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D E C I S I O N
of 7 February 2006

Case Number: T 0232/02 - 3.3.09

Application Number: 95202142.6

Publication Number: 0756828

IPC: A23L 1/308

Language of the proceedings: EN

Title of invention:

Nutritional composition containing fibres

Patentee:

N.V. Nutricia

Opponents:

Novartis Nutrition AG
Société des Produits Nestlé S.A.

Headword:

-

Relevant legal provisions:

EPC Art. 54, 56, 84, 123(2)(3)

Keyword:

"Main request, auxiliary request 1: clarity (no)"
"Auxiliary requests 2-5: compliance with Article 123(2),(3)
(yes), novelty (yes)"
"Auxiliary request 5: inventive step (yes)"
"Fresh ground of opposition (not admitted)"

Decisions cited:

G 0009/91, G 0010/91, G 0001/95, G 0007/95

Catchword:

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Case Number: T 0232/02 - 3.3.09

DECISION
of the Technical Board of Appeal 3.3.09
of 7 February 2006

Appellant: Société des Produits Nestlé S.A.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office orally
announced on 18 September 2001 and posted
8 January 2002 concerning maintenance of
European patent No. 0756828 in amended form.

Composition of the Board:

Chairman: P. Kitzmantel
Members: W. Ehrenreich
M. Tardo-Dino

Summary of Facts and Submissions

- I. Mention of the grant of European patent No. 0 756 828 in respect of European patent application No. 95 202 142.6 in the name of *N.V. Nutricia* filed on 4 August 1995, was announced on 18 November 1998.

The patent, entitled "*Nutritional composition containing fibres*", was granted with twelve claims, Claim 1 reading as follows:

"1. Nutritional composition, which, optionally after admixture of other food components and/or dilution with water, is suitable for enteral administration, comprising dietary fibre, characterised in that the fibre consists of 15-50 wt.% of soluble non-starch polysaccharides, 15-45 wt.% of insoluble non-starch polysaccharides, and 8-70 wt.% of non-digestible oligosaccharides and/or resistant starch."

Claims 2 to 12 were dependent on Claim 1.

- II. Notices of opposition requesting revocation of the patent in its entirety on the grounds of Articles 100(a) and (c) EPC were filed by

Novartis Nutrition AG - Opponent I - on 17 August 1999

and

Société des Produits Nestlé S.A. - Opponent II - on 18 August 1999.

With regard to Article 100(a) EPC the Opponents argued that the claimed subject-matter lacked both novelty (Article 54 EPC) and inventive step (Article 56 EPC) and based their submissions, inter alia, on the following documents:

- D1 JP-A 6-135 838 (English Translation);
- D2 US-A 5 234 706;
- D7 Gastrointestinal effects of food carbohydrates, *Am. J. Clin. Nutr.* 61(suppl.) (1995), 938S-945S;
- D10 JP-A 63-63366 (English Translation).

III. With a letter dated 18 July 2001 the Proprietor submitted a main request and four auxiliary requests. Furthermore, a test report - hereinafter D13 - comparing the production of short chain fatty acids (SCFAs) during the fermentation of hydrolysed inulin (commercial name: Raftilose®) and trans-galacto-oligosaccharide (TOS), was filed.

In the oral proceedings before the Opposition Division, which took place on 18 September 2001, the Patent Proprietor introduced amendments into the above main request, Claim 1 of this amended request reading as follows:

- "1. Nutritional composition, which, optionally after admixture of other food components and/or dilution with water, is suitable for enteral administration, comprising dietary fibre, characterised in that the fibre consists of
- a) 15-50 wt.% of soluble non-starch polysaccharides,
 - b) 15-45 wt.% of insoluble non-starch polysaccharides, and

- c) 8-70 wt.% of non-digestible oligosaccharides and/or resistant starch, comprising at least 8 wt.% of hydrolysed inulin or a derivative thereof and/or comprising resistant starch."

The Patent Proprietor requested that the patent be maintained on the basis of the amended main request, or alternatively with one of the four auxiliary requests filed with the letter dated 18 July 2001.

- IV. In its decision orally announced on 18 September 2001 and issued in writing on 8 January 2002 the Opposition Division maintained the patent in amended form on the basis of the amended main request, which was considered to comply with the requirements of the Articles 84, 123(2), 54 and 56 EPC.

With respect to Article 84, the Opposition Division argued that the passage in feature (c) of Claim 1 "comprising at least 8 wt.% of hydrolysed inulin or a derivative thereof and/or comprising resistant starch" was clear; this feature would be understood by a skilled person as relating to component (c) of the fibre and not to the whole nutritional composition.

In the light of the above interpretation the requirements of Article 123(2) EPC for the feature (c) were also considered to be met.

Concerning the issue of novelty, the Opposition Division held that the terms "fructo-oligosaccharides" used in D1 and "hydrolysed inulin" according to Claim 1 of the main request were not interchangeable because they did not necessarily describe the same substance.

Hydrolysis of inulin was only one of two routes leading to fructo-oligosaccharides, the other one being an enzymatic route. A comparison of the HPAEC elution pattern of hydrolysed inulin Raftilose® and Actilight®, a fructo-oligosaccharide obtained from sucrose via enzymatic reaction, showed differences between these two fructo-oligosaccharides (cf. D16).

Although D10 disclosed, as one alternative, the use of an inulin hydrolysate, this document was silent on its use in combination with the soluble polysaccharides (a) and the insoluble polysaccharides (b) of embodiment 1.

