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Datasheet for the decision of 24 September 2024

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Language of the proceedings: EN

Title of invention:
Nutrient Composition

Patent Proprietor:
Ajinomoto Co., Inc.

Opponent:
Fresenius Kabi Deutschland GmbH

Headword:
Nutritional composition /AJINOMOTO

Relevant legal provisions:
EPC Art. 56, 123(2)
RPBA 2020 Art. 12(6)

Keyword:
Main request, auxiliary requests 1 and 3 - inventive step - obvious alternative
Auxiliary request 2 - late-filed request - should have been submitted in first-instance proceedings (yes)
Auxiliary request 4 - added subject-matter (no)
Auxiliary request 4 - inventive step - non-obvious alternative

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Case Number: T 0584/22 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 24 September 2024

Appellant: (Patent Proprietor)	AJINOMOTO CO., INC. 15-1, Kyobashi 1-chome Chuo-ku Tokyo 104-8315 (JP)
Representative:	Mewburn Ellis LLP Aurora Building Counterslip Bristol BS1 6BX (GB)
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Representative:	Fresenius Kabi Deutschland GmbH Patent Department Pharmaceuticals Division Borkenberg 14 61440 Oberursel (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 3 January 2022 concerning maintenance of the European Patent No. 2374452 in amended form**

Composition of the Board:

Chair	A. Chakravarty
Members:	S. Albrecht
	L. Bühler

Summary of Facts and Submissions

I. European Patent 2 374 452 ("patent") is based on European patent application 09830480.1 ("application").

II. The patent was opposed by a single opponent. The grounds for opposition relied on were Article 100(a) EPC for lack of novelty and lack of inventive step, and Article 100(b) and (c) EPC.

III. In the course of the opposition proceedings, the patent proprietor submitted sets of claims of auxiliary requests 1 to 15.

IV. The opposition division decided that the patent, as amended in the form of auxiliary request 3, and the invention to which it related met the requirements of the EPC. The decision was based on the patent as granted as the main request and on sets of claims of auxiliary requests 1 to 3. The sets of claims of auxiliary requests 1 and 2 were filed on 26 October 2020. The set of claims of auxiliary request 3 was filed as auxiliary request 4 on the same date.

The opposition division found, *inter alia*, that the subject-matter of claim 1 of each of auxiliary requests 1 and 2 lacked inventive step in the light of the disclosure in document D4 taken in combination with the disclosure in document D5 or D12. By contrast, the subject-matter of auxiliary request 3 would not have been obvious starting from document D4 as the closest prior art.

V. The patent proprietor "appellant-patent proprietor") and the opponent ("appellant-opponent") each lodged an appeal against the opposition division's decision.

VI. The following documents are mentioned in this decision:

D3: WO 2008/001086 A1

D4: EP 0 747 395 B1

D5: J.W. Anderson, "Beneficial effects of soy protein consumption for renal function", Asia Pac J Clin Nutr 17(S1), 2008, pages 324 to 328

D6: L. Azadbakht et al., "Beneficiary effect of dietary soy protein on lowering plasma levels of lipid and improving kidney function in type II diabetes with nephropathy", European Journal of Clinical Nutrition 57, 2003, pages 1292 to 1294

D7: L. Azadbakht et al., "Soy Protein Intake, Cardiorenal Indices, and C-Reactive Protein in Type 2 Diabetes With Nephropathy", Diabetes Care 31(4), April 2008, pages 648 to 654

D9: WO 02/069964 A1

D10: WO 2004/082402 A1

D12: S.R. Teixeira et al., "Isolated Soy Protein Consumption Reduces Urinary Albumin Excretion and Improves the Serum Lipid Profile in Men with Type 2 Diabetes Mellitus and Nephropathy", J. Nutr. 134, 2004, pages 1874 to 1880

D16: Excerpt from the "ROSS 2006 POCKET GUIDE", ROSS Nutrition (pages 2 to 7, 32, 33, 42 to 47, 52 to 57, 60, 61, 135 to 139)

D19: Dr. G. Pasin et al., "U.S. Whey Products and Sports Nutrition", 2000, pages 1 to 8

VII. In its statement of grounds of appeal, the appellant-patent proprietor's main request was that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the set of claims of auxiliary request 1 underlying the decision under appeal.

The appellant-patent proprietor also filed sets of claims of 15 auxiliary requests, where

(a) the sets of claims of auxiliary requests 1 and 3 were identical to the sets of claims of auxiliary requests 2 and 3, respectively, underlying the decision under appeal,

(b) the set of claims of auxiliary request 2 was filed for the first time with the appellant-patent proprietor's statement of grounds of appeal,

(c) the sets of claims of auxiliary requests 4, and 6 to 15 were filed as auxiliary requests 5 to 15, respectively, with the reply to the notice of opposition,

(d) the set of claims of auxiliary request 5 was filed as auxiliary request 3 on 22 November 2021.

VIII. In a communication under Article 15(1) RPBA issued on 30 July 2024 ("Board's communication"), the Board drew the parties' attention to the points to be discussed during the oral proceedings. The Board gave a preliminary opinion on claim interpretation with respect to claims 1, and 8 to 10 of the main request. With regard to inventive step, the Board identified the the embodiment disclosed,*inter alia*, in paragraphs [0028], [0031], [0032], [0034], and [0037] of document

D4 as starting point for the analysis of inventive step (see points 20.3 to 20.5 of this communication). The Board furthermore informed the parties that it was inclined not to admit auxiliary request 2 into the appeal proceedings.

IX. Oral proceedings were held on 24 September 2024 by videoconference in the presence of both parties. At the end of the oral proceedings, the Chair announced the Board's decision.

X. Claim 1 of the main request reads:

"1. A nutrition composition comprising a protein or peptide, and one or more kinds of free amino acids selected from the group consisting of valine, leucine, isoleucine and histidine, and:
(a) a lipid comprising ω-3 fatty acid and ω-6 fatty acid at a weight ratio (ω-6 fatty acid to ω-3 fatty acid) of 0.5 - 3; and
(b) a soybean protein or a hydrolysate thereof, wherein the content of the protein or peptide in a nitrogen source per 100 kcal of the composition is not more than 3.5 g, and the content of the soybean protein or a hydrolysate thereof in the protein or peptide is 20 wt% - 100 wt%."

Claim 1 of auxiliary request 1 is identical to claim 1 of the main request with the exception that the expression "...from the group consisting of" is replaced by the wording "...from the group consisting exclusively of".

Claim 1 of auxiliary request 2 differs from claim 1 of the main request by the addition of the following passage at the end of the claim:

", wherein the nutrition composition is free of free amino acids other than valine, leucine, isoleucine or histidine."

Claim 1 of auxiliary request 3 differs from claim 1 of the main request in that the following passage is added at the end of the claim:

"wherein the one or more kinds of free amino acids selected from the group consisting of valine, leucine, isoleucine and histidine is(are) contained in a proportion of 0.1 g - 10 g per 100 kcal of the composition."

