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**Datasheet for the decision
of 18 January 2007**

Case Number: T 0741/04 - 3.3.09

Application Number: 95201852.1

Publication Number: 0691079

IPC: A23L 1/00

Language of the proceedings: EN

Title of invention:

Enteral composition for diabetic patients

Patentee:

SOCIETE DES PRODUITS NESTLE S.A.

Opponent:

Fresenius Kabi Deutschland GmbH

Headword:

-

Relevant legal provisions:

EPC Art. 83, 56

Keyword:

"Sufficiency of disclosure (yes)"

"Inventive step (no)"

Decisions cited:

-

Catchword:

-



Case Number: T 0741/04 - 3.3.09

DECISION
of the Technical Board of Appeal 3.3.09
of 18 January 2007

Appellant: Fresenius Kabi Deutschland GmbH
(Opponent) Else-Kröner-Straße 1
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Respondent: SOCIETE DES PRODUITS NESTLE S.A.
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Representative: Dixon, Sarah
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office orally
announced 17.02.04 and posted 15 April 2004
concerning maintenance of European patent
No. 0691079 in amended form.

Composition of the Board:

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

Summary of Facts and Submissions

I. Mention of the grant of European patent No. 0 691 079 in respect of European patent application No. 95 201 852.1 in the name of *Société des Produits Nestlé* filed on 6 July 1995 was announced on 14 November 2001.

The patent, entitled "*Enteral composition for diabetic patients*" was granted with nine claims, Claim 1 reading as follows:

"1. An enteral composition for providing nutrition to a diabetic patient without substantially increasing blood glucose levels, the composition comprising

- a protein source,
- a carbohydrate source that comprises high amylose starch, the high amylose starch comprising 25 to 75% by weight amylose and 75% to 25% by weight amylopectin, and
- a fat source that has an n-6:n-3 ratio of not more than 10 and includes long chain triglycerides and medium chain triglycerides."

II. Notice of opposition requesting revocation of the patent in its entirety on the grounds of Articles 100(a) and 100(b) EPC was filed by

Fresenius Kabi Deutschland GmbH

on 12 August 2002.

As to the opposition grounds of Article 100(a), the Opponent submitted that the claimed subject-matter was not new and did not involve an inventive step and based its objections *inter alia* on the following documents:

D1 EP-A 0 504 055

D4 J.B. Miller et al. in "Am. J. Clin. Nutr." (1992) 1034-1036.

After the expiry of the opposition period further documents were cited, *inter alia*

D10 Technical Service Bulletin Encapsul 855

D13 Letter of Chris Langley, National Starch & Chemical, dated 14 January 2004.

III. The Patent Proprietor defended the patent as granted and submitted with a letter dated 13 January 2004 two sets of claims as bases for auxiliary requests 1 and 2. Claim 1 of the auxiliary request 2, a combination of Claims 1 and 3 as granted, read as follows:

"1. An enteral composition for providing nutrition to a diabetic patient without substantially increasing blood glucose levels, the composition comprising

- a protein source,
- a carbohydrate source which provides less than 50% of the calories of the composition and that comprises high amylose starch, the high amylose starch comprising 25 to 75% by weight amylose and 75% to 25% by weight amylopectin, and

- a fat source that has an n-6:n-3 ratio of not more than 10 and includes long chain triglycerides and medium chain triglycerides."

IV. With the interlocutory decision, orally announced on 17 February 2004 and issued in writing on 15 April 2004, the Opposition Division maintained the patent on the basis of this auxiliary request 2.

As regards the opposition ground under Article 100(b) EPC, the Opposition Division reasoned that the skilled person would be aware of the fact that every composition suitable for providing nutrition to diabetic patients would seek to avoid increased blood glucose levels and that the Opponent had failed to establish that the information provided in the patent specification was insufficient for the preparation of nutritional compositions achieving this effect.

The Opposition Division also held that the claimed subject-matter was novel over D1, the distinguishing features being the high amylose content of 25 to 75% in the starch of the carbohydrate source and the energy intake attributable to the carbohydrates of less than 50%.

Concerning inventive step the problem to be solved by the invention was seen in the provision of alternative compositions for diabetic patients. The Opposition Division concluded that there was no disclosure in D1 which, in combination with other documents of the prior art, would prompt the skilled person to replace parts of the carbohydrate source of D1 by high amylose starch

and to simultaneously choose quantities of carbohydrates providing less than 50% energy intake.

- V. An appeal against the decision of the Opposition Division was filed by the Opponent (hereinafter: the Appellant) on 8 June 2004. The Statement of the Grounds of Appeal was submitted on 5 August 2004.

The Appellant maintained the objections of insufficiency of disclosure (Article 83 EPC) and lack of inventive step (Article 56 EPC) raised before the Opposition Division. Novelty was no longer contested.

