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Datasheet for the decision of 14 October 2009

Case Number: T 2022/07 - 3.3.09

Application Number: 98935394.1

Publication Number: 1001685

IPC: A23L 1/305

Language of the proceedings: EN

Title of invention:
Nutritional compositions containing methionine

Patentee:
N.V. Nutricia

Opponent:
Fresenius Kabi Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56, 84, 123(2)
RPBA Art. 13(1)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Added subject-matter - yes (main request and auxiliary requests 1, 2, 3, 7 and 8)"
"Novelty - no (auxiliary request 2A)"
"Clarity - no (auxiliary request 5)"
"Inventive step -no (auxiliary request 8A)"
"Auxiliary requests 4 and 6 - not admitted"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 2022/07 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 14 October 2009

Appellant I: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 5 November 2007 concerning maintenance of European patent No. 1001685 in amended form.**

Composition of the Board:

Chairman: P. Kitzmantel
Members: J. Jardón Álvarez
M-B. Tardo-Dino

Summary of Facts and Submissions

I. This decision concerns the appeals filed by the Opponent and the Patent Proprietor against the interlocutory decision of the Opposition Division which found that the European patent No. 1 001 685 in amended form satisfied the requirements of the EPC.

II. The patent was based on the European patent application No. 98935394.1 in the name of N.V. Nutricia, which had been filed on 14 July 1998, as International application PCT/NL98/00408 (WO - 99/03365). The grant was announced on 20 April 2005 (Bulletin 2005/16) on the basis of 12 claims. Independent Claims 1, 3, 11 and 12 read as follows:

"1. Food composition which is a complete enteral food for clinical or dietary use, containing per daily dosage:
(a) an energy content of 5024-10467 kJ (1200-2500 kcal), supplied by carbohydrates, fats and proteinaceous material, the carbohydrates accounting for at least 25% of the energy content and the proteinaceous material being present in an amount of at least 20 g, at least 50% of the proteinaceous material being present as proteins or peptides, and
(b) the following components or their nutritional equivalents: 1.5-7 g of methionine and cysteine taken together comprising at least 0.5 g of cysteine, 0.4-8 mg of folic acid, 3.2-20 mg of pyridoxal (vitamin B_6) and 24-120 mg of zinc.

3. Food composition which is an enteral food supplement for clinical or dietary use to be used in addition to a non-medicinal food, containing per daily dosage:
(a) an energy content from 1675 up to less than 6280 kJ (from 400 to less than 1500 kcal), supplied by at least carbohydrates and proteinaceous material, soluble digestible carbohydrates being present in an amount of at least 100 g and the proteinaceous material being present in an amount of at least 20 g, at least 50% of the proteinaceous material being present as proteins or peptides, and
(b) the following components or their nutritional equivalents: 0.6-7 g of methionine and cysteine taken together, 0.4-8 mg of folic acid, 3.2-20 mg of pyridoxal (vitamin B_6), 24-120 mg of zinc, and 0.3-6 g of betaine.

11. Process of producing a food composition according to any one of claims 1-10, which comprises preparing a premix of at least said methionine/cysteine, folic acid, pyridoxal and zinc, optionally with carbohydrates as a carrier.

12. Use of a composition according to any one of claims 1-10 for preparing a medicinal composition for the treatment or prophylaxis of increased plasma level of homocysteine, cardiovascular diseases, imparted immune function, inflammatory diseases, autoimmune diseases, arthritis, wound healing after surgery, decubitus, cancer, premature ageing, allergic conditions or neural disorders."

III. A Notice of Opposition was filed against the patent by Fresenius Kabi Deutschland GmbH on 16 January 2006. The

Opponent requested the revocation of the patent in its entirety based on Article 100(a) EPC (lack of novelty and inventive step) and on the grounds of Article 100(c) EPC (subject-matter extending beyond the content of the application as originally filed).

During the opposition proceedings *inter alia* the following documents were cited:

D1: Product brochure PROMOTE, Abbott Nutrition (h-09-94),

D2: Product brochure ENSURE, Abbott AG (010/01/94),

D1/2a: Statutory Declaration ("Eidesstattliche Versicherung") of Dr. Bernhard Ott dated 6 July 2007, and

D6: EP - A - 0 532 369

IV. By its interlocutory decision announced orally on 13 September 2007 and issued in writing on 5 November 2007 the Opposition Division found that the patent as amended in accordance with the claims of auxiliary request 4 filed by the Patent Proprietor during the oral proceedings met the requirements of the EPC.

