

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen
(D) [] No distribution

**Datasheet for the decision
of 28 July 2009**

Case Number: T 0409/05 - 3.3.09

Application Number: 96200047.7

Publication Number: 0721742

IPC: A23L 1/30

Language of the proceedings: EN

Title of invention:

Nutrition for elderly patients

Patentee:

SOCIETE DES PRODUITS NESTLE S.A.

Opponents:

Fresenius Kabi Deutschland GmbH
Numico Research B.V.

Headword:

-

Relevant legal provisions:

-

Relevant legal provisions (EPC 1973):

EPC Art. 54, 56, 83

Keyword:

"Main request (novelty - no)"

"Auxiliary request (novelty - yes; inventive step - no)"

Decisions cited:

-

Catchword:

-



Case Number: T 0409/05 - 3.3.09

DECISION
of the Technical Board of Appeal 3.3.09
of 28 July 2009

Appellant 1: Fresenius Kabi Deutschland GmbH
(Opponent 1) Else-Kröner-Strasse 1
D-61352 Bad-Homburg v.d.H. (DE)

Representative: ter Meer, Nicolaus
TER MEER STEINMEISTER & PARTNER GbR
Patentanwälte
Mauerkircherstrasse 45
D-81679 München (DE)

Appellant 2: Numico Research B.V.
(Opponent 2) Postbus 7005
NL-6700 CA Wageningen (NL)

Representative: Jorritsma, Ruurd
Nederlandsch Octrooibureau
Postbus 29720
NL-2502 LS Den Haag (NL)

Respondent: SOCIETE DES PRODUITS NESTLE S.A.
(Patent Proprietor) Case postale 353
CH-1800 Vevey (CH)

Representative: Lock, Graham James
Fry Heath & Spence LLP
The Gables
Massetts Road
Horley
Surrey RH6 7DQ (GB)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 8 February 2005
rejecting the opposition filed against European
patent No. 0721742 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: P. Kitzmantel
Members: N. Perakis
W. Sekretaruk

Summary of Facts and Submissions

I. Mention of the grant of European patent No. 0 721 742 in respect of European patent application No. 96200047.7 in the name of SOCIETE DES PRODUITS NESTLE S.A., which had been filed on 10 January 1996 claiming a US priority of 13 January 1995 (US 372558), was announced on 26 June 2002 (Bulletin 2002/26). The patent, entitled "Nutrition for elderly patients", was granted with nine claims, which correspond to the Main Request dealt with in this decision. Independent Claims 1 and 5 read as follows:

"1. Use of a nutritional composition in the manufacture of a medicament for the treatment or prevention of protein-energy malnutrition in an elderly patient wherein the nutritional composition comprises a protein source for providing at least 18% of the total calories of the composition, a carbohydrate source; a source of dietary fibre having a soluble fibre to insoluble fibre ratio of 1:4 to 4:1, and a lipid source including a mixture of medium and long chain triglycerides."

"5. A nutritional composition for providing nutrition to an elderly patient; the composition comprising: caseinate in an amount to provide at least 18% of the total calories of the composition; a carbohydrate source in an amount to provide 48% to 55% of the total calories of the composition and which includes a source of dietary fibre having a soluble fibre to insoluble fibre ratio of 1:4 to 4:1; and a lipid source in an amount to provide 26% to 36% of the total calories of the composition and including a mixture of medium and long chain triglycerides;

- 2 to 10 mg/l of β -carotene; and vitamins and minerals to meet or exceed the US RDA; the composition having an energy density of 5 kJ/ml (1.2 kcal/ml)."
- II. Notices of Opposition were filed against the patent by Fresenius Kabi Deutschland GmbH (Opponent 1) on 17 March 2003 and by Numico Research B.V. (Opponent 2) on 26 March 2003. Both Opponents requested the revocation of the patent in its full scope, relying on Article 100(a) EPC (lack of novelty and lack of inventive step) and Article 100(b) (that the European 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).
- III. The oppositions were *inter alia* supported by the following documents:
- D11: WO 94/27628
- D12: Fredstrom S B *et al*, "Determination of the Fiber Content of Enteral Feedings", *Journal of Parenteral and Enteral Nutrition*, 1991, 14(4), pp 450-453
- D13: Belitz H-D and Grosch W, *Lehrbuch der Lebensmittelchemie*, 1992, pp 275, 276, 296 and 297
- D14: Pak N *et al*, "A rapid and simultaneous determination of soluble and insoluble dietary fibre", *Nutrition Reports International*, 1989, 40(3), pp 551-565
- D15: Technical Information for the product SUPPORTAN[®]
- D16: Heimburger D C *et al*, "The Role of Protein in Nutrition, with Particular Reference to the Composition and Use of Enteral Feeding Formulas.

