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**Datasheet for the decision
of 18 February 2010**

Case Number: T 1218/06 - 3.3.09

Application Number: 98201018.3

Publication Number: 0898900

IPC: A23L 1/308

Language of the proceedings: EN

Title of invention:

Use of a nutritional composition for the preparation of a liquid composition for diabetics

Patentee:

SOCIETE DES PRODUITS NESTLE S.A.

Opponent:

Numico Research B.V.

Headword:

-

Relevant legal provisions:

EPC Art. 114(2), 83, 84, 54, 56
RPBA Art. 12(2)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Late-submitted material - partially not admitted"
"Novelty (yes)"
"Inventive step - effect (no, all requests)"

Decisions cited:

T 1002/92, T 0182/89, T 0197/86

Catchword:

-



Case Number: T 1218/06 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 18 February 2010

Appellant: Numico Research B.V.
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Respondent: SOCIETE DES PRODUITS NESTLE S.A.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office
announced orally on 9 May 2006 and issued in
writing on 9 June 2006 concerning maintenance
of the European patent No. 0898900 in amended
form.

Composition of the Board:

Chairman: W. Sieber
Members: M. O. Müller
M-B. Tardo-Dino

Summary of Facts and Submissions

I. The mention of the grant of European patent No. 0 898 900, in respect of European patent application No. 98201018.3, in the name of SOCIETE DES PRODUITS NESTLE S.A., filed on 31 March 1998 and claiming priority of EP 97201915 (23 June 1997), was published on 1 October 2003 in Bulletin 2003/40. The granted patent contained 8 claims, whereby Claim 1, the only independent claim, read as follows:

"The use of a protein source, a lipid source, a carbohydrate source, and a fibre mixture including

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

for the preparation of a liquid composition for the nutritional management of diabetes".

II. A notice of opposition was filed by Numico Research B.V. on 1 July 2004 requesting revocation of the patent in its entirety on the grounds that the claimed subject-matter was neither novel nor inventive and that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(a) and (b) EPC).

The following documents were *inter alia* submitted during first-instance opposition proceedings:

- D1: Sidorchenko et al, "Substances of Colloidal Particle Size in the Jerusalem Artichoke", Sakharnaya Svekla Proizvodstvo I Peretabotka no. 6, 1991, pages 54 to 55;
- D2: English translation of D1;
- D5: Product information "Innovate" by Orafti;
- D6: Letter of the Spanish Ministry of Health and Consumer Affairs, issued 04.07.90;
- D7: GB 2 295 954 A;
- D9: J. W. Anderson et al, "TREATMENT OF DIABETES WITH HIGH FIBER DIETS", CRC Handbook of dietary fiber in human nutrition, CRC Press Inc., 2nd edition, 1993, pages 443 to 470;
- D10: US 5 292 723 A;
- D12: F. Q. Nuttall, "Dietary Fiber in the Management of Diabetes", Diabetes vol. 42, April 1993, pages 503 to 508; and
- D15: Brochure "La nueva mezcla de fibra Pentaset".
- III. By an interlocutory decision which was announced orally on 9 May 2006 and issued in writing on 9 June 2006, the opposition division decided that the opposed patent in amended form with pages 1 - 7 and Claims 1 - 8 as filed during oral proceedings before the opposition division met the requirements of the EPC.

The only independent claim of the claims underlying the decision was Claim 1, which read as follows:

"The use of a protein source, a lipid source, a carbohydrate source, and a fibre mixture including

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

for the preparation of a liquid composition for the nutritional management of diabetes wherein the protein source provides 10% to 20% of the energy, the lipid source provides 30% to 50% of the energy, and the carbohydrate source provides 35% to 55% of the energy of the nutritional composition."

The following positions were taken in the decision:

- (a) The amended claims met the requirements of Articles 123(2) and (3) EPC.
- (b) The subject-matter of the amended patent was sufficiently disclosed.
- (c) The claimed subject-matter was novel, because *inter alia* D15 was not prior art within the meaning of Article 54 EPC.
- (d) The claimed subject-matter was inventive. More in particular, D10 was considered to represent the closest prior art. The claimed subject-matter differed from D10 in that the fibre mixture contained inulin or a hydrolysate thereof. The objective technical problem was the provision of

alternative nutritional compositions for the nutritional management of diabetes, which were suited to be tube-fed to patients and had an adequately reduced glycaemic response while retaining reasonable low viscosity. It was neither derivable from D10 alone, nor in combination with any of the further documents that fibre mixtures comprising viscous fibres and inulin would solve this problem.

- IV. With letter of 4 August 2006, the appellant (opponent) filed a notice of appeal against the above decision with simultaneous payment of the prescribed fee. A statement setting out the grounds of appeal was filed with letter of 19 October 2006 together with
- D20: Enlarged view of part of the front page of D15.
- V. With letters of 23 February 2007 and 13 January 2010, the respondent (proprietor) filed replies to the appeal.
- VI. With communication of 29 January 2010, the board *inter alia* questioned the allowability of some of the amendments effected before the opposition division and informed the parties of its preliminary opinion that the examples and comparative examples (commercial products) contained in the opposed patent appeared not to support any technical effect that was due to the presence of inulin.
- VII. With letter of 4 February 2010, the respondent filed three sets of claims, namely a main request, auxiliary request 1 and auxiliary request 2.

