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**Datasheet for the decision
of 6 February 2014**

Case Number: T 2460/11 - 3.3.09

Application Number: 03003009.2

Publication Number: 1310173

IPC: A23L1/308, A23L1/0528, A23L1/29

Language of the proceedings: EN

Title of invention:
Composition for providing nutrition to diabetics

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponent:
N.V. Nutricia

Headword:

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

Keyword:
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 2460/11 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 6 February 2014

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
24 October 2011 concerning maintenance of the
European Patent No. 1310173 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

I. Mention of the grant of European patent No. 1 310 173 in respect of European patent application 03 003 009.2 filed on 31 March 1998 as divisional application of European patent application 98 201 018.3 in the name of Société des Produits Nestlé was announced on 23 May 2007 in Bulletin 2007/21.

II. The patent was granted with 8 claims, claim 1 reading as follows:

"1. A nutritional composition for diabetic patients, the composition containing a protein source, a lipid source, and a carbohydrate source, the carbohydrate source including a fibre mixture comprising

- a viscous fibre selected from guar gum, xanthan gum, gum Arabic, pectin, β -glucan and mixtures of these, and
- inulin, a hydrolysate of inulin, or both,

wherein the nutritional composition is a liquid composition which has a viscosity, when measured at room temperature, of 0.015 to 0.03 kg/ms."

Claims 2 to 8 were dependent claims.

III. An opposition against the patent was filed by

Nutricia N.V. on 22 February 2008.

The opposition was based on the grounds according to Articles 100(a) (lack of novelty and lack of inventive step), 100(b) and 100(c) EPC.

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

- D3 Brochure "La nueva mezcla de fibra Pentaset";
- D3a English translation of D3;
- D5 Letter of the Spanish Ministry of Health and Consumer Affairs, issued 4 July 1990;
- D5a English translation of D5;
- D7 Sidorchenko et al, "Substances of Colloidal Particle Size in the Jerusalem Artichoke", *Sakharnaya Svekla Proizvodstvo I Peretabotka* no. 6, 1991, pp. 54-55;
- D7a English translation of D7;
- D14 J.W. Anderson et al. "TREATMENT OF DIABETICS WITH HIGH FIBER DIETS", *CRC Handbook of Dietary Fiber in Human Nutrition*, CRC Press Inc., 2nd edition, 1993, pp 443-470;
- D15 US-A 5 292 723;
- D18 Sworn statement of MR. JESUS FERNANDO IRZO ASENSIO;
- D18a English translation of D18.

IV. With its interlocutory decision announced orally on 4 October 2011 and issued in writing on 24 October 2011 the opposition division maintained the patent in amended form on the basis of claims 1 to 6 according to the main request filed on 28 September 2011. Claim 1 reads as follows:

"1. A nutritional composition for diabetic patients, the composition containing a protein source, a lipid source, and a carbohydrate source, the carbohydrate source including a fibre mixture comprising

- a viscous soluble fibre selected from guar gum, xanthan gum, gum Arabic, pectin, β -glucan and mixtures of these, and
- inulin, a hydrolysate of inulin, or both,

wherein the nutritional composition is a liquid composition which has a viscosity, when measured at room temperature, of 0.015 to 0.03 kg/ms and in which the fibre mixture includes a source of insoluble dietary fibre and is present in an amount of 1.0 g/100 ml to 2.0 g/100 ml. and the ratio of soluble fibre, including inulin, to insoluble fibre, is 1:3 to 3:1."

With regard to the objection of insufficiency of disclosure concerning the use of the expression "viscosity, measured at room temperature" the opposition division held that this feature would not prevent a skilled person from reproducing the invention over the whole scope of the claims without undue burden.

Concerning novelty, one issue was an alleged prior public use, which was mainly based on documents D3/D3a, D5/D5a and D18/D18a. In this respect the opposition division followed the conclusion drawn by the board in decision T 1218/06 concerning the appeal proceedings against the parent patent EP-B 0 898 900, namely that the alleged prior use, which in that case was based on the same documents, was not sufficiently proven. Further objections of lack of novelty based on other cited documents were also considered to be unfounded.

