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Datasheet for the decision of 13 October 2015

Case Number: T 0767/13 - 3.3.09

Application Number: 06733070.4

Publication Number: 1871181

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Language of the proceedings: EN

Title of invention:
NUTRITIONAL SUPPLEMENT FOR HIV PATIENTS

Patent Proprietor:
N.V. Nutricia

Opponent:
Fresenius Kabi Deutschland GmbH

Headword:

Relevant legal provisions:
RPBA Art. 12(4), 13(1)
EPC Art. 84, 83, 56

Keyword:
"Auxiliary request 1 - clarity (no)"
"Auxiliary request 2 - admitted (no)"
"Auxiliary request 3 - sufficiency (yes), inventive step (yes)"

Decisions cited:

Catchword:

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Case Number: T 0767/13 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 13 October 2015

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
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Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 16 January 2013 concerning the maintenance of European patent No. 1871181 in amended form.**

Composition of the Board:

Chairman	W. Sieber
Members:	J. Jardón Álvarez
	D. Prietzel-Funk

Summary of Facts and Submissions

I. This decision concerns the appeals filed by the patent proprietor and the opponent against the interlocutory decision of the opposition division that European patent EP-B-1 871 181, as amended, meets the requirements of the EPC.

II. The opponent had requested revocation of the patent in its entirety on the grounds of Article 100(a) (lack of novelty and inventive step), (b) and (c) EPC.

The documents cited during the opposition proceedings included:

D1: WO 2005/039597 A2;

D2: WO 2005/122790 A1;

D5: US 2003/0124198 A1;

D7: G. Lynch *et al.*, "Sulfated polyanions prevent HIV infection of lymphocytes by disruption of the CD4-gp120 interaction, but do not inhibit monocyte infection", Journal of Leukocyte Biology, 1994, 56, pages 266 to 272; and

D8: H. Liu *et al.*, "Multiple and multivalent interactions of novel anti-AIDS drug candidates, sulfated polymannuronate (SPMG)-derived oligosaccharides, with gp120 and their anti-HIV activities", Glycobiology, 2005, 15(5), pages 501 to 510.

III. The opposition division's decision was based on a main request and auxiliary requests 1 to 3 and can be summarised as follows:

- The subject-matter of claim 1 of the main request did not comply with the requirements of Article 123(2) EPC;

- The feature "wherein the cysteine and/or source of cysteine provide at least 100 mg cysteine equivalent in a daily dose" in claims 9 and 10 of auxiliary request 1 lacked clarity;

- The subject-matter of claim 1 of auxiliary request 2 lacked novelty in view of the disclosure of both D1 and D2; and

- The claims of auxiliary request 3 fulfilled all the requirements of the EPC.

IV. Auxiliary request 3 as maintained by the opposition division contained nine claims. Independent claims 1, 7 and 8 read as follows:

"1. Use of one or more acid and neutral oligosaccharides and cysteine and/or source of cysteine, in the manufacture of a composition for the treatment of HIV or AIDS in a mammal, said composition comprising a therapeutically effective amount of acid and neutral oligosaccharides wherein the acid oligosaccharides are prepared from pectin, pectate, alginate, chondroitine, hyaluronic acids, heparine, heparane, sialoglycans, fucoidan, fucooligosaccharides or carrageenan and the neutral oligosaccharide is selected from the group consisting of galactooligosaccharide, fructooligosaccharide,

transgalactooligosaccharide, xylooligosaccharide, lactosucrose and arabinooligosaccharides, and wherein said source of cysteine is N-acetylcysteine, whey, colostrum, egg proteins or a combination thereof or diacetylcysteine, wherein the composition further comprises polyunsaturated fatty acids (PUFA), and wherein the PUFA comprises at least 20% GLA plus EPA, based on the total fatty acid content."