With letter of 9 February 2010, the respondent further submitted

D4b: English translation of D4a;

D6a: English translation of D6;

D15b: English translation of D15;

D21: Product information sheet relating to the product "Sondalis DIABETES";

D22: Product information sheet relating to the product "FRESUBIN[®] DIABETES"; and

D23: Product information sheet relating to the product "FRESUBIN[®] DFNplus".

VIII. With letter of 10 February 2010, the appellant filed a sworn statement concerning the public availability of D15, namely

D24: Sworn statement of Mr JESUS FERNANDO IRZO ASENSIO (in Spanish).

The admissibility of D24 was contested by the respondent with letter of 11 February 2010.

With letter of 15 February 2010, the appellant filed

D25: English translation of D24.

IX. The appellant's position was, in as far as relevant to the present decision, as follows:

(a) Insufficiency of disclosure

The feature "viscous soluble fibre" in Claim 1 was not disclosed in sufficient detail. More in particular, D12 proved that the present invention could not be carried out with pectin, which fell under the definition of a viscous soluble fibre in Claim 1. Furthermore, the feature "for the nutritional management of diabetes" in Claim 1 led to insufficiency of disclosure as the only clear explanation of this feature was given in paragraph [0005] of the opposed patent while numerous further definitions were contained in or implied by the remaining disclosure of the opposed patent. Finally, it was impossible to reproduce the viscosity referred to in Claim 2 because there was no information in the patent specification at which shear stress and shear rate the viscosity had to be determined.

(b) Lack of novelty

D15 had been publicly available before the priority date of the opposed patent as proven by the sworn declaration D24, the expiry date printed on the product package shown in D15 and the market authorisation D6 for this product. The composition disclosed in D15 exhibited all features of Claim 1 and was described to be used for the nutritional management of diabetes. Consequently, D15 was novelty-destroying.

Further, the brochure D15, and in particular the expiry date on the product package shown in D15, substantiated the public availability of "Pentaset Fibra" prior to the priority date of the patent in suit.

(c) Lack of inventive step

Starting from D10 as closest prior art, the objective technical problem was the provision of an alternative composition for the nutritional management of diabetes. The skilled person would have found the solution in eg D1. The claimed subject-matter therefore lacked inventive step in view of D10 in combination with eg D1.

X. The respondent's position was, in as far as relevant to the present decision, as follows:

(a) D5 should be disregarded. D5 was a collocation of a number of separate documents and no evidence was available that any of them formed prior art.

(b) D24 should not be admitted into the proceedings as it was filed late.

(c) Sufficiency of disclosure

The feature "viscous soluble fibre" in Claim 1 did not lead to insufficiency of disclosure as no evidence had been provided by the appellant that the invention could not be carried out in this respect.

The appellant's objection against the feature "for the nutritional management of diabetes" in Claim 1 was at best an objection of lack of clarity which was not a ground of opposition.

Finally, the viscosity in Claim 2 did not lead to insufficiency of disclosure as detailed instructions were given in paragraph [0054] of the opposed patent as to how the viscosity had to be measured. No evidence had been provided that the viscosity cited in Claim 2 could not be reproduced when applying these instructions.

(d) Novelty

The expiry date on the product package shown in D15 did not provide any information on whether, when or by whom D15 was published. Consequently, D15 did not form prior art. Thus, D15 could not prejudice novelty.

Concerning the at least implicitly alleged public prior use occurring in connection with "Pentaset Fibra", such a public prior use had not been established.

(e) Inventive step

D10 represented the closest prior art. The claimed subject-matter differed from D10 in that inulin was additionally contained in the composition to be used.

From a comparison of the results obtained in the opposed patent for Product Example 1 and those obtained for the commercial products Fresubin Diabetes and Fresubin DFN Plus, it could be derived that due to the presence of inulin in Product Example 1, the product had an adequately reduced glycaemic response while having a viscosity low enough for tube feeding. Example 1 of D10 did not solve this problem. More in particular, though Example 1 mentioned administration by digestive probe, which equalled tube feeding, the composition of this example was actually used in a clinical study as oral sip feed and not as tube feeding which implied a high viscosity. Consequently, the objective technical problem in view of D10 was the provision of a liquid composition which provided an adequately reduced glycaemic response while still maintaining a viscosity suitable for tube feeding.

Neither D10 nor any of the further documents gave any indication that this problem could be solved by addition of inulin to the composition of Example 1 of D10. In particular D1, though disclosing the use of inulin, addressed a completely different subject. D1, a scientific paper, investigated the carbohydrate production depending on the variety of Jerusalem artichoke tubers, but D1 did not contain any indication that the use of inulin led to compositions with adequate glycaemic response at reduced viscosity. Consequently, the claimed subject-matter was inventive in view of D10 as closest prior art.