Document D15 was considered to represent the closest prior art for the assessment of inventive step. The

opposition identified the difference of the claimed subject-matter over D15 as follows:

- the presence of inulin;
- the presence of insoluble fibres and
- the requirement that the fibre mixture is present in an amount of 1.0 g/100 ml to 2.0 g/100 ml.

The objective technical problem starting from D15 was defined as the provision of alternative formulations for diabetic patients with adequately reduced glycaemic response, but increased amount of fibres, whilst retaining suitable viscosity for tube-feeding. In the opposition division's view the claimed solution to this problem was not obvious. With reference to D7/D7a the opposition division argued that the skilled person could have envisaged the use of inulin in addition to pectin in order to increase the concentration of the fibre mixture and to include insoluble fibres, but would have had no motivation to do so.

- V. Notice of appeal against the decision was filed by the opponent (hereinafter: the appellant) on 15 November 2011. The prescribed fee was paid on the same day. The grounds of appeal were received on 5 March 2012.

The appellant maintained the request for revocation of the patent based on the objections that the claimed subject-matter lacked both novelty and an inventive step. Arguments as regards Articles 100(b) and (c) EPC were not provided. Concerning the novelty issue, the appellant disagreed with the opposition division that the claimed subject-matter was novel over the alleged prior public use based on D18/D18a, D5/D5a and D3/D3a.

In addition, a new novelty attack was based on the document

D22 EP-A 0 756 828.

The appellant argued that the composition of example 2 of D22 anticipated the claimed nutritional composition. In order to show that the viscosity of the claimed composition, which was not explicitly mentioned in D22, was an inherent property of the composition of example 2 of D22, the experimental evidence D22a was submitted.

The appellant further requested reimbursement of the appeal fee due to an alleged procedural violation by the opposition division.

- VI. In its letter dated 25 July 2012 the patent proprietor (hereinafter: the respondent) defended the maintenance of the patent on the basis of the claims which were allowed by the opposition division (point IV above). The auxiliary request before the opposition division was re-filed with the same letter.

- VII. In its communication dated 22 November 2013 the board expressed its non-binding opinion on the issues of novelty and inventive step.

Concerning the alleged prior public use based on the brochure D3/D3a, it was the board's preliminary view that this brochure, for the same reasons as given in decision T 1218/06 concerning the parent patent EP-B 0 898 900, did not anticipate the claimed subject-matter. The board also expressed its doubts as to whether the experimental report D22a provided evidence that the nutritional composition described in example 2

of D22 inherently had viscosity which lie within the claimed range.

Concerning inventive step, the board confirmed that D15 represented the closest prior art. The difference of the claimed subject-matter over D15 was seen in

- the presence of inulin or its hydrolysate;
- the presence of an insoluble dietary fibre providing, together with the soluble fibre, a fibre mixture in an amount of 1.0 to 2.0 g/100 ml;
- the ratio of 1:3 to 3:1 for the soluble to insoluble fibre.

VIII. With its letter dated 10 January 2014 the respondent provided further arguments in favour of the presence of an inventive step with regard to D15 as the closest prior art.

With its letter dated 5 February 2014, claim sets for a second, third, fourth and fifth auxiliary request were filed.

IX. During the oral proceedings before the board, which took place on 6 February 2014, the issue of novelty with regard to example 2 of D22, and the issue of inventive step taking D15 as the closest prior art were discussed. As to the prior public use based on D3/D3a, D5/D5a and D18/D18a, the appellant relied on its written submissions. The appellant withdrew its request for reimbursement of the appeal fee.

X. After announcement of the board's conclusion that the prior use based on D3/D3a was not established to the required standard proof and that the subject-matter of the main request was novel over D22 and was based on an

inventive step, the respondent did not pursue the maintenance the patent on one of the auxiliary requests.

In the following the arguments of the parties are summarized.