The document

D14 EP-A 0 265 772

was cited for the first time in the appeal proceedings.

- VI. The Patent Proprietor (hereinafter: the Respondent) sought, as its main request, the maintenance of the patent on the basis of the auxiliary request 2 underlying the appealed decision and filed with the letter dated 15 December 2006 a set of claims of a so-called auxiliary request 3 which now constituted auxiliary request 1. The claims according to this auxiliary request 1 differ from those of the main request only by the insertion into Claim 1 of the feature that the amount of high amylose starch in the carbohydrate source is 1 to 5% of the composition. Claim 1 of the auxiliary request 1 reads as follows:

"1. An enteral composition for providing nutrition to a diabetic patient without substantially increasing blood glucose levels, the composition comprising

- a protein source,
- a carbohydrate source which provides less than 50% of the calories of the composition and that comprises 1% to 5% of the composition high amylose starch, the high amylose starch comprising 25 to 75% by weight amylose and 75% to 25% by weight amylopectin, and
- a fat source that has an n-6:n-3 ratio of not more than 10 and includes long chain triglycerides and medium chain triglycerides."

In the oral proceedings before the Board, which took place on 18 January 2007, the Respondent presented the document

D15 "Nutrition Recommendations and Principles for People With Diabetes Mellitus", in *Diabetes Care*, vol. 17, no. 5, May 1994, pages 519 to 522.

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

(a) Sufficiency of disclosure - Article 83 EPC

The wording "*without substantially increasing blood glucose levels*" in Claim 1 of the main request and the auxiliary request 1 was already part of Claim 1 as originally filed. In the examination proceedings, this feature was considered essential and limiting, and its

deletion from the claims was not allowed, see communication of the Examining Division dated 24 April 2001.

Since, however, there was no instruction in the patent specification as to how to avoid an increased blood glucose level - which depends heavily on the amount of the administered composition and the actual metabolism of the diabetic patient - the disclosure of the claimed invention was insufficient.

(b) Inventive step - Article 56 EPC

The document D1 was representative of the closest prior art. D1 pertained to an enteral liquid composition for diabetic patients on the basis of a protein source, a carbohydrate source and a lipid source, the latter having an n-6:n-3 ratio of 4 and including long chain triglycerides and medium chain triglycerides. According to the teaching in D1, it was the aim to provide nutritional compositions with a low glycaemic index.

In example 1 of D1 a composition with 11 wt.-% carbohydrates was described which amounted to an energy intake provided by the carbohydrates of 55%. In the light of the disclosure in Claim 3 that the carbohydrate content might be as low as 5 wt.-%, example 1 of D1 implied that the energy intake could also be below 50%.

In addition, it was disclosed in D14 that the recommendations in the guidelines of the American Diabetes Association (ADA) to provide more than

50% of energy by the carbohydrate source were problematic for liquid diabetic formulae because of the rapid carbohydrate absorption. It was therefore recommended in D14 that the energy provided by carbohydrates should be reduced to less than 50% in favour of the energy provided by fat.

For these reasons, and because the ADA guidelines as revised in 1994 allowed more flexibility as regards percentage of calories from carbohydrates, as stated in paragraph [0011] of the patent specification, a skilled person would contemplate reducing the carbohydrate calories in the liquid compositions of D1 to less than 50%. Besides, diabetic formulae with low carbohydrate energy intake were already sold on the market before the filing date and, indeed, the commercial product "Glucerna®", providing only 33.3% of the calories by carbohydrates, was compared with the claimed invention in the example of the patent specification.

The claimed subject-matter, therefore, differed from the composition according to D1 only in that the carbohydrate source contained a high amylose starch, whose amount was undefined in Claim 1 of the main request and was limited to 1 to 5% of the composition according to Claim 1 of the first auxiliary request.

A skilled person, however, intending to provide alternative enteral compositions with a low glycaemic index would consider D4, which disclosed

that high amylose rice starch with up to 28% amylose is suitable for providing low glycaemic index in food products for diabetic persons.

The subject-matter of Claim 1 of the main was therefore obvious from a combination of D1 with D4.

A skilled person would also add the high amylose starch in an amount within the range of 1 to 5% according to the auxiliary request 1 because the enteral composition according to example 1 of D1 contained the modified starch Cleargum CB 90 in an amount of 3.2% of the composition, i.e. in an amount squarely within the claimed range.

Thus, the subject-matter of the auxiliary request 1 was also obvious over the cited prior art.

VIII. The Respondent provided the following oral and written arguments:

(a) Sufficiency of disclosure - Article 83 EPC

Because any nutritional composition for diabetic patients should avoid glucose peaks in blood, the wording in Claim 1 "*without substantially increasing blood glucose levels*" would be well understood and implemented by the skilled person.

