement of grounds and at the oral proceedings, respectively) represents the closest prior art, because none of these documents deals with nutritional enteral compositions for young mammals.

In fact the preferred embodiments of D1 have utility for:

- providing enteral nutritional support for persons infected with the human immunodeficiency virus (column 16, lines 45 to 48);
- providing enteral nutritional support for persons afflicted with cancer and undergoing chemotherapy and/or radiation therapy (column 19, lines 63 to 67).

D6 relates to liquid enteral nutritional compositions useful in providing complete nutrition to metabolically stressed human patients, who are gastro-intestinally compromised due to surgery, trauma etc. (page 8, paragraph 2). One component of the composition is a protein source based on

- 20-30% by weight of free amino acids;
- 60-75% by weight hydrolysed casein with a DH of 25-35%;
- 5-15% intact caseinate protein;

(D6, Claims 1 and 12).

Rather, US-A-4 977 137 cited in paragraph [0004] of the patent specification represents, as pointed out by the respondent, the closest prior art. This document relates to the promotion of the growth of the gastro-intestinal tract of infants by the use of milk lactoferrin.
Thus, the board sees no reason to depart from the respondent's analysis with respect to the closest prior art.

6.2 As is apparent from paragraphs [0014], [0018] and [0021] of the patent in suit, the technical problem to be solved can be seen in the provision of an enteral composition containing a protein source which ensures optimal digestion, thereby increasing the protein concentration in the jejunum and optimizing protein synthesis in the gut and peripheral tissues in pre-mature mammals (paragraphs [0014], [0018] and [0021]).

6.3 The patent suggests, as the solution to this problem, an enteral composition containing:

(a) a mixture of protein hydrolysates having a DH of from 15% to less than 50%
  (i) being in the form of different size peptides and free amino acids;
  (ii) the free amino acids being present in an amount of up to 20% of the total protein;
  (iii) the protein hydrolysates containing at least 5% by weight of hydrolysate (based on total protein content) having a DH of about 40% and

(iv) the protein hydrolysates containing at least 5% by weight of hydrolysate having a DH of less than about 40%;

(b) intact proteins being partly in the form of bioactive peptides.

6.4 As stated in T 246/91 of 14 September 1993 (not published in OJ EPO, Reasons 4.3), "an objective definition of the technical problem should normally start from the technical problem that is described in the patent in suit. Only if it turns out that an incorrect state of the art was used to define the technical problem or that the technical problem disclosed has in fact not been solved, can an inquiry be made as to which other technical problem objectively existed."

In the present case, the board has no doubt that the proper document was used to define the technical problem. Since furthermore no evidence whatsoever has been provided which could question the success of the suggested solution, the board sees no reason to deviate from the technical problem set out in the patent for the assessment of inventive step.

6.5 Obviousness

US-A-4 977 137 itself contains no hint whatsoever to use lactoferrin in combination with a mixture of protein hydrolysates, let alone a mixture of hydrolysates as defined in Claim 1.

D1 and D6 are concerned, as shown above, with different technical problems unrelated to that underlying the present invention, and cannot therefore be combined

with the closest prior art. Apart from that, D1 and D6 do not disclose the specific protein profile required in Claim 1.

D7, in particular dealing with jejunal absorption of protein hydrolysates in relation to their peptide chain length (page 2, Table III), is silent on specific DH ranges and mixtures of protein hydrolysates. Therefore, a combination with D1 and/or D6 would not lead to the claimed invention.

The board therefore considers that the subject-matter claimed in the claims of the main request is also based on an inventive step.

7. For the above reasons, the claims according to the main request are allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar The Chairman

T. Buschek W. Sieber