XI. On 18 February 2010, oral proceedings were held before the board.

- (a) The respondent requested that D24 and the corresponding English translation D25 be not admitted into the proceedings, because they were filed too late and were *prima facie* not relevant. In particular, the statements in D24/D25 lacked any corroboration concerning the distribution of D15, eg exact dates or naming of concrete persons to whom the brochure had been distributed. The appellant held that it took a lot of time to find someone who could confirm the public availability of D15, which justified the late filing. Furthermore, the statements in D24/D25 were corroborated by the market authorisation D6 and the expiry date printed on the product package shown in D15. D24/D25 therefore proved that D15 was prior art and thus novelty-destroying. Hence, D24/D25 was *prima facie* relevant.
- (b) The appellant did not raise any objections against the admissibility of documents D21 - D23. Furthermore, the appellant did not rely any more on D5, whose public availability had been questioned by the respondent.
- (c) The appellant did not raise any formal objections under Articles 123(2), 123(3) and 84 EPC against the claims of the main request.
- (d) With regard to sufficiency of disclosure of the main request, the parties essentially relied on their written submissions.

- (e) Concerning novelty of the main request, the appellant did not pursue the public prior use having allegedly occurred in connection with "Pentaset Fibra", ie the product shown in D15. With regard to novelty in view of D15 itself, the parties essentially re-iterated their written submissions.

With regard to inventive step of the main request, both parties *inter alia* used D10 as closest prior art with regard to which the presence of inulin was considered to represent the distinguishing feature. A point of dispute was the question whether the presence of inulin led to any unexpected technical effect.

The appellant explained in this respect that Product Example 1 and the commercial products in the opposed patent differed not only in the presence of inulin but also in the use of different fibres, ie pectin was used in Product Example 1 but soy fibres were used in the commercial products. As evidenced by D7 and D10, soy fibres, contrary to pectin fibres, led to an undesired increase in viscosity. Therefore, the reduction in viscosity obtained in Product Example 1 of the opposed patent resulted from the replacement of the soy fibres by pectin rather than from the addition of inulin. It was thus not clear which effect, if any, was achieved by the addition of inulin.

The respondent relied on his detailed explanations already given in writing. With regard to the appellant's argument concerning the use of soy fibres, he referred to Example 2 of D10 which used soy fibres without reporting any problems related thereto. In addition, the respondent compared Product Example 1 in the opposed patent with Example 1 of D10 in order to demonstrate that the presence of inulin led to the desired low viscosity. In this respect, the respondent argued that a low viscosity was obtained for the inulin-containing Product Example 1 while the inulin-free composition of Example 1 of D10 was not used for tube feeding but as oral sip feed implying a high viscosity.

A further point of discussion was whether it would have been obvious to include inulin in the composition of Example 1 of D10. Reference was made in this respect *inter alia* to page 1 of the translation of D1 (D2) where it was stated that inulin had a beneficial effect on diabetic patients which could be increased by combining inulin with pectin. The respondent acknowledged that the beneficial effect of inulin on diabetics was known. However, a skilled person trying to modify D10 would simply replace the pectin used in Example 1 of D10 by inulin but would not mix it with inulin. With regard to D1, the respondent noted that this document did not specifically suggest the combination of inulin with pectin, but rather a combination of inulin with any or all other components of Jerusalem artichokes, of which

pectin was one. Furthermore, D1 did not relate to any effect on viscosity.

- (f) The respondent withdrew auxiliary request 1.
- (g) With regard to auxiliary request 2, the appellant noted that the viscosity which had been incorporated into Claim 1 by way of amendment was unclear. No further formal objections were raised.
- (h) The appellant did not make any submissions with regard to novelty of auxiliary request 2.
- (i) With regard to inventive step of auxiliary request 2, the appellant noted that
 - (i) the restriction of the energy percentage provided by the protein source in Claim 1 did not add anything,
 - (ii) the viscosity cited in Claim 1 could not contribute to inventive step as the composition of Example 1 of D10 was described to be suitable for tube feeding and, therefore, implicitly had a viscosity of less than $0.02 \text{ kgm}^{-1}\text{s}^{-1}$,
 - (iii) the combination of soluble and insoluble fibres in Claim 1 did not lead to any unexpected effect and further was known from Examples 1 and 5 of D7 and page 462 of D9, and
 - (iv) the ratio of soluble and insoluble fibres in Claim 1 did not lead to any unexpected effect and was disclosed in Example 1 of D7, too.

In the respondent's view, the necessity to combine the three documents D10, D7 and D9 supported the presence of inventive step. Furthermore, none of these documents could prejudice inventive step as D7 did not concern diabetes, D9 taught nutrient proportions different from those cited in Claim 1 and D10 did not contain any teaching of a mixture of soluble and insoluble fibres.

