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**Datasheet for the decision
of 15 October 2013**

Case Number: T 0171/10 - 3.3.09

Application Number: 01996314.9

Publication Number: 1339294

IPC: A23L1/29, A23L1/302, A23L1/304,
A61K35/74, A23L1/03, A23C9/123,
A23L1/0528

Language of the proceedings: EN

Title of invention:
NUTRITIONAL COMPOSITION FOR AN IMMUNE CONDITION

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponents:
Fresenius Kabi Deutschland GmbH
COMPAGNIE GERVAIS DANONE
Tiense Suikerraffinaderij n.v.
N.V. Nutricia
Friesland Brands B.V.
Unilever N.V.

Headword:

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

Keyword:

Amendments - added subject-matter (no)

Novelty - (yes)

Inventive step - (yes)

Sufficiency of disclosure - (yes)

Decisions cited:

T 0608/07

Catchword:



**Beschwerdekammern
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Chambres de recours**

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Case Number: T 0171/10 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 15 October 2013

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
20 November 2009 concerning maintenance of the
European Patent No. 1339294 in amended form.**

Composition of the Board:

Chairman: W. Sieber
Members: W. Ehrenreich
K. Garnett

Summary of Facts and Submissions

Mention of the grant of European patent No. 1 339 294 in respect of European patent application No. 01 996 314.9, filed as International application PCT/EP2001/013302 on 14 November 2001 in the name of Société des Produits Nestlé, was announced on 23 August 2006 in Bulletin 2006/34.

- I. The patent was granted with 16 claims, claim 1 reading as follows:

"1. A composition which comprises a source of protein, a source of carbohydrate, a source of fat, a probiotic lactic acid bacterium and additionally fructo-oligosaccharides and inulin."

Claims 2 to 13 were dependent product claims. Claims 14 and 15 related to a method of producing the composition according to any one of claims 1 to 13.

Claim 16 read as follows:

"16. Use of a composition according to any one of claims 1 to 13 in the manufacture of a functional food or a medicament for the prevention or treatment of an immune condition in an elderly patient."

- II. Oppositions against the patent were filed by six opponents (hereinafter abbreviated as "OI" to OVI"), namely:

OI Fresenius Kabi Deutschland GmbH;
OII Compagnie Gervais Danone;
OIII Tiense Suikerraffinaderij N.V.;
OIV N.V. Nutricia on 23 May 2007;

OV Friesland Brands B.V.; and
OVI Unilever N.V.

The oppositions were variously based on the grounds according to Article 100(a) EPC (lack of novelty and lack of an inventive step), Article 100(b) EPC and Article 100(c) EPC.

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

OI-D2 Product Sheet "Raftiline®ST" (Release 05/95);
OI-D3 Product Sheet "Raftilose®P95" (Release 05/95);
OII-D1 WO 01/64225 A1;
OII-D4 WO 00/53200 A1;
OIV-D4 WO 02/15719 A2;
OIV-D5 EP 1 195 095 A2; and
OIV-D7 WO 01/82715 A2.

III. With its letter dated 15 January 2008 the Patent Proprietor filed the documents

P-D1 Bunout et al: "Effects of a Nutritional Supplement on the Immune Response and Cytokine Production in Free-Living Chilean Elderly", Journal of Parenteral and Enteral Nutrition, vol. 28, No. 5, (2004), pages 348 to 354;
P-D2 Receipt for deposit of biological material (Lactobacillus paracasei strain "NCC 2461" labelled as "I-2116" by Collection Nationale de Cultures de Microorganismes).

By the same letter, a set of claims 1 to 15 according to a first auxiliary request was filed. Claims 1 and 15 read as follows:

"1. A composition which comprises a source of protein, a source of carbohydrate, a source of fat, a probiotic lactic acid bacterium and additionally fructo-oligosaccharides and inulin, characterised in that the probiotic lactic acid bacterium is a paracasei bacteria."

"15. Use of a composition according to any one of claims 1 to 12 in the manufacture of a functional food or a medicament for the prevention or treatment of an immune condition in an elderly patient."

IV. By its interlocutory decision announced orally on 13 October 2009 and issued in writing on 20 November 2009, the opposition division held that the patent in amended form, namely on the basis of the claims according to the first auxiliary request, met the requirements of the EPC.

