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Datasheet for the decision of 11 April 2013

Case Number: T 1761/10 - 3.3.09

Application Number: 02762401.4

Publication Number: 1414316

IPC: A23L 1/305, A23K 1/18, A61K 38/01, A61P 1/00

Language of the proceedings: EN

Title of invention:
Nutritional composition preventing bacterial overgrowth

Patent Proprietor:
SOCIETE DES PRODUITS NESTLE S.A.

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

Headword:
-

Relevant legal provisions:
EPC Art. 100(c), 54, 56
RPBA Art. 13(1) and (3)

Keyword:
"Amendments - added subject-matter (no)"
"Novelty (yes)"
"Inventive step (yes)"
"Admissibility of new inventive step attack (no)"
"Admissibility of late-filed documents (no)"

Decisions cited:
T 0491/08, T 1621/09, T 1685/10

Catchword:
Amendment to appellant's case consisting of new inventive step attack not admitted into the proceedings (point 5)

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Case Number: T 1761/10 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 11 April 2013

Appellant: (Opponent II)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 18 June 2010 rejecting the opposition filed against European patent No. 1414316 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman: W. Sieber
Members: M. O. Müller
K. Garnett

Summary of Facts and Submissions

I. This decision concerns the appeal by opponent II (N.V. Nutricia) against the decision of the opposition division to reject the opposition against European patent No. 1 414 316.

II. Opponent I (Friesland Brands B.V.) and opponent II had requested revocation of the patent in its entirety on the grounds that the claimed subject-matter was neither novel nor inventive (Article 100(a) EPC, raised by opponents I and II), that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC, raised by opponent I) and that the patent contained subject-matter which extended beyond the content of the application as filed (Article 100(c) EPC, raised by opponent I).

The documents submitted during the opposition proceedings included:

D1: US 5,821,217 A;

D2: JP 8-59500 A (in its English translation);

D3: S. Teraguchi et al, "Orally Administered Bovine Lactoferrin Inhibits Bacterial Translocation in Mice Fed Bovine Milk", Applied and Environmental Microbiology, 1995, pages 4131 to 4134;

D9: WO 00/2295 A2;

D10: WO 93/20717 A2;

D11: WO 99/56754 A1;

D12: JP 08-291198 A (in its English translation); and

D14: WO 02/15719 A2.

III. The opposition division's decision, announced orally on 19 May 2010 and issued in writing on 18 June 2010, was based on the claims as granted, the sole independent claim of which reads as follows:

"1. The use of whey protein hydrolyzate as the sole source of protein in the preparation of a nutritional composition for preventing bacterial overgrowth, necrotising enterocolitis, and/or bacterial translocation septicemia."

IV. In its decision, the opposition division reasoned essentially as follows:

The claims as granted met the requirements of Article 100(c) EPC. Firstly, there was no difference in scope between the expressions "whey protein hydrolyzate" in claim 1 as granted and "a whey protein hydrolyzate" as disclosed on page 5, line 35 and in claim 4 as filed. Both expressions were directed to the hydrolyzate of whey protein. The use of the indefinite article "a" merely indicated that no particular whey protein hydrolyzate was meant. Hence by omitting the article "a", the scope did not change. Secondly, the feature "as the sole source of protein" inserted into claim 1 was based on page 6, lines 26 to 28 as filed. Although this passage did not explicitly mention that

the protein hydrolyzate was whey protein hydrolyzate, its combination with claim 4 as filed directly led to the subject-matter of claim 1 as granted.

The invention was also sufficiently disclosed.

Furthermore, the subject-matter of the claims as granted was novel. More specifically, novelty over D1 could be acknowledged, as *inter alia* bacterial translocation septicemia as referred to in claim 1 had a narrower meaning than sepsis as disclosed in D1. Novelty over D2 could be acknowledged as the hydrolyzed lactoferrin disclosed therein constituted only a minor constituent of whey protein hydrolyzate and hence was different therefrom. As to practical example 4 of D2, the additional amino acids had to be considered as a source of protein and consequently the use of whey protein hydrolyzate as the sole protein source was not disclosed. D3 was not novelty-destroying either as it did not disclose a whey protein hydrolyzate or its use as the sole source of protein. Also D9 did not disclose the use of whey protein hydrolyzate as the sole source of protein. No health effect was associated with the selection of hydrolyzed whey in D10 and furthermore it was not used as the sole source of protein in the food product. D11 did not disclose whey protein hydrolyzate for the therapeutic indications referred to in claim 1 as granted. In D12 whey protein hydrolyzate was not used as the sole source of protein, eg in the peptide mixture, and was not used for the purpose of claim 1 as granted. As regards D14, the term "sepsis" could not anticipate the more specific therapeutic effect "bacterial translocation septicemia" in claim 1.

Lastly, inventive step could be acknowledged as well. D3 constituted the closest prior art in view of which the objective technical problem was the provision of an alternative composition for preventing bacterial translocation. D3 was silent about combining the milk diet used in this document with whey protein hydrolyzate. The skilled person would not expect the same bactericidal effect when replacing the active component of D3, namely hydrolyzed lactoferrin, with whey protein hydrolyzate, because the content of lactoferrin in whey was very low. Moreover D3 did not suggest preparing a nutritional composition in which whey protein hydrolyzate was used as the sole source of protein. The skilled person had finally no incentive to combine the teachings of D3 and D1 in a way to arrive at the subject-matter of claim 1 as D3 was silent about using whey protein hydrolyzate and lactoferrin was not mentioned in D1.

