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**Datasheet for the decision
of 10 June 2009**

Case Number: T 1328/06 - 3.3.09

Application Number: 98920738.6

Publication Number: 0910253

IPC: A23L 1/30

Language of the proceedings: EN

Title of invention:
PERI-OPERATIVE DRINK

Patentee:
N.V. Nutricia

Opponent:
Fresenius Kabi Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"Admission of new request submitted in the oral proceedings
(yes)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 1328/06 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 10 June 2009

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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office orally
announced 20 June 2006 and posted 17 July 2006
concerning maintenance of the European patent
No. 0910253 in amended form.

Composition of the Board:

Chairman: P. Kitzmantel
Members: W. Ehrenreich
W. Sekretaruk

Summary of Facts and Submissions

- I. Mention of the grant of European patent No. EP-B 0 910 253 in respect of European patent application No. 98 920 738.6, filed on 1 May 1998 as International application No. PCT/NL98/00242 in the name of *N.V. Nutricia* and published on 12 November 1998 as WO-A 98/49906, was announced on 22 October 2003 (Bulletin 2003/43).

The patent, entitled "*Peri-Operative Drink*" was granted with ten claims. Claim 1 read as follows:

"1. A liquid nutritional composition suitable for enteral peri-operative use, containing, per 400 ml, 5-130 g of soluble carbohydrates, at least 3.75 g of which are polysaccharides, less than 2 wt.% of fat and less than 0.5 wt.% of intact proteins that are insoluble at pH 3, the composition containing 1-30 g of glutamine or a glutamine precursor calculated as glutamine, and furthermore containing 0.2-8 g of methionine and/or cysteine, and/or containing 2-8 g of arginine."

Claims 2 to 9 were dependent on Claim 1. Claim 10 pertained to a process for preparing a liquid composition comprising adding water to the dry ingredients according to any one of Claims 1 to 9.

II. Opposition against the patent was filed by

Fresenius Kabi Deutschland GmbH

on 20 July 2004.

The opposition was based on the grounds of Article 100 (a) EPC, claiming that the claimed subject-matter was not novel and was not based on an inventive step. In support of its objections under Articles 54 and 56 EPC the Opponent *inter alia* cited the following documents:

D3 US-A 3 821 432

D8 EP-A 0 564 511.

III. With its interlocutory decision orally announced on 20 June 2006 and issued in writing on 17 July 2006 the Opposition Division maintained the patent in amended form on the basis of the fifth auxiliary request submitted in the oral proceedings.

As compared to the patent as granted, which contained a single independent product claim, this request comprised two independent product Claims 1 and 2 which read as follows:

"1. A liquid nutritional composition suitable for enteral peri-operative use, containing, per 400 ml, 24-80 g of soluble carbohydrates, at least 3.75 g of which are polysaccharides, less than 2 wt.% of fat and less than 0.5 wt.% of intact proteins that are insoluble at pH 3, the composition containing 1-30 g of glutamine or a glutamine precursor calculated as glutamine, and furthermore containing 0.2-8 g of methionine and/or

cysteine, and/or containing 2-8 g of arginine, and containing 0.5-4 wt.% of whey proteins."

"2. A liquid nutritional composition suitable for enteral peri-operative use, containing, per 400 ml, 24-80 g of soluble carbohydrates, at least 3.75 g of which are polysaccharides, less than 2 wt.% of fat and less than 0.5 wt.% of intact proteins that are insoluble at pH 3, the composition containing 5-25 g of glutamine or a glutamine precursor calculated as glutamine, and furthermore containing 0.2-8 g of methionine and/or cysteine, and/or containing 2-8 g of arginine."

Claim 1 was amended (features *in italics*) vis à vis Claim 1 as granted by limiting the amount of soluble carbohydrates to a range from 5-130g to 24-80g and by adding the further feature that the composition contained *0.5 - 4wt.% of whey proteins*.