XI. Arguments of the appellant

a) Novelty

Example 2 of D22 describes a complete liquid clinical food composition containing usual amounts of fat, carbohydrates and protein. Although these ingredients may vary within the ranges given in this example, the specific compositions A, B and C of the experimental report D22a, having viscosities within the claimed range, show that varying amounts of fat, carbohydrates, protein and fibre do not significantly influence the viscosity of the composition. This is a clear indication that no problems with viscosity occur with varying ??? amounts of fat, carbohydrates, protein and fibre. It is thus highly likely that all nutritional compositions embraced by example 2 of D22 have the claimed viscosity.

b) Inventive step

(i) The parent patent EP-B 0 898 900 is concerned, like the patent in suit, with the nutritional management of diabetes by using a liquid nutritional composition based on protein, carbohydrate, fat, a viscous soluble fibre and inulin, a hydrolysate of inulin or both, and an insoluble dietary fibre. The viscosity of the

composition is the same as for the composition claimed in claim 1 according to the main request in the present case. The difference of the claimed subject-matter over that of the parent patent is therefore only the amount of the total fibre mixture of 1.0 to 2.0 g/100 ml.

In the appeal case T 1218/06, concerning the parent patent, example 1 of D10 - which corresponds to D15 in the present case - was considered to represent the closest prior art. The board found that the distinguishing feature, namely the presence of inulin in the claimed composition, could not contribute to an inventive step in view of D10 in combination with D1 and its English translation D2 (corresponding to D7 and D7a in the present case), in view of the disclosure in D2 that "inulin - has a stabilising action on the content of glucose in the blood of patients with diabetes mellitus" and that "its effect increases in combination with other organic components of Jerusalem artichoke tubers, such as pectins ..." (first paragraph of page 1 of D2). Furthermore, the presence of soluble and insoluble fibre was considered to be obvious in view of D9, which corresponds to D14 in the present case.

- (ii) Because the composition claimed in the patent in suit contains all the features of the composition according to the parent patent (with the only exception that the total amount of fibre is from 1.0 to 2.0 g/100 ml), the considerations in T 1218/06, in which contribution of inulin and insoluble fibre to inventive step was denied, are in principle applicable in the present case.

Thus, D15 also represents the closest prior art in the present case, which is concerned with liquid nutritional compositions on the basis of protein, fat and a glucide fraction. Its low viscosity of < 0.05 kg/ms makes the composition suitable for tube feeding to diabetic patients. D15 is thus concerned with the same problem underlying the patent in suit. The composition exemplified in example 1 of D15 contains pectin as viscous soluble fibre in an amount of 0.56 g/100 ml.

The claimed composition differs therefrom in the presence of inulin and an insoluble dietary fibre, such that the total fibre mixture is present in an amount of from 1.0 to 2.0 g/100 ml.

Because no particular effect caused by the presence of inulin has been shown by the respondent, the reasoning given in T 1218/06 that the presence of inulin cannot establish inventive step also applies here. Thus, the addition of inulin to the composition according to example 1 of D15 is obvious from D7/D7a (corresponding to D1/D2 in T 1218/06).

The second distinguishing feature, namely the presence of insoluble dietary fibre, is obvious in view of D14, which discloses in the section "CONCLUSIONS", point 4, that insoluble dietary fibres are common ingredients in diabetic compositions. This all the more so as there is no pointer in D15 that the amount of dietary fibre is critical to the viscosity of the composition.

XII. Arguments of the respondent

a) Novelty

Concerning the alleged public prior use, the situation is the same as for the subject-matter claimed in the parent patent EP-B 0 898 900. The decision in T 1218/06 that the alleged prior public use has not been sufficiently substantiated thus also applies for the present case.

Example 2 of D22 does not describe specific compositions but gives ranges for each of the ingredients, i.e. the fibre mixture, protein, carbohydrate and fat. Thus the specific compositions A, B and C reworked in the experimental report D22a are not explicitly disclosed and thus have no basis in D22.