(b) Inventive step - Article 56 EPC

The document D1, which had to be considered to represent the closest prior art, did not teach the

provision of enteral compositions with an energy intake attributable to the carbohydrates of less than 50%. To the contrary, example 1 described a composition providing 54% of the energy by carbohydrates and it was indicated on page 3, last line to page 4, line 2 that the complete carbohydrate source, composed either of simple or complex carbohydrates or starch derivatives, provided at least 50% of the total energy. Furthermore, the disclosure in Claim 3 of D1 that the carbohydrate source amounted to 5 to 40% of the total weight of the composition would not justify the conclusion that - towards the lower limit of this range - the energy provided by carbohydrates would necessarily decrease to below 50% because the composition was a liquid containing considerable amounts of water and these have to be taken into account.

Furthermore, the historical perspective of the ADA nutrition recommendations referred to in Table 1 at page 522 of D15 showed between 1921 and 1986 an ever increasing energy from 20% to up to 60% provided by carbohydrates. Although no concrete ADA percentage recommendation was provided for 1994, but only the information that that year's revision of the ADA guidelines was more flexible regarding calories from carbohydrates, it was not reasonable to assume that this meant that the established trend to higher energy intake attributable to the carbohydrates was suddenly reversed to percentages below 50%.

A skilled person would therefore not combine D1 with D14 against the trend in the ADA guidelines.

In addition, it was taught in D1 that as a general rule modified starches were unsuitable for liquid enteral compositions because of their tendency to form stable and viscous gels in aqueous solution which was undesirable for an enteral administration. Three specific modified starches were, exceptionally, found to be suitable (cf. page 2, lines 54 to 56), one of them being Encapsul 855 containing 17.6 to 24% amylose according to the letter D13. This starch, however, has a pH value of 3, as indicated in the datasheet D10, and is therefore an acid-modified starch and not a natural starch in accordance with the invention.

In view of this teaching in D1, the skilled person would not contemplate using starches including amylose-rich starches and, hence, would not combine D1 with D4.

Even if a skilled person considered D4 in combination with D1, he would not be motivated to use the amylose-rich starch for the liquid enteral compositions according to D1 because, on the one hand D4 only dealt with solid rice products, and on the other hand these products were only tested on healthy volunteers, thus not suggesting any benefit for diabetic patients.

IX. The Appellant requested that the decision under appeal be set aside and that the patent be revoked.

The Respondent requested that the appeal be dismissed or, alternatively, that the patent be maintained on the basis of Claims 1 to 8 of the auxiliary request (ie auxiliary request 1) filed with the letter of 15 December 2006.

Reasons for the Decision

1. The appeal is admissible.
2. *Sufficiency of disclosure - Article 83 EPC*

The enteral composition according to Claim 1 of the main request and the auxiliary request 1 is defined such that the skilled person on the basis of the information in the specification is able to prepare it without undue burden. The passage in the claims "*without substantially increasing blood glucose levels*" has a purely explanatory character, conveying to any expert in the field of dietetic food a clearly understandable meaning as to the purpose behind the suggested formulation and not implying a specific administration regime.

In the Board's judgment, the invention is therefore sufficiently disclosed.

3. *Novelty of the subject-matter according to the main request and the auxiliary request 1*

Novelty was not in dispute between the parties. The Board sees no reason either to challenge the appealed decision on this issue.

4. *Inventive step*

4.1 The subject-matter according to the patent in suit

The patent in suit is concerned with an enteral composition for providing nutrition to a diabetic patient.

In Claim 1 of the main request and the auxiliary request 1 the composition is respectively characterised by three essential ingredients:

- a protein source;
- a carbohydrate source which provides less than 50% of the calories of the composition and which comprises high amylose starch comprising 25 to 75% by weight amylose and 75 to 25% by weight amylopectin;
- a fat source that has a ratio of omega-6 to omega-3 fatty acids (n-6 to n-3 ratio) of not more than 10 and that contains long chain triglycerides and medium chain triglycerides (the latter containing C₆ to C₁₂ fatty acids according to paragraph [0044] of the patent specification).

The content of the high amylose starch in the composition is undefined in Claim 1 of the main request

and is limited to 1% to 5% according to Claim 1 of the auxiliary request 1.

The composition, which is described as a moderate to low carbohydrate, high fat enteral formulation (page 3, lines 3/4), enhances the glycaemic control by reducing the rate at which glucose enters the blood stream. According to page 4, paragraph [0042], this is due to the use of a high amylose starch, because this starch type is resistant to digestion by pancreatic enzymes and is therefore slowly absorbable.

4.2 The closest prior art

As uncontested by the parties, D1 is representative of the closest prior art.

This document describes a composition for providing nutrition to a diabetic patient. The composition is liquid, suitable for oral or enteral application and comprises:

- a protein source,
- a carbohydrate source and
- a fat source;

cf. page 2, lines 25 to 27 and page 4, lines 46 to 49.