Claim 1 of auxiliary request 4 differs from claim 1 of the main request in that the claimed nutrition composition additionally comprises "a lipid comprising 10 wt% - 65 wt% of medium chain fatty acid oil".

XI. The appellant-patent proprietor's written and oral submissions relevant for the present decision can be summarised as follows.

Main request and auxiliary request 1
Claim construction - claim 1

The use of closed, "consisting"-type language in claim 1 of the main request clearly indicated that the only free amino acids included in the claimed composition were (one or more of) valine, leucine, isoleucine and histidine. Consequently, from the wording of claim 1 alone, the skilled person understood

that the claimed composition should not include additional free amino acids. The skilled person would derive the same understanding from the patent's disclosure and the application as filed.

In claim 1 of auxiliary request 1, the replacement of the expression "...from the group consisting of" by the wording "...from the group consisting exclusively of" emphasised that no free amino acids other than (one or more of) valine, leucine, isoleucine and histidine could be present in the claimed nutrition composition.

Main request and auxiliary request 1
Inventive step - claim 1

The distinguishing features between the claimed subject-matter and the closest prior art, i.e. the specific nutrition composition disclosed in paragraphs [0048] to [0050] of document D4, were threefold, i.e.

- the type of protein in the composition (i.e. soybean protein or a hydrolysate thereof instead of whey protein),

- the type of lipid (i.e. a lipid comprising ω-3 and ω-6 fatty acids at the specified ratio of 0.5 to 3), and

- the inclusion of only (one or more of) the specified free amino acids.

On the basis of the experimental data in the patent's experimental examples, the objective technical problem was "to provide an alternative nutritional composition suitable for the long-term treatment of patients with renal disease, which in particular prevents/improves

malnutrition whilst also suppressing inflammation associated with those diseases".

The solution proposed in claim 1 would not have been obvious having regard to the cited prior art.

Given the well-known sensitivity and unpredictability associated with adjusting nutritional compositions for renal patients (see paragraphs [0001] to [0003], and [0010] of the patent, paragraphs [0002], [0003], [0005] and [0010] of document D4, page 1292, right-hand column, lines 3 to 5 of document D6, and the first sentence of document D7), replacement of a specific protein with another protein in a nutritional composition suitable for the long-term treatment of patients with renal disease preventing malnutrition whilst also suppressing inflammation was not a simple exercise. Instead, a cautious and tailored approach was required to develop these kinds of compositions. The compositions of document D4 being built around whey, the skilled person would not have been motivated to replace whey with soy protein without a clear incentive to do so.

Neither the disclosure of document D5 nor that of document D19 provided any such incentive.

Document D5 lacked any guidance or technical assistance how soy protein should or even could be built into a composition suitable for improving malnutrition in patients with renal disease. Moreover, the practical teaching that the skilled person would have derived from document D5 was unclear and limited. For example, page 325, right-hand-column, first full paragraph, of this document stated that the components of soy protein diet that delivered the renoprotective effects had not

been delineated. Furthermore, page 326 of this document (see chapter titled "SOY PROTEIN CONSUMPTION AND DIABETIC RENAL DISEASE") reported that only five randomised controlled trials were available in this area and the results were mixed, and concluded that further controlled trials were required to determine the clinical benefits of soy protein intake for these individuals.

As for document D19, its disclosure reflected the common general knowledge of the skilled person at the priority date of the patent and how the skilled person would have viewed whey and soybean proteins as being nutritionally different (see page 3, left-hand column, third paragraph reporting whey protein as having a higher PDCAAS score than soy protein).

Auxiliary request 2
Admittance

The filing of this request with the statement of grounds of appeal constituted a legitimate and timely response to section 6.4. of the decision under appeal. In this section, the opposition division had commented, *inter alia*, on the interpretation of claim 1 of the then pending auxiliary request 2 (i.e. auxiliary request 2 underlying the decision under appeal).

This interpretation, which had been presented to the parties for the first time at the oral proceedings before the opposition division, was not foreseeable. Consequently, auxiliary request 2 could not have been filed earlier.

Auxiliary request 3
Inventive step - claim 1

The proportion of the one or more kinds of free amino acids recited in claim 1 constituted a further distinguishing feature over the closest prior art (as compared to the subject-matter of claim 1 of the main request). Together with the other distinguishing features, this distinguishing feature defined a nutrition composition suitable for renal patients having beneficial effects as shown in the patent. The objective technical problem was therefore the same as for claim 1 of the main request. The solution proposed in claim 1 of auxiliary request 3 would not have been obvious. No conclusions could be drawn based on document D4 regarding the precise amounts of valine, leucine, isoleucine and histidine in the composition.

Auxiliary request 4
Added subject-matter
Claims 3 and 4

The subject-matter of claims 3 and 4 found basis in claims 4 and 5 as filed, respectively, taken in combination with paragraph [0022] of the application as filed.

Claim 7

The subject-matter of this claim was directly and unambiguously derivable from the application as filed, e.g. clause [11] in paragraph [0015], taken in combination with paragraph [0016].

Claim 8

The subject-matter of this claim found basis in claims 12 and 17 as filed, as well as clauses [12] to [17] in paragraph [0015] of the application as filed. The medical conditions recited in claim 8 all being associated with a patient with renal disease, the dependency of claim 8 on claim 7 did not add subject-matter.

Claim 9

The subject-matter of this claim was directly and unambiguously derivable from clauses [1] to [42] in paragraph [0015] of the application as filed. Further support for the claimed subject-matter could be found in paragraphs [0020], [0024] and [0027] of the application as filed.

Auxiliary request 4
Inventive step

The presence of a lipid comprising 10 wt% to 65 wt% of medium chain fatty acid oil in the claimed composition constituted a further distinguishing feature over the closest prior art (as compared to the subject-matter of claim 1 of the main request). The objective technical problem remained the same as for claim 1 of the main request. The solution proposed in claim 1 of auxiliary request 4 would not have been obvious. Document D4 itself (see paragraph [0035]) taught away from using less than 70 wt% medium-chain triglycerides in the nutritional compositions disclosed in this document. The additional documents relied on by the appellant-opponent would not have rendered the claimed invention obvious either.

XII. The appellant-opponent's written and oral submissions relevant for the present decision can be summarised as follows.

Main request and auxiliary request 1
Claim construction - claim 1

The opposition division was correct in finding that the subject-matter of claim 1 of the main request did not exclude compositions comprising free amino acids in addition to one or more of those listed in this claim.

The addition of the term "exclusively" after the word "consisting" in claim 1 of auxiliary request 1 did not change the technical meaning of this claim compared to claim 1 of the main request.

Main request and auxiliary request 1
Inventive step - claim 1

Taking document D4, in particular claims 1, 3, paragraph [0013] *et seqq.*, paragraphs [0018], [0037], and [0048] to [0050], as the closest prior art, the claimed subject-matter differed from this solely in that the claimed composition contained at least 20 wt% soybean protein or a hydrolysate thereof.