The claims as granted (main request) were considered to be not allowable because the subject-matter of claim 1 lacked novelty over the disclosure in example 1 of OIV-D5. OIV-D5 was considered to represent prior art according to Article 54(3) EPC because, in the opposition division's view, the patent in suit was not entitled to its priority claim from GB 0027761 dated 14 November 2000.

V. Appeals against the decision of the opposition division were filed by:

OII (hereinafter appellant I) on 20 January 2010; and
OV (hereinafter appellant II) on 1 February 2010.

The appeal fees were paid on the day of the receipt of the respective appeals.

The grounds of appeal were received on 29 March 2010 (appellant I) and on 30 March 2010 (appellant II), respectively.

In respect of the claims according to the first auxiliary request as maintained by the opposition division, the appellants maintained their objections under Articles 83, 123(2), 54 and 56 EPC raised in the opposition proceedings.

- VI. In its letter of response dated 2 August 2010, the patent proprietor provided comments on each appeal and requested that the appeals be dismissed, i.e. that the patent be maintained on the basis of the claims upheld by the opposition division.
- VII. On 31 July 2013 the board issued a communication and made preliminary observations on essential issues of the case.
- a) Concerning the objection of appellant II that fructo-oligosaccharides and inulin, which both had to be present in the claimed composition, were not clearly distinguishable from each other and were not defined in the patent, it would have to be discussed whether this issue was a matter of insufficiency of disclosure or a matter of lack of clarity.
 - b) Concerning the objection of appellant I under Article 100(c)/123(2) EPC that the amendments in claims 1 and 15 resulted from an inadmissible multiple selection, namely:
 - elderly people, from the group of originally disclosed patients;

- the mixture of fructo-oligosaccharides and inulin, from the three variants embraced by the link "and/or" in original claim 1;
- the bacterium *Lb. paracasei*, from the two originally disclosed bacteria *Lb. paracasei* and *Lb. johnsonii*;

the board took the preliminary view that the amendments met the requirements of Article 123(2) EPC.

- c) Concerning Article 100(a) EPC the board considered documents OIV-D4 and OIV-D7 to be relevant for the assessment of novelty. Document OII-D1 was considered to represent the closest prior art for the assessment of an inventive step. In this context the board confirmed the opposition division's view that the patent was not entitled to its priority claim from GB 0027761 dated 14 November 2000 and concluded that OII-D1 thus represented full prior art under Articles 54(2) and 56 EPC.

VIII. With its letter dated 12 September 2013 the respondent filed new sets of claims as bases for auxiliary requests I to V. In addition, the document:

P-D6 Vidal et al., "Effect of *Lactobacillus paracasei* NCC2461 on Antigen-Specific T-Cell Mediated Immune Responses in Aged Mice", *Rejuvenation Research*, vol. 11, 2008

was *inter alia* submitted.

Opponents I, III, IV and VI did not file any requests or submissions relating to substantive issues in the written appeal proceedings.

On 15 October 2013 oral proceedings before the board took place which were attended by appellants I and II, the respondent and opponent I. As announced by letters dated 18 July 2013, 13 September 2013 and 25 February 2013 respectively, opponents III, IV and VI were not present at the oral proceedings. Opponent I confirmed that it had no requests.

After a discussion of the subject-matter of claims 1 and 15 of the then pending main request (i.e. the claims upheld by the opposition division, point III above) the board announced its conclusion that this request was not allowable, at least because the subject-matter of claim 1 was not based on an inventive step with regard to OII-D1 as the closest prior art in combination with OII-D4. Thereafter, the respondent withdrew auxiliary requests I to III and made auxiliary requests IV and V its first and second auxiliary request respectively.

Claims 1 and 14 of auxiliary request IV correspond to claims 1 and 15 of the main request, and include the additional limitation of the paracasei lactic acid bacterium to the specific strain ST11. They read as follows:

"1. A composition which comprises a source of protein, a source of carbohydrate, a source of fat, a probiotic lactic acid bacterium, fructo-oligosaccharides and inulin, characterised in that the probiotic lactic acid bacterium is a paracasei bacteria wherein the lactic

acid bacterium is ST11 (deposited under the number CNCM I-2116)".

"14. Use of a composition according to any one of claims 1 to 11 in the manufacture of a functional food or a medicament for the prevention or treatment of an immune condition in an elderly patient."

The description was adapted to the claims of auxiliary request IV.