V. On 13 August 2010, opponent II (hereinafter "the appellant") filed a notice of appeal against the above decision and paid the prescribed fee on the same day. The statement setting out the grounds of appeal was filed on 26 October 2010.

VI. With letter of 9 March 2011, the patent proprietor (hereinafter "the respondent") filed its response to the appeal, which response relied simply on the opposition division's reasoning.

VII. With its communication of 24 July 2012, the board issued its preliminary opinion. The board discussed the requirements of Article 100(c) EPC with respect to the term "whey protein hydrolyzate" and the wording "as the

sole source of protein" in claim 1 as granted. In addition the question of inventive step in view of D3 as closest prior art was addressed.

VIII. In its subsequent letter of 12 February 2013, the respondent maintained its main request that the appeal be dismissed and submitted auxiliary requests 1 to 9 together with

D19: WO 99/13738 A1;

D20: Result of a Google search on "whey protein hydrolyzate";

D21: US 5,691,165 A; and

D22: S. Teraguchi et al, "The Bacteriostatic Effects of Orally Administered Bovine Lactoferrin on Intestinal Enterobacteriaceae of SPF Mice Fed Bovine Milk", Biosci. Biotech. Biochem. 58(3), 1994, pages 482 to 487.

IX. With its letter of 19 March 2013, the appellant submitted

D23: "Bioactive Components in Milk and Diary Products", Y. W. Park (ed.), Wiley-Blackwell, 2009, page 337.

X. Opponent I did not make any written submissions in the present appeal proceedings and did not file any requests.

XI. On 11 April 2013, oral proceedings were held before the board at which opponent I, although duly summoned, was

absent. The appellant maintained its requests previously submitted in writing, namely that the decision under appeal be set aside and the patent be revoked, and that the documents D20 to D22 should not be admitted into the proceedings. Furthermore, a new inventive step attack was made. The respondent maintained its main request that the appeal be dismissed and requested that the appellant's new inventive step attack should not be admitted into the proceedings. After discussion of the claims as granted, the respondent withdrew its auxiliary requests 1 to 9.

XII. The appellant's arguments can be summarized as follows:

The term "whey protein hydrolyzate" in claim 1 as granted did not meet the requirements of Article 100(c) EPC. Claim 1 as filed referred to protein hydrolyzates. However, there existed a difference in meaning between the originally-disclosed plural form "protein hydrolyzates" and the singular form "protein hydrolyzate" in claim 1 as granted. This was even confirmed by the respondent in its letter of 28 November 2005. Also the term "a whey protein hydrolyzate" as used in the application as filed could not support the term "whey protein hydrolyzate" in claim 1 as granted. Again, there was a difference in meaning between the originally-disclosed term "a whey protein hydrolyzate" and the term "whey protein hydrolyzate" in claim 1 as granted. More specifically, the term "a whey protein hydrolyzate" referred to one single component of whey protein hydrolyzate, such as lactoferrin hydrolyzate, while the term "whey protein hydrolyzate" without the indefinite article referred to

the entirety of all components of whey protein hydrolyzate.

Nor was the combination of the above amendment with the requirement as to the sole source of protein based on the application as filed.

The subject-matter of the claims as granted lacked novelty in view of any of D1 to D3, D9 to D12 and D14. In particular, D1 disclosed the therapeutic indication of sepsis which included bacterial translocation septicemia mentioned in claim 1 and which, according to paragraph [0026] of the patent, was furthermore covered by the therapeutic indication "bacterial overgrowth" in this claim. The use of hydrolyzed lactoferrin as disclosed in D2 and D12 anticipated the claimed use of hydrolyzed whey protein, because lactoferrin was a whey protein constituent and was therefore a species of the genus "whey protein hydrolyzate". Furthermore, practical example 4 of D2 was also novelty-destroying. D3 was novelty destroying as, in the same way as for D2, the use of hydrolyzed lactoferrin anticipated the use of hydrolyzed whey protein. As regards D9, the fact that this document did not disclose the use of whey protein hydrolyzate as the sole source of protein was not relevant as according to page 8, lines 24 to 26 of the application as filed, partial replacement by the whey protein was covered by the claims. D10 and D11 disclosed the prevention or treatment of necrotising enterocolitis with a composition which included hydrolyzed whey protein. Finally D14 disclosed the use of whey protein hydrolyzate for preventing or treating sepsis and there was no difference between sepsis in

D14 and bacterial translocation septicemia in the patent.

The subject-matter of the claims as granted was finally not inventive. D3 or product B of the practical example 4 of D2 constituted the closest prior art. As regards D3, the problem was the provision of an alternative nutritional composition for the prevention of bacterial overgrowth without the need to isolate hydrolyzed lactoferrin. The skilled person would deduce from D3 that hydrolyzed lactoferrin was the active component for preventing bacterial overgrowth and this suggested that hydrolyzed whey protein, which contained hydrolyzed lactoferrin, would be equally effective. D3 did also not give the message that it was necessary to always isolate hydrolyzed lactoferrin. It was therefore obvious not to isolate lactoferrin and just to use hydrolyzed whey protein instead. Furthermore the skilled person would deduce from D1 that hydrolyzed whey protein could be used for similar therapeutic indications. Therefore the claimed subject-matter lacked an inventive step over D3 in combination with D1.