The Opposition Division also acknowledged novelty with respect to D2, holding that two selections were necessary in order to arrive at the disclosure of the claimed subject-matter, namely

- the selection of the claimed amounts of starch, insoluble fiber and soluble fiber from the ratios 1 : 0.09-1.5 : 0.02-0.36, and
- the selection of starch with a satisfactory level of resistant starch from a list of numerous starches mentioned in D2.

With regard to the question of inventive step, the Opposition Division considered D10 representative of the closest prior art. Since the document did not, however, address the problem solved by the invention, namely the production of short-chain fatty acids (SCFAs) at a uniform rate during the transit of the food through the ileum and the large intestine, it could not render the claimed invention obvious.

V. On 27 February 2002 the Opponent II (Appellant) lodged an appeal against the decision of the Opposition Division and paid the prescribed fee on the same day. The Statement of the Grounds of Appeal was submitted on 16 May 2002.

The Appellant maintained its objections of lack of novelty, lack of inventive step and added subject-matter raised in the first instance opposition proceedings and submitted further that Claim 1 as allowed in the appealed decision lacked clarity, contrary to Article 84 EPC, and extended beyond the scope of protection as compared to Claim 1 as granted, contrary to Article 123(3) EPC.

In addition, the opposition ground under Article 100 (b) EPC was raised for the first time.

Inter alia, the following further documents were also cited for the first time:

- D14a Effects of the in-vitro fermentation of oligofructose and inulin by bacteria growing in the human large intestine, *J. Applied Bacteriology*, 75 (1993), 373-380;
- D17 Declaration of Dr P. Stöber, Structural Chemist, Nestlé dated 17 April 2002;
- D19 US-A 5 169 662;
- D20 Dietary Fiber, Inulin, and Oligofructose: a Review Comparing their Physiological Effects, *Critical Reviews in Food Science and Nutrition*, 33(2): 103-148 (1993);
- D23 Åkerberg et al. in *American Society for Nutritional Sciences* 22-3166 (1998), 651-660;

D25 Undigestible sugars in food products, *Am. J. Clin. Nutr.* 1994 59(suppl), 763S-769S.

With a letter dated 2 December 2002 the Respondent/Patent Proprietor (hereinafter "the Respondent") defended the patent as maintained by the appealed decision and also filed auxiliary requests 1 to 3.

In response to a communication dated 20 October 2005, in which the Board expressed concerns with respect to the issues of clarity (Article 84 EPC) and added subject-matter (Article 123(2) EPC), the Respondent, with a letter dated 28 December 2005, filed new auxiliary requests 1 to 9, which he replaced by a further set of auxiliary requests 1 to 11 submitted with the letter of 23 January 2006 in response to the written submissions of the Appellant dated 6 January 2006.

In the oral proceedings before the Board the Respondent substituted amended auxiliary requests 3 to 7 for auxiliary requests 3 to 11 of the afore-mentioned set of requests.

Claims 1 of the operative auxiliary requests 1 to 5 read as follows (in view of the outcome of the appeal there is no need to refer to the content of auxiliary requests 6 and 7):

Auxiliary request 1

"1. Nutritional composition, which, optionally after admixture of other food components and/or dilution with

water, is suitable for enteral administration, comprising dietary fibre, characterised in that the fibre consists of

- [a)] 15-50 wt.% of soluble non-starch polysaccharides,
- [b)] 15-45 wt.% of insoluble non-starch polysaccharides, and
- [c)] 8-70 wt.% of non-digestible oligosaccharides and/or resistant starch, comprising 8-70 wt.%, on the basis of the fibre, of hydrolysed inulin, and/or comprising resistant starch."

Auxiliary request 2

"1. Nutritional composition, which, optionally after admixture of other food components and/or dilution with water, is suitable for enteral administration, comprising dietary fibre, characterised in that the fibre consists of

- a) 15-50 wt.% of soluble non-starch polysaccharides,
- b) 15-45 wt.% of insoluble non-starch polysaccharides and
- c1) 8-70 wt.% of non-digestible oligosaccharides, comprising at least 8 wt.%, on the basis of the fibre, of hydrolysed inulin, or
- c2) 8-70 wt.% of resistant starch, or
- c3) 8-70 wt.% of non-digestible oligosaccharides, and resistant starch."

Auxiliary request 3

"1. Nutritional composition, which, optionally after admixture of other food components and/or dilution with water, is suitable for enteral administration,

comprising dietary fibre, characterised in that the fibre consists of

- a) 15-50 wt.% of soluble non-starch polysaccharides,
- b) 15-45 wt.% of insoluble non-starch polysaccharides, and
- c) 8-70 wt.% of non-digestible oligosaccharides, comprising at least 8 wt.%, on the basis of the fibre, of hydrolysed inulin and optionally comprising resistant starch."

Auxiliary request 4

"1. Nutritional composition, which, optionally after admixture of other food components and/or dilution with water, is suitable for enteral administration, comprising dietary fibre, characterised in that the fibre consists of

- a) 15-50 wt.% of soluble non-starch polysaccharides,
- b) 15-45 wt.% of insoluble non-starch polysaccharides, and
- c) 8-70 wt.% of non-digestible oligosaccharides, comprising at least 8 wt.%, on the basis of the fibre, of hydrolysed inulin and comprising resistant starch."