Claim 1 as maintained by the Opposition Division read as follows:

"1. Food composition which is a complete enteral food for clinical or dietary use, containing per daily dosage:

(a) an energy content of 5024-10467 kJ (1200-2500 kcal), supplied by carbohydrates, fats and proteinaceous material,
the carbohydrates accounting for at least 25% of the energy content i.e. at least 400 kcal (1675 kJ),
at least 30% of the energy content being in the form of lipids;
proteins, protein hydrolysates and amino acids being present in an amount of at least 70 g, at least 50% thereof being in the form of proteins, and
(b) the following components or their nutritional equivalents: 1.5-7 g of methionine and cysteine taken together comprising at least 1 g of methionine and at least 0.5 g of cysteine, 0.4-8 mg of folic acid, 3.2-20 mg of pyridoxal (vitamin B_6) and 24-120 mg of zinc;
further containing at least 0.8 g of phospholipids."

Claim 2 was deleted and the remaining claims renumbered.

The Opposition Division held in its decision that the subject-matter of the claims of the main, first and second auxiliary requests extended beyond the content of the application as originally filed, in particular because in its opinion the feature "1.5-7 g of methionine and cysteine taken together comprising at least 0.5 g cysteine" and the feature "the carbohydrates accounting for at least 25% of the energy content" were not supported. The Opposition Division rejected the third auxiliary request because the subject-matter of Claim 1 lacked novelty having regard to the disclosure of D2. This document, as well as document D1, were considered to be prior art according to Article 54(2) EPC.

Finally, the Opposition Division acknowledged novelty and inventive step of the claims according to the fourth auxiliary request. In its opinion the subject-matter of Claim 1 of this request differed from the disclosure of D2 in that the composition further included "at least 0.8 g of phospholipids". Concerning inventive step, the Opposition Division, starting from D6 as closest prior art document, saw the problem to be solved by the patent as being to provide a complete, balanced enteral food composition or food supplement having an improved supporting effect on total methionine metabolism and the transsulfuration pathway, in order to prevent or treat diseases associated with insufficiencies in total methionine metabolism. The Opposition Division acknowledged an inventive step of the solution to this problem according to Claims 1 and 2 because the skilled person would not have had any incentive to combine the teachings of D6 and D2, the latter not referring to a stimulation of the methionine metabolism. The Opposition Division arrived at the same conclusion when starting from D2 as closest prior art.

V. On 12 December 2007 the Opponent (Appellant I) lodged an appeal against the decision of the Opposition Division and paid the appeal fee on the same day.

In the Statement of Grounds of Appeal filed on 5 March 2008, Appellant I requested the revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC) and added subject-matter (Article 100(c) EPC).

Appellant I also filed the following documents:

D11: RÖMPP Chemielexikon. Bd. 1, 9. Auflage (1989), page 719, and

D12: RÖMPP Chemielexikon. Bd. 3, 9. Auflage (1990), pages 2474-2475

VI. On 28 December 2007 the Patent Proprietor (Appellant II) also lodged an appeal against the decision of the Opposition Division and paid the appeal fee on the same day.

In the Statement of Grounds of Appeal filed on 13 March 2008, Appellant II requested that the decision under appeal be set aside and that the patent be maintained with the set of claims according to an amended main request, or with the sets of claims as specified in auxiliary requests 1 - 3 all filed together with the Statement of Grounds of Appeal.

VII. With letter dated 6 October 2008, Appellant II filed further submissions in response to the Grounds of Appeal of Appellant I.

VIII. In response to the Board's communication, issued on 19 May 2009 in preparation for the oral proceedings, Appellant II filed, with letter dated 14 September 2009, two additional auxiliary requests and renumbered its previous requests.

IX. On 25 September 2009 Appellant I filed a new document, D13 and requested that it be admitted into the proceedings.

D13: J. Am. Diet Assoc. 1995; 95(1), pages 46-52 (Abstract).

X. In response Appellant II filed with letter dated 6 October 2009 two further auxiliary requests numbered auxiliary requests 4 and 6.

XI. During the oral proceedings held on 14 October 2009, Appellant II filed two further auxiliary requests, namely auxiliary requests 2A and 8A, based on previous auxiliary requests 2 and 8 and amended by deletion of, respectively, Claims 2 and 3 of the respective previous requests.