IX. After an indication by the board that it was prepared to make an order for the maintenance of the patent on the basis of claims 1 to 14 according to auxiliary request IV, the respondent withdrew the main request and auxiliary request V, auxiliary request IV thus becoming its sole request. The arguments of the parties as summarized in the following thus only relate to the subject-matter of auxiliary request IV.

X. Arguments of the appellants I and II

a) Amendments - Article 123(2) EPC

The amendment in claim 1 that the prebiotic is a mixture of fructo-oligosaccharide and inulin and the probiotic is the paracasei lactic acid bacterium requires several selections, namely:

a first selection from the three variants: fructo-oligosaccharide alone, inulin alone or fructo-oligosaccharide and inulin, as disclosed in claim 1 as originally filed by the link "and/or";
and

a second selection from the two bacteria *Lb. paracasei* and *johnsonii* disclosed in claim 9 as originally filed.

In claim 14 a further selection has to be made, namely elderly people as a specific group of persons mentioned in the original description as one of several possible groups.

b) Novelty over OIV-D4 (Article 54(3) EPC)

Claim 1 of OIV-D4 discloses a composition comprising a protein source, a source of fat and a source of carbohydrate. Prebiotic fibres, like fructo-oligosaccharides and inulin are indicated in claim 13, which refers back to claim 1. Claim 14 also refers back to claim 1 and relates to probiotic microorganisms. A preferred prebiotic in the sense of claim 13 is a mixture of fructo-oligosaccharides and inulin (page 9, lines 21/22) and a preferred probiotic microorganism in the sense of claim 14 is the *Lb. paracasei* strain deposited under the number NCC2461 (page 6, lines 16/17). Thus, OIV-D4 anticipates the subject-matter of claim 1.

The novelty objection with regard to OIV-D7 was not pursued in the oral proceedings.

c) Inventive step (Article 56 EPC) in conjunction with sufficiency of disclosure (Article 83 EPC)

(i) The patent is not entitled to its priority claim from GB 0027761 dated 14 November 2000. Thus, OII-D1 constitutes full prior art and is considered to represent the closest prior art for

the assessment of an inventive step. For the same reasons, OIV-D7 is full prior art.

OII-D1 discloses a composition which may be employed to enhance an immune response and which may contain a source of protein, a source of carbohydrate, a source of fat, a prebiotic mixture comprising fructo-oligosaccharides and inulin and a probiotic microorganism. Example 2 of OII-D1 discloses a food supplement comprising fructo-oligosaccharides and inulin as a prebiotic mixture which can be added to milk, yogurt etc., which inherently always contain sources of protein, fat, carbohydrates and lactobacilli as probiotic bacteria. The composition claimed in claim 1 differs therefrom in that the probiotic bacterium is an *Lb. paracasei* strain ST11 deposited under the number CNCM I-2116. The patent, however, shows no effect which is caused by this *paracasei* strain.

The respondent had referred to the document P-D1, discussing, at page 350, right column and page 352, left column, a reduced natural killer (NK) cell activity in elderly people of a nutritional supplementation including the *Lb. paracasei* NCC 2461 (which is an internal numbering of the strain ST11). However, it should be noted that such an effect was shown only for a nutritional composition including each of the ingredients in a specific portion, namely 31.4 g protein, 12.4 g fat, 62 g carbohydrates, 120 IU vitamin E, 0.24 mg thiamin, 0.4 g riboflavin, 6 g fructo-oligosaccharides as a mixture of raftilose® (i.e. oligofructose) and raftiline® (i.e. chicory inulin) in a ratio 2:1.

In contrast thereto, claim 1 is directed to a composition wherein the portions of all ingredients are unlimited. This is also true for the use of the composition in the manufacture of a functional food or medicament for the prevention or treatment of an immune condition in an elderly patient according to claim 14. The effect shown for the very specific composition in P-D1 on the immune response in elderly people is therefore not transferable to the subject-matter of claims 1 and 14 in their claimed broadness. Thus, the objective problem to be solved by the claimed invention can only be seen in the provision of an alternative.

The use of the *Lb. paracasei* (NCC 2461) deposited under reference CNMC I-2116 in food compositions is, however, already known from OIV-D7 (page 16, lines 8 and 16 to 19). It was thus obvious to add the *Lb. paracasei* NCC 2461 as probiotic microorganism to the nutritional composition disclosed in OII-D1.