Since there were no data on file with a comparison to the closest prior art, the objective technical problem could only be formulated as the provision of an alternative nutritional composition.

Based on document D4's disclosure in combination with the skilled person's common general knowledge, as evidenced by e.g. documents D5 and D19, the skilled

person would have been motivated to substitute the whey protein contained in the compositions of document D4 for soybean protein.

Auxiliary request 2
Admittance

Considering the subject-matter and scope of this request, there was no reason why the appellant-patent proprietor could not have presented it at the time of the oral proceedings before the opposition division. The decision under appeal did not bring up any objections that had not been made prior to these oral proceedings.

Auxiliary request 3
Inventive step - claim 1

The claimed subject-matter differed from the nutrition composition set out in paragraphs [0048] to [0050] of document D4 in (i) the type of protein used (soybean instead of whey protein) and (ii) in that the free amino acids valine, leucine, isoleucine and histidine were contained in a proportion of 0.1 g – 10 g per 100 kcal of the composition.

In the absence of any functional interaction between these two distinguishing features, two partial technical problems had to be formulated. The objective technical problem resulting from the first distinguishing feature was the same as for the main request. The second partial problem was the provision of an alternative nutrition composition with a defined proportion of free amino acids.

The solution proposed in claim 1 would have been obvious considering document D4 alone.

Auxiliary request 4
Added subject-matter
Claims 3 and 4

The application as filed did not directly and unambiguously disclose the fatty acids recited in claims 3 and 4, respectively, in combination with the technical features of claim 1 relating to (i) the free amino acids specified in this claim, (ii) the content of the protein or peptide in a nitrogen source per 100 kcal of the composition, and (iii) the content of the soybean protein or a hydrolysate thereof in the protein or peptide.

Claim 7

The subject-matter of this claim, insofar as it related to medical uses, lacked direct and unambiguous disclosure in the application as filed. The term "*treatment*" in this claim presupposed a causal relationship between the nutritional composition on the one hand and the alleged therapeutic effect achieved on the other hand. Such a causal relationship was not disclosed in the application as filed.

Claim 8

The skilled person was presented with new technical information generated by formulating claim 8 as a dependent claim of claim 7.

Claim 9

The application as filed did not disclose the claimed combination of (i) protein or peptide, (ii) lipid, and (iii) free amino acid(s) without any link to "a nutrition composition" or "an agent", let alone in a Swiss-type format. In addition, the application as filed did not disclose the claimed feature "lipid comprising 10 – 65 wt% of medium chain fatty acid oil" in combination with the technical features of claim 9 relating to (i) the soybean protein or a hydrolysate thereof, and (ii) the protein or peptide content.

Auxiliary request 4
Inventive step

The claimed subject-matter differed from the nutrition composition set out in paragraphs [0048] to [0050] of document D4 in (i) the type of protein used (soybean instead of whey protein) and (ii) in the amount of medium chain fatty acid oil.

In the absence of any functional interaction between these two distinguishing features, two partial technical problems had to be formulated. The objective technical problem resulting from the first distinguishing feature (i.e. the first partial problem) was the same as for the main request. The partial problem with regard to the second distinguishing feature (i.e. the second partial problem) was to provide an alternative nutrition composition with different distribution of the fats.

The solution proposed in claim 1 to the first partial problem, i.e. the substitution of whey protein with soy

protein, would have been obvious for the reasons given in respect of claim 1 of the main request.

The solution proposed in claim 1 to the second partial problem, i.e. values of medium chain fatty acid oil falling within the claimed range of 10 wt% to 65 wt%, did not render the claimed subject-matter inventive either. Contrary to the appellant-patent proprietor's view, document D4 did not teach away from using medium chain fatty acid oil in amounts falling within the claimed range. Moreover, the use of such amounts in nutritional compositions was commonly known at the effective date of the patent, as evidenced by documents D3, D9, D10, D12 and D16. Consequently, the claimed range of 10 wt% to 65 wt% merely represented an arbitrary selection, which the skilled person would have arrived at by performing routine experiments.

XIII. The parties' final requests, in so far as relevant to the present decision, were as follows.

The appellant-patent proprietor requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the set of claims of the main request, alternatively, that the patent be maintained in amended form on the basis of one of the sets of claims of auxiliary requests 1 to 15 (see point VII. above).

The appellant-opponent requested that that the decision under appeal be set aside and that the patent be revoked. The appellant-opponent further requested that auxiliary request 2 not be admitted into the appeal proceedings.

Both parties requested that document D19 be admitted into the appeal proceedings.

Reasons for the Decision

1. The appeals are admissible.

Admittance of document D19

2. This document was filed by the appellant-patent proprietor with its statement of grounds of appeal.

3. As requested by the parties (see point XIII. above), the Board decided to admit this document into the proceedings (Article 12(6) RPBA).

Main request - claim 1

Claim construction

The meaning of "A nutrition composition comprising a protein or peptide, and one or more kinds of free amino acids selected from the group consisting of valine, leucine, isoleucine and histidine [...]"

4. In line with established case law, the Board interprets claim 1 giving the terms used their broadest technically sensible meaning (cf. Case Law of the Boards of Appeal of the European Patent Office, 10th edn., 2022, in the following "Case Law", II.A.6.1.).

5. Applying these principles, the subject-matter of claim 1 is a nutrition composition comprising the following mandatory components:

(i) A soybean protein or a hydrolysate thereof

(ii) One or more kinds of free amino acids selected from the group consisting of valine, leucine, isoleucine and histidine

(iii) A lipid comprising a ω-3 fatty acid and a ω-6 fatty acid at a weight ratio (ω-6 fatty acid to ω-3 fatty acid) of 0.5 - 3

6. As set out in the decision under appeal (see section 5.4.3), the preamble of this claim ("*A nutrition composition comprising [...]*") uses the open terminology "comprising". The claimed composition can thus contain further components in addition to the mandatory ingredients identified in point 5. above.

7. In contrast to the appellant-patent proprietor's view, the Board cannot recognise any wording in claim 1 that would indicate to the skilled reader that such further components may not include further free amino acids in addition to (one or more of) valine, leucine, isoleucine and histidine.

7.1 The feature in claim 1 "*and one or more kinds of free amino acids selected from the group consisting of valine, leucine, isoleucine and histidine*" is presented as an exhaustive list of four specific free amino acids, the presence of one or more of which is mandatory in the claimed composition. However, the skilled reader, when considering this feature in the context of claim 1 as a whole and in particular, in view of the use of the open language "comprising" in its preamble (see point 6. above), would understand that the phrase "*selected from the group consisting of valine, leucine, isoleucine and histidine*" relates only to the previously mentioned "*one or more kinds of free*

amino acids" but does not have any bearing on the nature of the other components of the claimed composition. In particular, it does not serve to exclude the presence in the composition of further free amino acids in addition to one or more of those listed in claim 1.