Claim 1 of the main request reads as follows:

"1. Food composition which is a complete enteral food for clinical or dietary use, containing per daily dosage:
(a) an energy content of 5024-10467 kJ (1200-2500 kcal), supplied by carbohydrates, fats and proteinaceous material,
the carbohydrates accounting for at least 25% of the energy content i.e. at least 400 kcal (1675 kJ), and the proteinaceous material being present in an amount of at least 20 g, at least 50% of the proteinaceous material being present as proteins or peptides, and
(b) the following components or their nutritional equivalents: 1.5-7 g of methionine and cysteine taken together comprising at least 1 g of methionine and at least 0.5 g of cysteine, 0.4-8 mg of folic acid, 3.2-20 mg of pyridoxal (vitamin B_6) and 24-120 mg of zinc".

Claim 1 of the auxiliary request 1 is based on Claim 1 of the main request wherein the paragraph "the proteinaceous material ... peptides, and" has been replaced by:

"proteins, protein hydrolysates and amino acids being present in an amount of at least 70 g, at least 50% thereof being in the form of proteins, and"

Claims 1 and 2 of auxiliary request 2 read as follows:

"1. Food composition which is a complete enteral food for clinical or dietary use, containing per daily dosage:
(a) an energy content of 5024-10467 kJ (1200-2500 kcal), supplied by carbohydrates, fats and proteinaceous material,
the carbohydrates accounting for at least 25% of the energy content i.e. at least 400 kcal (1675 kJ),
at least 30% of the energy content being in the form of lipids; and
proteins, protein hydrolysates and amino acids being present in an amount of at least 70 g, at least 50% thereof being in the form of proteins, and
(b) the following components or their nutritional equivalents: 1.5-7 g of methionine and cysteine taken together comprising at least 1 g of methionine and at least 0.5 g of cysteine, 0.4-8 mg of folic acid, 3.2-20 mg of pyridoxal (vitamin B_6) and 24-120 mg of zinc.

2. Food composition which is an enteral food supplement for clinical or dietary use to be used in addition to a non-medicinal food, containing per daily dosage:

(a) an energy content from 1675 up to less than 6280 kJ (from 400 to less than 1500 kcal), supplied by at least carbohydrates and proteinaceous material, soluble digestible carbohydrates being present in an amount of at least 100 g and the proteinaceous material being present in an amount of at least 20 g, at least 50% of the proteinaceous material being present as proteins or peptides, and
(b) the following components or their nutritional equivalents: 0.6-7 g of methionine and cysteine taken together, 0.4-8 mg of folic acid, 3.2-20 mg of pyridoxal (vitamin B_6), 24-120 mg of zinc, and 0.3-6 g of betaine."

Claim 1 of auxiliary request 2A is identical to Claim 1 of auxiliary request 2.

Claims 2 of auxiliary requests 3, 4 and 8 and Claim 3 of auxiliary request 7 are identical to Claim 2 of auxiliary request 2.

Claim 1 of auxiliary request 5 is based on Claim 1 of auxiliary request 2 wherein the term "proteinaceous material" in the first statement of feature (a) has been replaced by "milk proteins".

Claim 1 of the auxiliary request 6 is based on Claim 1 of auxiliary request 2 but specifies the proteins in the last statement of feature (a) by the phrase "the proteins comprising casein and whey proteins".

Finally, Claim 1 of auxiliary request 8A is Claim 1 of the request allowed by the Opposition Division (see point IV above).

XII. The arguments presented by Appellant I in its written submissions and at the oral proceedings may be summarized as follows:

– Appellant I objected to the admittance of auxiliary requests 4 and 6 filed with letter dated 6 October 2009 and of auxiliary requests 2A and 8A filed during the oral proceedings. The reason for the objection to the admittance of auxiliary requests 4 and 6 was mainly the introduction of technical features from the description and the short time left to Appellant I to study these requests. The reason for the objection to auxiliary requests 2A and 8A was that there was already another request on file wherein the claims directed to the food supplement had been deleted and consequently there was no necessity for further requests comprising the same amendment.

– Appellant I objected that Claim 1 of the main and first auxiliary requests did not fulfil the requirements of Article 123(2) EPC because the feature "1.5-7 g of methionine and cysteine taken together comprising at least 1 g of methionine and at least 0.5 g of cysteine" was disclosed in the application as originally filed only in combination with a given amount of lipids (cf. "at least 30 energy% of which is in the form of lipids"). By not including this feature into amended Claim 1 of the main and the first auxiliary requests the subject-matter now claimed extended beyond the content of the application as originally filed.