Auxiliary request 5

"1. Liquid nutritional composition, which, optionally after admixture of other food components and/or dilution with water, is suitable for enteral administration, and contains 5-120 g of dietary fibre per l, characterised in that the fibre consists of

- [a)] 15-50 wt.% of soluble non-starch polysaccharides,

- [b)] 15-45 wt.% of insoluble non-starch polysaccharides, and
- [c)] 8-70 wt.% of non-digestible oligosaccharides comprising at least 8 wt.%, on the basis of the fibre, of hydrolysed inulin, and comprising resistant starch."

VI. The written and oral arguments of the Appellant are summarized as follows:

(a) *Clarity - Article 84 EPC*

The definition in feature (c) of Claim 1 of the main request "comprising at least 8 wt.% of hydrolysed inulin" did not clearly specify the basis to which this amount was related.

The feature "hydrolysed inulin" was vague because the chain length of the hydrolysed species was not mentioned.

(b) *Added subject-matter and extension of the protection conferred - Articles 123(2) and (3) EPC*

The term "at least 8 wt.% of hydrolysed inulin" in Claim 1 of the main request signified that the amount of hydrolysed inulin referred specifically to a part of component (c) but not to component (c) as such, contrary to Article 123(2) EPC. Only component (c) as a whole was described in terms of its percentage amount of the entire fibre composition as providing 8-70 wt.%.

The above wording, in context with the non-digestible oligosaccharide defined in Claim 1 by its amount, also allowed for a mixture of two or more oligosaccharides (c), for instance 8 to 62 wt.% of a (non-specified) oligosaccharide and 8 wt.% hydrolysed inulin. In contrast thereto, Claim 1 as granted did not envisage a combination of two different non-digestible oligosaccharides. Claim 1 according to the main request and the auxiliary requests, also allowing for an admixture of two or more oligosaccharides, did not therefore comply with Article 123(3) EPC.

(c) *Novelty - Article 54 EPC*

A nutritional composition comprising dietary fibre, wherein the fibre consisted of a) soluble non-starch polysaccharides, b) insoluble non-starch polysaccharides and c) oligosaccharides, selected inter alia from fructo-oligosaccharides, in the amounts as claimed in Claim 1 was described in D1. Although D1 did not mention how the fructo-oligosaccharides were obtained - either via hydrolysis of inulin or enzymatic inversion (transfructosylase) of sucrose - the method of its production was not relevant because fructo-oligosaccharide and hydrolysed inulin had essentially the same composition and were used for exactly the same purposes. This was for instance evident from the declaration D17, points 7 to 23. D1 was therefore novelty-destroying to the nutritional compositions of the embodiment where the non-digestible fiber (c) was an oligosaccharide comprising hydrolysed inulin.

For similar reasons, the composition according to embodiment 1 as described at page 6 of the document D10 was novelty-destroying.

D2 disclosed in column 4 an edible flour comprising soluble fibres a), insoluble fibres b) and starch c) in amounts overlapping the ranges for (a) to (c) defined in Claim 1 of all requests. According to column 4, lines 36 to 47, potato starch and banana starch were suitable starch components which contained high amounts of resistant starch, as was known for instance from D7, the table 3 at page 941S.

Therefore, D2 disclosed the subject-matter of the claimed invention, as far as the use of resistant starch as fibre (c) was concerned and, consequently, was prejudicial to the novelty.

Likewise, example 1 of D19, which described a dietary food product in the form of a mixture of specific amounts of oat bran, corn bran, corn meal and triticale, was novelty-destroying. The content of soluble and insoluble fibre given in the table at column 8 was within the range claimed for the fibres (a) and (b) and the amount of resistant starch brought in by corn meal also met the requirement of feature (c) when considering D23, which disclosed in table 2 that corn meal contained more than 70 wt.% resistant starch.

(d) *Inventive step - Article 56 EPC*

The problem to be solved by the claimed invention was the provision of a nutritional composition which produced short chain fatty acids (SCFAs) at a sufficient and uniform rate during fermentation and transit through the large intestine.

The closest prior art was represented by D10 lying in the field of nutritional compositions promoting regular intestinal function. It was mentioned therein that the oligosaccharides contained in the composition were fermentable by bifidobacteria which were responsible for the production of SCFAs. Example 2 of D10 described a composition containing all ingredients in the corresponding amounts required by the patent in suit, but with the proviso that fructo-oligosaccharides derived from inversion of sucrose instead from inulin hydrolysis were used.

The problem to be solved by this difference was merely seen in the provision of an alternative. Because, however, it was known from page 5, lines 1 to 4 of D10 that fructo-oligosaccharides could be formed by the hydrolysis of inulin, no inventive effort could be seen in exchanging the fructo-oligosaccharide of example 2 by hydrolysed inulin.

The claimed embodiment of using resistant starch instead of non-digestible oligosaccharides or in addition thereto was also obvious from D10 in combination with D7 because the skilled person

looking for an alternative component having the same property, i.e. being non-digestible in the intestinal tract and also providing a fermentable source for bifidobacteria, would have considered D7, which discloses in the figure 1 at page 939S starches as a fermentable source for bifidobacteria. In a similar manner, the skilled person would have considered D14a, which compares the bacterial growth in various carbohydrates, inter alia oligofructose, inulin and starch, and states in the paragraph "Discussion" at pages 378 to 379 that starch fermentation *in vitro* produced butyrate (i.e. an SCFA) in a relatively high concentration.