A Consensus Report", *Journal of Parenteral and Enteral Nutrition*, 1986, 10(4), pp 425-430

D21: WO 93/00019

D24: EP 0 564 804

D25: Campbell W W et al, "Increased protein requirements in elderly people: new data and retrospective reassessments", *Am J Clin Nutr*, 1994, 60, pp 501-509

D28: Internet extract on protein energy malnutrition <http://www.ehendrick.org/healthy/001109.htm> of 16 November 2004

The following document was filed by the Patent Proprietor:

D31: Internet extract of the Merck Manual of Diagnosis and Therapy on Protein Energy Malnutrition <http://www.merck.com/pubs/mmanual/section1/chapter2/2c.htm> of 9 October 2003

IV. By its decision announced orally at the oral proceedings of 16 December 2004 and issued in writing on 8 February 2005 the Opposition Division rejected the oppositions. The Opposition Division held that the claimed subject-matter was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and that it was novel and not obvious over the cited state of the art.

With regard to the issue of sufficiency it held that the skilled person on the basis of his common general knowledge and the information provided in the patent would have no difficulties in understanding the contested terms "medicament", "protein-energy-malnutrition" and "elderly patients".

With regard to the issue of novelty of Claim 1 it held that none of the cited documents D11, D15, D21 or D24 referred to protein-energy malnutrition (in the following PEM) in an elderly patient. Similarly the subject-matter of Claim 5 was novel over D11, D15 and D21, which did not disclose the claimed amount of caseinate in the nutritional composition.

With regard to the issue of inventive step for both Claims 1 and 5, the Opposition Division considered D16 to represent the closest state of the art because it referred to the use of a composition for the treatment or prevention of PEM in an elderly patient. As regards particularly Claim 1 it argued that the skilled person looking for a composition for that use would not combine the composition of any of D11, D15, D21 or D24 with D16 as he would not find any incentive in those documents to do so. Particularly, as regards Claim 5 it reasoned that the skilled person would not find in any of the cited documents the claimed amount of caseinate and would therefore not arrive in an obvious manner at the claimed solution of the problem.

V. The Opponents appealed the decision of the Opposition Division: Appellant 1 (Opponent 1) on 5 April 2005 paying the appeal fee on the same day and Appellant 2 (Opponent 2) on 7 April 2005 paying the appeal fee on the same day.

VI. The respective Statements setting out the Grounds of Appeal were submitted on 20 June 2005 (Appellant 1) and 17 June 2005 (Appellant 2).

The Appellants maintained their objections of insufficient disclosure, lack of novelty and inventive step.

In support of their arguments Appellant 1 submitted *inter alia* documents D113 to D118 and Appellant 2 *inter alia* documents D41 to D43:

- D113: Clinical Nutrition, Enteral and Tube Feeding, 2nd ed., 1990, p 392
- D114: Parnes H L *et al*, "Protein Calorie Malnutrition and Cancer Therapy", *Drug Safety*, 1992, 7(6), pp 404-416
- D115: Liebermann M D *et al*, "Comparison of Acute and Chronic Protein-Energy Malnutrition on Host Antitumor Immune Mechanisms", *Journal of Parenteral and Enteral Nutrition*, 1991, 15(1), p 15
- D116: Nixon D W *et al*, "Protein-Calorie Undernutrition in Hospitalized Cancer Patients", *The American Journal of Medicine*, 1980, 68, p 683
- D117: Cederholm T, "Protein-Energy Malnutrition in Chronic Disease", The Department of Medicine Stockholm Söder Hospital, Karolinska Institute, Stockholm, Sweden, (1994), abstract and pp 16, 23, 37 and 39
- D118: Slavin J, "Nutritional Benefits of Soy Protein and Soy Fiber", *Journal of the American Dietetic Association*, 1991, 9(7), pp 816-819
- D41: Holmes S *et al*, "Malignant disease: nutritional implications of disease and treatment", *Cancer Metastasis Rev*, 1987, 6(3), abstract
- D42: Parnes H L *et al*, "Protein calorie malnutrition cancer therapy", *Drug Saf*, 1992, 7(6), abstract

D43: Rivadeneira D E *et al*, "Nutritional support of the cancer patient", *CA Cancer J Clin*, 1998, 48(2), abstract

Within the context of insufficient disclosure, beside the arguments already put forward, Appellant 1 raised the issue of the uncertainty of the ratio of the soluble and insoluble dietary fibres.