(ii) Article 83 EPC requires that the skilled person can carry out the invention. For the subject-matter of the patent in suit this means that the skilled person must be able to meet the need to improve health, in particular with regard to an improved immune condition in elderly people as indicated in paragraphs [0007/0008] of the patent specification. However, nothing in this respect has been shown in the patent specification, e.g. by way of suitable experimental evidence. It is thus not evident that a skilled person can achieve the aim of improved immune condition in the elderly with the claimed

nutritional composition, including with the ingredients present in any amount. Thus, the patent gives no guidance to a skilled person how to use the claimed composition in accordance with claim 14 in order to prevent or treat the immune condition in an elderly patient. The invention is thus insufficiently disclosed.

XI. Arguments of the respondent

a) Amendments - Article 123(2) EPC

The embodiment "fructo-oligosaccharides and inulin" is literally disclosed in claim 1 of the application as filed in the link "and/or". Thus, the limitation in claim 1 to the mixture of both ingredients merely results from the deletion of the "or"-variant, which is no selection. Therefore, the limitation to *Lb. paracasei* only requires one selection from the two alternatives disclosed in claim 9 as originally filed.

The treatment of the immune condition according to claim 15 is disclosed in claims 16 and 17 as originally filed. Elderly people as a target group for the prevention or treatment of an immune condition is disclosed on page 6, lines 5 to 8 of the original description.

b) Novelty over OIV-D4

According to OIV-D4, the prebiotic fibres and the probiotic microorganism are indicated in two separate dependent claims and are therefore optional components. In addition, the combination of fructo-oligosaccharides and inulin and the *Lb.*

paracasei strain NCC 2461 have to be selected from pages 6 and 9 of the description. Consequently several selections in OIV-D4 are necessary in order to come to the composition of claim 1. Furthermore, there is no pointer in the examples of OIV-D4 to a combination of prebiotic fibre with a probiotic microorganism.

OIV-D4 does thus not explicitly and unambiguously disclose the subject-matter of claim 1.

c) Inventive step and sufficiency of disclosure

It is the aim of the claimed invention to provide a nutritional composition which is suitable for the prevention or treatment of an immune condition to an elderly patient. The positive effect on the immune response of the elderly by the enhancement of the natural killer cell (NK) activity is clearly shown in P-D1 for a composition including protein, fat, carbohydrate fructo-oligosaccharides, inulin and the Lb. paracasei strain NCC 2461.

As regards the argument of the appellants that such an effect has been shown for Lb. paracasei NCC 2461 only in combination with the very specific composition disclosed in P-D1, reference is made to P-D6. This document shows that with aged mice the probiotic Lb. paracasei strain NCC 2461 as such has an immune-enhancing effect for the elderly by improving the NK cell activity. It is clearly stated in P-D6 that such an effect occurs irrespective of whether or not Lb. paracasei NCC 2461 is combined with fructo-oligosaccharides and inulin (P-D6, abstract and

page 958, left column, second and third paragraph). In P-D6 it is also pointed out, on page 958, first paragraph of left column, that such an immune-enhancing effect in adults aged from 40 to 65 years is not provided by the Lb. paracasei strain Shirota, which is a Lb. paracasei strain different from NCC 2461. From P-D6 it is thus evident that the administration of a supplement containing the specific Lb. paracasei strain ST11 provides a positive effect on the immune response of the elderly, either alone or optionally in combination with fructo-oligosaccharides and inulin.

It is also well-known that proteins, fat and carbohydrates are common ingredients in nutritional supplements. Thus, a detrimental effect on the activity of the Lb. paracasei NCC 2461 for the improvement of the immune response, caused by the additional intake of these components, is not to be expected. Document P-D1 in conjunction with P-D6 thus provide sufficient evidence that the composition in its claimed broadness is beneficial to the prevention and treatment of an immune condition in an elderly patient when used in the manufacture of a functional food or medicament according to claim 14.

The above considerations also show that a skilled person is able to achieve a positive effect on the immune condition in the elderly patient according to claim 14 with the composition in its claimed broadness. The invention is thus also sufficiently disclosed, in compliance with Article 83 EPC.