– Appellant I also raised a similar objection against Claim 2 of the second auxiliary request, the reason being that the suppression of the feature (that the composition comprises) "at least 400 kcal of carbohydrates" in the amended claim resulted in compositions now being covered that were not covered by the application as filed.

– Claim 1 of auxiliary request 2A lacked novelty having regard to the disclosure of D2 which disclosed a composition with the same ingredients. The term "per daily dosage" was in the opinion of Appellant I not a technical feature limiting the subject-matter of a composition claim. In any case the amount of the composition of D2 which was necessary as a daily dosage in order to meet the compositional requirements of this claim, namely 2.5 litres, was a realistic amount that could be taken by a person.

– Appellant I objected to amended Claim 1 of auxiliary request 5 as lacking clarity because in line 4 it was said that the energy content was supplied by carbohydrates, fats and milk proteins while later in the claim reference was made to "protein, protein hydrolysates and amino acids", the presence of these protein hydrolysates and amino acids (not being comprised in the term "protein") resulting in a composition having a higher energy content than the one claimed.

– Concerning auxiliary request 6, Appellant I argued that the inclusion of the expression "comprising

casein and whey proteins" infringed Article 123(2) EPC.

– Appellant I acknowledged the novelty of Claim 1 of auxiliary request 8A but maintained that it lacked inventive step. Starting from the disclosure of D2 as the closest prior art it saw the problem to be solved by the patent as being to find an alternative enteral food. The solution to this problem, namely the addition of at least 0.8 g of phospholipids was obvious for the skilled person, essentially because no unexpected effect was due to its presence and because phospholipids such as lecithin were commonly used as emulsifiers in food products.

XIII. The written and oral arguments of Appellant II may be summarized as follows:

– the amended claims overcame the objections under Article 123(2) EPC of the Opposition Division. The amendments were all supported by the application as originally filed. It pointed out that the (restricted) combination of features in Claims 1 and 7 was supported by the original application because there was no close functional or structural relationship between those features and other features disclosed together in particular embodiments; this was especially the case for the fat content, whose minimum amount of 30 energy% according to original Claim 7 directed to a complete food was functionally unrelated to the further features of this claim.

– Concerning novelty, Appellant II noted that it had not been established beyond reasonable doubt that D1 and D2 were publicly available before the priority date and that these documents should not be regarded as prior art. In any case neither D1 nor D2 was novelty destroying for the claimed subject-matter because neither of these documents disclosed a daily dosage as claimed.

– Concerning inventive step, Appellant II supported the conclusions of the Opposition Division that D6 represented the closest prior art and that it was not obvious to arrive at the claimed compositions in view of the available prior art. Further it pointed out that actually D2 taught away from the patient consuming the large amounts of this product which would provide the levels of the components of Claims 1 and 2, in particular methionine, cysteine, folic acid, vitamin B_6 and zinc.

XIV. Appellant I (Opponent) requested that the decision under appeal be set aside and that the European patent No. 1 001 685 be revoked in its entirety. It further objected to the admittance of auxiliary requests 4 and 6 filed with the letter of 6 October 2009, and of auxiliary requests 2A and 8A filed during the oral proceedings.

XV. Appellant II (Patent Proprietor) requested that the decision under appeal be set aside and that the patent be maintained in amended form with the set of claims according to the main request or the auxiliary requests 1, 2, 2A, 3 to 8 and 8A, the main request and

auxiliary requests 1, 2 and 7 being those filed with letter dated 13 March 2008 as the main request and auxiliary requests 1, 3 and 2 respectively, auxiliary requests 3 and 5 being those filed with letter dated 14 September 2009 as the "new 3rd" and "new 4th" auxiliary requests, auxiliary requests 4 and 6 being those filed with letter dated 6 October 2009, auxiliary request 8 being the request allowed by the Opposition Division, and auxiliary requests 2A and 8A being those filed during the oral proceedings.

Reasons for the Decision

1. The appeals are admissible.

2. *Procedural matters.*

2.1 Admissibility of auxiliary requests 4, 6, 2A and 8A.

2.1.1 Appellant II filed these auxiliary requests at a very late stage, namely auxiliary requests 4 and 6 shortly before the oral proceedings with letter dated 6 October 2009 and auxiliary requests 2A and 8A on 14 October 2009 during the oral proceedings.