VII. The arguments of the Respondent provided orally and in written form may be summarized as follows:

(a) *Clarity - Article 84 EPC*

The term "8 wt.% hydrolysed inulin" in Claim 1 of the main request was clear to a skilled person. It was always pointed out in the written submissions that this range related to the total fibre composition (a) + (b) + (c).

Feature (c) of the first auxiliary request had to be understood in two ways:

Firstly, the part reading "8-70 wt.% of non-digestible oligosaccharides and/or resistant starch, comprising 8-70 wt.% ... of hydrolysed inulin" meant that the oligosaccharide should comprise 8-70 wt.% of hydrolysed inulin if starch was not present.

Secondly, the part reading "comprising 8-70 wt.%, on the basis of the fibre, of hydrolysed inulin, and/or comprising resistant starch" signified that the oligosaccharide should consist of 8-70 wt.% of hydrolysed inulin if no resistant starch was present.

In the patent specification, it was explained in column 3, lines 19 to 22, that the oligosaccharides contained 2 to 20 monosaccharide units. It was therefore clear to a skilled person that hydrolysed inulin contained fragments consisting of 2 to 20 units, either represented by $G-F_n$ or F_m , whereby "G" represented glucose and "F" fructose moieties.

- (b) *Added subject-matter and extension of the protection conferred - Articles 123(2) and (3) EPC*

The amended feature (c) in the auxiliary requests 1, 3, 4 and 5 reading: "8-70 wt.% of non-digestible oligosaccharides comprising 8-70 wt.% and at least 8 wt.%, respectively, on the basis of the fibre, of hydrolysed inulin ..." [emphasis added] could be derived from a combination of the original Claims 1 and 4 and therefore complied with Article 123(2) EPC.

Because, as regards the presence of the non-digestible oligosaccharides, Claim 1 as granted was formulated in the plural form with respect to the word "oligosaccharides", a mixture of two or more oligosaccharides was within the scope of the claim. Therefore, no extension of the protection

conferred could be seen by the amended claims allowing a mixture of oligosaccharides with hydrolysed inulin.

(c) *Novelty - Article 54 EPC*

The terms "oligofructose/fructo-oligosaccharide (FOS)" were more general and therefore represented a broader spectrum of oligosaccharides than hydrolysed inulin. Consequently, a hydrolysed inulin was embraced by the above term but FOS was not necessarily chemically identical with hydrolysed inulin.

For these reasons, neither D1 nor D10 anticipated the claimed subject-matter.

With regard to the disclosure in D2, two selections had to be made, i.e.

- the claimed values had to be selected from the weight ratios of the soluble/insoluble non-starch polymers and starch disclosed in column 4 and
- from the numerous suitable starches listed at column 4, potato and/or banana starch had to be selected in order to arrive at the claimed invention.

The fact that the disclosure in D2 led to the claimed subject-matter by coincidence only, was evident from the table presented at page 8 of the letter dated 28 December 2005, which clearly showed that no embodiment depicted in example 2 of D2 was embraced by the claimed invention.

D19 disclosed erroneous and contradictory amounts of soluble and insoluble fibers in oat bran. It was known in the prior art that oat bran consisted predominantly of insoluble fiber (72 to 87 wt.%), whereas the table in column 4 of D19 indicated amounts for insoluble fibers of 26-27 wt.% and for soluble fibers of 56 to 57 wt.%.

Furthermore, the dough mix according to the example 1 of D19 was outside the claimed invention, contrary to the Appellant's view. The Appellant's calculation given in the Statement of the Grounds of Appeal was based on the assumption - with respect to table 2 of D23 - that corn meal contained more than 70 wt.% resistant starch. This was not correct because the corresponding data in this table related to high amylose corn starch and not to corn meal. Indeed, as outlined in table 3 of D7, corn meal only contained a few weight percent of resistant starch and, therefore, the dough mix of example 1 had a content of resistant starch considerably below the claimed range.

Neither D2 nor D19 were therefore prejudicial to the novelty of the claimed nutritional composition as far as the presence of resistant starch was mandatory.

(d) *Inventive step - Article 56 EPC*

The document D10, considered representative of the closest prior art by the Appellant, was concerned with the provision of health food stimulating bifidobacteria propagation.

In contrast thereto and in accordance with column 1, lines 22 to 34 and column 2, lines 13 to 22 of the patent specification, the present invention sought to provide a balanced fibre composition resulting in a constant release of SCFAs, in particular propionic acid and butyric acid, over a greater length of the colon and with a constant and modest gas production. One particular preferred non-digestible oligosaccharide, which promotes the higher production of propionate and butyrate, was hydrolysed inulin (see column 3, lines 29 to 32 of the patent specification). The superior property of hydrolysed inulin was demonstrated in the test report D13.

Although hydrolysed inulin was mentioned in D10 amongst other oligosaccharides, the specific function of this compound was not illustrated and the skilled person had no reason to use it in order to enhance the propionate/butyrate production. Furthermore, D10 was silent on resistant starch.

A combination of D10 and D7 would not lead the skilled person to the claimed invention either, because D7 - like D10 - was not concerned with balanced SCFA production in the large intestine.

D14a described the use of oligofructose and inulin for bacterial growth in the intestine. Both components differed, however, from hydrolysed inulin. The skilled person being aware of D14a had no incentive to use inulin for promoting the propionic/butyric acid production and even less

would he expect that hydrolysed inulin was capable of obtaining long-term effects in this respect.

VIII. The Appellant requested that the decision under appeal be set aside and that the European patent No. 0 756 828 be revoked.