"7. A food composition comprising between 15 and 50 en% lipid, between 25 and 60 en% protein, between 15 and 45 en% carbohydrate, acid oligosaccharide prepared from pectin, pectate, alginate, chondroitine, hyaluronic acids, heparine, heparane, sialoglycans, fucoidan, fucooligosaccharides or carrageenan, preferably pectin hydrolysate and neutral oligosaccharide selected from the group consisting of galactooligosaccharide, fructooligosaccharide, transgalactooligosaccharide, xylooligosaccharide, lactosucrose and arabinooligosaccharides, and cysteine or NAC, whey, colostrum, egg proteins or combinations thereof, wherein said lipid comprises GLA."

"8. A food composition comprising between 15 and 50 en% lipid, between 35 and 60 en% protein, between 15 and 45 en% carbohydrate, acid oligosaccharide prepared from pectin, pectate, alginate, chondroitine, hyaluronic acids, heparine, heparane, sialoglycans, fucoidan, fucooligosaccharides or carrageenan, preferably pectin hydrolysate and neutral oligosaccharide selected from the group consisting of galactooligosaccharide, fructooligosaccharide, transgalactooligosaccharide, xylooligosaccharide, lactosucrose and arabinooligosaccharides, and cysteine or NAC, whey, colostrum, egg proteins or combinations thereof, wherein said lipid comprises GLA."

Claims 2 to 6 and 9 were dependent claims.

V. On 26 March 2013 both the patent proprietor and the opponent lodged an appeal against this decision.

As the patent proprietor and the opponent are respectively the appellant and the respondent in these proceedings, for simplicity the board will continue to refer to them as the patent proprietor and the opponent.

VI. In its statement of grounds of appeal filed on 24 May 2013, the patent proprietor requested maintenance of the patent on the basis of a main request corresponding to to its main request in the opposition proceedings or, alternatively, on the basis of newly filed auxiliary requests 1 to 4.

VII. In its statement of grounds of appeal filed on 27 May 2013, the opponent requested that the decision under appeal be set aside and that the patent be revoked in its entirety. It also filed the following documents:

D14: Printout from the homepage of www.livestrong.com, "Does whey protein promote yeast infections?" (1 page);

D15: F.V.K. Young, "The Chemical & Physical Properties of Crude Fish Oils for Refiners & Hydrogenators", Fish Oil Bulletin No. 18, 1986, pages i to vi and 1 to 18;

D16: M. Clément *et al.*, "Purification and Identification of Bovine Cheese Whey Fatty Acids

Exhibiting In Vitro Antifungal Activity", J. Dairy Sci. 2008, 91, pages 2535 to 2544;

D17: US 2004/0077590 A1;

D18: WO 99/64022 A1;

D19: G. Bounous *et al.*, "Immunoenhancing Property of Dietary Whey Protein in Mice: Role of Glutathione", Clinical and Investigative Medicine, 1989, 12(3), pages 154 to 161;

D20: P. K. Gopal *et al.*, "Oligosaccharides and glycoconjugates in bovine milk and colostrum", British Journal of Nutrition (2000), 84, Suppl. 1. pages S69 to S74; and

D21: EP 0 626 177 A2.

VIII. Replies to the respective statements of grounds of appeal were filed by the opponent on 12 September 2013 and by the patent proprietor on 3 October 2013. The patent proprietor filed a further auxiliary request, namely auxiliary request 5, and also requested to be allowed to correct the word "colostrums" to read "colostrum" in claim 2 of all the requests.

IX. In response to the board's communication, issued on 8 May 2015 in preparation for the oral proceedings, the patent proprietor withdrew the former main request and auxiliary requests 3 and 5, renumbered former auxiliary requests 1, 2 and 4 as main request and auxiliary requests 1 and 3, and filed new auxiliary requests 2 and 4.

X. At the beginning of the oral proceedings held on 13 October 2015, the patent proprietor withdrew its main request. Later in the proceedings, the opponent withdrew its clarity objection to the word "colostrums" in claim 2 of the third auxiliary request and, in reaction thereto, the patent proprietor withdrew its request to amend claim 2 to deal with this objection.

The claims relevant for the present decision are claim 7 of auxiliary request 1 and auxiliary request 2 and the claims of auxiliary request 3.