2.1.2 Auxiliary requests filed at such a late stage of the proceedings are usually only admitted into the appeal proceedings under exceptional circumstances. It is established case law of the Boards of Appeal that late filed requests are normally not to be admitted if they are still objectionable and if there is no proper justification for their being late filed.

2.1.3 Auxiliary request 4 includes Claim 2 of auxiliary request 2, a claim which, as explained below under points 5.1 to 5.4, does not fulfil the requirements of Article 123(2) EPC.

2.1.4 The amendment made to Claim 1 of auxiliary request 6, namely that the protein comprises "casein and whey proteins" is not supported by the application as originally filed, which on page 6, first paragraph refers to the possibility of using methionine-rich proteins such as casein, caseinates and casein hydrolysates and cysteine-rich proteins including dairy whey proteins and specific proteins thereof such as lactalbumin, etc. The specific combination of casein with whey proteins is however not disclosed in the application as originally filed. This amendment thus generates fresh subject-matter which extends beyond the content of the application as filed, contrary to the requirements of Article 123(2) EPC.

2.1.5 For these reasons, auxiliary requests 4 and 6 are clearly not allowable and the Board exercised its discretion under Article 13(1) of the Rules of Procedure of the Boards of Appeal of the EPO not to admit these requests into the proceedings.

2.1.6 Auxiliary requests 2A and 8A are based on the pending auxiliary requests 2 and 8 respectively but with deletion of the claims directed to the food supplement (Claims 2 and 3).

2.1.7 The Board decided to admit these requests into the proceedings, in spite of their late submission, because by deleting the claims referred to the objection of

lack of support under Article 123(2) EPC (which only concerned the deleted claims) against auxiliary requests 2 and 8 (then 2A and 8A) became redundant, and because this amendment did not confront Appellant I with a new factual situation. The formalistic argument of Appellant I that requests not comprising a claim to a food supplement already existed (and that for this reason the amended requests should not be admitted) did not convince the Board, particularly where the remaining subject-matter had been extensively debated throughout the prosecution of the appeal.

2.2 Status of D1 and D2

2.2.1 The Opposition Division in its decision considered that documents D1 and D2 had been made available to the public before the priority date of the patent in suit.

2.2.2 Appellant II expressed doubts that this finding of the Opposition Division was correct. It pointed out in particular that it was not clear who distributed these documents during the exhibition "European Society for Parenteral and Enteral Nutrition (ESPEN)" and that it had not been proven to whom the documents were distributed or if they had been given personally to Dr. Ott under obligation of secrecy. Moreover the indication "h-09-94" on the last page of D1 and the indication of "010/01/94" on the last page of D2 were, on their faces, not indications of a date, and the mere number 94 did not necessarily indicate the year 1994.

2.2.3 The Board does not share the doubts of Appellant II concerning the public availability of D1 and D2.

2.2.4 Dr Ott made statements in his statutory declaration, about the precise circumstances in which he got the brochures D1 and D2, such statements being of a sufficiently detailed nature to give his declaration as a whole credibility. He maintained that the two brochures D1 and D2 on which are written the questionable indications about the date, were in fact handed out during the industry exhibition which took place at the same time as the Congress of the European Society for Parenteral and Enteral Nutrition (ESPEN), namely from 08.09.1996 to 11.09.1996, in Geneva. The Board has no reason to doubt the statutory declaration of Dr. Ott given that the Respondent has not provided any evidence casting doubt on the correctness of Dr. Ott's recollection of the situation. The Board considers that Dr.Ott's statement about the two brochures proves sufficiently that they had been made available to the public during the congress.

2.2.5 The Board is therefore satisfied that documents D1 and D2 were made available to the public before the priority date of the patent in suit and are to be considered as state of the art.

MAIN REQUEST

3. *Amendments (Article 123(2) EPC)*

3.1 Amended Claim 1 is essentially based on Claims 1 and 7 as originally filed. It further includes ranges for some of the components (folic acid, pyridoxal and zinc) taken from Table 1 of the application as filed. Concerning methionine and cysteine, it defines the amount of these components as being "1.5-7 g of

methionine and cysteine taken together comprising at least 1 g of methionine and at least 0.5 g of cysteine".

The minimum amounts of cysteine and methionine were disclosed in the application as originally filed in Claim 7 only in combination with other characteristics of the compositions, in particular with the features that:
- at least 30 energy% of the composition was in the form of lipids; and
- at least 70 g per daily dosage of proteins, protein hydrolysates and amino acids, at least 50% thereof were in the form of proteins.