He further requested that the experimental evidence and all the documents filed with the Respondent's letters of 28 December 2005 and 23 January 2006 be not admitted into the proceedings.

IX. The Respondent requested that the appeal be dismissed or, alternatively, that the patent be maintained on the basis of the auxiliary requests 1 and 2 submitted with the letter of 23 January 2006 or on the basis of any of the auxiliary requests 3 to 7 filed during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.
2. According to the principle set out in G 9/91 (OJ 1993, page 408 et seq.) and G 10/91 (OJ 1993, page 420 et seq.) and confirmed in G 1/95 (OJ 1996, page 615 et seq.) and G 7/95 (OJ 1996, page 626 et seq.) a fresh ground of opposition may not be introduced into the proceedings either by an opponent or by the Boards of Appeal of its own motion without the agreement of the Patentee.

In the present case, the ground of opposition under Article 100(b) EPC was newly raised by the Appellant in the appeal proceedings and the Patent Proprietor did not agree to its introduction. Consequently, this fresh ground will not be examined.

3. *Article 84 EPC*

3.1 Main request and auxiliary request 1

3.1.1 In view of the amendment present in Claim 1 of the main request as compared to its granted version, compliance of the claim with the requirements of Article 84 EPC has to be examined, resulting in the conclusion that there is no clear reference basis for the amount of hydrolysed inulin in the added feature "at least 8 wt.% of hydrolysed inulin". This percentage could either refer to the total fiber composition [consisting of (a) plus (b) plus (c)] or just to the fiber component (c), leading to vastly different minimum amounts of hydrolysed inulin: 8 wt.% in the first case, 0.64 wt% (8 wt.% hydrolysed inulin of minimum 8 wt.% non-digestible oligosaccharide (c) in the latter case.

3.1.2 Although the basis for the amount of hydrolysed inulin is given in Claim 1 of the first auxiliary request, feature (c) of this claim is still not clear because the twice-repeated passage "and/or comprising resistant starch" in different syntactic levels renders this feature incomprehensible. It does not lend itself, in particular, unambiguously to the Respondent's interpretation given in the oral proceedings that, if no resistant starch was present, the oligosaccharide consisted entirely of 8-70 wt. hydrolysed inulin.

3.1.3 For the reasons discussed in points 3.1.1 and 3.1.2 above, the Claims 1 of the main request and the auxiliary request 1 are not allowable because they contravene Article 84 EPC.

3.1.4 The main request and the auxiliary request 1 must therefore be refused.

3.2 Auxiliary Requests 2 to 5

The Claims 1 of the auxiliary requests 2 to 5 do not suffer from the above mentioned deficiencies.

In the Board's judgment, a skilled person would furthermore understand the meaning of "hydrolysed inulin" in context with the term "oligosaccharides" as a mixture of oligomeric G-F_n and F_m entities. In this respect the Board makes reference to the document D20 where this constitution of hydrolysed inulin is set out at page 132, paragraph VI.A.

4. *Articles 123 (2) and (3) EPC - Auxiliary Requests 2 to 5*

It is disclosed in the original Claim 1 in conjunction with Claim 4, referring back to Claim 1, that the basis for the amount of hydrolysed inulin and resistant starch, respectively, is the total dietary fiber composition. From these claims taken together it can be derived that the amount of hydrolysed inulin, if present, is at least 8 wt.% as long as it does not exceed the amount of 70 wt.% based on the fiber. This disclosure is part of Claims 1 of the auxiliary

requests 2 to 5 which, therefore, meet the requirements of Article 123(2) EPC.

The Board also concurs with the position of the Respondent that Claim 1 as granted not only allows for the presence of a single non-digestible oligosaccharide but also of a mixture of different oligosaccharides, hydrolysed inulin inclusive, in that the corresponding feature "... 8-70 wt.% of ... oligosaccharides ..." is formulated in the plural form. Hence, the Claims 1 of the auxiliary requests 2 to 5 do not extend the protection conferred and comply with Article 123(3) EPC.

5. *Novelty*

5.1 *Novelty of the claimed composition according to Claims 1 of auxiliary requests 2 and 3 in which the fibre (c) comprises, in one variant, non-digestible oligosaccharides including hydrolysed inulin.*

For this embodiment, the disclosure of D1 and D10 is of relevance.

5.1.1 D1

D1 discloses a nutritional composition for oral and tube feeding comprising 2 to 10 wt.% of dietary non-starch polysaccharide fibres and 1 to 5 wt.% oligosaccharides, selected inter alia from fructo-oligosaccharides, which are normally non-digestible in the sense of the teaching of the patent. The proportions of water-soluble dietary fibre and water-insoluble dietary fibers are 4:6 to 6:4. The ratio of

total dietary fiber and oligosaccharide can be 5:5 (page 3, Claims 1 to 3). From the above data the following amounts for the dietary fibre composition can be calculated:

- a) 20 to 30 wt.% soluble non-starch polysaccharides;
- b) 30 to 20 wt.% non-soluble non-starch polysaccharides;
- c) 50 wt.% fructo-oligosaccharides.

These weight ranges overlap with the corresponding ranges indicated in the Claims 1 of the auxiliary requests 2 and 3.

In assessing novelty, the question has to be answered whether the terms "fructo-oligosaccharide/oligofructose" and "hydrolysed inulin" are synonyms and represent the same chemical composition.