7.2 It is the Board's view that defining the subject-matter of claim 1 using both the open terminology "*comprising*" in the claim's preamble and the closed terminology "*consisting of*" in relation to the feature "*one or more kinds of free amino acids selected from the group consisting of valine, leucine, isoleucine and histidine*" does not give rise to any unclarity or ambiguity. Since the subject-matter of claim 1 is clearly defined in itself, it is not necessary to resort to the description of the patent for its construction (see Case Law, II.A.6.3.1).

8. In summary, the Board finds that the subject-matter of claim 1 encompasses nutrition compositions comprising other free amino acids in addition to one or more of valine, leucine, isoleucine, and histidine, which are mandatory.

Inventive step (Article 56 EPC)

The closest prior art

9. Both parties made their analysis of inventive step starting from document D4 as the closest prior art. The Board sees no reason to differ.

Disclosure of document D4

9.1 Document D4 is a patent specification relating to nutritional compositions and methods of using these for preventing or treating renal failure (see paragraph [0001]).

9.2 In one embodiment of this invention (see paragraph [0027] in conjunction with paragraph [0024]), the nutritional composition is an amino acid-based, liquid ready-to-use composition, having a very high caloric density with a moderate osmolality ("ready-to-use composition").

9.3 It has not been contested that this ready-to-use composition incorporates the following mandatory components:

(a) A protein source that has an amino acid profile specifically designed for renal patients and that contains free amino acids and whey protein (see paragraph [0028] of document D4)

(b) Carbohydrates (e.g. maltodextrin, see paragraph [0033] of document D4)

(c) A lipid source that contains a mixture of medium-chain triglycerides (MCT) and long-chain triglycerides (see paragraph [0034] of document D4)

9.4 Further details on the aforementioned protein source are disclosed in paragraphs [0031] and [0032] of document D4. Paragraph [0031] (see table) presents a preferred amino acid profile of the protein source which consists of 18 different amino acids - including

valine, leucine, isoleucine, and histidine - in specified mole percent ranges.

9.5 Paragraph [0032] of document D4 in turn explains that the protein source preferably provides approximately 5 to 10% of the total calories of the composition, i.e. approximately 1.25 g to 2.5 g per 100 kcal of the nutritional composition when applying the conversion factor of 4 (as done in Tables 1 and 2 of the patent).

9.6 Turning to the lipid source, paragraph [0037], second sentence of document D4, explains that suitable sources of long-chain triglycerides (LCT) are canola oil, corn oil, soy lecithin and residual milk fat. Paragraph [0037] continues by stating:

"*[t]he lipid profiles containing such long-chain triglycerides are designed to have a polyunsaturated fatty acid omega-6 (n-6) to omega-3 (n-3) ratio of the composition is approximately 1:1 to 10:1.*"

9.7 Paragraphs [0027], [0028], [0031] to [0034] and [0037] therefore disclose, in a general manner, a ready-to-use composition which is exemplified in paragraphs [0048] to [0050] of document D4 ("example composition"). This example composition is defined in paragraph [0049] as follows:

"The composition includes the following ingredients: water, maltodextrin, medium-chain triglycerides, (MCT source: fractionated coconut oil); canola oil; whey protein concentrate; modified corn starch, L-valine; corn oil; L-arginine, L-histidine, L-methionine, L-phenylalanine; L-leucine; L-lysine acetate; L-isoleucine; soy lecithin, glycine; L-threonine

L-alanine; L-proline; choline bitartrate; L-tryptophan; L-serine; ascorbic acid; L-carnitine; taurine; zinc sulphate; niacinamide; calcium pantothenate; pyridoxine hydrochloride; biotin; riboflavin; thiamine mononitrate; folic acid; sodium selenate and cyanocobalamin."

9.8 With regard to this latter disclosure, it has not been contested that

(a) the 14 amino acids listed in this paragraph are free amino acids, and that these - together with the whey protein concentrate - form the protein source of the example composition of document D4,

(b) maltodextrin represents the carbohydrate source of this same composition,

(c) fractionated coconut oil (MCT source) and the LCT sources canola oil, corn oil, and soy lecithin constitute the lipid source of this same composition.

9.9 When comparing the general disclosure of the ready-to-use composition with the example composition, the following observations can be made:

(a) The protein source of the example composition is an embodiment of the protein source of the "ready-to-use" composition (see paragraphs [0028] and [0031] of document D4).

(b) The carbohydrate and the lipidic components of the example composition are embodiments of the carbohydrate and lipid sources of the ready-to-use composition.

Starting point(s) in document D4

10. The appellant-patent proprietor selected the example composition of document D4 as starting point.

11. In accordance with the established case law of the Boards of Appeal, a conclusion that the subject-matter claimed is inventive can only be reached after assessing this requirement starting from any prior art disclosure, including other parts of the same document.

12. In the board's opinion, as expressed in points 20.3 to 20.5 of its communication (see point VIII. above), document D4's disclosure of the ready-to-use composition may also serve as starting point.

Distinguishing feature(s) over the ready-to-use composition of document D4 ("closest prior art")

13. It is common ground that the subject-matter of claim 1 differs from the closest prior art in that the claimed composition comprises at least 20 wt% soybean protein or a hydrolysate thereof.

14. The appellant-patent proprietor identified two further distinguishing features, i.e.

(i) the presence of (one or more of) the four free amino acids specified in claim 1 as the only free amino acids in the claimed composition ("feature (i)"),

(ii) a lipid comprising ω-3 fatty acid and ω-6 fatty acid at a weight ratio (ω-6 fatty acid to ω-3 fatty acid) of 0.5 to 3 ("feature (ii)").

15. The Board does not agree that the above features, referred to by the appellant-patent proprietor, represent differences between the disclosure in document D4 and the claimed subject-matter.

Feature (i)

15.1 As set out in point 9.4 above, paragraph [0031] of document D4 lists a preferred amino acid profile of the protein source of the ready-to-use composition. This profile contains 18 amino acids, including valine, leucine, isoleucine and histidine. While this paragraph does not explicitly indicate whether one or more of these four amino acids is/are in free form, the skilled person would have noted that 14 of the 18 amino acids listed in the table of paragraph [0031] are included in free form in a composition that is representative of the ready-to-use composition (i.e. the example composition of document D4, see points 9.1 to 9.9 above).

15.2 From these facts, the skilled person would have directly and unambiguously derived that the 18 amino acids listed in the table of paragraph [0031] of document D4 are in free form.

15.3 Hence, the ready-to-use composition of document D4 comprises the 18 amino acids listed in paragraph [0031] in free form, including the four amino acids listed in claim 1. The presence of 14 additional free amino acids in this composition is not a difference between the claimed subject-matter and the ready-to-use composition of document D4 (see points 7. and 8. above).