The amendment results in an unsupported generalisation since Claim 1 now covers the above amounts of methionine and cysteine with any amount of fat (lipids) and with a different amount of proteinaceus material.

3.2 According to the Boards' jurisprudence, such an amendment resulting in isolating a specific feature from a particular embodiment and generalising it will only be allowable if the skilled person would have readily recognised this feature as not closely associated with the other features of the embodiment.

3.3 In the present case, however, the values for methionine and cysteine were originally disclosed only in the particular context of a composition having at least 30% energy content in the form of lipids. Taking into account that the application as originally filed indicates that the gist of the invention lies in the "combination of components [*emphasis added by the Board*] that play a key role in the various parts of the total

methionine metabolism" (page 4, lines 11 - 13) and that these components "methionine/cysteine" and the "energy content" were found essential as primary support of the transsulfuration pathway" (see page 6, lines 13 - 16) the skilled person would see these features as closely interrelated.

As a consequence of the non inclusion of the feature "at least 30 energy% of which is in the form of lipids" in amended Claim 1, the claim embraces food compositions with different amounts of fat providing the skilled person with technical information which is not directly and unambiguously derivable from the application as filed.

3.4 For these reasons, the main request must be rejected as not fulfilling the requirements of Article 123(2) EPC.

AUXILIARY REQUEST 1

4. *Amendments (Article 123(2) EPC)*

4.1 Amended Claim 1 of auxiliary request 1 also does not include the feature that "at least 30 energy% of the composition is in the form of lipids" in accordance with Claim 7 as originally filed. Hence, the conclusion reached in point 3.4 above also applies to Claim 1 of auxiliary request 1, which does not therefore satisfy the requirements of Article 123(2) EPC.

AUXILIARY REQUEST 2

5. *Amendments (Article 123(2) EPC)*

5.1 Amended Claim 2 of the second auxiliary request is directed to an enteral food supplement and results mainly in a combination of Claims 1 and 8 as originally filed. The claim further indicates the presence of betaine in accordance with Claim 4 as originally filed and includes the ranges of the components taken from Table 1.

5.2 Analogous to the situation discussed above with regard to Claim 1 of the main request, Appellant II, when combining Claims 1 and 8, has failed to incorporate into Claim 2 the feature of original Claim 1 "at least 400 kcal of carbohydrates".

The deletion of this feature results in food supplement compositions having possibly less than 400 kcal of carbohydrates. These compositions are not part of the original disclosure and the subject-matter of amended Claim 2 of auxiliary request 2 therefore extends beyond the content of the application as originally filed.

5.3 The above conclusion is not invalidated by the argument of Appellant II that, in view of the statement on page 8, lines 3 to 5 of the application as filed referring to a complete food having at least 400 kcal, the respective statement in original Claim 1 would only apply to a complete food and not to a food supplement. This assertion is not convincing because the statement is silent about the minimum energy content derived from carbohydrates in food supplements and cannot therefore

override the generic definition encompassing both the complete food and the food supplement in original Claim 1.

5.4 For these reasons Claim 2 of auxiliary request 2 does not fulfil the requirements of Article 123(2) EPC.

5.5 Auxiliary request 2 is therefore not allowable.

AUXILIARY REQUESTS 3, 7 and 8

6. Claim 2 of auxiliary requests 3 and 8 and Claim 3 of auxiliary request 7 are identical to Claim 2 of auxiliary request 2. The reasoning given above for auxiliary request 2 thus applies *mutatis mutandis* to auxiliary requests 3, 7 and 8, which are therefore also not allowable.

AUXILIARY REQUEST 2A

7. *Novelty (Article 54 EPC)*

7.1 Claim 1 is directed to a food composition which is a complete enteral food for clinical or dietary use, containing per daily dosage:
(a) an energy content of 1200 - 2500 kcal supplied by carbohydrates, fats and proteinaceous material, and
(b) certain components or their nutritional equivalents in certain amounts.

Concerning (a) the composition specifies that:
(a.1) at least 25% of the energy content is in the form of carbohydrates,

(a.2) at least 30% of the energy content are in the form of lipids, and
(a.3) it contains 70 g of proteinaceous material, at least 50% of which is in the form of proteins.

Concerning (b) the following components or their nutritional components are present:
(b.1) 1.5-7 g of methionine and cysteine together; wherein
(b.1.1) at least 1 g is methionine,
(b.1.2) at least 0.5 g is cysteine;
(b.2) 0.4-8 mg of folic acid;
(b.3) 3.2-20 mg of pyridoxal; and
(b.4) 24-120 mg of zinc.