- XII. The appellants I and II requested that the decision under appeal be set aside and the patent be revoked.
- XIII. The respondent requested that the decision under appeal be set aside and the patent be maintained on the basis of the fourth auxiliary request filed with its letter dated 12 September 2013 and the amended description as filed during the oral proceedings.

Reasons for the Decision

1. The appeals are admissible.
2. Amendments - Article 123(2) EPC
 - 2.1 Amended claim 1 of auxiliary request IV (sole remaining request) requires that:
 - (a) the prebiotic ingredient is a combination of fructo-oligosaccharide and inulin, and
 - (b) the probiotic lactic acid bacterium is paracasei ST11 deposited under the number CNCM I-2116.
 - 2.2 Requirement (a) is based on claim 1 as filed, which refers to "A composition which comprises ... additionally fructo-oligosaccharides and/or inulin" (emphasis added). Thus, claim 1 as filed relates to three separate variants:
 - 1) A composition which comprises a source of protein, a source of carbohydrate, a source of fat, a probiotic lactic acid bacterium and additionally fructo-oligosaccharides and inulin.

2) A composition which comprises a source of protein, a source of carbohydrate, a source of fat, a probiotic lactic acid bacterium and additionally fructo-oligosaccharides.

3) A composition which comprises a source of protein, a source of carbohydrate, a source of fat, a probiotic lactic acid bacterium and additionally inulin.

Claim 1 of auxiliary request IV has been limited to the first variant which requires the presence of both fructo-oligosaccharides and inulin.

As regards the lactic acid bacterium strain "ST11", this requirement is based on dependent claim 10 as filed according to which the lactic acid bacterium is selected from the group consisting of "ST11" (a strain of *Lb. paracasei*) and "La1" (a strain of *Lb. johnsonii*).

2.3 The appellants argued that a two-fold selection was necessary from the application as filed in order to arrive at the subject-matter of claim 1, a selection which was not clearly and unambiguously derivable from the application as filed.

However, as mentioned above, the variant requiring the presence of both fructo-oligosaccharides and inulin was explicitly present in claim 1 as filed. Furthermore, the application as filed indicates at page 6, lines 24 to 27 that "For the purpose of clarity and a concise description features are described herein as part of the same or separate embodiments, however, it will be appreciated that that the scope of the invention may include embodiments having combinations of all or some

of the features described". In view of this passage it is evident to the skilled reader that the variants of claim 1 as filed may be combined with other features described in the application as filed, in particular with features disclosed in the dependent claims, such claims usually relating to the most preferred embodiments of an invention. Thus, in the board's view there is a clear und unambiguous implicit disclosure for the subject-matter of claim 1 of auxiliary request IV.

Furthermore, the board notes that example 1 as illustrated in Table 1 of the application as filed discloses a composition comprising a prebiotic mixture of fructo-oligosaccharides and inulin in combination with *Lb. paracasei*. Since ST11 is a strain of *Lb. paracasei*, example 1 is also a pointer to the composition of claim 1.

Hence, the board does not see a violation of Article 123(2) EPC by the amendment in claim 1.

- 2.4 The further amendment in claim 1 concerning the introduction of the correct deposition number "CNCM I-2116" instead of "NCCMI-2116" as disclosed on page 4 and in claim 10 of the application as filed is a correction of an obvious error in view of the correct abbreviation "CNCM" for "Collection Nationale de Cultures de Microorganismes" as indicated in P-D2.
- 2.5 Claim 14 relates to the use of the composition of claim 1 in the manufacture of a functional food or a medicament for the prevention or treatment of an immune condition in an elderly patient. It is based on the disclosure on page 6, lines 5 to 8, which reads as follows:

"Another advantage of the present invention is that it provides a single composition that can be adapted and administered simply in a food for the prevention or treatment [of] an immune condition. The composition can be provided in clinical or performance nutrition settings and is particularly suitable for an elderly patient."

This passage links the compositions of the invention, including the composition now claimed in claim 1, with the prevention or treatment of an immune condition to an elderly patient. Thus, also claim 14 of the sole request meets the requirements of Article 123(2) EPC.

3. Novelty

3.1 Novelty of the claimed subject-matter was objected to in view of documents OIV-D4 and OIV-D7.

3.2 OIV-D4

OIV-D4 discloses in claim 1 a composition comprising a protein source, a lipid source and a carbohydrate source. Additional components are optional, such as the at least one prebiotic fibre selected from the group consisting of inulin, acacia gum, resistant starch, dextran, xylo-oligosaccharides, fructo-oligosaccharides and/or combinations thereof (dependent claim 13) or the at least one probiotic micro-organism (dependent claim 14).