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

XIII. The respondent (proprietor) requested that the patent be maintained on the basis of the main request (Claims 1 to 8) or, in the alternative, on the basis of auxiliary request 2 (Claims 1 to 5), both requests filed with letter of 4 February 2010.

Claim 1 of the main request read as follows:

"The use of a protein source, a lipid source, a carbohydrate source, and a fibre mixture including

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

for the preparation of a liquid composition for the nutritional management of diabetes wherein the protein source provides 10% to 20% of the energy, the lipid source provides 30% to 50% of the energy, and the carbohydrate source provides 35% to 55% of the energy of the nutritional composition".

Claim 1 of auxiliary request 2 differed from Claim 1 of the main request in that the energy provided by the protein source had been restricted to 12% to 18% and the following wording had been added at the end of the claim:

"..., the liquid nutritional composition has a viscosity, when measured at room temperature, of 0.015 to 0.03 kg/ms, and in which the fibre mixture further includes a source of insoluble dietary fibre in which the ratio of soluble fibre, including inulin, to insoluble fibre is 1:3 to 3:1".

Reasons for the Decision

1. The appeal is admissible.
2. *Late filed documents D24/D25*
 - 2.1 D24 is a sworn declaration in Spanish by an employee of Nutricia S.R.L. Madrid, Mr Irzo Asensio. As apparent from the English translation D25, Mr Irzo Asensio declares that he has submitted at least one copy of D15 to an institution/person without any obligation to secrecy during the period prior to 23 June 1997 (the priority date of the opposed patent).

D24 and D25 were filed at a very late stage of the appeal proceedings with letters of 10 and 15 February 2010, ie eight and three days prior to the date of oral proceedings before the board.

2.2 According to Article 12(2) of the Rules of Procedure of the Boards of Appeal, the statement of the grounds of appeal shall contain the appellant's complete case. Furthermore, it is established case law of the boards of appeal that late-filed evidence should only very exceptionally be admitted into the proceedings in the appropriate exercise of the board's discretion under Article 114(2) EPC, if such new material is *prima facie* highly relevant in the sense that it can reasonably be expected to change the eventual result and is thus highly likely to prejudice maintenance of the European patent (see T 1002/92 (OJ EPO 1995, 605; point 3) as an illustration of this case law).

2.3 In the present case, already during oral proceedings before the opposition division on 9 May 2006, it had been decided that D15 did not form prior art. Consequently, the appellant knew at the latest from that date on that the public availability of D15 had not been sufficiently proven. Therefore, any evidence overcoming this deficiency should have been provided with the statement of grounds of appeal, in accordance with Article 12(2) of the Rules of Procedure of the Boards of Appeal.

2.4 During oral proceedings before the board, the appellant stated that filing D24/D25 only shortly before the date of oral proceedings was due to difficulties in finding a person that could confirm the public availability of D15.

However, this argument is not convincing, because the person who gave the declaration, Mr Irzo Asensio, still is an employee of Nutricia S.R.L., ie the company which

issued D15. No reasons were given why an inquiry within said company could not have been made earlier.

2.5 Furthermore, the filing of D24/D25 cannot be considered as a reaction to any of the respondent's replies or the board's communication. On the contrary, as has been set out above, the public availability of D15 has already been an issue in the decision under appeal.

2.6 Thus, the filing of D24 and D25 was not in due time in the sense of Article 114(2) EPC.

2.7 With regard to *prima facie* relevance of D24/D25, the situation is as follows:

2.7.1 The declaration does not contain any details about the question of who has received copies of D15, but only cites in general terms medical institutions and health professionals. The declaration does also not contain any concrete date at which said copies have been distributed, but only refers in general terms to the time period prior to 23 June 1997. Thus, in the board's view, the declaration lacks corroboration about the exact circumstances at which the alleged events took place.

2.7.2 The appellant held the view that the statements in D24/D25 were corroborated by the expiry date "BEST BEFORE 18-06-97" printed on the product depicted in D15, which was prior to the priority date of the opposed patent, and the market authorisation D6 for this product which was issued equally prior to the priority date of the opposed patent.

However, the appellant's argumentation is not convincing for the following reasons:

The words "BEST BEFORE 18-06-97" are just legible on the photograph of a tube-feeding bag at the top right of the first page of D15 (at least on the enlarged view D20). This date presumably means 18 June 1997 which is 5 days before the priority date of the patent in suit. However, the date shown on the bag depicted in D15 **does not relate directly** to the date of D15 as a document. As pointed out by the respondent, it is merely a date printed on the particular bag that was photographed as the date by which the product should be used but there is no evidence as to whether this photograph shows a real product, a prototype or even a dummy product. Even if the photograph shows a real product from an actual production batch, the significance of the date is very limited in that the only assumption that can be made is that the photograph cannot have been taken before the date on which batches with that "best before" date would have been packaged, but no evidence has been presented as to what that date might have been. The fact that the photograph could not have been taken before a particular date does not mean that it was taken on or near to that date and it could have been taken at any time thereafter, quite possibly well after the priority date. Similarly, and even more importantly, the brochure D15 including the photograph could have been produced at any time after the photograph was taken.