The lack of novelty objection against the subject-matter of Claim 1 was maintained in view of the disclosure of D11, D15, D21 and D24. That against the subject-matter of Claim 5 was maintained in view of the disclosure of D11. The main argument was that PEM accompanied cancer and other serious illnesses with the consequence that any cancer-oriented nutrition was at the same time directed towards PEM.

Concerning the objection of lack of inventive step, it was argued that the skilled person starting from D16 as closest state of the art, and looking for a further composition to address PEM would find the solution in any of D11, D15, D21 or D24 as regards Claim 1 and in any of D11 or D21 as regards Claim 5. He would thus arrive at the claimed subject-matter without exercising any inventive skill. Additionally the Appellants argued that apart from D16 any of D11, D15, D21 or D24 could also be considered to represent the closest state of the art. In that case the technical problem to be solved would be either to find a further use for the disclosed nutritional composition (Claim 1) or to improve the composition itself (Claim 5). The solution of the first problem was obvious in view of the prior art document itself or in view of D16 while that of the

second was obvious in view of the lack of criticality of the alleged improvement, with the consequence that the claimed limiting parameters must be considered as relating to arbitrary modifications within the general common knowledge of the skilled person in the art.

VII. The Respondent (Patent Proprietor) essentially agreed with the reasoning of the Opposition Division and contested the arguments of the Appellants. In support of its arguments the following documents were submitted:

D32: The Merck Manual of Geriatrics, Section 8, Chapter 61, Protein-Energy Malnutrition, <http://www.merck.com/mrkshared/mmg/sec8/ch61/ch61a.jsp> of 14 December 2005

D33: Visvanathan R, "Under-Nutrition in Older People: A Serious and Growing Global Problem!", *J Postgrad Med*, 2003, 49(4), pp 352-360
[http://www.jpgmonline.com/article.asp?issn=0022-3859; year=2003;volume=49;issue...](http://www.jpgmonline.com/article.asp?issn=0022-3859;year=2003;volume=49;issue...) of 14 December 2005

Exhibit A: Vahlquist Bo, "A Two-Century Perspective of some major Nutritional Deficiency Diseases in Childhood", *Acta Paediadr Scand* 64, 1975, pp 161-171

Exhibit B: Bulletin de terminologie N° 28/F, Terminologie de l'alimentation et de la nutrition, FAO, 1976, pp 24-27

VIII. On 28 July 2009 oral proceedings were held before the Board. At those oral proceedings the Respondent filed as Auxiliary Request a set of claims which was based on

granted Claims 5 to 9 with the necessary adjustment of the claims dependency.

- IX. Both Appellants (Opponents) requested that the decision under appeal be set aside and that the European patent No. 0 7210742 be revoked.

The Respondent (Patent Proprietor) requested that the appeals be dismissed or the European patent be maintained on the basis of the claims of the Auxiliary Request of 28 July 2009.

- X. The arguments put forward by the Appellants (Opponents) in their written submissions and at the oral proceedings can be summarized as follows:

Main Request

- The claimed invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
- The opposed patent was silent about the way a medicament could be obtained from the disclosed nutritional composition. Should the Respondent consider that the term "medicament" meant something different than a nutritional composition, the subject-matter of Claim 1 would not be clearly and fully disclosed.
- Neither the opposed patent nor the state of the art gave a clear definition of PEM and it was impossible to conclude which conditions were covered by that term and which were not. Under those circumstances the patent did not instruct the skilled person as to the conditions under which the claimed nutritional composition should be used.