7.2 The novelty of Claim 1 of auxiliary request 2A was contested by Appellant I having regard to the disclosure of D2.

7.3 Document D2 discloses a complete or supplemental liquid food composition for patients requiring a balanced, easily tolerated diet without fibre alimentation (see page 3, second paragraph and page 2, third paragraph). The energy content is supplied by carbohydrates, fats and proteins in amounts falling within the values of features (a.1) and (a.2) (cf. page 3, lines 15 - 18).

7.4 A detailed nutrient composition is given on page 4 on the basis of the amounts for 250 ml (which corresponds to 250 kcal) and for 1000 ml (1000 kcal).

In order to enable a comparison with the values given in the patent in suit which relate to an energy content of 1200-2500 Kcal, Appellant I calculated the amounts

given in D2 for a composition containing 2500 kcal. This calculation results in values for methionine, cysteine, folic acid, pyridoxal, zinc and proteins, that is to say for features (a.2) and (b.1) to (b.4) all falling within the ranges covered by Claim 1. As this calculation was not disputed by Appellant II, there is no need for the Board to give detailed reasons on this issue.

7.5 Appellant I then concluded that the disclosure of D2 anticipated the subject-matter of Claim 1 of auxiliary request 2A.

7.6 While Appellant II did not dispute during the oral proceedings the calculations *per se* made by Appellant I it was still argued that the claim was novel because D2 did not disclose a daily dosage. In that respect Appellant II argued that the amount of 250 ml contained in the cans disclosed in D2 comprised, for most if not all of the ingredients, amounts well below the claimed ranges. Furthermore the only compositional quantity disclosed in D2 for possible daily consumption contained 1400 kcal, thus comprising even lower amounts of the ingredients of present Claim 1. Moreover, since the product of D2 was a spicy soup, it could not be realistically assumed that a person could consume 2.5 l of this soup as their only daily nutrition.

7.7 In the Board's judgement, the subject-matter of Claim 1 of auxiliary request 2A indeed lacks novelty for the following reasons:

7.7.1 Claim 1 is directed to a composition as such, including the ingredients (a.1)-(a.3) and (b.1)-(b.4) recited

above. In a claim which is directed to a food composition the expression "which is a complete enteral food for clinical or dietary use" and the expression "per daily dosage" are to be construed as meaning that the composition is an enteral food suitable as complete food on a daily basis. That is to say, the patient does not need any additional nutrition and can take this composition as their only alimentation. Thus the term "per daily dosage" is a limiting feature of the claim only insofar as it indicates the suitability for daily consumption as sole alimentation. It is in this sense that the term "complete food" is also to be interpreted.

7.7.2 The question to be decided is therefore whether the food composition of D2, which on the basis of 2500 kcal (2.5 l) includes all the features of the composition of Claim 1 (as set out above), is suitable as a complete food. The Board is satisfied that this is indeed the case. D2 itself indicates on page 3, second paragraph that it is suitable as a patient's exclusive nutrition. The argument of Appellant I that this information was given only in the context of hot meals is not convincing, since - while primarily directed to such use - the compositions of D2 are also envisaged for tube feeding (see inscription on picture of the can). The Board also cannot share the concerns of Appellant II that a liquid amount of 2.5 l is unrealistically high, because 2.5 l fed over a whole day is not an excessive quantity. Moreover Claim 1 of the patent also includes compositions which would require at least 2.5 l of liquid (cf. Claim 6 of this request which refers to compositions having an energy density of between 1 and 2.5 kcal/ml).

7.8 For these reasons the subject-matter of Claim 1 according to auxiliary request 2A is anticipated by the disclosure of document D2.

7.9 Auxiliary request 2A is therefore not allowable.

AUXILIARY REQUEST 5

8. *Clarity (Article 84 EPC)*

8.1 In Claim 1 of this request the wording "proteinaceous material" has been replaced by "milk proteins". The energy content of such amended claim is now supplied by carbohydrates, fats and milk proteins (cf. Claim 1, (a)). However the claim further requires that "proteins, protein hydrolysates and amino acids [*emphasis added by the Board*] are present in an amount of at least 70 g, at least 50% thereof being in the form of proteins".