Composition A is outside the invention because the amount of dietary fibre is below the claimed range of from 1.0 to 2.0 g/100 ml. For B and C, multiple selections have been made by the appellant in D22a in order to arrive at a composition having the claimed viscosity. This does not constitute proof that the viscosity of all compositions embraced by example 2 of D22, irrespective of the amounts of its ingredients, is in the claimed viscosity range.

b) Inventive step

The subject-matter of the main request differs from the subject-matter of the second auxiliary request considered in T 1218/06 concerning the parent patent by virtue of the limitation of the total amount of dietary fibre to 1.0 to 2.0 g/100 ml. In T 1218/06, example 1 of D15 was considered to represent the closest prior art and the problem

to be solved in the light of this prior art was defined as "the provision of a further nutritional composition that has an adequately reduced glycaemic response".

Taking example 1 of D15 as the closest prior art for the subject-matter of the present case also, and taking into account the limitation of the amount of the total dietary fibre vis à vis the subject-matter in the case T 1218/06, the situation is different from T 1218/06 insofar as the claimed composition now differs from the composition exemplified in example 1 of D15 in three essential aspects, namely:

- the presence of inulin;
- the presence of an insoluble dietary fibre;
- the total amount of dietary fibre (soluble + insoluble) of from 1.0 to 2.0 g/100 ml, which is therefore considerably than the amount of dietary fibre in the composition of example 1 of D15, which amounts to 0.56 g/100 ml pectin.

Thus, a different technical problem has to be defined for the claimed composition, namely the modification or adaptation of the formulations of D15 to provide alternative compositions suitable for diabetic patients - thus with adequately reduced glycaemic response - thereby increasing the amount of fibre, whilst maintaining suitable low viscosity for tube feeding.

The claimed solution to this problem is not obvious from the prior art. Firstly, D15 identifies the low viscosity of the composition only with soluble fibres (column 2, lines 57 to

62) and gives no incentive to increase the amount of soluble fibres, i.e. pectin used in example 1, above 0.56 g/100 ml. Furthermore, there is no disclosure in D15 to add an insoluble fibre in order to arrive at a total amount of fibre of 1.0 to 2.0 g/100 ml for the fibre mixture, as required by claim 1.

Although D7a discloses that inulin is beneficial in nutritional compositions for diabetic patients, the presence of inulin is only mentioned in conjunction with an unique carbohydrate complex based on fructose and its polymers (page 1, first paragraph of D7a). Moreover, no disclosure is found in this document concerning the viscosity problem or with the addition of insoluble fibre.

D14 recommends the addition of soluble and insoluble fibres to diabetic diet compositions but is not concerned with liquid compositions and thus does not deal with the viscosity problem of liquid compositions suitable for tube-feeding.

The claimed composition is therefore not obvious either from D15 alone or from a combination of D15 with D7a and D14.

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

XIV. The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Amendments

In the appeal proceedings the appellant raised no objections against clarity (Article 84 EPC), added subject-matter (Article 123(2) EPC) and extended protection (Article 123(3) EPC) in respect of the amended claims of the respondent's main request.

The board is also satisfied that the amended claims meet the requirements of Articles 84 and 123(2)/(3) EPC.

3. Sufficiency of disclosure

In the appealed decision (point 1.2) the opposition division found that the requirements of Articles 83 EPC were met. In the appeal proceedings the objection of insufficiency of disclosure was not pursued by the appellant. The board sees no reason to deviate from the opposition division's view that the invention is sufficiently disclosed.

4. Novelty

4.1 Prior public use

4.1.1 In the opposition proceedings the prior public use objection was based on the brochure D3/D3a. The opponent argued that the composition disclosed in D3 (and its English translation D3a) was available to the public before the date of the effective priority claimed for the patent in suit and that this composition anticipated the claimed composition. In order to support this allegation, the documents D5/D5a and D18/D18a were submitted in the course of the opposition proceedings. This objection corresponds to

the objection of prior public use raised in the opposition proceedings and pursued in the appeal case T 1218/06 concerning the parent patent EP-B 0 898 900 on the basis of the same documents, which were designated there as D15/D15b, D24/D25 and D6/D6a.

4.1.2 In its decision the opposition division followed the conclusion drawn by the board in T 1218/06 that the alleged prior use was not substantiated and did not prove the public availability of the composition of the brochure D15.