- The patent referred to "protein depletion" which might be corrected by high protein intake; this term might also correlate to conditions such as immunological deficiencies, skin breakdown and decrease of body protein stores caused from age; however, that was not a definition of PEM and age could not be considered a disease.
- Furthermore there was no agreed definition in the state of the art for the term PEM when applied to elderly persons; in the state of the art PEM was essentially related to the severe symptoms caused by protein deficiency in undernourished young people, especially sucklings/infants, in the third world.
- To the extent that Exhibits A and B submitted by the Respondent referred to pathological conditions of PEM in general, such conditions were not specified.
- Furthermore, the claim concerned not only the treatment but also the prevention of PEM; therefore it did not necessarily address a pathological condition.
- In conclusion, in the absence of a clear and unequivocal definition of PEM, and in view of the very broad variation in its interpretation in the art, this essential feature was not sufficiently disclosed for the reproduction of the invention across its claimed scope.
- The opposed patent did not disclose the method according to which the ratio of soluble/insoluble fibre was measured. In fact D118 and D119 disclosed various methods providing very different results.
- Contrary to the allegation of the Respondent, in the absence of evidence the skilled person would not

automatically consider that the method according to AOAC was the established method.

- Furthermore the subject-matter of Claim 1 lacked novelty over the disclosures of D11, D15, D21 and D24. These documents disclosed both a nutritional composition and its use according to Claim 1.
- For the comparison of the claimed subject-matter with the disclosure of those documents, the unclear terms "prevention of PEM" and "elderly patients" were to be given the broadest interpretation.
- Contrary to the allegation of the Respondent the cited documents disclosed nutritional compositions which were implicitly disclosed to be suitable for the prevention or treatment of PEM. Such an implicit disclosure was supported by D113-D117, according to which PEM was a secondary condition related to a primary disease, such as cancer and gastrointestinal problems.
- Thus according to D11, a person afflicted with cancer would implicitly suffer or be at risk of suffering from PEM. It was important in this context that D11 did not concern the treatment of cancer but the treatment of patients suffering from cancer. The conditions of such patients included PEM or pre-PEM conditions. The limitation of the group of patients to elderly people according to the patent in suit was not a genuine selection since statistically the majority of people suffering from cancer were elderly people.
- According to D15 patients treated for cancer suffered also from inadequate protein supply.
- As regards D21 it explicitly disclosed elderly patients who were unable to chew and swallow food and risked PEM. The way of feeding the liquid

nutritional product to those patients did not distinguish the claimed subject-matter from the disclosure of D21 because also the patent (see paragraph [14]) disclosed a nutritional diet for tube use.

- Finally D24 disclosed patients suffering from depletion of lean body mass whose specific metabolic needs were met by a liquid nutritional product. D24 made specific reference to extremely malnourished patients and even explicitly mentioned protein-energy malnutrition.
- In view of the cited state of the art the skilled person would be aware that there was an overlap between on the one hand patients suffering from cancer (D11 and D15), unable to chew and swallow (D21) or suffering from slow wound healing (D24) and on the other hand those who suffered or risked suffering from PEM.
- In all those documents a deficit in proteins was disclosed, which was obviously related to PEM. All the more, these documents disclosed the treatment with a nutritional composition comprising a high level of proteins which in view of the comparable amount of protein in the claimed subject-matter would be understood to mean treatment of PEM.
- Beside the claimed use the claimed nutritional composition was also disclosed in D11, D15, D21 and D24.
- Contrary to the argument of the Respondent, D11 disclosed the claimed ratio of soluble/insoluble fibres (bottom of page 3; Table 6; claim 7).
- This ratio was not explicitly disclosed in D24. It could, however, be derived from the use of soy polysaccharide as source of dietary fibre because

soy polysaccharide was always a mixture of soluble and insoluble dietary fibres; that the claimed ratio was indeed met could be inferred from the information in D118 which enabled the determination of this ratio.