As a consequence of this amendment there is now a contradiction in paragraph (a) of the claim because it requires on one hand that the energy content is supplied (exclusively) by carbohydrates, fats and proteins and on the other that there are also present in the composition protein hydrolysates and amino acids which also contribute to the energy supply. The argument of Appellant II that protein hydrolysates and amino acids are comprised by the term "protein" is at variance with the normal understanding of these terms and there is nothing in the description justifying some other interpretation.

8.2 This contradiction in the claim results in Claim 1 of auxiliary request 5 not satisfying the requirements of Article 84 EPC.

8.3 Auxiliary request 5 is therefore not allowable.

AUXILIARY REQUEST 8A

9. Claim 1 of auxiliary request 8A differs from Claim 1 of auxiliary request 2A in that it specifies that the composition further contains "at least 0.8 g of phospholipids" in accordance with Claim 3 as originally filed.

As the novelty of this Claim has been acknowledged by Appellant II it needs only to be decided if the subject-matter of this claim involves an inventive step.

10. *Inventive step (Article 56 EPC).*

10.1 Closest prior art.

10.1.1 The Board considers, in agreement with Appellant II, that the closest prior art is represented by document D2.

10.1.2 As already discussed in detail above under point 7, D2 discloses compositions including all the features of the subject-matter of Claim 1 of auxiliary request 2A. The composition of D2 does not include the further feature of Claim 1 of auxiliary request 8A that the composition contains at least 0.8 g of phospholipids.

10.1.3 Thus, the subject-matter of Claim 1 of auxiliary request 8A differs from the disclosure of D2 by the presence of phospholipids.

10.2 Problem to be solved and its solution.

10.2.1 The patent in suit does not attribute any specific effect to this distinguishing feature. The patent mentions in paragraph [0033] that the fats should contain phospholipids such as lecithin or an equivalent thereof and that they can be partly substituted by equivalents such as choline or betaine, but it does not mention any advantage due to their use. Appellant II did not rely during the proceedings on any improved property of the claimed compositions when compared with food compositions without phospholipids.

10.2.2 Thus, in the absence of any unexpected effect over the disclosure of D2, the objective technical problem to be solved by the patent in suit is to provide alternative food compositions for the same use.

10.2.3 The solution to this problem is provided by the claimed compositions. Although the patent in suit does not include any example of an enteral food composition, the Board is satisfied that these compositions may be prepared and solve the above mentioned problem. This was not challenged by Appellant I.

10.2.4 The Board cannot accept the arguments of Appellant II that D2 does not represent the closest prior art document because it is silent about the methionine metabolism and that the problem to be solved by the patent in suit is to provide an enteral food supplement

with an improved supporting effect on total methionine metabolism.

According to EPO practice, the closest prior art is generally that which corresponds to a similar use and requires the minimum of structural and functional modifications to arrive at the claimed invention. These conditions are met by the disclosure of D2 which discloses very closely related compositions in the same field. The fact that there is no reference in D2 to the methionine metabolism does not disqualify D2 as closest prior art because this is a scientific explanation of why the compositions of D2 have the mentioned uses but not a distinguishing feature of the compositions. Moreover in the scheme of the methionine metabolism depicted on page 7 of the patent in suit no reference is made to phospholipids and there is no evidence on file that phospholipids have any effect on the total methionine metabolism.

10.3 Obviousness.

10.3.1 The question which remains to be decided is whether this solution involves an inventive step.

10.3.2 As pointed out by Appellant I, phospholipids such as lecithin are commonly used as food additives, mostly due to their emulsifying properties (see, for instance, D12). The addition of a component which is commonly used in food compositions to the composition of D2 is in the absence of any unexpected effect regarded as an arbitrary measure not involving an inventive step.

10.4 Consequently, the subject-matter of Claim 1 of auxiliary request 8A lacks inventive step.

10.5 Auxiliary request 8A is therefore likewise not allowable.

11. In summary, none of the requests of Appellant II admitted into the proceedings relates to patentable subject-matter because

- the subject-matter of Claim 1 of the main request and auxiliary request 1, the subject-matter of Claim 2 of auxiliary requests 2, 3, and 8 and the subject-matter of Claim 3 of auxiliary request 7 do not fulfil the requirements of Article 123(2) EPC (see points 3.4, 4.1, 5.4 and 6),
- the subject-matter of Claim 1 of auxiliary request 2A lacks novelty (see point 7.8),
- the subject-matter of Claim 1 of auxiliary request 5 lacks clarity (see point 8.1), and
- the subject-matter of auxiliary request 8A does not involve an inventive step (see point 10.4).

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar The Chairman

G. Röhn P. Kitzmantel