As regards D6, this document purports to be a marketing authorisation regarding "Pentaset Fibra" (ie the product referred to in D15) issued by the Ministry of

Health and Consumer Affairs (Ministerio de Sanidad y Consumo) in Spain. However, a marketing authorisation does not prove that anything was ever marketed, and even if this were to be the case, it still cannot possibly provide evidence that brochures apparently relating to the product were part of the state of the art before the priority date of the patent in suit.

2.7.3 In summary, D24 and D25 cannot be considered to be *prima facie* highly relevant according to the established case law (see T 1002/92 mentioned above).

2.8 In view of the above, the board exercised its discretion not to admit D24 and D25 into the proceedings (Article 114(2) EPC).

Main request

3. *Amendments*

3.1 Claim 1 of the main request differs from Claim 1 as granted in that

- (a) the wording "a viscous soluble fibre selected from the group comprising" has been replaced by the wording "a viscous soluble fibre selected from the group consisting of", and
- (b) the percentages of energy provided by the protein, lipid and carbohydrate source have been added into the claim.

3.2 Amendment (a) of Claim 1 of the main request is based on page 3, lines 26-30 of the application as filed.

Amendment (b) is based on the passage on page 4, line 34 to page 5, line 31 of the application as filed.

3.3 Since, furthermore, the amendments do not extend the scope of granted Claim 1 and are clear, no objections under Articles 84, 123(2) or 123(3) EPC arise against Claim 1 of the main request. Nor was any objection raised by the appellant in this context.

4. *Sufficiency of disclosure*

4.1 The feature "viscous soluble fibre" in Claim 1

Claim 1 of the main request contains the term "viscous soluble fibre". The appellant argued that the claimed invention could not be carried out with pectin, which was one of the viscous soluble fibres cited in Claim 1. According to D12, viscous soluble fibres such as pectin and psyllium had little or no effect on the glucose rise after glucose ingestion ('Mechanism of Action' on page 505 of D12, right hand column). Thus, pectin was not suitable for the preparation of a liquid composition for the nutritional management of diabetes.

However, the passage in D12 relied upon by the appellant refers *expressis verbis* to "little or no effect". Thus, the passage itself cannot provide incontestable proof for the appellant's allegation that pectin would be unsuitable for the preparation of a liquid composition for the nutritional management of diabetes. Furthermore, it is apparent from Table 2 of

D12 that various other antithetic results are reported on the efficiency of pectin. More in particular, Holt et al. reported a reduction of glucose rise caused by pectin fibres while the opposite was found by other authors. In view of the above, D12 cannot support the appellant's allegation that pectin has no beneficial effect at all and would therefore be not suitable for the claimed use. Hence, no evidence is available that the invention cannot be carried out with pectin as viscous soluble fibre. In the absence of any evidence and in view of the fact that the burden of proof in opposition proceedings rests on the opponent (T 182/89, OJ EPO 1991, 391; headnote), the term "viscous soluble fibre" in Claim 1 does not give rise to any objection under Article 83 EPC.

4.2 The feature "for the nutritional management of diabetes" in Claim 1

The appellant argued that it was unclear to the skilled person what had to be understood by the term "for the nutritional management of diabetes" in Claim 1.

However, contrary to the position of the appellant, the term in question is quite clear. For example, the patent in suit states at paragraph [0002] that:

"Diabetes is a general term for a group of metabolic disorders which are characterised by the inability to properly metabolise glucose. ..., if untreated, the inability leads to hyperglycaemia and its complications of morbidity and mortality."

This could not be clearer and, in any event, any person with experience in the field knows that diabetes is all about blood sugar level; many diabetics monitor this level themselves daily or even several times daily. Management of diabetes is thus management of blood sugar level and particularly managing post-prandial glycaemia. This in turn will manage the other physical manifestations of diabetes and the complications referred to in the passage quoted above. The word "nutritional" makes it clear that management takes place by adjusting the diet of the patient and not by administration of exogenous insulin or antihyperglycaemic drugs.

For the above reasons, the objection that the European patent does not provide sufficient disclosure of what is meant by nutritional management of diabetes for the person skilled in the art to put the invention into practice is clearly without foundation.

Irrespective of the above, it appears that the appellant's objection relates to lack of clarity rather than sufficiency of disclosure. No evidence has been provided by the appellant that, due to the alleged unclarity, the feature covers types of management that could not be achieved with the teaching of the opposed patent. Also for this reason, the appellant's objection must fail.

4.3 The viscosity in Claim 2

4.3.1 Dependent Claim 2 of the main request reads as follows:

"The use according to claim 1, wherein the liquid nutritional composition has a viscosity, when measured at room temperature, of 0.015 to 0.03 kg/ms."