Auxiliary Request

- That request should not be admitted because it was filed at a very late stage and was not obviously novel and inventive.
- The subject-matter of Claim 1 (corresponding to granted Claim 5) lacked novelty over the disclosure of D11. Table 6 disclosed less than 18% of the total calories of the composition originating from caseinate; however, D11 taken as a whole, encompassed the possibility of an at least 18% contribution of caseinate. In particular Tables 1 and 2 disclosed that the total protein contribution was about 19% [page 9, lines 9-11 together with claim 6 disclosed values of more than 18%].
- The preciseness of the caloric contribution measurement in D11 could not be criticized because also according to the sole example of the opposed patent (table of page 6) the calculated caloric protein contribution was 17,9% ie below the claimed minimum value of 18%; the latter value was therefore not to be understood as a numerically exact limit.
- Nor could a distinction be made over D11 on the basis of its use as protein source of a combination of soy protein isolate and sodium caseinate because - due to the term "comprising" in present Claim 1 - the presence of eg soy protein isolate in addition to caseinate was not excluded.

- Additionally the subject-matter of Claim 1 lacked an inventive step in view of the disclosure of D11 considered alone or in combination with the general technical knowledge of the person skilled in the art.
- The technical difference of the claimed subject-matter from the disclosure of D11 was the amount of caseinate in the nutritional composition which provided at least 18% of the total calories of the composition. Even on the assumption that D11's disclosure failed to disclose exactly an amount of caseinate meeting this requirement, this feature could not contribute an inventive step because it set an arbitrary limit that was uncritical in the absence of any evidence exhibiting a surprising effect or property of the nutritional composition related to the increase of the caseinate in the protein composition.

XI. The Respondent (Patent Proprietor) essentially argued as follows:

Main Request

- The new documents submitted by the Appellants, namely D113 to D118 and D41 to D44, should not be admitted into the proceedings as they were late filed and not sufficiently relevant to prejudice the maintenance of the opposed patent.
- Contrary to the objections raised by the Appellants, the claimed invention was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, the claimed subject-matter was novel and involved an inventive step.

- In the context of the present invention the meaning of the term "medicament" as used in Claim 1 was the same as "nutritional composition"; this term could not therefore be construed to give rise to any lack of sufficiency.
- As regards PEM there was no universally agreed definition because PEM might arise as a complication of various different diseases. However, there was no doubt that this was an accepted and recognised medical condition (see Exhibits A and B). PEM was a body condition indicating too low an availability of proteins. Exhibits A and B confirmed that PEM was defined by certain pathological conditions and thus corresponded to a pathological status. In the medical profession PEM was understood to relate to protein deficient persons, whose health was already affected or particularly at risk if, being elderly, they fell ill (see D41).
- Even if in the state of the art PEM was especially related to infants and children, it was obvious that it could also relate to elderly people.
- As regards the method used for establishing the ratio of soluble/insoluble fibres it was admitted that this was not provided in the opposed patent. Nonetheless, it was obvious that the skilled person would apply the method according to AOAC, which was the established method for that type of measurement.
- Concerning the novelty of the subject-matter of Claim 1, none of D11, D15, D21 and D24 disclosed the claimed use. In none of these documents were the primary diseases linked to PEM. Though PEM could be associated with cancer, the fact that it concerned a different condition established a distinction. Furthermore, the Appellants were wrong to assert

that the great majority of cancer patients were elderly people.

- Concerning the claimed nutritional composition, it was admitted that D21 disclosed such a composition having all the features disclosed in Claim 1. The same conclusion could not be drawn with regard to D11 because this document failed to identify the claimed ratio of soluble/insoluble fibres.

Auxiliary Request

- The Auxiliary Request should be admitted, since it corresponded to claims which formed part of the Main Request and could not surprise the Appellants. Furthermore the Appellants had already raised objections against the patentability of this subject-matter.
- The nutritional composition of Claim 1 (corresponding to granted claim 5) was novel over the disclosure of D11 for the reasons set out above, namely because this document failed to disclose (i) a caloric contribution of at least 18% of caseinate and (ii) the claimed ratio of soluble/insoluble fibres.
- The subject-matter of Claim 1 was also not obvious in view of the disclosure of D11, contrary to the allegations of the Appellants.
- The technical problem to be solved was to provide a nutritional composition for elderly patients. The solution could not be found in the state of the art. D11 itself disclosed a maximum of 15% of total calories from caseinate.
- Moreover, D11 taught away from the claimed invention as it focused on the fat profile of the composition and did not specifically concern the elderly. In

addition to that it disclosed that the soy protein isolate was an important constituent of the nutritional composition which could not be neglected as the protein source and could not be fully replaced by protein from caseinate.

- The Appellants' arguments were based on an arbitrary mosaicing of features found in D11 and the other cited state of the art. Such a combination was based on hindsight.