In the Board's judgment and contrary to the opinion of the Appellant, this is not the case. It is uncontested by the parties that fructo-oligosaccharides are principally obtainable by two routes, either via hydrolysis of inulin or by the enzymatic action of a fructosyltransferase on sucrose. Both routes lead to fructo-oligosaccharides which, however, have a different composition of the oligosaccharide fragments. The disclosure in D20 (page 132, paragraph VI.A., right column) shows that the hydrolysis of inulin produces linear oligomers both of the $G-F_n$ and F_m type (with n and $m = 2$ to 9), which means that only part of the fructose chains bear a terminal glucose unit. It is further disclosed in the same passage of this document that the enzymatic route starting from sucrose

leads to oligomers of the G-F_n type (n = 2 to 5). From this disclosure, it can be deduced that nearly all fructose chains bear a terminal glucose unit.

This disclosure is corroborated by the HPAEC elution pattern of Raftilose® (hydrolysed inulin, pattern A) and Actilight® (inverted sucrose, pattern B) depicted in D16 which was submitted by the Respondent.

The term "fructo-oligosaccharide" embraces both types of compositions and is therefore more general in that it represents a broader spectrum of saccharide oligomers than the term "hydrolysed inulin". Consequently, D1, which only discloses this general term, cannot anticipate the subject-matter of the main requests 2 and 3.

5.1.2 D10

In a similar manner, as in D1, the following amounts for the fiber composition in the embodiment 1 of D10 can be calculated:

- a) 13.3 wt.% soluble fibre (pectin)
- b) 44.7 wt.% insoluble fibre (hemicellulose + cellulose + lignin);
- c) 43.0 wt. fructo-oligosaccharide

Although D10 discloses in its general description at page 5, lines 4/5 an inulin hydrolysate as one possible oligosaccharide which might be present in the fiber composition, the fructo-oligosaccharide used in the specific embodiment 1 is one obtained enzymatically via fructosyltransferase. There is thus no unambiguous direct disclosure of the combination of features

specified in Claims 1 of auxiliary requests 2 and 3. The subject-matter of these claims is therefore novel over D10.

5.2 Novelty of the claimed composition according to *Claims 1 of the auxiliary request 2 in the alternative that the fibre component (c) is resistant starch only.*

For this alternative, the documents D2 and D19 are of relevance.

5.2.1 D2

The document D2 discloses in Claim 1 in conjunction with column 4, lines 3 to 12, an edible flour prepared from starch, insoluble fibre and soluble fibre in proportions ranging from 1:0.9-1.5:0.02-0.36. From these data, the following ranges can be calculated:

- a) 0.8 - 24.8 wt.% soluble fibre;
- b) 6.2 - 59.5 wt.% insoluble fibre;
- c) 34.9 - 90 wt.% starch.

It is evident that each of the three ranges only partially overlaps the corresponding ranges of Claim 1 of the second auxiliary request. Therefore, a selection from each of the above ranges in D2 has to be made in order to arrive at the invention with respect to the amounts of the fibres in the composition.

According to D2, column 4, lines 36 to 47, the starch (c) can be selected from a list of numerous possible starches, but only potato starch and banana starch contain resistant starch in a proportion (70 wt.% and

56 wt.%, respectively, see D7, the table 3 at page 941S) which is high enough to provide the required amount of resistant starch in component (c).

From the above it follows that two separate selections are necessary in order to meet the requirements of the claimed invention. This does not amount to a clear and unambiguous disclosure of the claimed subject-matter and the disclosure of D2 is therefore not novelty-destroying.

5.2.2 D19

Despite the objection of the Respondent, this document was considered admissible because it was filed with the Statement of the Grounds of Appeal in order to overcome the appealed decision. In this respect, it was filed in due time within the meaning of Article 114(2) EPC, given that the purpose of the appeal procedure inter partes is mainly to give the losing Party the possibility of challenging the decision of the Opposition Division on its merits and, in perfect compliance with the general principle of procedural economy.

The Appellant's objection raised in the appeal proceedings, that the base dough mix according to example 1 of D19 was prejudicial to the novelty of the subject-matter of this request, was based on the allegation that corn meal contained high proportions of resistant starch. In this respect, the Appellant referred to the table 2 of D23 indicating 71.4 wt.% resistant starch for native high amylose cornstarch.

However, native high amylose cornstarch cannot be equated with corn meal used according to example 1 of D19, the latter containing resistant starch in the much lower order of eg 2 wt.% only (see the reference to "white flour" in table 3 of D7). Therefore, the Board is satisfied that the Respondent's calculation presented in this context at page 6 of the letter dated 28 December 2005 and showing that example 1 of D19 is outside the claimed invention, convincingly demonstrates that D19 does not anticipate the claimed subject-matter.

5.3 Novelty of the composition according to the Claims 1 *of auxiliary requests 2 to 5 concerning the embodiment that the fibre (c) is a combination of oligosaccharides and resistant starch.*

5.3.1 Auxiliary request 2

In the alternative (c3) of auxiliary request 2, the fibre can be 8 to 70 wt.% of a non-digestible oligosaccharide, which is not further specified, and resistant starch.

A combination of oligosaccharides and resistant starch is not expressly mentioned in any of the documents D1, D2, D10 and D19.

As far as the Appellant alleges in the Statement of the Grounds of Appeal with reference to D25, page 765S, that triticale used in the example 1 of D19 contained fructo-oligosaccharides, no convincing evidence was provided that these fructo-oligosaccharides are present in the amounts as claimed in Claim 1 of the auxiliary request 2.