Claim 7 of auxiliary request 1 reads as follows:

"7. A food composition comprising between 15 and 50 en% lipid, between 25 and 60 en% protein, between 15 and 45 en% carbohydrate, acid oligosaccharide prepared from pectin, pectate, alginate, chondroitine, hyaluronic acids, heparine, heparane, sialoglycans, fucoidan, fucooligosaccharides or carrageenan, preferably pectin hydrolysate and neutral oligosaccharide selected from the group consisting of galactooligosaccharide, fructooligosaccharide, transgalactooligosaccharide, xylooligosaccharide, lactosucrose and arabinooligosaccharides, and cysteine or NAC, whey, colostrum, egg proteins or combinations thereof, wherein the composition comprises at least 25 en% of a fat blend comprising n-3 and/or n-6 fatty acids."

Claim 7 of auxiliary request 2 is based on claim 7 of auxiliary request 1, wherein the feature:

"wherein the composition comprises at least 25 en% of a fat blend comprising n-3 and/or n-6 fatty acids"

has been replaced by the feature:

"wherein said lipid comprises EPA and/or GLA."

The claims of auxiliary request 3 are the claims maintained by the opposition division (see above point IV).

XI. The arguments presented by the patent proprietor, insofar as they are relevant for the present decision, may be summarised as follows:

- The wording "at least 25 en% of a fat blend comprising n-3 and/or n-6 fatty acids" at the end of claim 7 of auxiliary request 1 automatically limited the energy percentage (15-50%) of the lipid mentioned at the beginning of the claim to values between "25 and 50 en%". In the field of the patent no distinction was made between "fat" and "lipid". The subject-matter of claim 7 was therefore clear.

- The subject-matter of auxiliary request 2 had not been deliberately abandoned during the opposition proceedings. In fact, its subject-matter had been discussed during the opposition proceedings. In any case, auxiliary request 2 had been filed one month before the oral proceedings and merely combined granted claims and should therefore be admitted into the appeal proceedings.

- Example 1 of the patent rendered plausible that acid and neutral oligosaccharides provided a treatment for HIV/AIDS. Moreover, there was no experimental evidence on file showing that an embodiment of the invention would not work.

Therefore, the invention, as claimed in all requests, was sufficiently disclosed.

- Documents D17, D18 and D20 should not be admitted into the proceedings because none of them was *prima facie* relevant.

- The claims of auxiliary request 3 involved an inventive step. The patent was directed to the provision of a composition that was effective in the treatment of HIV or AIDS in a mammal. D18, relied upon by the opponent, was directed to a composition comprising whey, FOS and colostrum for the maintenance of a healthy intestinal flora and for enhancement of the immune system, not for the treatment of HIV or AIDS. D18 did not disclose an anti-HIV/AIDS activity of neutral oligosaccharides. Even if D8 and D17 disclosed such activity, there was no reason for the skilled person to combine these two documents with D18. Additionally, no polyunsaturated fatty acids were present in the compositions of D18.

XII. The relevant arguments of the opponent may be summarised as follows:

- Claim 7 of auxiliary request 1 was fundamentally unclear because it required on the one hand between 15 and 50 en% lipid and on the other at least 25 en% of a fat blend. The skilled person would not know if a given composition would fall within the scope of the claim or not.

- Auxiliary request 2 should not be admitted into the proceedings because it related to subject-matter already filed during the opposition

proceedings and then abandoned. Moreover, the request had been filed at a late stage in the appeal proceedings.

- There was no information in the patent that the claimed compositions were indeed effective in treating HIV or AIDS, the only example in the specification related to a binding experiment. In any case, there was no information that the invention was sufficiently disclosed over the breadth of the subject-matter claimed.

- Documents D17, D18 and D20 should be admitted into the proceedings because they were filed as a direct reaction to the reasoning of the opposition division. Moreover they were *prima facie* pertinent.

- The claimed subject-matter lacked inventive step, starting from D18 as closest prior art in combination with D10 and the general knowledge of the skilled person. The efficacy of acid and neutral oligosaccharides for the treatment of HIV was already known to the skilled person from the disclosure of D7, D8 and D17. In any case, there was no information on file of any synergistic effect. The composition resulted from the combination of components already well known in the field of nutritional compositions.