Reasons for the Decision

1. The appeals are admissible.
2. Admittance of new documents

During the appeal proceedings the Appellants filed *inter alia* documents D113-D118 and D41-D43 and the Respondent documents D32, D33, Exhibit A and Exhibit B.

The Appellants filed these documents in view of the decision of the Opposition Division with regard to the issue of sufficiency of disclosure and in order to provide evidence in the context of the definition of PEM and its link with a primary disease. The Respondent filed the corresponding documents in order to address some arguments of the Appellants.

Under these circumstances and taking into consideration the relevance of these documents for the raised issues the Board decided to introduce them into the proceedings.

The Main Request

3. Sufficiency of disclosure - Article 83 EPC 1973
 - 3.1 The Appellants raised objections against the sufficiency of the disclosure of the claimed invention on the basis of the absence of a definition in the opposed patent of the terms "medicament" and "protein-energy malnutrition (PEM)" as well as of the method used for determining the ratio soluble to insoluble fibres. The Board, in disagreement with the Appellants, considers that these objections are in reality directed to aspects of clarity which is not a ground for opposition under Article 100 EPC 1973. While lack of clarity cannot therefore be attacked under these grounds, it may have repercussions when it comes to determine the breadth of an unclear term. In such a situation the broadest possible interpretation must prevail.
 - 3.2 In agreement with the Respondent/Proprietor the Board considers that in the present context the term "medicament" can be broadly interpreted to relate to the nutritional composition (see observations of the Proprietor filed with the letter dated 20 December 2005 confirming the opinion expressed by the Opposition Division in the appealed decision (paragraph 2 of the Reasons)).

Furthermore, the Board considers that protein-energy malnutrition (PEM) is a common term in the art which however does not provide a universal and exact meaning when occurring in elderly people, let alone one that provides a symptomatically clear definition (D28:

page 1, definition and description; D31: page 1; D114: page 405, left hand column, lines 1-4; D115: abstract; D116: page 683, paragraphs 1 to 3; D117: abstract, left hand column, lines 12-19; D41: abstract; D32: page 1, line 1; D33: abstract; Exhibit A: page 161, bridging paragraph of left and right hand columns; page 166, right hand column, last paragraph to page 167, left hand column, first paragraph; Exhibit B: page 24, point 56).

Concerning the method for measuring the soluble to insoluble fibres ratio the Board, on the basis of the evidence provided, considers that several methods are known in the art which however deliver very different results (D118: page 817, right column, lines 15-12 from the bottom; page 818, Table 1). The consequence of the omission in the patent specification of a reference to a method to be used is at last that when assessing novelty and inventive step of the claimed subject-matter the corresponding feature will be given the broadest possible definition, namely that the claimed ratio could be obtained from any one of those methods.

In this context the Board considers that in the absence of convincing evidence, the contention of the Respondent, on whom rests the burden of proof, that the skilled person would as a matter of course apply the AOAC method cannot be accepted.

4. Novelty - Article 54 EPC 1973

4.1 Claim 1 of the Main Request is directed to the use of a nutritional composition in the manufacture of a

medicament for the treatment or prevention of protein-energy malnutrition in an elderly patient.

4.2 The Appellants contested the novelty of Claim 1 on the basis of the disclosure of D21, which according to their argument discloses on the one hand the claimed composition and on the other hand the claimed use.

4.3 With regard to the first part of this argument the Board concurs with the Appellants that D21 (Table XIV) discloses a nutritional composition which cannot be distinguished from the one claimed. Moreover, as already explained above, this nutritional composition can be considered to be a medicament, in accordance with the submission of the Respondent (see observations filed with letter dated 20 December 2005, page 2, first paragraph).

4.3.1 In concrete terms Table XIV of D21 discloses a nutritional product - it is disclosed to be according to the best mode (page 34, lines 12-15) - which comprises:

- a protein source based on calcium caseinate and sodium caseinate
- a carbohydrate source based on hydrolyzed corn starch
- a source of dietary fibre based on gum arabic, oat hull fibre and sodium carboxymethyl cellulose, and
- a lipid source based on canola oil, high oleic safflower oil, medium chain triglycerides and oil soluble vitamin lecithin, thus including a mixture of medium and long chain triglycerides.