4.1.3 In the appeal proceedings the appellant did not provide additional arguments in order to further support its allegation of prior public use, but merely stated in its grounds of appeal (page 1) that it:

"disagrees with the OD that the Main Request as maintained would be novel over the prior use demonstrated by D18, D18a, D5 and D3, which should be regarded sufficient evidence on the public availability of D15 [*sic*; this should read: D3 - remark of the board] before the effective date of the claims".

In the oral proceedings the appellant merely relied on its written submissions.

In the absence of further convincing arguments supporting the allegation that the composition "fibra Pentaset" described in D3 is available to the public, the board follows the reasoning given in the decision T 1218/06 that no sufficient proof for the public availability of the product "Pentaset Fibra" has been provided. (T 1218/06, points 5.1 and 5.2 in conjunction with point 2.7.2).

4.1.4 The product "Pentaset Fibra" shown in D3 does thus not anticipate the claimed composition.

4.2 Novelty over D22

4.2.1 Example 2 of D22 describes a complete liquid clinical food composition by mixing several ingredients, including:

- 1-2 g of the dietary fibre mixture of example 1;
- 1.0-7.5 g protein;
- 12-24 g carbohydrate;
- 1-11 g fat.

From this disclosure it follows that example 2 embraces multiple compositions which result from various combinations of specific amounts for each of the ingredients from the respective numerical ranges.

4.2.2 A viscosity is not disclosed. In order to demonstrate that the multiple compositions embraced by example 2 inherently possess a viscosity within the claimed range, the appellant has prepared, in its experimental report D22a, three compositions A, B and C including the above ingredients of example 2 in the following specific amounts (in g per 100 ml for A/B/C):

- dietary fibre mixture: 0.75/1.51/1.45;
- carbohydrates: 12.3/18.8/14.1;
- fat: 4.44/6.82/4.86;
- protein: 2.69/3.31/6.25.

The viscosity of each of the compositions A, B and C was measured and it was found that for all three samples it was within the claimed range of from 0.015 to 0.03 kg/ms. The appellant therefore argued that the

composition of example 2 of D22 anticipates the claimed subject-matter.

- 4.2.3 Experimental report D22a, including only three compositions is, however, not representative for the multiple compositions embraced by example 2 of D22. It has first to be noted that none of the specific amounts selected for each of the components in compositions A, B or C are explicitly disclosed in example 2, but result from various selections of values out of the numerical ranges given in example 2 for the dietary fibre mixture, carbohydrates, fat and protein (see point 5.2.1). Secondly, the board is not satisfied that it is sufficient to select only three specific compositions A, B and C within the ranges indicated in example 2 of D22 in order to unambiguously demonstrate that each of the numerous possible compositions embraced by example 2 of D22 has a viscosity within the range required by claim 1.

The appellant's, argument, that the report D22a shows the low influence of the varying amounts of protein, carbohydrate and fat on the viscosity of the compositions A, B and C is not convincing either because not only the amounts of the ingredients should be taken into account, but also their chemical constitution or molecular weight.

- 4.2.4 Example 2 of D22 therefore does not anticipate the claimed composition.

5. Inventive step

- 5.1 The claimed invention relates to a nutritional liquid composition on the basis of lipid, carbohydrate and fat which composition contains dietary fibre (soluble and

insoluble). The composition is particularly suitable for providing nutrition to diabetic patients and should have good flow characteristics in order to make it suitable for patients requiring tube-feeding (paragraphs [0001], [0006],[0010] and [0018] of the patent specification).

5.2 Document D15 represents the closest prior art. This was agreed by the parties.

D15 is concerned with liquid nutritional compositions comprising a lipid fraction, a protein fraction and a glucide fraction comprising at least both glucose polymers and slowly absorbed glucides (column 1, lines 38 to 41). The composition is particularly suitable in the case of glucide metabolism anomalies running the risk of an excessive variation of glycemia such as sugar diabetes, intolerance to glucose etc. (column 4, line 60 to column 5, line 6). D15 thus lies in the same technical field as the invention.