Feature (ii)

15.4 According to paragraph [0037] of document D4 (see point 9.6 above), the ready-to-use composition contains ω-3 fatty acids and ω-6 fatty acids at a weight ratio (ω-6 fatty acid to ω-3 fatty acid) of approximately 1:1 to 10:1.

15.5 This range overlaps with the claimed range of 0.5 to 3. Therefore, feature (ii) does not distinguish the claimed subject-matter from the ready-to-use composition of document D4 either.

Objective technical problem and solution

16. To formulate the objective technical problem effectively solved by the claimed subject-matter over the closest prior art, the technical effect(s) associated with the distinguishing feature(s) must be identified.

17. The patent's experimental examples, relied on by the appellant-patent proprietor for formulating the objective technical problem, do not contain any comparative data showing a technical effect linked to the distinguishing feature (i.e. the presence of at least 20 wt% soybean protein or a hydrolysate thereof in the claimed composition) in comparison with the ready-to-use composition of document D4 representing the closest prior art.

18. Therefore, the Board cannot agree with the appellant-patent proprietor's formulation of the technical problem to be solved (see point XI. above).

19. The appellant-opponent defined the objective technical problem as "the provision of an alternative nutritional composition".

20. The Board considers that the overall disclosure of the invention in the patent should be taken into account in the formulation of the objective technical problem, which is therefore worded as "the provision of an alternative nutritional composition, suitable for patients suffering from renal disease".

Obviousness of the proposed solution

21. In the Board's judgement, the claimed subject-matter would have been obvious to the skilled person starting from the disclosure in document D4, taken in combination with the skilled person's common general knowledge reflected, *inter alia*, in documents D5 and D19. The reasons for this are as follows.

21.1 At the effective date of the patent, whey protein was a commonly known animal protein, as was not been contested by the appellant-patent proprietor.

21.2 Document D5 is a scientific review article, and is thus, by definition, an account of the common general knowledge in the art prior to its own publication date (see Case Law, I.C.2.8.1).

21.2.1 This document concerns the beneficial effects of soy protein consumption for renal function (see title). From the abstract, it can already be taken that:

"[a]lterations in dietary protein intake have an important role in prevention and management of several forms of kidney disease. Using soy protein instead of

animal protein reduces development of kidney disease in animals. Reducing protein intake preserves kidney function in persons with early diabetic kidney disease. Our clinical observations led us to the soy-protein hypothesis that 'substitution of soy protein for animal protein results in less hyperfiltration and glomerular hypertension with resulting protection from diabetic nephropathy.' These components of soy protein may lead to the benefits: specific peptides, amino acids, and isoflavones. Substituting soy protein for animal protein usually decreases hyperfiltration in diabetic subjects and may reduce urine albumin excretion. Limited data are available on effects of soy peptides, isoflavones, and other soy components on renal function on renal function in diabetes. Further studies are required to discern the specific benefits of soy protein and its components on renal function in diabetic subjects."

21.2.2 From these disclosures, the skilled person would have understood that soy protein was a suitable dietary source of protein for patients with diabetic renal disease and with the additional advantage of providing clinical benefits in renal function in these patients.

21.3 The skilled person would furthermore have been aware from their common general knowledge reflected in document D19 (see page 3, left-hand column, third paragraph) that, with a PDCAAS score of 1.00, soy protein is an ideal protein that meets all the essential amino acid requirements of the human body. The PDCAAS score is a value measuring protein quality based on the amino acid requirements of humans (see document D19, page 3, left-hand column, second full paragraph).

21.4 Consequently, the skilled person starting from the disclosure in document D4 and faced with the technical problem defined in point 20. above, would have replaced the animal protein contained in the ready-to-use composition with soy protein, and thereby have arrived at the claimed subject-matter. The board notes that no explicit motivation or prompt in the prior art is required to apply the aforementioned common general knowledge, given the fact that this knowledge forms the technical background for any activities the skilled person performs, feeding into all their decisions (see Case Law, I.D.8.3).

22. The appellant-patent proprietor's counter arguments are not persuasive as explained below.

22.1 These counter arguments are based on a formulation of the objective technical problem which includes medical effects (i.e. prevention/improvement of malnutrition and suppression of inflammation associated with renal disease; see point XI. above).

22.2 To demonstrate that the claimed invention would not have been an obvious solution to this problem, the appellant-patent proprietor underlined the difficulties and challenges in the prior art in respect of dietary intervention in the therapeutic treatment of renal disease (see point XI. above). To further support its case, the appellant-patent proprietor also made reference to document D5's disclosures on pages 325 and 326 (see point XI. above) which pertain to the therapeutic effect (or lack thereof) of soy protein in patients with diabetic renal disease.

22.3 However, as set out above, the objective technical problem is the provision an alternative nutritional

composition, suitable for patients suffering from renal disease (see point 20. above).

22.4 In other words, this composition must only be able to provide nutrition to patients with renal diseases. Compositions provided as solutions to this objective technical problem do not have to be suitable for the therapeutic treatment of renal diseases, let alone for the long-term treatment thereof by preventing malnutrition whilst also suppressing inflammation. Nor need a composition representing a solution to said problem be better in terms of its nutritional properties (e.g. PDCAAS score) than the ready-to-use composition of document D4. As explained in point 21.3 above, document D19 (see page 3, left-hand column, third paragraph) qualifies soy protein as an ideal protein that meets all the essential amino acid requirements of the human body.

22.5 Consequently, in the absence of any indication in document D5 that would have led the skilled person to conclude that soybean protein was not a suitable dietary protein source for patients with renal disease, the appellant-patent proprietor's arguments cannot succeed.

22.6 The appellant-patent proprietor's argument based on the lack of practical assistance in document D5 (see point XI. above) is not found persuasive either. As convincingly argued by the appellant-opponent at the oral proceedings on the basis of documents D12 (see page 1875, right-hand column, third full paragraph) and D19 (see page 6, the section titled "Vanilla Flavored Protein Drink"), it was commonly known at the effective date of the patent that a dietary protein provided in powder form (e.g. whey and soy protein) can be

incorporated into a liquid nutritional composition by adding this protein to the composition and mixing it with the other components. Consequently, the skilled person would not have had any practical difficulty in replacing whey in the ready-to-use composition of document D4 for soy protein.

Overall conclusion on inventive step of claim 1 of the main request

23. In view of the foregoing considerations, the Board does not see any reason to deviate from the opposition division's conclusion that the subject-matter of claim 1 of the main request lacks inventive step (Article 56 EPC).

Auxiliary request 1 - claim 1
Claim construction and inventive step

24. Claim 1 of auxiliary request 1 is identical to claim 1 of the main request with the exception that the expression "...from the group consisting of" is replaced by the wording "...from the group consisting exclusively of".

25. The Board finds that this amendment does not change the technical meaning of claim 1 of this request compared to claim 1 of the main request, as also argued by the appellant-opponent. The wording "*[..] selected from the group consisting exclusively of valine, leucine, isoleucine and histidine [..]*" still defines the previously mentioned "*one or more kinds of free amino acids*" whose presence is mandatory but does not exclude that the claimed composition contains further free amino acids in addition to one or more of those listed in claim 1 (see point 7.1 above).