4.3.2 The appellant held the view that the European patent did not provide sufficient information as to how viscosity was measured to put the invention into effect. In particular, it was not indicated which shear stress and shear rate had to be applied in the viscosity measurement. However, the patent in suit does, in fact, teach the person skilled in the art exactly how viscosity is to be measured. In paragraph [0054] the patent in suit says in the context of Example 3 that:

"The viscosity of each composition is determined at 25°C using a Contraves Rheomat according to the manufacturer's instructions".

4.3.3 As pointed out by the respondent, the Contraves Rheomat is a commonly used rheometer with which the person skilled in the art would be likely to be familiar, but in case of any doubt reference could be made to the manufacturer's instructions that come with this piece of equipment. No evidence was provided by the appellant that said instructions were insufficient (in particular with respect to shear stress and shear rate) to carry out the viscosity measurement. For this reason alone, the appellant's argument is not convincing.

Consequently, the viscosity cited in Claim 2 cannot lead to any insufficiency of disclosure.

4.4 In summary, the main request meets the requirements of Article 83 EPC.

5. *Novelty*

5.1 The appellant cited D15 as novelty-destroying. A precondition for a document to be novelty-destroying is its public availability before the filing date and the priority date, respectively, of the opposed patent. According to the appellant, said public availability was proven by the expiry date printed on the product shown in D15 and by the market authorisation D6.

As has been set out in point 2.7.2, above, said expiry date and market authorisation D6 are *per se* unsuitable to prove the public availability of D15 before the priority date of the opposed patent. Hence, no valid proof for the public availability of D15 is available. D15 is therefore not state of the art within the meaning of Article 54 EPC. Consequently, novelty of the subject-matter of the main request over D15 is acknowledged.

5.2 The public prior use having allegedly occurred in connection with "Pentaset Fibra", ie the product shown in D15, was not pursued by the appellant during oral proceedings. Since, furthermore, said alleged public prior use has not been sufficiently substantiated in the written submissions, novelty in view of this alleged public prior use has to be acknowledged.

6. *Inventive step*

6.1 Selection of the closest prior art

The object of the claimed subject-matter is the provision of a liquid nutritional composition suitable for diabetic patients and having good flow characteristics so that it can be used in tube-feeding (page 2, lines 34, 46 - 47 and 56 - 57 of the patent specification).

D1, D9 and D12, though related to the therapeutic benefits of fibres in diabetes, do not address the problem of flow characteristics and tube-feeding.

D7 refers to a method of lowering the viscosity of food compositions. The nutritional management of diabetes in the widest sense is mentioned on page 1, lines 10 - 14. However, this passage only refers to prior art uses of dietary fibres in general and does not represent an object of D7 itself.

On the other hand, D10 is directed to liquid nutritional compositions comprising a lipid fraction, a protein fraction and a specific combination of glucides useful as dietetics and therapeutics for diabetic patients. The compositions have good flow characteristics which allow an optional administration by digestive probe (column 1, lines 38 - 49, column 3, lines 12 - 20 and column 4, lines 39 - 45). Further, Example 1 of D10 describes the preparation of a dietary and/or therapeutic liquid composition for oral or enteral use for administration by digestive probe.

Thus, D10, and in particular Example 1 of D10, has to be considered to represent the closest prior art.

6.2 Distinguishing features

The liquid dietary and/or therapeutic composition of Example 1 of D10 is obtained from

- 11 g glucides (corresponding to the carbohydrate source cited in Claim 1) including
- pectin (corresponding to the viscous soluble fibre cited in Claim 1),
- 2.67 g lipids (corresponding to the lipid source as cited in Claim 1), and
- 3 g proteins (corresponding to the protein source as cited in Claim 1).

In a clinical study, the product of Example 1 was consumed daily by six diabetics of type II (paragraph bridging columns 6 and 7), corresponding to a nutritional management of diabetes as cited in Claim 1.

The subject-matter of Claim 1 of the main request differs from Example 1 of D10 in that

- inulin or a hydrolysate thereof (in the following, the term "inulin" is used for "inulin or a hydrolysate thereof") is additionally present in the composition to be used and
- the energy contributions of the carbohydrate, lipid and protein source are not specified.

6.3 Objective technical problem

6.3.1 The problem relied upon by the respondent in the assessment of inventive step was the problem stated in the opposed patent, namely the provision of a nutritional composition that has an adequately reduced glycaemic response while having good flow characteristics, ie low viscosity, so that it can be used in tube feeding (page 2, lines 34, 46 - 47 and 56 - 57).

With regard to the achievement of good flow characteristics / lower viscosity, the respondent saw this effect demonstrated by a comparison of Product Example 1 in the opposed patent with

- (a) Example 1 of D10 and
- (b) the commercial product Fresubin DFN Plus, which is a comparative example in the opposed patent.

6.3.2 With regard to comparison (a), the respondent argued that the inulin-free composition of Example 1 of D10 was not used for tube feeding but was applied as oral sip feed in the clinical study of D10. A sip feed would have a higher viscosity than a digestive probe. On the other hand, the inulin-containing Product Example 1 in the opposed patent had the desired low viscosity. Thus, the low viscosity was caused by the distinguishing feature with regard to D10, namely the presence of inulin.