As regards product B of practical example 4 of D2 taken as closest prior art, the claimed subject-matter differed therefrom only in that no further amino acids, apart from those contained in hydrolyzed whey protein, were present. The omission of these amino acids was however a matter of simple optimisation. Furthermore, this example proved that the problem addressed by the patent was not solved over the entire scope of claim 1. This attack should be admitted into the proceedings, as it could not have been made previously by the

appellant. More specifically, only after the appellant had learned that the novelty attack in view of D2 did not succeed, could the appellant be expected to make an inventive step attack on the basis of D2.

As to D20 and D21, these documents should not be admitted into the proceedings. It was in particular not disputed that whey protein hydrolyzate was known in the art and hence these documents were not relevant. As to D22, this document could not affect the result established by D3 that hydrolyzed lactoferrin was better than lactoferrin. This document therefore was not relevant and should not be admitted into the proceedings.

XIII. The respondent's arguments can be summarized as follows:

Claim 1 as granted met the requirements of Article 100(c) EPC. The amendment of the term "protein hydrolyzates" in claim 1 as filed to "protein hydrolyzate" was based on page 5, line 35 and claim 4 as filed, which disclosed this term in the singular form. Contrary to the appellant's assertions, the omission of the indefinite article "a" from the disclosure of "a whey protein hydrolyzate" on page 5, line 35 and in claim 4 as filed did not convey any additional technical information. The term "a whey protein hydrolyzate" had the same meaning as the term "whey protein hydrolyzate", namely the hydrolyzate of all the proteins present in whey. Apart from that, the respondent had not confirmed in its letter of 28 November 2005 that there was a difference in meaning between the plural and singular form of protein hydrolyzate. More specifically, according to this

letter, it was the examiner rather than the respondent that made this distinction.

Further, the combination of the definition of the protein hydrolyzate as whey protein hydrolyzate together with the requirement that the hydrolyzate was used as the sole protein source was based on the application as filed. More specifically both features were disclosed as preferred in the application as filed and this preference was confirmed by the only example of the patent, namely DH30.

The claimed subject-matter was also novel. In particular, sepsis as disclosed in D1 was a very broad condition while claim 1 referred to one specific type of sepsis, namely bacterial translocation septicemia. The general disclosure of D2 differed from the claimed subject-matter in that hydrolyzed lactoferrin was used, which was different from hydrolyzed whey protein. Furthermore neither product A nor B of practical example 4 of D1 used whey protein hydrolyzate as the sole protein source. In this respect, the fact that amino acids constituted a protein source was confirmed by page 2, lines 2 to 3 of D1 and page 7, line 24 of D14. As regards D3, this document did not disclose the use of hydrolyzed whey protein and furthermore did not describe the use of hydrolyzed whey protein as the sole protein source. That hydrolyzed whey protein was different from hydrolyzed lactoferrin as disclosed in D3 could be deduced from the opposed patent itself which made a clear distinction between whey protein to be used according to the patent and hydrolyzed lactoferrin as used in the prior art D2 and which used the hydrolyzate of entire whey protein in the only

specific product, DH30. D9 to D11 did not disclose whey protein as an essential component, did not disclose that the whey protein needed to be a hydrolyzate, did not ascribe any activity to whey protein hydrolyzate and finally did not disclose that whey protein hydrolyzate was used as the sole protein source. D12 did not disclose the use of whey protein hydrolyzate and D14 did not disclose any of the claimed medical indications.

The claimed subject-matter was also inventive. D3 constituted the closest prior art as it was the only document that dealt with bacterial overgrowth as central issue. The claimed subject-matter differed from D3 in that hydrolyzed whey protein was used instead of hydrolyzed lactoferrin and in that the hydrolyzed whey was used as the sole protein source. The objective technical problem was the provision of an alternative composition that was at least as effective in the prevention of bacterial overgrowth as mother's milk and that was also easily available. It was demonstrated in the opposed patent that the hydrolyzed whey protein DH30 was equivalent to mother's milk in the prevention of bacterial overgrowth. It was not obvious on the basis of D3 to use hydrolyzed whey protein as the sole protein instead of hydrolyzed lactoferrin to solve this problem. In this respect, the appellant's argument that the skilled person would deduce from D3 that hydrolyzed lactoferrin was the active component for preventing bacterial overgrowth and that this suggested that hydrolyzed whey protein, which contained hydrolyzed lactoferrin, would be equally effective in the prevention of bacterial overgrowth as mother's milk was not convincing. Hydrolyzed lactoferrin and non-

hydrolyzed lactoferrin were equally effective in preventing bacterial overgrowth in D3. Hence, if the appellant's argument was correct, then also non-hydrolyzed whey protein, which contained non-hydrolyzed lactoferrin, would be effective in preventing bacterial overgrowth. But this was not the case, as could be deduced from the experimental data on the non-hydrolyzed whey protein "DH0" in the patent.

The appellant's inventive step attack on the basis of practical example 4 of D2 as closest prior art had never been presented prior to the oral proceedings and thus was filed late. This attack represented a change of case that would make an adjournment of oral proceedings necessary in order to give the respondent enough time to react. Therefore, in line with Article 13(3) RPBA, this attack should not be admitted into the proceedings. The appellant's argument that it could not have been expected that the board would acknowledge novelty over D2 and therefore the appellant could not reasonably have presented this inventive step attack at an earlier point in time was wrong. Novelty had already been acknowledged in the opposition division's decision. Furthermore, the appellant's assertion that the therapeutic effect of claim 1 could not be achieved over the entire scope of the claim in fact did not relate to inventive step but sufficiency of disclosure.