26. Claim 1 of auxiliary request 1, directed to the same subject-matter as claim 1 of the main request, does not fulfil the requirements of Article 56 EPC for the same reasons as set out for claim 1 of the main request.

Auxiliary request 2
Admittance

27. Claim 1 of auxiliary request 2, filed with the appellant-patent proprietor's statement of grounds of appeal, differs from claim 1 of the main request in that it includes a disclaimer which specifically excludes free amino acids other than valine, leucine, isoleucine and histidine from the claimed nutrition composition (see point X. above).

28. The appellant-patent proprietor filed auxiliary request 2 for the first time with its statement of grounds of appeal.

29. According to Article 12(6), second sentence, RPBA the Board shall not admit requests, facts, objections or evidence which should have been submitted, or which were no longer maintained, in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify their admittance.

30. The appellant-patent proprietor submitted that auxiliary request 2 had been filed in response to the opposition division's claim interpretation set out in section 6.4 of the decision under appeal, and could therefore not have been presented earlier.

31. This claim interpretation concerns claim 1 of auxiliary request 2 underlying the decision under appeal.

32. This claim is identical to claim 1 of auxiliary request 1 underlying the decision under appeal with the exception that the term "consisting of" in the claimed feature *"one or more kinds of free amino acids selected from the group consisting of valine, leucine, isoleucine and histidine"* ("'consisting of-type' language") has been amended to read *"consisting exclusively of"* ("'consisting exclusively of-type' language").

33. In the opposition division's view, this amendment did not change the scope of claim 1 (as compared to that of claim 1 of auxiliary request 1 underlying the decision under appeal). The opposition division further explained that *"[t]he restriction to valine, leucine, isoleucine and histidine applies only to the claimed group, however claim 1 is still drafted in an open format and the composition could include another group of amino acids."*

34. When stating *"however claim 1 is still drafted in an open format and the composition could include another group of amino acids"*, the opposition division was referring to its claim interpretation set out in section 5.4.3 of the decision under appeal. There, the opposition division stated that the term "comprising" first mentioned in claim 1 of auxiliary request 1 underlying the decision under appeal was open terminology, and hence did not exclude the presence of other components such as other amino acids selected from another group in the nutritional composition.

35. Thus, according to the decision under appeal, neither the 'consisting of-type' language used in claim 1 of auxiliary request 1 underlying the decision under

appeal nor the 'consisting exclusively of-type' language used in claim 1 of auxiliary request 2 underlying the decision under appeal imposed any restriction on the open definition of the term "comprising" first mentioned in claim 1 of each of these two auxiliary requests.

36. In the appellant-patent proprietor's view, the opposition division's interpretation set out in section 6.4. of the decision under appeal was not foreseeable.

37. The Board does not concur.

37.1 The Board acknowledges that the opposition division's communication annexed to the summons to attend oral proceedings does not include any opinion on the interpretation of claim 1 of auxiliary request 2 underlying the decision under appeal.

37.2 However, the appellant-patent proprietor knew from this same communication (see section 12.2 thereof) that in the opposition division's preliminary view the 'consisting of-type' language used in claim 1 as granted (which is identical to claim 1 of auxiliary request 1 underlying the decision under appeal) did not have any limitative effect on the open definition of the term "comprising" first mentioned in that same claim.

37.3 In view of this, the appellant-patent proprietor should have expected that its attempt to introduce such limitative effect (in respect of the claimed free amino acids) merely by changing the 'consisting-of-type' language in claim of the then pending auxiliary request 1 into 'consisting-exclusively-of-type' language in

claim 1 of the then pending auxiliary request 2 might fail.

38. Consequently, the appellant-patent proprietor could and should already have filed current auxiliary request 2 with its submission under Rule 116 EPC, dated 1 October 2021.

39. Therefore, the Board decided not to admit this request into the appeal proceedings.

Auxiliary request 3 - claim 1
Inventive step

40. In the Board's judgement, the subject-matter of claim 1 of auxiliary request 3 would have been obvious to the skilled person at the relevant date of the patent. The reasons are as follows.

40.1 Claim 1 of this request differs from claim 1 of the main request in that it further requires that "*the one or more kinds of free amino acids selected from the group consisting of valine, leucine, isoleucine and histidine is(are) contained in a proportion of 0.1 g - 10 g per 100 kcal of the composition*".

40.2 Undisputedly, this latter feature ("claimed amino acid proportion") constitutes a further distinguishing feature over the ready-to-use composition of document D4 representing the closest prior art.

40.3 However, the appellant-patent proprietor did not make the case that any technical effect was linked to the amino acid proportion now defined in the claim beyond those effects already associated with the subject-matter of claim 1 of the main request.

40.4 Consequently, the objective technical problem remains the same as for claim 1 of the main request, i.e. how to provide an alternative nutritional composition, suitable for patients suffering from renal disease (see point 20. above).

40.5 As submitted by the appellant-opponent, the skilled person seeking to put into practice document D4's teaching relating to the ready-to-use composition, would necessarily have had to select a certain amount of free amino acids. To find such an amount, the skilled person would have consulted document D4's disclosure as a whole, and would in particular have taken note of paragraphs [0031], [0032], and claim 8.

Paragraph [0031] of document D4

40.5.1 This paragraph discloses a preferred amino acid profile of the ready-to-use composition containing 18 different amino acids in their free form (see points 9.4 and 15.1 to 15.2 above). The respective amino acid amounts are recited in mole percent ranges only.

40.5.2 However, as observed by the appellant-opponent and not contested by the appellant-patent proprietor, the given mole percent ranges could be easily re-stated in grams using the molar mass of each amino acid.

40.5.3 The appellant-opponent explained in writing and orally that based on the mean value of the mole percent ranges given for each amino acid (which added up to 100%) and their respective molar masses, the four amino acids valine, leucine, isoleucine and histidine amounted to 38.65 wt% of all depicted amino acids.

40.5.4 In the absence of any arguments to the contrary by the appellant-patent proprietor, the Board does not see any reason to call into question the appellant-opponent's calculations.

Paragraph [0032] of document D4

40.5.5 This paragraph teaches that the protein source of the ready-to-use composition preferably provides approximately 1.25 g to 2.5 g per 100 kcal of the nutritional composition (see point 9.5 above).

Claim 8 of document D4

40.5.6 This claim pertains to *"[t]he composition or use of any of claims 1 to 7 in which the protein source comprises up to 50% whey protein".*

40.5.7 The composition of claim 1 referred to in claim 8 is an enteral composition for treating renal failure comprising a therapeutically effective amount of a protein source including free amino acids and whey protein, and having an amino acid profile comprising 18 specific amino acids.