The protein source provides 10 to 17 % of the total energy (page 4, lines 7 to 9);

The carbohydrate source contains slowly digestible varieties, thereby providing a significantly reduced glycaemic index, which source includes modified

starches (page 2, lines 31 to 36). The carbohydrate source preferably provides at least 50% of the total energy of the composition (page 3, last line to page 4, line 2);

The fat source comprises linolic acid - which is an omega-6 (n-6) polyunsaturated fatty acid - and linolenic acid - an omega-3 (n-3) polyunsaturated fatty acid - in a ratio of 6.4% : 1.6 % (page 4, lines 24 to 27). This results in a n-6 : n-3 ratio of 4. The fat source includes long chain triglycerides and medium chain triglycerides (page 4, lines 12 to 22), something that was also not contested by the parties. The total energy provided by the fat source amounts to 20 to 40% (page 4, line 12).

The Respondent's argument (see point VIII (b)) that there was no teaching in D1 to provide less than 50% of the calories of the composition from the carbohydrate source, as claimed, is not accepted by the Board. The wording in D1 at page 3 last line to page 4, line 2, that the carbohydrates preferably ("*De préférence*", cf. last line at page 3) provide at least 50% of the energy, implies that an energy intake of less than 50% is also contemplated. That this is the case can also be derived from the values of the energy intake of from 10 to 17% for the proteins (page 4, lines 7/8) and of from 20 to 40% for the lipids (page 4, line 12). These values leave room for a carbohydrate energy intake of less than 50%, for instance if the proteins provide close to 17% and the lipids close to 40% energy.

The feature in Claims 1 of the main request and the auxiliary request 1 that the carbohydrate source

provides less than 50% of the calories of the composition is therefore not a distinguishing feature vis à vis D1.

Main Request

4.3 The problem to be solved

The composition according to Claim 1 of the main request differs from the composition according to D1 therefore only in that the carbohydrate source comprises high amylose starch comprising 25 to 75% by weight amylose and 75 to 25% by weight amylopectin.

The problem to be solved by the invention is therefore seen in the provision of an alternative enteral composition with a low glycaemic index.

4.4 Obviousness

The incorporation of high amylose starches into the carbohydrate source of the composition according to D1 in order to provide a low glycaemic index is, however, obvious from D4. This document, discussing the glycaemic index of rice products in conjunction with diabetes (cf. page 1034, left column under "Key words") discloses that rice starch varieties with a higher proportion of amylose (e.g. 28%) have a slower rate of digestion and therefore produce lower glycaemic and insulin responses (page 1034, left column under "Introduction" and page 1035, left column under "Results").

In this context, the argument of the Respondent that D4 is concerned with solid rice products and not with enteral liquid compositions, is not decisive.

When setting out to provide an enteral composition for diabetic patients in accordance with D1 the skilled person would clearly be encouraged by the teaching in D4 concerning the particular suitability of high amylose rice starch to provide a low glycaemic index (see the abovementioned passage at page 1035) to use this starch as a carbohydrate source; no more than routine experimentation would be required for an expert to convert this natural product into the form required as an ingredient for an enteral composition and to combine it in the right amounts with the further ingredients protein, fat and water used according to D1.

For the above reasons the disclosure in D1 that only specific modified starches are considered suitable for the preparation of stable liquid compositions would not - contrary to the Respondent's opinion, see point VIII (b) - prevent a skilled person investigating whether high amylose starch could be incorporated into enteral compositions; given the already relatively high content of up to 24% amylose in Encapsul 855, one of the starch varieties recommended in D1, the skilled person would clearly act with a reasonable expectation of success.

The subject-matter of Claim 1 of the main request therefore does not involve an inventive step in the light of a combination of D1 with D4.

Consequently, the main request is not allowable.

Auxiliary Request 1

4.5 The problem to be solved and obviousness

In contrast to Claim 1 of the main request, the amount of high amylose starch in the carbohydrate source is specified in Claim 1 of the auxiliary request 1 to be 1 to 5%.

The Respondent, however, has not demonstrated that this range of amounts gives rise to any particular effect. The problem to be solved is therefore again seen in the provision of an alternative enteral composition with a low glycaemic index.

Adaptation of the amounts of ingredients in a composition in order to optimise its properties is, however, a common routine task for a skilled person.

Moreover, an enteral composition with 3% of the modified starch Cleargum CB 90 is described in example 1 of D1. This would motivate a skilled person to also use the high amylose starch in similar amounts, ie amounts within the claimed range of from 1 to 5%.

The composition according to Claim 1 of the auxiliary request 1 is therefore not inventive and the auxiliary request 1 is also not allowable.

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

P. Kitzmantel