D20 and D21 confirmed the fact that the term "hydrolyzed whey protein" was well known in the art. These documents were therefore highly relevant and should be admitted into the proceedings. D22 firstly showed that a whey protein comprised only about one percent of lactoferrin, secondly it confirmed the

results obtained in the opposed patent for the non-hydrolyzed whey protein DH0, and thirdly it proved that the results obtained in D3 implied that lactoferrin and hydrolyzed lactoferrin were equivalent in terms of their effects on bacterial translocation. This document was thus highly relevant and therefore should be admitted into the proceedings.

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

XV. The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

Main request (claims as granted)

2. *Amendments - Article 100(c) EPC*

2.1 Claim 1 as granted refers to **the use of whey protein hydrolyzate as the sole source of protein** in the preparation of a nutritional composition for preventing bacterial overgrowth, necrotizing enterocolitis, and/or bacterial translocation septicemia.

2.2 Claim 1 as granted differs from claim 1 as filed *inter alia* in that the term "protein hydrolyzates" in claim 1 as filed has been amended to "whey protein hydrolyzate".

2.2.1 This amendment is based on claim 4 as well as on page 5, line 35 of the application as filed, where it is stated

that "the protein hydrolyzate is a whey protein hydrolyzate".

2.2.2 In the appellant's view, this amendment nevertheless did not meet the requirements of Article 100(c) EPC because there was a difference in meaning between the term "a whey protein hydrolyzate" as used in claim 4 and page 5, line 35 as filed and the term "whey protein hydrolyzate" (without the indefinite article "a") in claim 1 as granted. More specifically, the appellant argued that the term "a whey protein hydrolyzate" referred to one single component of whey protein hydrolyzate, such as lactoferrin hydrolyzate, while the term "whey protein hydrolyzate" without the indefinite article referred to the entirety of all components of whey protein hydrolyzate. Hence, claim 4 and page 5, line 35 as filed could not provide a basis for the term "whey protein hydrolyzate" (without the indefinite article "a") in claim 1.

It is indeed true that claim 4 and page 5, line 35 as filed differ from claim 1 as granted in terms of the presence of the indefinite article "a" prior to the term "whey protein hydrolyzate". In the board's view, however, the indefinite article "a" does not convey any additional technical information. As acknowledged by the appellant, whey protein comprises various different types of protein. Hence both "a whey protein hydrolyzate" (as disclosed in claim 4 and page 5, line 35 as filed) and "whey protein hydrolyzate" (as cited in claim 1 as granted) refer to a composition resulting upon hydrolysis of all these different protein components present in whey protein, rather than to only one specific hydrolyzed component of whey.

This interpretation is also supported by the application as filed, which exclusively refers to the hydrolyzate of whey protein and makes a clear distinction to hydrolyzed lactoferrin as used in the prior art (D2) (see page 1, lines 28 to 31 of the application as filed). Also, the only specific hydrolyzed product disclosed in the application as filed, namely DH30, is the hydrolyzate of "intact whey protein" (denoted as "DH0", footnotes 1 and 2 of table 1), ie of all components present in whey. The appellant's argument must therefore fail.

2.2.3 The appellant further argued that the amendment was not allowable under Article 100(c) EPC as there was a difference in meaning between the plural form "protein hydrolyzates" in claim 1 as filed and the singular form "protein hydrolyzate" in claim 1 as granted. The appellant in this respect referred to the respondent's letter of 28 November 2005 where, according to the appellant, the respondent had confirmed that there was a difference in meaning between the plural and singular form.

However, claim 4 as well as page 5, line 35 of the application as filed already form a basis for claim 1 as granted (point 2.2.2 above). It is thus irrelevant whether such a basis is present in claim 1 as filed, in particular as to whether or not there is a difference in meaning between the plural and singular. Apart from this, the appellant's assertion with regard to the respondent's letter is not even correct. More specifically, what the letter in fact says is that the plural form was amended to the singular form **in view of**

an objection raised by the examiner, which by no means implies that it was the respondent's view that a difference in meaning between the plural and singular form existed (see the last sentence of the second paragraph on page 1 of this letter).

2.2.4 In summary, the amendment of "protein hydrolyzates" to "whey protein hydrolyzate" in claim 1 as granted meets the requirements of Article 100(c) EPC.

2.3 Claim 1 as granted has been further amended compared to claim 1 as filed by defining the whey protein hydrolyzate as "the sole source of protein".

2.3.1 This amendment is based on page 6, lines 27 to 28 as filed (*"Preferably, the protein hydrolyzate is the only source of protein of the nutritional composition."*).

2.3.2 The appellant argued that the combination of the above-discussed definition of the protein hydrolyzates as whey protein hydrolyzate together with the requirement that it be the sole source of protein was not based on the application as filed.