Combination of the disclosures of paragraphs [0031], [0032] and claim 8 of document D4

40.6 These 18 amino acids are the same as the ones listed in paragraph [0031] of document D4. Consequently, the skilled person would have read the disclosures of claim 8, and paragraphs [0031] and [0032] in combination.

40.7 In doing so, the skilled person would have selected an amount of whey protein of not more than 50% (see claim 8) and, as a consequence thereof, an amount free amino

acids of at least 50% of the total amount of protein source, i.e. at least 50% of 1.25 g to 2.5 g per 100 kcal of the nutritional composition (see paragraph [0032]).

40.8 Assuming that the skilled person would have taken the values of 50% and 1.25 g, respectively (which is the best possible scenario for the appellant-patent proprietor), they would have arrived at a total amount of free amino acids of 0.6125 g. This amount includes 38.65 wt% of L-valine, L-leucine, L-isoleucine, and L-histidine (see point 40.5.3 above), i.e. an amount of approximately 0.2367 g, which falls within the claimed range of 0.1 g to 10 g per 100 kcal of the composition.

40.9 The appellant-opponent is therefore correct in arguing that the claimed amino acid proportion is merely the result of a routine modification of the teaching of document D4, which cannot impart an inventive step to the subject-matter of claim 1 of auxiliary request 3.

40.10 The appellant-patent proprietor criticised the calculations set out in point 40.8 above as being based on many speculative assumptions. In its view, document D4 did not contain any clear disclosure of the precise amounts of valine, leucine, isoleucine and histidine in the composition.

40.11 The Board does not agree. The aforementioned calculations are not mere assumptions but instead rely on technical facts presented in document D4. Moreover, these calculations are based on the best possible scenario for the appellant-patent proprietor.

Overall conclusion on inventive step of claim 1 of auxiliary request 3

41. In view of the foregoing considerations, the Board concludes that the subject-matter of claim 1 of auxiliary request 3 does not involve an inventive step.

Auxiliary request 4
Added subject-matter
Claims 3 and 4

42. The appellant-opponent contended that the application as filed did not directly and unambiguously disclose the fatty acids recited in claims 3 and 4, respectively, in combination with the technical features of claim 1 relating to (i) the free amino acids specified in this claim, (ii) the content of the protein or peptide in a nitrogen source per 100 kcal of the composition, and (iii) the content of the soybean protein or a hydrolysate thereof in the protein or peptide.

43. Claim 3 of auxiliary request 4 is a dependent claim of claim 1 (see point X. above), and stipulates that the ω-3 fatty acid is one or more kinds of fatty acid selected from the group consisting of α-linolenic acid, eicosapentaenoic acid, docosapentaenoic acid and docosahexaenoic acid.

44. Claim 4 of auxiliary request 4 is likewise worded as a dependent claim of claim 1, and stipulates that the ω-6 fatty acid is one or more kinds of fatty acid selected from the group consisting of linoleic acid, γ-linolenic acid, stearidonic acid and arachidonic acid.

45. Contrary to the appellant-opponent's opinion, the application as filed directly and unambiguously discloses the specific ω-3 and ω-6 fatty acids recited in these two claims, in combination with the technical features (i), (ii), and (iii) referred to in point 42. above.

45.1 Specifically, paragraph [0022] of the application as filed refers to the ω-3 fatty acids recited in claim 3 and the ω-6 fatty acids recited in claim 4 as one or more kinds of ω-3 fatty acids and ω-6 fatty acids selected and used in the *"present invention"*.

45.2 Claim 1 of the application as filed defines a nutrition composition comprising one or more kinds of free amino acids selected from the group consisting of valine, leucine, isoleucine and histidine, and a lipid comprising a ω-3 fatty acid and a ω-6 fatty acid at a weight ratio (ω-6 fatty acid to ω-3 fatty acid) of 0.5 to 5.5 (see claim 1 of the application as filed).

45.3 According to paragraph [0024] of the application as filed, a ω-6 fatty acid to ω-3 fatty acid weight ratio from 0.5 to 3 is preferred.

45.4 Paragraph [0027] of the application as filed, in turn, provides basis for the technical features of claims 3 and 4 relating to the content of the protein or peptide in a nitrogen source per 100 kcal of the composition, and the content of the soybean protein or a hydrolysate thereof in the protein or peptide.

Claim 7

46. The subject-matter of this claim is a nutrition composition according to claim 1 *"for use in treatment of a patient with a renal disease"*.

47. Contrary to the appellant-opponent's contention (see point XII. above), the application as filed directly and unambiguously discloses medical uses of the claimed nutrition composition in patients with renal diseases. The reasons are as follows.

47.1 Paragraph [0015] of the application as filed describes embodiments of the *"present invention"* (i.e. the invention according to the application as filed) in the form of 42 clauses, i.e. clauses [1] to [42]. Clause [11] is directed to a nutrition composition as defined in any of clauses [1] to [10], "*which is for a patient with a renal disease*".

47.2 The next paragraph (see paragraph [0016] of the application as filed) states:

"The nutrition composition of the present invention is useful for patients with renal diseases, can effectively prevent or improve malnutrition, inflammation, arteriosclerosis, abnormal lipid metabolism, oxidative stress and the like associated with renal diseases, and is useful for the prevention or improvement of diabetic nephropathy. Furthermore, the nutrition composition of the present invention is highly safe, and can be continuously used as a food for nutrition supplementation for patients with a renal disease and decreased kidney function."

47.3 From this , it is clear that the nutrition composition according to the invention described in the application as filed (e.g. the nutrition composition according to clause [11]) serves two main purposes in patients with renal diseases, i.e. medical purposes (see first sentence of this paragraph) as well as non-medical, nutritional purposes (see second sentence of this paragraph). As a consequence, the skilled reader would understand the term "useful" in the first sentence of paragraph [0016] to mean therapeutically beneficial.

Claim 8

48. Claim 8 reads:

"The nutrition composition according to claim 7 for use in the prevention or improvement of:
malnutrition associated with renal disease;
inflammation associated with renal disease;
arteriosclerosis associated with renal diseases;
abnormal lipid metabolism associated with renal disease;
oxidative stress associated with renal disease; or
diabetic nephropathy."

49. This subject-matter is directly and unambiguously disclosed in paragraph [0016] and claims 12 to 17 of the application as filed.

50. Contrary to the appellant-opponent's position, the dependency of claim 8 on claim 7 does not add subject-matter. As correctly observed by the appellant-patent proprietor, the medical conditions recited in claim 8 are all associated with a patient with renal disease, i.e the patient group referred to in claim 7.

Claim 9

51. Claim 9 is drafted in the Swiss-type format, and reads as follows.

"Use of a protein or peptide, and one or more kinds of free amino acids selected from the group consisting of valine, leucine, isoleucine and histidine, and (a) a lipid comprising ω-3 fatty acid and ω-6 fatty acid at a weight ratio (ω-6 fatty acid to ω-3 fatty acid) of 0.5 - 3; and (b) a soybean protein or a hydrolysate thereof, wherein the content of the protein or peptide in a nitrogen source per 100 kcal of the agent is not more than 3.5 g, and the content of the soybean protein or a hydrolysate thereof in the protein or peptide is 20 wt% - 100 wt%; in the manufacture of an agent for the prevention or improvement of one or more symptoms selected from the group abnormal lipid metabolism and oxidative stress, associated with renal disease, or for the prevention or improvement of diabetic nephropathy.