The amendment to Claim 2 vis à vis Claim 1 as granted involved the limitation of the soluble carbohydrates to 24 - 80g (as in Claim 1 above) and of the amount of the glutamine/glutamine precursor from 1 - 30g to 5 - 25g.

The fifth auxiliary request was one of a series of requests submitted by the Proprietor in the written and oral proceedings, which comprised multiple independent product claims in one single request. Objections under Rule 57a EPC 1973 (Rule 80 EPC) and Article 84 EPC had been raised by the Opponent against this split of the sole independent product Claim 1 as granted into several independent claims.

According to the decision of the Opposition Division the fifth auxiliary request was not objectionable under Article 84 EPC because the number of two independent claims was considered to meet the requirement of conciseness. No statement as to Rule 80 EPC or novelty was given.

As to the issue of inventive step, the Opposition Division considered D8 representative of the closest prior art. In its view, document D3 was further away than D8 as it did not address the problem of the invention which was to adjust the metabolism towards an anabolic condition. The Opposition Division argued that the composition according to independent Claims 1 and 2 of the fifth auxiliary request differed from the pre-operative beverage according to D8 in that the amino acids methionine and/or cysteine and/or arginine were present and that the composition of Claim 1 furthermore contained whey proteins. The presence of these components was not suggested by D8, which only related to beverages containing carbohydrate mixtures, salts, flavouring agents and preservatives.

IV. Notices of appeal against the decision of the Opposition Division were lodged by the

Patent Proprietor (hereinafter: the Appellant/Proprietor) - on 18 September 2006

Opponent (hereinafter: the Appellant/Opponent - on 24 August 2006.

The Statements of the Grounds of Appeal were submitted

by the Appellant/Proprietor on 24 November 2006 and by the Appellant/Opponent on 17 November 2006.

V. With its grounds of appeal the Appellant/Proprietor filed five sets of claims for a new main request and auxiliary requests 1 to 4. Auxiliary requests 5 and 6 were submitted with the letter of 8 May 2009 and thereafter replaced by new sets of claims according to auxiliary requests 5 to 9 enclosed with the letter of 28 May 2009.

VI. With respect of the multiple independent claims contained in the Appellant/Proprietor's new requests (except auxiliary request 3) the Appellant/Opponent reiterated its objections under Rule 80 EPC and Article 84 EPC. Furthermore, the objections against novelty and inventive step were maintained and further objections were raised under Article 123(2) against independent Claims 2,3 and 4 of the main request and under Article 123(3) against Claim 3 of the main request.

As regards novelty and inventive step, the Appellant/Opponent considered D3 the most pertinent prior art.

VII. During the oral proceedings, held on 10 June 2009 before the Board, novelty of the subject-matter of independent Claims 3 of the main and auxiliary requests 1 and 2, inventive step of the subject-matter of independent Claims 1 of auxiliary requests 3, 5 and 9 and of independent Claim 2 of auxiliary request 6, the amendment to Claim 3 of auxiliary request 4 under Article 123(2) EPC, and admittance into the proceedings

of auxiliary requests 7 and 8 were discussed. After the Board had informed the Parties that the last-mentioned two requests would not be admitted and that none of the other than operative requests were considered to be allowable, an opportunity was given to the Appellant/Proprietor to file an amended request. After adjournment of the oral proceedings the Appellant/Proprietor submitted an amended new request and withdrew all previous requests. The set of Claims 1 to 9 according to this new request contains only one independent product Claim which reads as follows:

"1. A liquid nutritional composition suitable for enteral peri-operative use, containing, per 400 ml, 24-80 g of soluble carbohydrates, at least 3.75 g of which are polysaccharides, less than 2 wt.% of fat and less than 0.5 wt.% of intact proteins that are insoluble at pH 3, the composition containing 1-30 g of glutamine or a glutamine precursor calculated as glutamine, and furthermore containing 0.2-8 g of methionine and/or cysteine, and/or containing 2-8 g of arginine, and containing 0.5-4 wt.% of whey proteins being soluble at pH 2.0 to 7.5."