2.3.3 The board does not find the appellant's argument convincing. More specifically, there is a clear preference in the application as filed for both the selection of whey protein hydrolyzate and the use as the sole protein source (page 5, line 35: *"Preferably, the protein hydrolyzate is a whey protein hydrolyzate."* (emphasis added); page 6, lines 26-27: *"Preferably, the protein hydrolyzate is the only source of protein of a nutritional composition."* (Emphasis added)). This preference is confirmed by the only example of the

application as filed, in which DH30, ie hydrolyzed whey protein, is used as the sole protein source (page 11, line 6 to page 12, line 3 and in particular table 1 which discloses DH30 as the only protein source). There is thus a clear pointer in the application as filed to the combination of the two features of claim 1 as granted. This combination is therefore clearly and unambiguously derivable from the application as filed. The requirements of Article 100(c) EPC are thus met for this amendment as well.

2.4 The appellant did not raise any further objections under Article 100(c) EPC and the board is satisfied that this article does not prejudice the maintenance of the opposed patent as granted.

3. *Novelty*

3.1 Novelty was attacked by the appellant on the basis of each of D1 to D3, D9 to D12, and D14.

3.2 D1 discloses a method of minimising the risk of pulmonary aspiration and/or gastrointestinal dysfunction in critically ill patients due to eg sepsis by administering a certain enteral formulation containing protein hydrolyzate such as whey protein hydrolyzates (column 2, lines 20 to 23, column 3, lines 62 to 65 and column 4, line 41).

3.2.1 D1 does not disclose the therapeutic effects to be achieved according to claim 1 as granted.

In this respect, the appellant's argument that sepsis as disclosed in D1 anticipates the therapeutic effect

of "bacterial translocation septicemia" in claim 1 is not convincing. More specifically, sepsis is a condition that can result from many different causes, of which the claimed therapeutic condition of bacterial translocation septicemia is only one example. According to established case law of the boards of appeal, a broad generic term, such as sepsis, cannot take away the novelty of one specific embodiment covered by this broad term.

The appellant further argued that according to paragraph [0026] of the opposed patent, the therapeutic effect of bacterial overgrowth as referred to in claim 1 covered septicemia and that this was equivalent to sepsis as disclosed in D1. However, the only septicemia disclosed in the opposed patent is bacterial translocation septicemia and it is this type of septicemia to which claim 1 in fact is restricted. Therefore, it is clear to the skilled reader that the term "septicemia" in paragraph [0026] of the patent refers to bacterial translocation septicemia. Contrary to the appellant's assertion, it can therefore not be derived from this paragraph that the therapeutic condition "bacterial overgrowth" in claim 1 covers sepsis in general terms as disclosed in D1.

3.2.2 The subject-matter of claim 1 as granted, and by the same token that of dependent claims 2 to 5 as granted, is therefore novel in view of D1.

3.3 D2 (claim 1) discloses the use of hydrolyzed lactoferrin for the prevention of bacterial translocation septicemia ("BT" in D2).

3.3.1 The appellant argued that lactoferrin is a component of whey and hence the disclosure of hydrolyzed lactoferrin in D2 anticipated "whey protein hydrolyzate" as referred to in claim 1. This argument is however not convincing. As has been set out above, the term "whey protein hydrolyzate" refers to the hydrolyzate of all protein components present in whey rather than to the hydrolyzate of only one component thereof, let alone to hydrolyzed lactoferrin, which is present in whey protein in an amount of only about 1%. This was indeed confirmed by the appellant on page 2 of its letter dated 26 October 2010, where it was stated that "lactoferrin hydrolyzate is a species of the genus whey protein hydrolyzate". Consequently, there is a clear difference between hydrolyzed lactoferrin and hydrolyzed whey protein. The use of hydrolyzed lactoferrin for the prevention of bacterial translocation septicemia as disclosed in D2 is therefore not novelty-destroying for the use of hydrolyzed whey protein in this context.

3.3.2 In addition to the use of hydrolyzed lactoferrin, D2 also discloses the use of whey protein hydrolyzate to treat bacterial translocation septicemia in practical example 4. According to the appellant, this disclosure was novelty-destroying to the subject-matter of claim 1 as well.

In the first part of practical example 4 of D2 (in particular paragraph [0053]), hydrolyzed whey protein ("intermediate product powder") is mixed with hydrolyzed lactoferrin ("peptide mixture powder" produced in practical example 3) and an amino acid mixture powder to form "nutrition product A". In the

second part of practical example 4, hydrolyzed whey protein ("intermediate product powder" and "whey protein enzymatic decomposition product") is mixed with an amino acid mixture powder to form "nutrition product B".

Neither nutrition product A nor nutrition product B of practical example 4 uses whey protein hydrolyzate **as the sole protein source**. More specifically, both nutritional products A and B additionally contain *inter alia* amino acids, which are an additional source of protein (see column 2, lines 2 to 3 of D1: *"... all of the protein in the form of free amino acids"* and page 7, lines 24 to 25 of D14: *"Further, if desired, the protein source may further include minor amounts of free amino acids."*).

Consequently, the nutritional products A and B disclosed in practical example 4 of D2 are not novelty-destroying for the claimed subject-matter either.

3.3.3 Therefore, the claimed subject-matter is also novel in view of D2.

3.4 D3 investigates the effect of supplementing a bovine milk diet with lactoferrin ("bLF") or its hydrolyzate ("bLFH") on bacterial translocation from the intestines of mice to organs (mesenteric lymph nodes) and bacterial overgrowth in their guts.