52. Contrary to the appellant-opponent's contention (see point XII. above), the subject-matter of this claim is directly and unambiguously disclosed in the application as filed.

52.1 As explained in point 47.1 above, paragraph [0015] of the application as filed discloses embodiments of the invention according to the application as filed in the form of 42 clauses, i.e. clauses [1] to [42].

52.2 Clause [22] refers to an agent for the prevention or treatment of the same diseases as those referred to in claim 9. The physical entities forming part of this agent are identical to those of claim 9 (see point 51.

above) except for the lipid which has a ω-6 fatty acid to ω-3 fatty acid weight ratio of 0.5 to 5.5 instead of 0.5 to 3 (see clauses [18] and [19], respectively, to which clause [22] indirectly refers to via clause [20]). Moreover, clause [22] does not indicate that the lipid comprises 10 wt% to 65 wt% of medium chain fatty acid oil ("MCFA oil").

52.3 Basis for the claimed ω-6 fatty acid to ω-3 fatty acid weight ratio and the claimed MCFA oil may, however, be found in paragraph [0024] and clause [25], respectively, of the application as filed. Like the disclosure of clause [22], these disclosures are set within the context of the *"present invention".* Consequently, the skilled person would consider these disclosures to be combinable with the disclosure of clause [22].

Inventive step

53. In the Board's judgement, the subject-matter of claim 1 of auxiliary request 4 would not have been obvious having regard to the state of the art. The reasons are as follows.

53.1 Document D4's disclosure of the ready-to-use composition remains the closest prior art. According to paragraph [0034] of this document, this composition includes a lipid source comprising MCT and LCT. The next paragraph (see paragraph [0035]) reads:

"The lipid profile of the composition is designed to meet essential fatty acid needs (omega-3 and omega-6) while also keeping MCT content high and LCT content low compared with prior formulas. For example, the lipid source includes at least 70% medium-chain

triglycerides. In a preferred embodiment, the medium-chain triglyceride source is fractionated coconut oil."

53.2 Hence, compared to the subject-matter of claim 1 of the main request, the subject-matter of claim 1 of auxiliary request 4 differs from the ready-to-use composition of document D4 not only in that the claimed composition includes at least 20 wt% soybean protein or a hydrolysate thereof but also in that it contains a lipid comprising at most 65 wt% of MCFA oil.

The objective technical problem

53.3 The appellant-patent proprietor did not make the case that any technical effects were linked to the claimed amounts of MCFA oil, beyond those effects asserted for claim 1 of the main request.

53.4 Consequently, the objective technical problem remains the same as for claim 1 of the main request, i.e. how to provide an alternative nutritional composition, suitable for patients suffering from renal disease (see point 20. above).

53.5 In the appellant-opponent's view, the objective technical problem consisted of two partial technical problems, i.e.

(a) A first partial problem being the provision of an alternative nutrition composition

(b) A second partial problem being the provision of an alternative nutrition composition with different distribution of the fats

53.6 The Board does not concur with the appellant-opponent on this. As submitted by the appellant-patent proprietor, the reference in the second partial problem to a "different distribution in fats" represents an pointer to the solution claimed, made with the benefit of hindsight. In any case, both of the two distinguishing features identified in point 53.2 above contribute to solving the objective technical problem stated in point 53.4 above.

Obviousness

53.7 The claimed subject-matter would not have been obvious to the skilled person having regard to the prior art relied on by the appellant-opponent. Although nutritional compositions comprising MCT values falling within the claimed range were commonly known at the effective date of the patent (see document D3, page 11 and claims 17, 18, 20 and 21; document D9, page 4 *et seqq.;* document D10, Example 1; document D16, pages 42 to 47, 54 to 57, 60 and 61), the skilled person starting from the disclosure of a ready-to-use composition of document D4 would first have considered the disclosure of document D4 as a whole and in particular would have taken note of paragraph [0035]. According to this paragraph (see point 53.1 above), the MCT content in the ready-to-use composition was "high" compared to that in prior formulas, giving a value of "*at least 70%*" as an example for this. From the fact that the value of 70% is preceded by the expression "at least", the skilled person would have understood that the MCT content of this composition should be not less than 70%.

53.8 Moreover, paragraphs [0034] and [0036] of document D4 underline the importance of an MCT content of at least

70 wt% for the nutritional properties of the ready-to-use composition. Specifically, paragraph [0034] (see last sentence) teaches that the MCT in the ready-to-use composition contribute to providing a calorically-dense energy source that allows for better fat absorption. Likewise, paragraph [0036] of this document (relied on by the appellant-opponent in its statement of grounds of appeal; see page 20, fifth paragraph), states:

"Moreover, the preferred 70:30 ratio sufficiently satisfies patients' high caloric requirements without creating fat intolerant conditions. The composition provides a more calorically dense energy source as compared with products comprised of only long-chain triglycerides."

53.9 In light of the above, the skilled person would have recognised a MCT content of at least 70 wt% was an essential feature for achieving the desired nutritional properties of the ready-to-use composition. Consequently, the skilled person faced with the objective technical problem posed would not have considered reducing the MCT content in this composition to an amount below 70 wt%.

53.10 In coming to this conclusion, the Board did not overlook claim 3 of document D4. This claim refers to a composition according to claim 1 of this document (see point 40.5.7 above) which further comprises a mixture of medium and long-chain triglycerides having a ratio of approximately 1:1 to 4:1 (e.g. a ratio MCT/LCT of approximately 1:1 which amounts to 50% of MCT). The same ratio is disclosed in paragraph [0018] of this document.

53.11 However, document D4 does not disclose this 1:1 to 4:1 ratio in the context of the ready-to-use composition but instead explicitly refers to an MCT content of at least 70% (see points 53.7 and 53.8 above).

53.12 Consequently, the skilled person, starting from the ready-to-use composition of document D4, would not have reduced its MCT content to values of 65 wt% or less to solve the technical problem posed.

Overall conclusion on inventive step of auxiliary request 4

54. The claimed subject-matter of auxiliary request 4 involves an inventive step (Article 56 EPC).

Overall conclusion on auxiliary request 4

55. Auxiliary request 4 is allowable. Accordingly, there is no need for the Board to consider the appellant-patent proprietor's lower ranking auxiliary requests 5 to 15.

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 in amended form with the following claims and a description adapted thereto if necessary:

   Claims 1 to 9 of auxiliary request 4 filed with the statement of grounds of appeal.

The Registrar: The Chair:

C. Vodz A. Chakravarty

Decision electronically authenticated