XIII. The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of one of auxiliary requests 1 to 4, all filed with letter dated 7 September 2015.

The opponent requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

Reasons for the Decision

AUXILIARY REQUEST 1

1. Amendments - Clarity

1.1 Claim 7 of auxiliary request 1 is based on granted claim 10 and has been further limited by adding at the end of the claim the feature "wherein the composition comprises at least 25 en% of a fat blend comprising n/3 and or n/6 fatty acids". The amendment is supported by the disclosure of page 15, lines 8 to 12 of the application as filed.

1.2 Thus, claim 7 is now directed to a food composition comprising on one side between 15 and 50 en% (energy percentage) lipid and on the other side at least 25 en% of a fat blend.

1.3 The patent proprietor argued that, although the claim might be not perfectly drafted, it was clear that the lower limit of 25 en% of the fat blend also restricted the lower limit of the energy percentage for the lipid. The terms "fat" and "lipid" were used synonymously in the application as filed so that the skilled reader would understand that in the claim the energy percentage of lipid/fat was restricted in a "cascade" manner.

1.4 The board cannot accept that the terms "fat" and "lipid" are used synonymously in the application as filed. There is no statement whatsoever to this effect

in the application as filed. In fact, fats (triglycerides) are a subgroup of lipids, which encompass other substances, such as waxes, sterols and phospholipids.

Nevertheless, the board can accept that the introduction of the lower limit of 25 en% for the fat blend automatically restricts the energy percentage of (total) lipid in the claim. If there are at least 25 en% of a fat blend in the food composition, this inevitably restricts also the lower limit of the energy percentage for (total) lipids. In other words, if no other lipid but the fat blend is in the food composition, then the lower limit of at least 25 en% for the fat blend is also the lower limit of (total) lipids. If, in addition to the fat blend, other lipids are present, the lower limit would still be above 25 en%, namely 25 en% plus the contribution of the other lipids.

1.5 However, the use of the different terms "fat" and "lipid" in the same context leads to an inconsistency with at least one other claim of auxiliary request 1. As pointed out by the board at the oral proceedings, according to the amendment in claim 7 the **fat blend** comprises n-3 and/or n-6 fatty acids. But claim 9 of auxiliary request 1 states that the **lipid** comprises EPA and/or GLA (EPA and GLA being a n-3 and n-6 polyunsaturated fatty acid, respectively). Claim 9 reads as follows:

"A food composition comprising [*sic*] according to claim 7 or 8, wherein said lipid comprises EPA and/or GLA."

Since lipid is broader in scope than fat, the question arises as to where the n-3 and/or n-6 fatty acids actually have to be, (a) in the fat/triglycerides as required by claim 7 (normally as part of the triglyceride itself because a triglyceride is an ester derived from glycerol with three fatty acids) or (b) in another subgroup of lipid, which is still possible according to claim 9. Therefore, the amendment to claim 7 gives rise to an objection under Article 84 EPC in the context of dependent claim 9.

1.6 It may well be that sometimes the terms "fat" and "lipid" are used synonymously, but it is not apparent that this is the case here. As set out above, the application as filed contains no indication in this respect. The sloppy use of terms cannot, in the board's view, work to the advantage of the patent proprietor when it comes to the amendment of a granted claim.

1.7 Auxiliary request 1 therefore does not meet the requirements of Article 84 EPC.

AUXILIARY REQUEST 2

2. Admissibility

2.1 Auxiliary request 2 was filed at a late stage in the appeal proceedings, namely one month before the oral proceedings. The opponent objected to its admissibility basically because the patent proprietor had prevented the opposition division from giving a reasoned decision on the critical issues, thereby compelling the board of appeal either to give a first ruling on those issues or to remit the case to the opposition division.

2.2 As pointed out by the opponent, claim 7 of auxiliary request 2 was filed for the first time on 19 December 2011, with the reply to the notice of opposition, as claim 10 of the then main request. This request was later abandoned as a reaction to the preliminary opinion of the opposition division wherein, *inter alia*, it was stated that the subject-matter of claim 10 of the main request lacked novelty in view of both D1 and D2.