The subject-matter of claim 1 differs from D3 in that whey protein hydrolyzate rather than lactoferrin hydrolyzate is used and in that the whey protein hydrolyzate is used as the sole source of protein. In

D3 the lactoferrin or lactoferrin hydrolyzate is used together with milk, which is an additional source of protein.

The claimed subject-matter is thus novel over D3.

3.5 D9 discloses an isolated protein having no O-glycosylation and at least 70% homology of amino acid sequence with human serum CD14 (claim 1). Also disclosed is the use of this CD14 variant in a composition for the treatment or prevention of eg intestinal bacterial overgrowth, necrotising enterocolitis and bacterial translocation from the gut to other compartments of the body (page 9, line 31 to page 10, line 5 and claim 17). The further components of the composition are those conventionally added to infant formulae or enteral products (page 9, lines 11 to 15), and include proteins, carbohydrates, fats, minerals and vitamins (page 10, line 10 to page 11, line 24). An example of the proteins, which can be in the form of an intact or hydrolyzed isolate or concentrate, is whey protein (page 10, lines 12 to 15).

Contrary to claim 1 as granted, the whey protein or its hydrolyzate are not the sole protein source in D9, but are in admixture with the CD14 protein variant.

The appellant argued in this respect that the application as filed disclosed the possibility that the whey protein hydrolyzate can be a **partial** replacement of the protein of a food product and hence can be present in addition to other proteins. This is however irrelevant to the novelty of the subject-matter of claim 1 as granted, as this claim no longer covers

embodiments in which the proteins are only partially replaced by whey protein hydrolyzate. More specifically, according to claim 1 as granted, whey protein hydrolyzate is used as the sole protein source.

The claimed subject-matter is therefore novel over D9.

3.6 D10 (claim 1) refers to a food product for providing nutritive value to an infant comprising one or more components selected from the group consisting of a protein source, a carbohydrate source, a vitamin source, a source of medium-chain fatty acids, and a mineral source, and which is devoid of free fatty acids containing 16 to 22 carbon atoms and of triglycerides of said fatty acids or comprises either or both of such acids and such triglycerides in amounts insufficient to damage the intestinal epithelium of an infant (claim 1). The protein source may be casein, salts of casein, whey protein concentrate, soybean protein isolate, cow's milk protein or hydrolyzed whey or casein protein (first sentence of the paragraph bridging pages 5 and 6). The proteins may be used in combination (last sentence of the paragraph bridging pages 5 and 6). The food product is effective in preventing necrotizing enterocolitis (paragraph bridging pages 1 and 2).

In order to arrive at the subject-matter of claim 1 on the basis of D10, a multiple selection is necessary, namely:

(a) the selection of a protein source as an additional component,
(b) the selection of hydrolyzed whey protein to be this protein source, and

(c) the selection of this hydrolyzed whey protein as the sole protein source of the composition.

This multiple selection is not disclosed in D10. The claimed subject-matter therefore is also novel in view of this document.

3.7 D11 (claim 3) discloses a nutritional composition comprising at least one fucose residue in an α1-2 linkage, at least one protein not found in human breast milk, and at least one member selected from the group consisting of edible fat, a carbohydrate, a protein, a vitamin and a mineral. The protein may be soy protein, electrodialyzed whey, electrodialyzed skim milk, milk whey, or hydrolyzates of these proteins (sentence bridging pages 12 and 13). The composition may be used for the treatment or prevention of diarrhea, enterocolitis or necrotic enterocolitis (page 13, lines 16 to 18).

D11 discloses nowhere a composition containing hydrolyzed whey as the sole protein source. On the contrary, as set out above, the composition contains at least a further protein not found in human breast milk. Irrespective of this, a multiple selection is needed in order to arrive at the remaining features of claim 1 on the basis of D11, namely of a composition containing hydrolyzed whey protein as additional component, and its use for the prevention of necrotic enterocolitis. Such a double selection is not disclosed in D11. The claimed subject-matter therefore is also novel in view of D11.

3.8 D12 refers to a "sugar chain peptide mixture of the lactoferrin origin" which is effective in the prevention of diseases such as bacterial enteritis and septicemia (first paragraph on the second page of D12). D12 discloses nowhere the use of hydrolyzed whey protein as the sole protein source to achieve the therapeutic effects required by claim 1. The claimed subject-matter therefore is also novel in view of D12.

3.9 D14 discloses the use of a nutritional composition comprising hydrolyzed whey protein, also as the sole protein source, for the treatment of conditions such as sepsis, injury, burns, inflammation, malnutrition, cystic fibrosis, malignancy, chronic inflammatory bowel diseases, ulcerative colitis and Crohn's disease (claims 1 and 2 in conjunction with page 12, lines 3 to 26). None of the therapeutic conditions to be treated according to claim 1 of the opposed patent is disclosed in D14. The appellant in this respect argued again that the treatment of sepsis as disclosed in D14 anticipated the therapeutic conditions of claim 1. However, for the same reasons as given above (point 3.2.1) with regard to D1, this argument must fail. The claimed subject-matter therefore is also novel in view of D14.

4. *Inventive step*

4.1 The invention concerns the use of a nutritional composition preventing bacterial overgrowth, bacterial translocation and linked therewith necrotising enterocolitis and bacterial translocation septicemia (paragraph [0001]).