However, even if the product of Example 1 of D10 were applied to the patients as a sip feed, there is nothing in D10 suggesting a high viscosity of the product used in the clinical study of D10, ie the product of

Example 1. On the contrary, the liquid composition of Example 1 of D10 is explicitly described as being suitable "for oral or enteral use for administration by digestive probe" (column 5, lines 32 - 33), which, as acknowledged by the respondent during oral proceedings, is tantamount to tube feeding. In addition it is stated in column 3, lines 15 - 20 that "Compositions which have retained a viscosity of less than $0.02 \text{ kgm}^{-1}\text{s}^{-1}$... and which allow an optional administration by digestive probe, are also preferred". In the absence of any evidence, respondent's remarks appear to be rather an assertion than a convincing line of argumentation. If any assumption concerning the viscosity of the composition of Example 1 of D10 can be made, it is the assumption that the composition has a viscosity of less than $0.02 \text{ kgm}^{-1}\text{s}^{-1}$ as indicated in the text of D10. Since, furthermore, the respondent's line of argument is not supported by any evidence, a comparison of Product Example 1 with Example 1 of D10 can never demonstrate that the presence of inulin would induce good flow characteristics / low viscosity to a composition.

- 6.3.3 With regard to comparison (b) (Product Example 1 versus commercial product Fresubin DFN Plus), the respondent referred to the first table on page 7 of the opposed patent. This table shows that the inulin-containing composition of Product Example 1 has a viscosity of $0.23 \text{ kgm}^{-1}\text{s}^{-1}$, which is significantly lower than the viscosity for the inulin-free Fresubin DFN Plus ($0.035 \text{ kgm}^{-1}\text{s}^{-1}$), and that the flow rate for Product Example 1 is significantly improved compared to Fresubin DFN Plus (60 and 66 min/500 ml versus 129 and 158 min/500 ml). In the respondent's view, this

comparison demonstrated the beneficial effect of inulin on flow rate / viscosity.

However, as acknowledged by both parties, Product Example 1 and the commercial product Fresubin DFN Plus differ not only in the presence of inulin but also in the type of (further) fibres used. More in particular, Product Example 1 uses pectin whereas the commercial product uses soy fibres. As apparent from D7 and D10, this further difference has an influence on the viscosity of the composition.

D7 discloses that "soy fiber when used in tube feeding nutritional products can cause a viscosity increase to the extent such that undesirably low flow rates can occur, or the tubes can even clog in extreme situations" (sentence bridging pages 1 and 2). D10, which aims at low viscosities (as set out in points 6.1 and 6.3.2, above), refers to pectin as preferred soluble fibre (column 5, line 23).

In view of the cited prior art, it must be assumed, that, as pointed out by the appellant, pectin fibres are superior to soy fibres in terms of flow rate / impact on viscosity. Consequently, it is not possible to attribute any improvement in flow rate /reduced viscosity of Product Example 1 of the opposed patent over the commercial product Fresubin DFN Plus to the presence of inulin.

6.3.4 In summary, the comparative data referred to by the respondent cannot constitute any proof that good flow rates / low viscosities are obtained by the

distinguishing feature with regard to closest prior art document D10, namely the presence of inulin.

In other words, the comparisons relied upon by the respondent are not a fair comparison with the closest prior art as they do not meet the criterion set out in decision T 197/86 (OJ EPO 1989, 371; point 6.1.3): "... in the case where comparative tests are chosen to demonstrate an inventive step with an improved effect over a claimed area, the nature of the comparison with the closest state of the art must be such that the effect is convincingly shown to have its origin in the distinguishing feature of the invention."

6.3.5 As regards the second distinguishing feature of the claimed subject-matter over the closest prior art, ie the energy distribution specified for the carbohydrate, lipid and protein source, this feature does not lead to any tangible, technical effect, and in particular not to good flow characteristics or low viscosity.

6.3.6 For the above reasons, the achievement of a good flow rate / low of viscosity cannot be taken into account when formulating the **objective** technical problem. In fact, the problem referred to by the respondent and cited in the opposed patent has to be re-formulated in a less ambitious manner as the provision of a further nutritional composition that has an adequately reduced glycaemic response.

6.4 Obviousness of solution

6.4.1 A person skilled in the art starting from Example 1 of D10 as the closest prior art and faced with the problem

of providing alternative nutritional compositions having an adequately reduced glycaemic response would immediately contemplate the addition of inulin to the composition of Example 1 of D10 in view of the first paragraph of page 1 of D2 (English translation of D1) where it reads:

"... inulin - has a stabilising action on the content of glucose in the blood of patients with diabetes mellitus ... **Its effect increases** in combination with other organic components of Jerusalem artichoke tubers, such as **pectins...**" (emphasis added by the board).

In view of this explicit teaching of D1, the respondent's argument that a skilled person would not use a combination of inulin and pectin must fail.

Consequently, the presence of inulin cannot contribute to inventive step in view of D10 in combination with D1.