2.3 Thus, the patent proprietor voluntarily withdrew or abandoned the subject-matter of claim 7 of present auxiliary request 2, with the effect that no reasoned decision was given by the opposition division on its patentability.

The board has no reason to doubt that the abandonment of the claim was not made deliberately, but the result of this abandonment is that the patent proprietor prevented the opposition division from giving a reasoned decision on this subject-matter.

2.4 In view of the above considerations, the board in exercise of its discretion under Article 13(1) RPBA decided not to admit auxiliary request 2 into the proceedings.

AUXILIARY REQUEST 3 (claims maintained by the opposition division)

3. The only objections maintained by the opponent against this request during the oral proceedings were that the invention was not sufficiently disclosed and that the subject-matter of all the claims lacked inventive step. In this context it was necessary to decide on the admissibility of documents D17, D18 and D20.

4. Admissibility of D17, D18 and D20

4.1 Documents D17, D18 and D20 constitute new evidence, cited for the first time in the opponent's statement of grounds of appeal. The patent proprietor requested that these documents not be admitted into the appeal proceedings on the grounds that they were late-filed and not relevant.

4.2 The opponent filed these documents as a direct reaction to the comment of the opposition division that it might have arrived at a different conclusion if the neutral oligosaccharides were known to show anti-HIV/AIDS activity (see page 15, lines 2 to 9 of the decision). D18 discloses a food composition wherein neutral oligosaccharides are not optional, and represents prior art that is closer to the claimed subject-matter than D5 used in the appealed decision. D17 relates to the use of neutral oligosaccharides in the treatment of HIV and D20 confirms the presence of acid oligosaccharides in bovine colostrum. Both documents were cited in connection with D18.

4.3 Thus, D17, D18 and D20 are *prima facie* more relevant than D5. Furthermore, they were filed at an early stage in the proceedings, namely with the statement of grounds of appeal. Consequently, the board sees no reason to hold these documents inadmissible under Article 12(4) RPBA.

5. Sufficiency

5.1 The opponent had contested sufficiency of disclosure of claim 1 of the patent because in its view there was not enough information in the patent to show that the

compositions used were indeed effective in the treatment of HIV or AIDS. In particular, the opponent noted that the claim was directed to the treatment of HIV or AIDS, while the only working example merely showed that some specific oligosaccharides bound to DC-SIGN. However, there was no experimental evidence that the oligosaccharides indeed block DC-SIGN and/or that they were useful for the treatment of HIV. This objection still applied to auxiliary request 3.

5.2 According to EPO practice, a claim drafted in the form of the use of a composition for the manufacture of a medicament for a defined therapeutic application must disclose the suitability of the product for the claimed therapeutic application. In order to meet the requirements of sufficiency, however, it is not mandatory that results of applying the claimed composition in clinical trials, or at least to animals, are reported. In any case, the patent must provide some information showing that the composition has a direct effect on a metabolic mechanism specifically involved in the disease (see Case Law of the Boards of Appeal of the EPO 7th edition 2013, Chapter II.C.6.2).

5.3 In the present case, example 1 shows that acid and neutral oligosaccharides bind to and can block DC-SIGN receptors with different efficacy. In view of this information in the specification, and taking into account that it is known that blocking the DC-SIGN receptor can prevent the receptor from first adhering to and then internalising HIV and thus from translocation to CD4 cells, example 1 renders plausible that food compositions containing acid and neutral oligosaccharides provide a treatment for HIV or AIDS (see paragraph [0026]). In any case, binding

experiments are also used in D7 and D17 to study the anti-HIV activity of oligosaccharides.

5.4 The board is therefore satisfied that the invention can be carried out by the skilled person without undue burden. Moreover, the opponent did not show that an embodiment of the invention could not be carried out. The onus of proof in this respect lies with the opponent.

5.5 For these reasons, the board concludes that the requirements of sufficiency of disclosure are met.

6. Inventive step

6.1 The invention aims to provide nutritional compositions for treating HIV patients, in order to improve their nutritional status and to reduce HIV infection related dysfunctions, in particular immune dysfunction, intestinal dysfunction and/or low glutathione status (see paragraphs [0022] and [0023]).