4.2 D3 is a scientific article about a study investigating bacterial overgrowth in the guts of mice as well as bacterial translocation from the intestines of mice to their organs caused by the feeding of bovine milk (abstract). D3 thus lies in the same technical field and has the same objective as the opposed patent. As acknowledged by both parties and the opposition division, D3 can therefore be considered to represent the closest prior art.

In a first experiment of D3, the milk feeding of four-week old mice was supplemented with bovine lactoferrin ("bLF") or its hydrolyzate ("bLFH"). Faeces were collected from each mouse and the number of certain bacteria in the faeces was determined. It was observed that when the bovine milk was supplemented with lactoferrin or hydrolyzed lactoferrin, the number of certain bacteria in the faeces decreased significantly implying a reduction in the tendency for bacterial overgrowth (left-hand column and table 1 on page 4132).

In a second experiment, the milk feeding of mice was supplemented with lactoferrin, hydrolyzed lactoferrin or sodium casein as a control protein. After receiving this feeding for 7 days, the mice were killed, their organs were removed and the number of translocated bacteria in the organs was determined. It was found that the addition of lactoferrin or hydrolyzed lactoferrin to bovine milk resulted in a significant decrease in the incidence of bacterial translocation while the addition of the control protein sodium casein to bovine milk did not show this effect (table 2 and first paragraph of the left-hand column on page 4133).

4.3 The problem underlying the patent in suit in the light of D3 is the provision of an easy-to-produce nutritional composition which is equally effective as mother's milk in the prevention of bacterial overgrowth and linked therewith necrotising enterocolitis and bacterial translocation septicemia (paragraphs [0001], [0009] and [0026] in conjunction with paragraph [0010] of the patent; for simplicity, reference in the following will be made exclusively to bacterial overgrowth in this context).

4.4 As a solution to this problem the patent in suit proposes the use according to claim 1, which is characterised in that whey protein hydrolyzate is used as the sole protein source. As has been set out above (point 3.4), D3 neither discloses the use of hydrolyzed whey protein nor its use as the sole protein source.

4.5 In the experiments described in the opposed patent, four-days old rats were fed with non-hydrolyzed intact whey protein ("DH0"), hydrolyzed whey protein ("DH30") and mother's milk ("MF"). After 14 days, the rats were killed, the gastrointestinal tract was removed and the bacterial flora thereof was analysed. The results of this analysis are shown in figures 2 to 4 with the white, black and grey bars corresponding to the results obtained by mother's milk feeding, feeding with non-hydrolyzed whey protein, and feeding with hydrolyzed whey protein, respectively. As can be deduced from these figures, the numbers of bacteria in the small intestine (Jejunum and Ileum) is equally low for rats fed with mother's milk and hydrolyzed whey protein, respectively. This implies that both mother's milk and

hydrolyzed whey protein are equally effective in the prevention of bacterial overgrowth from the colon (cecum) to the small intestine (see conclusions in paragraph [0068] of the opposed patent).

Furthermore, whey protein is conventionally available as a by-product of cheesemaking while lactoferrin needs to be isolated from whey protein by an additional isolation process. Consequently, hydrolyzed whey protein is easy to produce compared to hydrolyzed lactoferrin.

The above problem thus has been credibly solved.

Since the problem identified in the patent in suit is defined in view of the correct closest prior art and this problem is solved, this "subjective" problem constitutes also the "objective" technical problem.

4.6 It must be examined whether the claimed solution to this problem, namely the use of hydrolyzed whey protein as the sole protein source, was obvious on the basis of D3.

4.6.1 D3 does not contain any suggestion that the use of hydrolyzed whey protein as the sole protein source can prevent bacterial overgrowth in the same way as mother's milk, which is the "gold standard" in the field. More specifically, D3 refers to the supplementation of bovine milk with lactoferrin or hydrolyzed lactoferrin to prevent bacterial overgrowth caused by the bovine milk. This is different from the objective technical problem of finding an easy-to-produce nutritional composition that is equally

effective in the prevention of bacterial overgrowth as mother's milk.

The appellant argued in this respect that the skilled person would deduce from D3 that hydrolyzed lactoferrin is the active component for preventing bacterial overgrowth and that this suggested that hydrolyzed whey protein, which contains hydrolyzed lactoferrin, would be effective as well. This argument is however not convincing. As can be deduced from table 1 of D3, hydrolyzed lactoferrin and non-hydrolyzed lactoferrin are nearly equally effective in preventing bacterial overgrowth (compare the fourth and fifth column from the left of table 1). Hence, if the appellant's argument were correct, then also non-hydrolyzed whey protein, which contains non-hydrolyzed lactoferrin, would be effective in preventing bacterial overgrowth. However, the opposite is true, as can be deduced from the opposed patent. More specifically, the non-hydrolyzed whey protein "DH0" in the opposed patent, which contains non-hydrolyzed lactoferrin, is not effective in preventing bacterial overgrowth (black columns in figures 2 to 4). Consequently, the alleged simple correlation between the activity of hydrolyzed lactoferrin as disclosed in D3 on the one hand and that of hydrolyzed whey protein on the other does not exist.

It was thus not obvious on the basis of D3 that hydrolyzed whey protein would be effective in the prevention of bacterial overgrowth, let alone that it would be equally effective as mother's milk.

4.6.2 The appellant argued that the skilled person starting from D3 would know from D1 that hydrolyzed whey protein

could be used to treat sepsis, which was similar to the therapeutic indications in the opposed patent. It was thus obvious to use hydrolyzed whey protein instead of the hydrolyzed lactoferrin in D3.