In order to arrive at a composition comprising the components of claim 1 of auxiliary request IV the skilled person would have first to combine the embodiment of claim 13 with that of claim 14. Secondly,

he would have to select from several possibilities of prebiotic fibres indicated in claim 13 the combination of inulin and fructo-oligosaccharides. In a third selection he would have to choose *Lb paracasei* NCC 2461 from the group of microorganisms consisting of *Lb. johnsonii*, *Lb. Paracasei* or a combination thereof as disclosed in the description at page 6, lines 11 to 17. Although the individual components, namely the mixture of fructo-oligosaccharides and inulin (page 9, line 17) and *Lb. paracasei* NCC 2461 (page 6, lines 16 to 17) are preferred, there is no explicit or implicit disclosure in OIV-D4 which unambiguously points to a combination of both a prebiotic fibre with a probiotic microorganism. In this context it is to be noted that none of the nutritional supplements disclosed in the examples of OIV-D4 contains a prebiotic fibre, let alone the combination of fructo-oligosaccharides and inulin. The probiotic bacteria that are suggested in the examples are *Lb. johnsonii* (example 4) and *B. bifidus* and *S. thermophilus* (example 6).

The appellants argued that if one applied the same standard in the assessment of added subject-matter (as for claim 1) and for novelty (as for OIV-D4) the subject-matter of claim 1 clearly lacked novelty over the disclosure of OIV-D4. However, although the board applied the same standard in both assessments, namely as to whether or not the subject-matter was clearly and unambiguously derivable for the application as filed and OIV-D4, respectively, the particular disclosures led to different results.

OIV-D4 does therefore not anticipate the subject-matter of claim 1 and, by the same token, of claim 14.

3.3 OIV-D7

The novelty objection based on OIV-D7 was no longer pursued in the oral proceedings.

In the board's judgment, OIV-D7 is not novelty-destroying because also several selections from various parts of the description have to be made in order to arrive at the claimed subject-matter without there being any pointer towards such selections.

- 3.4 Because none of the other documents cited anticipates the composition of claim 1 and its use according to claim 14, something which was not contested by either of the appellants, the claimed subject-matter is new over the cited prior art.

4. Validity of the priority claim

The patent in suit claims the priority from GB 0027761.6 dated 14 November 2000. This document discloses a composition comprising a protein source, a carbohydrate source a fat source, a lactic acid bacterium as probiotic and fructo-oligosaccharides and/or gum acacia as prebiotic (claim 1).

In contrast thereto, claim 1 of auxiliary request IV relates to a composition comprising as prebiotic a mixture of fructo-oligosaccharides and inulin, and thus relates to an invention which is different from that defined in the priority document.

The board cannot agree with the respondent's argument that the first example in Table 1 of the priority document supports the priority claim, because in this example a very specific composition is disclosed including, besides specific amounts of protein, fat, carbohydrate minerals and vitamins, fructo-

oligosaccharides and inulin in a specific weight ratio. This specific example cannot therefore support the invention in its claimed broadness.

Consequently, the priority claim is not valid and the effective filing date for the claimed invention is 14 November 2001.

5. Inventive step

5.1 In view of the finding on priority, above, document OII-D1, published on 7 September 2001, constitutes prior art according to Article 54(2) EPC.

5.2 The board agrees with the appellants that OII-D1 can be considered to represent the closest prior art for the consideration of inventive step.

OII-D1 discloses in claim 1 a composition for use in the treatment and/or prevention of measles, which contains at least one prebiotic. The focus of the use of the formulation lies in enhanced immune response after vaccination of children (page 2, lines 19 to 24).

The prebiotic comprises fructo-oligosaccharides, inulin or a mixture thereof (claim 3). According to page 3, lines 12 to 14, the prebiotic comprises most preferably a mixture of fructo-oligosaccharide and inulin.

Notably, OII-D1 discloses for this purpose a mixture of commercially available Raftilose[®] and Raftiline[®] (page 3, lines 14 to 15). A probiotic selected *inter alia* from the genus "Lactobacillus" may also be present (claims 6 and 7). According to page 4, lines 18 to 25, the prebiotic composition of claim 3, in the form of a 70:30 mixture of fructo-oligosaccharide and inulin, is used as a food supplement by adding it e.g. to milk-

based cereal. The resulting composition inherently contains lactobacilli, proteins, fat and carbohydrates, as natural ingredients of the milk.