Claim 1 is drafted as a second medical use claim and comprises the following features:

a) use in the manufacture of a composition for the treatment of HIV/AIDS in a mammal of a composition comprising:
b) acid oligosaccharides prepared from pectin, etc.; and
c) neutral oligosaccharides selected from the group consisting of galactooligosaccharide, etc.; and
d) cysteine and/or source of cysteine; and
e) polyunsaturated fatty acids (PUFA) comprising at least 20% gamma-linolenic acid (GLA) plus

eicosapentaenoic acid (EPA), based on the total fatty acid content.

6.2 Closest prior art

6.2.1 The only inventive step attack maintained by the opponent was based on D18 as closest prior art.

6.2.2 D18 discloses nutritive compositions that are useful in the creation and/or maintenance of a health protective intestinal bacterial flora and simultaneously in the enhancement of the immune system. The nutritive compositions of D18 contain whey protein concentrates or isolates, fructooligosaccharides, and bovine or caprine colostrum (page 1, lines 6 to 12). These ingredients in combination are said to have a prophylactic and therapeutic effect in maintaining and enhancing beneficial gastrointestinal microflora (page 15, lines 21 to 23).

6.2.3 More specifically, the fructooligosaccharides and oligosaccharides naturally present in colostrum are said to help in maintaining a healthy gastrointestinal microflora (see paragraph bridging pages 22 and 23) and the whey protein is said to be useful in weight control and in enhancing the immune system (page 18, lines 13 to 16) due to its ability to enhance glutathione levels (see page 19, lines 16 to 21).

6.2.4 D18 does not specifically concern compositions for the treatment of HIV or AIDS, it merely notes that HIV seropositive persons suffering from chronic diarrhea and malabsorption of nutrients may benefit from the immune-enhancing effects of whey protein (see page 20, last paragraph, in particular, lines 18 to 19; see also page 4, lines 4 to 10).

6.3 Problem and solution

6.3.1 According to the patent proprietor, the technical problem underlying the patent in view of D18 is the provision of a composition for the treatment of HIV or AIDS that restores not only low glutathione levels, but also improves HIV infection related dysfunctions, namely:

- immune dysfunction, *i.e.* a decrease in $CD4^+$ T cell count leading to impaired immune function; and

- intestinal dysfunction, *i.e.* intestinal problems, specifically HIV induced malabsorption and diarrhea (see paragraphs [0023] und [0020]).

6.3.2 This problem is solved by using compositions as defined in claim 1 which contain, in addition to whey/cysteine to improve glutathione levels, polyunsaturated fatty acids (feature e)) to reduce inflammatory intestinal dysfunction (see paragraph [0061]) and acid oligosaccharides (feature b)) and neutral oligosaccharides (feature c)) to improve immune dysfunction by decreasing systemic $CD4^+$ T cell activation (see paragraph [0072]).

In particular, the invention is said to be based on the finding that certain acid and neutral oligosaccharides can block DC-SIGN preventing viral translocation from dendritic cells to $CD4^+$ T-cells, preventing further spread of the virus and development of HIV infection related dysfunctions (see paragraph [0086]; see also paragraphs [0025] and [0026]). The compositions comprising features b) to e) are therefore useful in the treatment of HIV/AIDS.

6.3.3 As discussed above in relation to sufficiency of disclosure, example 1 of the patent convincingly shows that acid and neutral oligosaccharides as defined in claim 1 are, in view of its blocking efficacy of the DC-SIGN receptor, potentially suitable for HIV treatment. Taking this into account, and the lack of experimental evidence to the contrary, the board is satisfied that the above problem has been credibly solved by the measures taken.

6.4 Obviousness

6.4.1 It remains to be decided whether, in view of the available prior art, it would have been obvious for the skilled person to solve this technical problem by the means claimed.

6.4.2 D18 itself gives no hint to the claimed solution. As pointed out above, the oligosaccharides in D18 are exclusively used to maintain a healthy gastrointestinal microflora. D18 is completely silent about any positive influence of acid and neutral oligosaccharides on $CD4^+$ T-cells decline. Moreover, the compositions of D18 do not include any polyunsaturated fatty acids.