Therefore, D1, D2, D10 and D19 cannot anticipate the subject-matter in which the two alternatives are present in combination.

5.3.2 Auxiliary requests 3 to 5

According to one embodiment of the feature (c) of auxiliary request 3, a non-digestible oligosaccharide comprising at least 8 wt.%, on the basis of the fibre, of hydrolysed inulin, and resistant starch is present. This combination is mandatory in the auxiliary requests 4 and 5.

For the same reasons mentioned under point 5.3.1, and because it was not convincingly demonstrated by the Appellant that triticale used in example 1 of D19 contains hydrolysed inulin, the documents D1, D2, D10 and D19 are not novelty-destroying for this alternative.

5.4 The other documents cited cannot change the above conclusion.

5.5 The subject-matter of the auxiliary requests 2 to 5 is therefore novel over the cited prior art.

6. *Inventive step, auxiliary requests 2 to 5*

6.1 The patent in suit

In its generality, the patent is concerned with a nutritional composition comprising dietary fibre consisting of a combination of three types of fibres

(a), (b) and (c) in specific amounts. The fibre (a) is a soluble non-starch polysaccharide and the fibre (b) consists of an insoluble non-starch polysaccharide. The fibre (c) can be either a non-digestible oligosaccharide or a resistant starch or a combination of both.

In the patent specification it is further stated in column 2, lines 14 to 19 that the fibre mixture (a) plus (b) plus (c) is fermented at a relatively uniform rate, starting in the first part of the colon and continuing in more distal parts of the colon, to yield a relatively constant amount of SCFA's comprising a relatively high amount of propionic and/or butyric acid and to produce a relatively constant level of gas.

According to column 2, lines 25 to 32, compositions of dry consistency can be added to other food materials and compositions of liquid consistency are particularly suitable for enteral administration and comprise tube feeds in different forms.

According to the auxiliary requests 2 to 5 the claimed composition is specifically characterised by the following elements with respect to its constitution and to the nature of the fibre (c):

Auxiliary request 2

In Claim 1 of this request it is not specified whether the composition is solid, pasty or liquid. The fibre (c) can be either a non-digestible oligosaccharide comprising at least 8 wt.%, on the basis of (a) to (c), of hydrolysed inulin or resistant starch or a

combination of a non-digestible oligosaccharide (not further specified) and resistant starch.

Auxiliary request 3

In contrast to the auxiliary request 2, the fibre component (c) according to Claim 1 of auxiliary request 3 consists either of a non-digestible oligosaccharide composition including hydrolysed inulin or its combination with resistant starch.

Auxiliary request 4

The composition according to Claim 1 of this request differs from that according to the auxiliary request 3 only in that the combination of the non-digestible oligosaccharide/hydrolysed inulin and resistant starch is mandatory.

Auxiliary request 5

The composition according to Claim 1 of this request is defined as a liquid containing 5 to 120 g of the dietary fibre [(a) plus (b) plus (c)] per litre. The fibre component (c) is specified as a combination of a non-digestible oligosaccharide comprising hydrolysed inulin and resistant starch.

6.2 Auxiliary requests 2 to 4 - The closest prior art

D10 is representative of the closest prior art for this subject-matter. This document is concerned with a nutritional composition suitable for the production of health food which is efficacious in promoting regular

intestinal function. Essential ingredients of the composition are edible fibres selected from soluble fibre (a) like pectin, insoluble fibre (b) like cellulose/hemicellulose, and - as the primary ingredient - non-digestible oligosaccharides of 3 to 10 monosaccharide units, *inter alia* fructo-oligosaccharides. The health food preferably has the consistency of a jelly or pudding (see the claims at pages 1 and (2)). On page 3, lines 17 to 20 it is mentioned that the oligosaccharides of 3 to 10 monosaccharide units have been employed for propagating bifidobacteria and at page 5, lines 1 to 4, it is stated that the oligosaccharides, *inter alia*, can be formed by the hydrolysis of inulin.

6.2.1 *Inventive step of the subject-matter according to auxiliary requests 2 and 3 concerning the embodiment where (c) are non-digestible oligosaccharides comprising hydrolysed inulin*

(a) Problem and Solution

Embodiment 1 of D10, which uses as fibre component (c) a fructo-oligosaccharide produced enzymatically via fructosyltransferase discloses a health food composition coming closest to the above-mentioned embodiment.

The claimed subject-matter differs therefrom essentially in that a fructo-oligosaccharide produced via hydrolysis of inulin is present in the composition.

In view of the disclosure in column 3, lines 22 to 25 of the patent specification exhibiting

hydrolysed inulin only as one of various possible oligosaccharides, no teaching can be derived from the patent that hydrolysed inulin is specifically linked to the improved formation of SCFAs in the intestinal tract. Likewise, example 1 of the patent using Raftilose® (hydrolysed inulin) is silent on a technical effect which would qualify hydrolysed inulin as a particularly preferred oligosaccharide.

Therefore, the problem to be solved by the invention is merely seen in providing an alternative nutritional composition.

(b) Obviousness

The solution to the problem, namely to use - at least partly - hydrolysed inulin as oligosaccharide is obvious to a skilled person with respect to the disclosure at page 5 of D10 that a fructo-oligosaccharide formed by the hydrolysis of inulin can be used.

The Respondent argues that D10 pertained to the growth of bifidobacteria and was not concerned with the production of SCFAs as taught in the patent.