Claims 2 to 8 are dependent on Claim 1 and Claim 9 is directed to a process for preparing a liquid composition comprising adding water to the dry ingredients of any of Claims 1 to 8.

VIII. As regards the composition claimed in Claim 1 of the new request - which now constituted the sole request - the Appellant/Proprietor argued that a skilled person, would not be induced to add whey proteins to the peri-operative drink of D3 or the pre-operative beverage of

D8 because the presence of whey proteins in such drinks was nowhere disclosed or suggested. The subject-matter according to the new request was therefore novel and inventive.

- IX. The Appellant/Opponent contested admissibility of the new request as being late-filed. No formal objections and objections as to lack of novelty were raised.

As regards inventive step the Appellant/Opponent argued that the claimed composition differed from that disclosed in D3 essentially by the presence of whey proteins. However, since D3 already disclosed the presence of free amino acids in a peri-operative drink it was obvious to a skilled person to provide further amino acids also in the form of digestible proteins, including whey proteins. The claimed composition was therefore obvious over D3 in combination with general common knowledge.

- X. The Appellant/Proprietor requested that the decision under appeal be set aside and the patent be maintained on the basis of Claims 1 to 9 of the request filed on 10 June 2009.

- XI. The Appellant/Opponent requested that the decision under appeal be set aside and the patent be revoked.

Reasons for the Decision

1. The appeals are admissible.

2. Claim 1 of the new request is based on Claim 1 of the fourth auxiliary request which was submitted with the Appellant/Proprietor's grounds of appeal and takes into account the Appellant/Opponent's objections under Article 123(2) EPC as to the missing pH range for the solubility of the whey proteins to which this feature was limited according to page 3, lines 4-5 of the application as filed.

The request therefore does not confront the Appellant/Opponent with a new situation he could not deal with at short notice in the oral proceedings and is therefore admitted in accordance with Article 13 (1) of the Rules of Procedure of the Boards of Appeal (OJ 11/2007, 536-547).

3. *Rule 80 EPC; Articles 84, 123(2), (3) EPC*

The claims according to the new request meet these criteria. The Appellant/Opponent raised no objections in this respect and also the Board acknowledges that these requirements are met.

4. *Novelty*

The claimed composition is novel in that none of the prior art documents discloses a nutritional composition comprising the combination of amino acids specified in Claim 1 with whey proteins. This was not contested by the Appellant/Opponent.

5. *Inventive step*

The closest prior art is represented by D3. This document discloses a liquid nutritional composition which can be administered to pre- and post-operative patients, and which comprises soluble carbohydrates, minor amounts of fat, a selection of amino acids, e.g. glutamine, methionine and arginine, vitamins and minerals (column 1, lines 18 to 20 in conjunction with examples 7 and 8).

The claimed composition differs therefrom in that it additionally contains whey proteins.

The Appellant/Opponent's argument that the presence of whey proteins was obvious because a skilled person would routinely consider their addition to a peri-operative drink comprising low amounts of carbohydrates, very low amounts of fat and intact proteins and certain amounts of glutamine (or glutamine precursor), methionine and/or cysteine, and/or arginine is a mere assertion, not supported by any evidence. While the nutritive value of whey proteins is known, the feasibility of their addition to a peri-operative drink is not by that self-evident, because such compositions have to meet special requirements (cf. paragraph [0010] of the specification). There is no indication whatsoever in any of the available citations which would induce the skilled person to add these specific proteins to the peri-operative composition of D3.

The claimed peri-operative composition - which constitutes an alternative to the composition of D3 -

is therefore not obvious over D3 in combination with any of the other documents of the prior art.

6. The request submitted on 10 June 2009 is therefore allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of Claims 1 to 9 of the request of 10 June 2009, after any necessary consequential adaptation of the description.

The Registrar

The Chairman

G. Röhn

P. Kitzmantel