- 6.4.2 The energy contributions provided by the carbohydrate, lipid and protein source represent an arbitrary selection out of the ranges given for the energy contributions in column 3, lines 52 - 61 of D10 (protein source: 10 - 17% energy intake, lipid source: 20 - 40% energy intake, carbohydrate source: remaining energy intake). Such an arbitrary selection is a matter of routine experimentation. Consequently, as not disputed by the respondent, the energy contributions provided by the carbohydrate, lipid and protein source cited in Claim 1 cannot contribute to inventive step either.

6.5 In summary, the subject-matter of Claim 1 of the main request is obvious over a combination of D10 with D1. Consequently, the main request has to be refused.

7. It may be appropriate to recall at this point that auxiliary request 1 has been withdrawn at the oral proceedings before the board.

Auxiliary request 2

8. *Amendments - Article 123(2) and (3) EPC*

8.1 Claim 1 of auxiliary request 2 differs from Claim 1 of the main request in that

- (a) the amount of energy provided by the protein source has been restricted to 12 to 18% of the energy of the nutritional composition,
- (b) the composition has a viscosity, when measured at room temperature, of 0.015 to 0.03 kg/ms,
- (c) the fibre mixture further includes a source of insoluble dietary fibre
- (d) in a certain ratio of soluble to insoluble fibre.

8.2 Amendment (a) finds its basis on page 5, line 1 of the application as filed. Amendments (b) - (d) are based on granted Claim 2 (corresponding to Claim 3 as filed) granted Claim 3 (corresponding to Claim 5 as filed) and granted Claim 5 (corresponding to Claim 7 as filed). These amendments further limit the scope of the only independent Claim 1.

As not disputed by the appellant, these amendments thus meet the requirements of Article 123(2) and (3) EPC.

9. *Amendments - Article 84 EPC*

The appellant argued that the viscosity now cited in Claim 1 was unclear, because it was not indicated in the patent in suit which shear stress and shear rate had to be applied in the viscosity measurement. This unclarity had been introduced into Claim 1 by way of amendment and was thus open to an objection under Article 84 EPC. However, as set out in point 4.3, above, the patent in suit provides information about the viscosity measurement, and it has not been shown by the appellant that this information with regard to the measurement of the viscosity was insufficient and/or unclear. Consequently, for this reasons alone, the appellant's argument must fail.

10. *Sufficiency of disclosure and novelty*

For the reasons given with regard to the main request, also the subject-matter of auxiliary request 2 is sufficiently disclosed and novel.

11. *Inventive step*

11.1 Claim 1 of auxiliary request 2 contains further restrictions over Claim 1 of the main request. However, none of the further limiting features appears suitable to overcome the inventive step objection against Claim 1 of the main request.

As not disputed by the respondent, the further restriction in energy percentage (amendment (a), above) does not give rise to any technical effect. Said restriction hence cannot add any inventive subject-

matter to the subject-matter of Claim 1 of auxiliary request 2.

No technical effect has been attributed by the respondent to the further distinguishing features, namely the restricted viscosity, the presence of soluble and insoluble fibres, or the ratio thereof (amendments (b) - (d), above). Nor is any technical effect associated with these features apparent from the opposed patent.

11.2 Consequently, D10, and in particular Example 1 of D10, remain the closest prior art for the subject-matter of Claim 1 of auxiliary request 2. Since the further limiting features introduced into Claim 1 do not provide any technical effect, the objective technical problem to be solved over the closest prior art remains the provision of a further nutritional composition that has an adequately reduced glycaemic response.

11.3 As set out for the main request, the addition of inulin is obvious from D1 and the energy distribution obvious from the closest prior art itself, namely D10. Without providing any technical effect, the further restriction in the energy provided by the protein source is merely an arbitrary selection from the known broader range.

D10 also discloses a preferred viscosity of less than $0.02 \text{ kgm}^{-1}\text{s}^{-1}$ for nutritional compositions allowing an optional administration by digestive probe (see point 6.3.2, above). Thus, D10 suggests viscosities which fall within the range now required in Claim 1 of auxiliary request 2, ie 0.015 to 0.03 kg/ms.

The presence of soluble and insoluble fibres is recommended for diabetic diets in D9 (point 4 of "CONCLUSIONS" on page 462). Said presence is therefore a commonly known feature, which cannot, in the absence of any technical effect, contribute to inventive step. As regards the ratio of soluble to insoluble fibre in Claim 1 of the main request, said ratio is, in the absence of any technical effect achieved thereby, an arbitrary selection of the fibre amounts. The latter is a matter of routine experimentation that cannot contribute to inventive step.

In the end, amendments (a) - (d) in Claim 1 of auxiliary request 2 are a mere collocation of generally known and/or arbitrarily selected features which cannot alter the finding on inventive step reached with regard to the subject-matter of Claim 1 of the main request.

- 11.4 In summary, the subject-matter of Claim 1 of auxiliary request 2 is obvious in view of D10 in combination with D1 and D9.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

G. Röhn

W. Sieber