6.4.3 The opponent argued that, starting from D18, claim 1 lacked inventive step because:

a) it was common general knowledge that acid oligosaccharides were components of bovine colostrum (as confirmed by D20); and that acid and neutral oligosaccharides showed anti-HIV activity (cf. D7 and D8 for acid oligosaccharides and D17 for neutral oligosaccharides); and

b) it would have been obvious to add polyunsaturated fatty acids to the compositions of D18 because their use for the treatment of HIV/AIDS patients was already suggested in D10.

6.4.4 The board disagrees for the following reasons:

Concerning a) it is noted that, although D7, D8 and D17 show indeed that certain oligosaccharides are able to inhibit HIV infections, the oligosaccharides in these documents are not the ones present in the compositions of D18. Thus, in D17 lactose and globotriose are said to competitively inhibit HIV-1 fusion with cell membranes (see [0014]), but these are not the fructooligosaccharides present in the compositions of D18 (see page 21, line 20 to page 22, line 6). Moreover, acid oligosaccharides are not mentioned at all in D18, even if they could be present in bovine colostrum. In this context, the patent proprietor questioned whether acid oligosaccharides were present in colostrum in an effective amount to treat HIV-symptoms. In any case, the acid oligosaccharides in bovine colostrum (see D20, Table 4) are not the oligosaccharides mentioned in D7 and/or D8 as the ones that can inhibit HIV infection (D7, table 1; D8, abstract).

The skilled person had no motivation from these citations to use the compositions of D18, or to add other oligosaccharides to the compositions of D18, to treat further HIV-related symptoms, because, as explained in point 5.2 above, the main aim of D18 is to maintain health protective microflora in the intestinal tract of mammals. This argument of the opponent is clearly made with the knowledge of the invention and cannot call into doubt the inventiveness of claim 1.

Concerning b) it is noted that, although D10 discloses a fat blend comprising GLA plus EPA that can be used for the treatment of HIV/AIDS patients (see claim 1 and page 9, line 45), the skilled person has again no motivation to add these fatty acids to the compositions of D18 in view of their different use. Moreover, a combination of D18 with D10 would not result in the compositions used in claim 1. Even if the amount of GLA plus EPA covered by claim 1 of D10 theoretically embraces values over 20%, the amount used in the examples of D10 (see table 2) is in all cases well below the 10% required by claim 1.

6.4.5 In summary, there is no incentive in the prior art for the skilled person to modify the compositions of D18 to solve the above-mentioned problem, namely to provide compositions that are useful for the treatment of HIV or AIDS by improving not only the low glutathione status but also intestinal and immune dysfunctions.

6.4.6 For these reasons, the subject-matter of claim 1, and by the same token the subject-matter of dependent claims 2 to 6, involves an inventive step.

6.4.7 The subject-matter of claims 7 to 9 is directed to food compositions comprising essentially the same components as the compositions used in claim 1, namely:

- acid oligosaccharides prepared from pectin, etc.;
- neutral oligosaccharides selected from the group consisting of galactooligosaccharide, etc.;
- cysteine and/or source of cysteine; and
- lipid comprising gamma linolenic acid (GLA),

further defined by the energy percentage, that is to say, comprising between 15 and 50% energy lipid, between 25/35 and 60% energy percent protein and between 15 and 45 energy percent carbohydrate.

6.4.8 The inventive step of these claims was contested by the opponent, starting from D18 as the closest prior art, with arguments similar to those used for claim 1.

6.4.9 The compositions of claims 7 to 9 have the same use as the compositions used in claim 1, namely the treatment of HIV patients in order to improve not only low glutathione levels but also other HIV infection related dysfunctions (see point 6.3.1 above). The reasoning above for the use claims also applies to the composition claims, which are therefore inventive for exactly the same reasons.

AUXILIARY REQUEST 4

7. As auxiliary request 3 is allowable, there is no need for the board to deal with this request.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar: The Chairman:

M. Cañueto Carbajo W. Sieber

Decision electronically authenticated