However, as set out above, sepsis as disclosed in D1 covers various different embodiments of which the bacterial translocation septicemia as referred to in claim 1 is only one specific example. There is no indication in D1 that hydrolyzed whey protein could be used to treat this specific condition, let alone that any suggestion is present that hydrolyzed whey protein would be equally effective as the gold standard of mother's milk. Therefore, also in view of D3 in combination with D1, the claimed invention was not obvious.

4.7 The claimed subject-matter therefore is inventive.

5. *Admissibility of the appellant's new inventive step attack*

5.1 During the oral proceedings before the board, the appellant for the first time raised an inventive step objection starting from product B of practical example 4 of D2 as closest prior art. The appellant in particular argued that the claimed subject-matter differed from this practical example only in that no further amino acids (apart from those contained in hydrolyzed whey protein) were present, and that the omission of these amino acids was a matter of simple optimisation. The appellant also argued that this example proved that the problem addressed by the patent was not solved over the entire scope of claim 1.

The respondent requested that this attack not be admitted into the proceedings.

5.2 During the opposition proceedings, the parties exclusively relied on D3 as closest prior art and it was also this document that was used as closest prior art by the opposition division in its decision on inventive step. Also in its statement of grounds of appeal, the appellant did not challenge the opposition division's choice of D3 as closest prior art. In its preliminary opinion, the board followed the parties' and the opposition division's approach using D3 as closest prior art. Also in the written proceedings subsequent thereto, neither of the parties objected to this selection of the closest prior art.

5.3 In view of this, the appellant's new inventive step attack based on product B of practical example 4 of D2 as closest prior art came as a complete surprise to both the respondent and the board. This attack, even though being based on evidence (D2) already on file at the start of the opposition proceedings, represented an amendment to the appellant's case that should only be introduced into the proceedings at the discretion of the board under Article 13 RPBA (T 1621/09 of 22 September 2011, not published in OJ EPO, point 37(a)).

5.4 The appellant argued in this respect that its argument was that the claimed subject-matter lacked novelty in view of D2. Only after it was clear that this attack would not succeed before the board was it reasonable to have expected the appellant to make an inventive step

attack on the basis of this document. However, novelty over D2 had already been acknowledged in the opposition division's decision. Consequently the appellant should have envisaged the possibility that the novelty attack on the basis of D2 would not be successful in appeal either and should have submitted its inventive step attack on the basis of D2 with the statement of grounds of appeal. The appellant's argument in this respect is therefore not convincing.

5.5 The appellant's attack also raises complex new issues. First of all it would involve examining whether the skilled person would indeed start from product B of practical example 4 of D2 as closest prior art, in particular in view of the fact that this example is the only example using whey protein hydrolyzate, while the remaining part of D2 focuses on the use of hydrolyzed lactoferrin. Furthermore it would have to be analysed whether the omission of additional amino acids is indeed a simple matter of optimization as asserted by the appellant.

Lastly, it would have to be analysed whether this practical example of D2 could indeed establish that the problem addressed by the opposed patent was not solved over the entire scope of claim 1 and whether this would be a matter to be discussed under inventive step. The board notes in this context that the problem addressed by the opposed patent corresponds to the therapeutic effects to be achieved according to the claims and that the question whether these effects can indeed be achieved is a matter of sufficiency of disclosure rather than inventive step (see T 1685/10 of 6 June

2011, point 3.1 and T 491/08 of 21 October 2010, point 6, neither of which published in OJ EPO).

In view of these complex new issues, the oral proceedings would have had to have been adjourned in order to give the board and the respondent sufficient time to address these issues. Therefore, pursuant to Articles 13(1) and (3) RPBA, the board decided not to admit the amendment to the appellant's case based on this new attack.

6. *Admissibility of D20 to D22*

6.1 By its letter of 12 February 2013, the respondent submitted D20 to D22, arguing that these documents were highly relevant and therefore should be admitted into the proceedings. The appellant requested that these documents should not be admitted into the proceedings.

6.2 By being filed only two months prior to the oral proceedings before the board, these documents are filed late.

6.3 D20 is a printout of the result of a search carried out by the respondent using Google for articles published up to 2001 which included the term "whey protein hydrolyzate" and D21 is one of the results found by this search. According to the respondent, the two documents were highly relevant since they showed that the term "whey protein hydrolyzate" was well understood in the art. This was however not disputed by the appellant. Hence, D20 and D21 are not relevant.

The board therefore decided not to admit these documents into the proceedings.

6.4 In the respondent's view, D22 was highly relevant as regards inventive step since, firstly, it showed that a whey protein comprises only about one percent of lactoferrin, secondly, it confirmed the results obtained in the opposed patent for the non-hydrolyzed whey protein DH0 and, thirdly, it proved that the results obtained in D3 implied that lactoferrin and hydrolyzed lactoferrin were equivalent in terms of their effects on bacterial translocation. The first and second points were however not disputed by the appellant and there is thus no need to refer to D22 as regards these issues. As to the third point, D3 is a study on its own on the effects of lactoferrin and hydrolyzed lactoferrin and the board does not see how the results obtained in D3 could be changed by any results obtained in the different study D22.

The board therefore decided not to admit D22 into the proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Cañueto Carbajo W. Sieber