5.3 In view of OII-D1 the respondent saw the problem to be solved by the claimed invention in the provision of a composition which addresses the problems of immune conditions in the elderly people and which can help to improve health, in particular with regard to an immune condition in an elderly patient (patent specification, paragraphs [0006] to [0008] of the patent specification).

5.4 This problem is allegedly solved by the features of claim 1 of auxiliary request IV, in particular by the presence of a probiotic paracasei bacterium of the strain ST11.

The patent specification itself does not contain any experimental evidence showing that the above problem is solved by the features of claim 1. In order to demonstrate that the problem is indeed solved the respondent has *inter alia* submitted documents P-D1 and P-D6. Although post-published, these documents were used as evidence to show the alleged effect.

5.4.1 P-D1 is a study on the effects of a nutritional supplement on the immune response in elderly people. The nutritional supplement includes proteins, fat carbohydrates, a mixture of fructo-oligosaccharides and inulin and *Lb. paracasei* NCC2461 in defined amounts (page 349, second paragraph of the left column). As shown in this study the natural killer cell (NK) activity can be enhanced in elderly people supplemented with the nutritional composition. This leads to an

improved immune response reflected by a lower incidence of infections and a better IL-2 production in the elderly people (page 350, right column in context with the first paragraph on page 351, right column, under the heading "Discussion").

- 5.4.2 P-D6 is a study on the effect of *Lb. paracasei* NCC2461 (combined or not with fructo-oligosaccharides and inulin) on the immune response in aged mice. Although directed to aged mice, it is evident from the study itself that the results can be transferred to elderly people. This in particular emerges from the last sentence in the abstract reading:

"The poor responsiveness to antigenic challenge, frequently observed in elderly people, may be improved by supplementation with *L. paracasei* NCC2461".

An important result of the study in P-D6 is that the feeding of *Lb. paracasei* NCC2461, with or without prebiotic fructo-oligosaccharides/inulin, in the elderly strengthens cell-mediated immune response, with the consequence that intake of *Lb. paracasei* NCC2461 may be beneficial in counteracting the immune defects that occur with ageing. These results are summarized in the paragraph bridging the right column of page 962 with the left column of page 963 and are confirmed by figure 3 showing an improved DHT-response in aged mice fed with drinking water supplemented with *Lb. paracasei* NCC2461, without or with prebiotic fructo-oligosaccharides/inulin. In addition, it is stated on page 958, left column that oral administration of a supplement containing *Lb. paracasei* NCC2461 combined with prebiotics (fructo-oligosaccharides/inulin) and a cocktail of micronutrients reduces the incidence of

winter infections in free-living elderly, possibly by improving NK activity.

In contrast to the results shown for *Lb. paracasei* NCC2461, the different *Lb. paracasei* strain Shirota is inactive with regard to an enhancement of an immune-response in adults aged from 40 to 65 years (page 958 first paragraph of the left column).

5.4.3 From P-D1 and P-D6 the following conclusions can be drawn:

While P-D1 shows an improved immune response in elderly people for *Lb. paracasei* NCC2461 in conjunction with a specific nutritional composition, P-D6 confirms that these results have to be considered in a broader aspect in that *Lb. paracasei* NCC2461 is responsible for the achievement of an improved immune response and its success is neither bound to the administration of prebiotics like fructo-oligosaccharides/inulin or other micronutrients, nor to specific amounts of these ingredients.

5.4.4 The board is therefore satisfied that the composition in its claimed broadness according to claim 1 and its use according to claim 14 successfully solve the above mentioned problem defined in the patent. Therefore this problem constitutes the objective problem to be solved.

5.5 It remains to be examined whether the solution to this problem, namely the provision of the nutritional composition according to claim 1 and its use according to claim 14, is obvious.