This argument, however, is not convincing because the skilled person knows from D7 that fructo-oligosaccharides, inter alia those obtained via hydrolysis of inulin, not only stimulate the growth of bifidobacteria but are also fermented to SCFAs including acetate, propionate and butyrate (page 939S, left column, last complete sentence).

For the above reasons the Board concludes that the corresponding embodiments of the Claims 1 of each of the auxiliary requests 2 and 3 are not based on an inventive step.

Thus, the auxiliary requests 2 and 3 as a whole are refused.

6.2.2 *Inventive step of the subject-matter of the auxiliary request 4 concerning the embodiment wherein the fibre (c) is a non-digestible oligosaccharide including hydrolysed inulin and resistant starch in combination*

(a) Problem and solution

The subject-matter of Claim 1 of the auxiliary request 4 differs from the embodiment 1 of D10, which again represents the closest prior art, in that resistant starch and hydrolysed inulin are present in combination.

For similar reasons mentioned under point 6.2.1 and in the absence of any experimental evidence that a combination of resistant starch and hydrolysed inulin provides a beneficial effect in the production of SCFAs vis à vis oligosaccharides alone, the problem to be solved is seen again in the provision of an alternative nutritional composition.

(b) Obviousness

The combination of hydrolysed inulin and resistant starch, however, is obvious for a skilled person being aware of D7, which discloses in the right-hand column of page 940S (first paragraph) that physically inaccessible (resistant) starch may enter the colon and be fermented. When considering this information in context with the passage on page 939S of D7 relating to fructo-oligosaccharides (see point 6.2.1), the skilled person would conclude that fructo-oligosaccharides, hydrolysed inulin inclusive, and resistant starch have a similar behaviour during fermentation. This conclusion is confirmed by D14a, which in the paragraph bridging pages 378 and 379 points to the production of butyrate in relatively high concentration during in-vitro fermentation of resistant starch.

Hence, the subject-matter of Claim 1 of the auxiliary request 4 is also not based on an inventive step and the request as a whole must therefore be refused.

6.3 Auxiliary request 5 - The closest prior art

For the consideration of the issue of inventive step of the subject-matter of auxiliary request 5, the situation changes, in that this request is concerned with a nutritional composition in a liquid consistency which - as outlined in the patent specification, column 2, lines 24 to 29 in conjunction with column 1, lines 3 to 16 - is suitable as clinical food for

enteral administration, for instance in the form of tube feeds.

For this subject-matter, D1 is representative of the closest prior art, lying in the field of clinical nutritional compositions, e.g. in liquid form, suitable for enteral tube feeding and promoting bifidobacteria growth (paragraphs [0005] and [0008], page 9, lines 22 to 25 and paragraph [0017]).

As already mentioned in point 5.1.1 under the issue of novelty, the compositions of D1 contain a mixture of dietary fibres consisting of soluble and insoluble non-starch polysaccharides and oligosaccharides, for instance fructo-oligosaccharides, as bifidobacteria promoter, in amounts overlapping with the claimed range.

6.3.1 Problem and solution

The subject-matter of auxiliary request 5 differs from the liquid composition in D1 in that the oligosaccharide contains hydrolysed inulin as fructo-oligosaccharide, in combination with resistant starch.

The experimental evidence D13 on file shows, in a simulated colon model harbouring a human faecal microflora, that the fermentation of hydrolysed inulin produces considerably higher amounts of butyrate during prolonged digestion after either 24 or 48 hours than trans-galacto-oligosaccharides.

Starting from D1, the problem to be solved is therefore seen in the provision of a liquid nutritional

composition producing high amounts of butyrate during fermentation in the human colon.

6.3.2 Obviousness

Although the skilled person knows from D7 that fructo-oligosaccharides stimulate bifidobacteria growth and are fermented to SCFAs, he would not expect that hydrolysed inulin is a particularly suitable fructo-oligosaccharide for the production of considerably high amounts of butyrate. In view of D7, which states in the passage in the left-hand column, lines 1 to 3 from the bottom at page 939S, that in-vitro fructo-oligosaccharides are fermented mostly to acetate and propionate with some butyrate, the skilled person would be put off from choosing hydrolysed inulin in order to produce particularly enhanced amounts of butyrate. All the more so as at page 6, lines 28 to 30, D1 qualifies galacto-oligosaccharide as an oligosaccharide with an intense bifidobacteria growth factor effect.

Because D14a does not contain any additional information which would motivate the skilled person starting from D1 to select hydrolysed inulin for producing particularly high amounts of butyrate, the subject-matter of Claim 1 of the auxiliary request 5 is not obvious over D1 in combination with either D7 or D14a.

Under these circumstances, it is irrelevant for the acknowledgment of the inventive step that the claimed composition contains - in combination with hydrolysed inulin - resistant starch, whose fermentability to butyrate is known from D14a, because both these non-

digestible oligo/poly saccharides are separately fermented in the intestine.

6.3.3 Conclusion

Since the combination of the closest prior art according to D1 with the teaching in the other relevant documents D7 and D14a does not render the liquid composition of Claim 1 obvious and since the further Claims 2 to 10 of the auxiliary request 5 are dependent on Claim 1, the entire subject-matter claimed by this request involves an inventive step over the cited prior art.

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 Claims 1 to 10 of the fifth auxiliary request filed during the oral proceedings before the Board after any necessary consequential amendment of the description.

The Registrar:

The Chairman:

G. Röhn

P. Kitzmantel