In column 3, lines 12 to 20 it is pointed out that the liquid nature of the composition is very important and that its viscosity is less than 0.05 kg/ms and preferably less than 0.03 kg/ms. This viscosity range overlaps with the claimed viscosity range of 0.015 to 0.03 kg/ms.

The slowly absorbed glucides can be soluble fibres, such as pectin, which are characterised as having a gelling action in a complex solution during sterilisation, thereby increasing the viscosity of finished ready-to-use products (column 2, lines 23 to 29). As an unexpected effect of the composition of D15, the retention of a low viscosity of less than 0.05 kg/

ms after sterilisation is disclosed in column 2, lines 57 to 64.

A typical nutritional composition of D15 is described in example 1 and its composition is illustrated in the table in column 6. The composition contains a carbohydrate source (maltodextrins, modified starch) a protein source (milk protein) a fat source (soya lecithin, corn oil, rapeseed oil, glycerol stearate) and pectin as the only viscous soluble fibre. From the amounts of all ingredients of the composition given in the table a pectin portion of 0.56 g/100 ml can be calculated.

5.3 The problem to be solved by the invention in the light of document D15 was seen by the respondent in the provision of a liquid nutritional composition with an increased amount of dietary fibre as active ingredient against a glyceemic response, thereby retaining a low viscosity in order to make the composition suitable for tube-feeding.

5.4 As a solution to this problem claim 1 of the respondent's request proposes, in distinction to the composition of D15:

- the addition of inulin, its hydrolysate or both;
- the addition of an insoluble dietary fibre;
- the increase of the total amount of dietary fibre (soluble and insoluble) to an amount of 1.0 to 2.0 g/100 ml.

5.5 Example 2 of the patent specification, which compares the glycaemic response of a composition according to the claimed invention (as prepared in example 1) with that of two commercial products, shows the lowest

glycaemic response for the product of the invention. Example 3 furthermore shows that the free flow rate of the composition prepared in example 1 is considerably lower than that of the commercial product "Fresubin DFN Plus" and is thus better suitable for enteral tube-feeding. The board is therefore satisfied that the problem has credibly been solved by the invention.

5.6 In the oral proceedings the respondent pointed out that a package of three interlinked measures, namely:

- (a) the addition of inulin(hydrolysate),
- (b) the addition of an insoluble dietary fibre and
- (c) the increase of the total amount of dietary fibre

as set out in claim 1 guarantees the success of the invention (see section XI b) above). In order to assess whether the combination of these measures (a), (b) and (c) is obvious, it has to be considered whether the skilled person starting from D15 would have combined these three measures in view of the disclosure in D7a and D14.

5.7 D7a deals with the substances of colloidal particle size in Jerusalem Artichokes and mentions the beneficial effect of inulin for the stabilization of the content of glucose in the blood of patients with diabetes mellitus (page 1, first paragraph, lines 1 to 9). Although it is disclosed in the next sentence that this effect increases in combination with other organic components of Jerusalem Artichoke tubers, *inter alia* pectins, this disclosure should not be considered in isolation, but has to be read in the context of the specific combination of the ingredients of Jerusalem Artichoke tubers.

Even if the skilled person, in the light of the above disclosure, would consider the addition of inulin to the composition of example 1 of D15 to be beneficial, there is nothing in D7a which would prompt him to further increase the amount of dietary fibre by the addition of insoluble dietary fibre to the liquid composition of D15, thereby keeping its viscosity at a low level.

- 5.8 D14 is concerned with high fibre diets for diabetic patients and recommends in the section "CONCLUSIONS" at page 462 the addition of dietary fibre including soluble and insoluble fibres. D14, however, does not deal with liquid compositions and is thus not capable of giving an incentive to a skilled person wishing to provide a low-viscosity nutritional composition to add an insoluble fibre to the liquid composition of D15.
- 5.9 The solution to the problem as identified in point 6.3 above is thus not obvious from a combination of D15 with D7a and D14.
- 5.10 The subject-matter of claim 1 and by the same token that of the dependent claims 2 to 6 of the respondent's sole request therefore involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



R. Schumacher

W. Sieber

Decision electronically authenticated