4.3.2 Gum arabic and sodium carboxymethyl cellulose are soluble fibres whereas oat hull fibres are insoluble (page 6, lines 13-17). Therefore the soluble fibre to insoluble fibre ratio calculated on the basis of the amount of these fibres given in Table XIV is 1:3,6. This ratio anticipates the claimed range of 1:4 to 4:1.

4.3.3 The protein source provides at least 18% of the total calories of the composition. This value can be calculated taking as a basis the disclosure of D25 (page 503, left column, lines 1-3), which provides the approximate coefficients necessary for the transformation of the amount of proteins, carbohydrates and lipids into their respective calorie contribution to the composition. These coefficients are: 4 kcal/g for 1 g of protein, 4 kcal/g for 1 g of carbohydrate and 9 kcal/g for 1 g of lipid. On the basis of these values the amount of calories from the protein source of table XIV of D21 provides approximately 17,7% of the total calories of the composition. Despite the fact that this value is slightly below the lower limit of 18% literally required by Claim 1, it nevertheless meets this feature when rounded up in the same manner as this must be done for the sole example of the opposed patent (table of page 6), which discloses a protein source contribution to the total calories of the composition of 17,9%. This was not contested by the Respondent.

4.4 With regard to the second part of this argument the Board in agreement with the Appellants considers that D21, beside the nutritional composition, discloses also the specified use of that composition.

- 4.4.1 The Board firstly notes that D21 (page 1, lines 1-6) discloses nutritional compositions as a nutritional complete liquid food for total enteral support of elderly patients who are unable to chew food. D21 thus discloses in an unambiguous manner a group of persons who will use the disclosed nutritional composition and who are in no way different from the group of elderly patients addressed by the claimed invention.
- 4.4.2 Furthermore in the Board's judgment the provision of such a nutritionally complete food for total enteral support of elderly patients necessarily implies the aim of preventing malnutrition - thus avoiding the treatment of malnutrition as a consequence of a primary disease. This would be the normal understanding of a person skilled in the technical field of nutritional products in view of the terminology used in D21 and is supported by the general technical knowledge of the person skilled in the art (see D113: page 392, right hand column, lines 34-42; D114: summary, lines 7-8; D117: page 23, right hand column, lines 7-11; page 39, right hand column, lines 25-31; D42: abstract; D43: abstract).
- 4.4.3 In arriving at this conclusion the Board accepts the Appellants' argument that the skilled person in view of his general technical knowledge would be aware that there is a specific danger of protein-energy malnutrition in the case of malnourished elderly patients particularly those suffering from cancer (D41: abstract; D113: page 392, under "Protein Energy Malnutrition in the Elderly"; D114: page 405, top of left hand column to right hand column line 3; D115:

first two paragraphs; D116: page, 683; D117: page 16, under "Prevalence").

- 4.5 Under these circumstances the Board finds that the subject-matter of Claim 1 lacks novelty over D21 and consequently that the Main Request is not allowable.

The Auxiliary Request

5. Admittance

The Board concurs with the reasoning of the Respondent that this request should be held admissible because the subject-matter claimed in this request was part of the Main Request, against the patentability of which the Appellants had already raised objections. On this basis the Board considers the Auxiliary Request admissible.

6. Novelty

- 6.1 The subject-matter of Claim 1 of the Auxiliary request concerns a nutritional composition (suitable) for providing nutrition to an elderly patient.

- 6.2 The Appellants objected to the novelty of the subject-matter of Claim 1 based on the disclosure in Table 6 (page 13) of D11.

- 6.3 The Board, however, in agreement with the Respondent, does not find in that part of D11 the disclosure of a nutritional composition comprising caseinate in an amount to provide at least 18% of the total calories of the composition. As all parties agreed upon, Table 6