5.5.1 OII-D1 itself is not concerned with the immune response in elderly people but in young subjects. As explained

in PD-1 (page 348, left and right column) ageing, however, is associated with alterations in the immune responsiveness that *inter alia* increase the susceptibility of elderly subjects to infections. Furthermore, the adequate natural killer (NK) cell function is altered with ageing. Moreover, OII-D1 does not contain a single example demonstrating the use of a probiotic or the combination of a probiotic and a prebiotic. It merely discloses the use of a prebiotic mix of fructo-oligosaccharides and inulin. Hence, a skilled person does not get any hint from OII-D1 itself suggesting that the relevant features of claim 1 might solve the posed problem.

5.5.2 The appellants pointed out that the paracasei bacterium was well-known for use in food compositions, and referred in this context to OIV-D7, page 16, line 8 and lines 16 to 19. Therefore the skilled person would combine this document with the closest prior art. OIV-D7, however, is concerned with confectionery products containing a functional ingredient and comprising a filling within a specifically designed casing and is unrelated to the objectives of the claimed invention. Probiotic bacteria are only mentioned as one possible functional ingredient in a long list of functional ingredients disclosed on pages 14/15, bridging paragraph. *Lb. paracasei* NCC2461 is mentioned on page 16, line 18 besides other probiotic bacteria like *Lb. johnsonii* and various bifidobacteria. There is no pointer in OIV-D7 which would motivate the skilled person to add *Lb. paracasei* NCC2461 to the nutritional composition disclosed in OII-D1 in order to solve the problem posed.

5.5.3 In a similar manner the other documents cited cannot contribute to the solution of the problem.

5.6 In the light of the above, the claimed subject-matter is based on an inventive step.

6. Sufficiency of disclosure

6.1 Composition of claim 1

The first objection raised by the appellants under Article 83 EPC was that the patent contains no definition for "fructo-oligosaccharides" and "inulin". Because both definitions overlap, doubts exist whether the skilled person would know when he was working in the forbidden areas of the claims.

The board does not share this view. It is well known that fructo-oligosaccharides and inulin are both commercial products which are for example sold under the trade names Raftilose[®]P95 and Raftiline[®]ST (cf. OI-D2 and OI-D3). The skilled person is therefore able to prepare the composition according to claim 1 simply by mixing the two commercial products with the other essential ingredients of the claimed composition.

Although it may be true that fructo-oligosaccharides and inulin are not perfectly distinguishable from each other because the polymerisation degree of inulin can overlap with that of fructo-oligosaccharide, this overlap only occurs at the lower edge of the polymerisation degree of inulin. In general, inulin has a considerable higher polymerisation degree than fructo-oligosaccharides. Such an overlap at the edges of a range is, however, considered to be a problem of clarity rather than of insufficiency of disclosure (in this context see T 608/07 of 27 April 2009, point 2.5.2 of the reasons).

6.2 Achievement of the desired effect

In the written appeal proceedings and during the oral proceedings the appellants pointed to the broad definition of the claimed invention in that no amounts are given for the ingredients of the composition of claim 1, in particular for the prebiotic materials fructo-oligosaccharide and inulin, which consequently could be used in any ratio. Because the patent specification does not show, by way of experimental evidence, that the aim of the invention, i.e. the improvement of the immune response in the elderly people, is achieved by the use of the composition in accordance with claim 14, the skilled person is not able to carry out the invention in the sense of Article 83 EPC over the whole claimed range.

In view of the respondent's arguments and evidence provided in favour of an inventive step (see point 4 above) the board, however, is satisfied that the respondent has convincingly shown by way of the documents P-D1 and P-D6 that *lactobacillus paracasei* NCC2461 is the essentially active component for the achievement of the improved immune response, irrespective of whether it is applied as such or is combined with fructo-oligosaccharides and inulin and optionally other micronutrients normally present in a nutritional composition.

The board is therefore satisfied that the achievement of the desired effect does not depend on any specific amounts of prebiotic components and micronutrients in the nutritional composition and concludes that the skilled person is able to carry out the invention in the whole claimed range.

- 6.3 In the light of the above, the invention is sufficiently disclosed.
7. During the oral proceedings before the board the patent specification was brought into line with the the claims of auxiliary request IV. The parties present at the oral proceedings raised no objections against the final version of the amended patent specification.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent on the basis of:
 - (a) Claims 1 to 14 according to auxiliary request IV filed with the proprietor's letter dated 12 September 2013;
 - (b) The amended description pages numbered 3 to 6 as filed during the oral proceedings.

The Registrar:

The Chairman:



M. Cañueto Carbajo

W. Sieber

Decision electronically authenticated