- discloses caseinate in an amount such as to provide 15% of the total calories of the composition.
- 6.4 Under these circumstances the Board cannot concur with the Appellants when they argued that this specific caseinate value could be extrapolated to values of at least 18% in view of Tables 1 and 2 of D11, which disclose, in general terms, a protein content in excess of 18%. Neither the information in these tables nor in any other part of D11 lends itself to such an extrapolation, which is purely speculative.
- 6.5 On the other hand, contrary to the argument of the Respondent, the Board does not accept that the claimed composition is further distinguished from that of D11 by the soluble fibre to insoluble fibre ratio of 1:4 to 4:1. According to the disclosure of D11 (Table 6, page 13) the nutritional composition comprises dietary fibres of soy polysaccharide, gum arabic, carboxymethyl cellulose and oat fibres. Classifying these fibres according to their solubility, the skilled person is aware that gum arabic is soluble (D13: page 276, left hand column, lines 8-10; D21: abstract), carboxymethyl cellulose can be either soluble or insoluble depending on the degree of substitution (D13: page 296, right hand column, lines 15-18), oat fibres are in their majority insoluble (D14: page 559, table VI; D21: abstract), and soy polysaccharide contains a majority of insoluble fibres (D12: page 450, left hand column, lines 6-10). Considering the amounts of each of these types of fibre disclosed in D11, while taking into account that the carboxymethyl cellulose content is relatively small and would not essentially influence the soluble/insoluble fibres ratio, a fairly plausible

value of approximately 1:1 for this ratio can be calculated, which falls within the claimed range (see also the calculation provided by Opponent 1/Appellant 1 in its Notice of opposition (page 8, Table)).

6.6 The Board thus concludes that the subject-matter of Claim 1 of the Auxiliary Request is novel over D11 because of the lower caloric contribution of caseinate disclosed therein.

7. Inventive step

7.1 The closest state of the art

In agreement with the Appellants the Board is satisfied that D11, which discloses an enteral nutritional composition comprising all the constituents of the claimed composition, can be considered to represent the most promising starting point for assessing the inventive step of the claimed invention. This conclusion takes into account the health problems from which may be suffering the addressees of the nutritional product of D11, namely cancer patients (cf page 1, penultimate paragraph). These health problems cannot with any certainty be distinguished with regard to some of their symptoms from PEM-derived symptoms in a human being, including the elderly. At the very least these cancer patients are at risk of developing PEM-derived symptoms, which in any event are not unique to this deficiency. Therefore the composition of D11 satisfies the terms of present Claim 1 as being capable of preventing PEM.

7.2 The technical problem

7.2.1 The Respondent argued at the oral proceedings held before the Board that the technical problem solved by the claimed invention was the provision of a nutritional composition suitable for the elderly. The Board concurs with this problem-definition insofar as the purpose-related passage "for the elderly" does not impose any particular restriction because, as correctly argued by the Appellants, there is no technical evidence in the opposed patent illustrating the particular suitability of the claimed composition for elderly people/patients. Account being taken of the fact that the claimed composition may be designed to be nutritionally complete (paragraph [0013]) it goes without saying that also the protein content is such as to meet the needs of the people to whom the composition is administered.

7.3 The issue of obviousness

The Board, in agreement with the Appellants, considers that the claimed solution of this problem would be obvious to the skilled person in view of the disclosure of D11 alone or in combination with general common knowledge because the variation of the caloric contribution of caseinate would be within the frame of his normal technical activities. In the absence of any technical evidence relating to an unexpected effect caused by the claimed minimum amount of caseinate the skilled person would not require any inventive skill to vary the ratio of soy protein isolate and sodium caseinate (see D11: page 9, lines 1-2) at will,

including an enhancement of the latter up to and above the value of 18%.

As to the Respondent's argument that D11 is not specifically concerned with elderly people, it has already be explained above that the disclosure of the patent in suit as well as the cited prior art is devoid of any special definition of PEM when occurring in elderly people distinguishing it from PEM as a consequence of *eg* cancer. This feature is therefore of no relevance for the assessment of inventive step.

As to the further arguments that D11 emphasizes the importance of a certain fatty acid profile and does not point at any benefit to be gained from the choice of the origin of the protein (soy protein isolate or sodium caseinate) this is without substance. On the one hand the claimed invention might as well involve an adjustment of the fatty acid profile to the needs in a nutritionally complete product. On the other hand concerning the preference of caseinate as protein source according to Claim 1 of the auxiliary request, it can only be repeated that no evidence is on file for any benefit to be gained from that choice.

- 7.4 Under these circumstances the Board considers that the subject-matter of Claim 1 of the Auxiliary Request lacks an inventive step, with the consequence that this request is not allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The European Patent is revoked.

The Registrar

The Chairman

G. Röhn

P. Kitzmantel