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Datasheet for the decision of 29 June 2015

Case Number: T 0073/11 - 3.3.02

Application Number: 04801850.1

Publication Number: 1660067

IPC: A61K31/195, A61P3/00

Language of the proceedings: EN

Title of invention:
METHODS AND MATERIALS FOR TREATING CONDITIONS ASSOCIATED WITH METABOLIC DISORDERS

Patent Proprietor:
Prekulab Ltd. A/S af 8. marts 2004

Opponent:
N.V. Nutricia

Headword:
LNAA supplements for treating phenylketonuria and phenylalanemia/PREKULAB LTD.

Relevant legal provisions:
EPC Art. 54(5), 100(c), 123(2), 123(3), 111(1)
RPBA Art. 12, 13

Keyword:
Admission of auxiliary requests I and III (no); admission of auxiliary requests VIII, IX, X (yes). Allowability of auxiliary requests VII to IX (no): added matter. Auxiliary request X does not contain added matter. Remittal (yes).

Decisions cited:

Catchword:

Europäisches Patentamt
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Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 0073/11 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 29 June 2015

Appellant: (Patent Proprietor)	Prekulab Ltd. A/S af 8. marts 2004 Revvej 41 4220 Korsør (DK)
Representative:	Zacco Denmark A/S Arne Jacobsens Allé 15 2300 Copenhagen S (DK)
Respondent: (Opponent)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 16 November 2010 revoking European patent No. 1660067 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	U. Oswald
Members:	M. C. Ortega Plaza
	L. Bühler

Summary of Facts and Submissions

I. European patent No. 1 660 067, based on European patent application 04801850.1, which was filed as an international application published as WO 2005/016330, was granted with eight claims. The date of publication and mention of the grant of the patent is 16 July 2008.

II. Opposition was filed and revocation of the patent in its entirety was requested under the grounds pursuant to Article 100(a) EPC (lack of novelty and inventive step) and Article 100(b) and (c) EPC.

III. The present appeal lies from a decision of the opposition division posted on 16 November 2010 revoking the patent under Article 101(3)(b) EPC.

The opposition division considered that the claims of the main request filed with letter of 19 November 2009 and of auxiliary requests 1 and 2, filed at the oral proceedings before the opposition division, contained added subject-matter (Articles 100(c) and 123(2) EPC). Additionally, the opposition division found that the claims of auxiliary request 1 lacked clarity (Article 84 EPC) and extended the scope of protection (Article 123(3) EPC).

IV. The appellant (patentee) lodged an appeal against said decision and filed grounds thereto with its letter dated 23 March 2011. With the statement of grounds of appeal it filed a main request, which is identical to the set of claims filed with letter of 19 November 2009 (i.e. the main request before the opposition division), and auxiliary requests 1 to 6.

The appellant further filed with its grounds of appeal the following document:

D17 Koch et al. "Large neutral amino acid therapy and phenylketonuria: a promising approach to treatment" Molecular Genetics and Metabolism 79 (2003) 110-113

and stated that its publication date was 22 April 2003.

V. The respondent (opponent) filed a substantive response to the grounds of appeal and requested that the appeal be dismissed. It further requested that auxiliary requests 1, 3 and 5 not be admitted into the proceedings. The respondent considered that the amendments introduced in these requests were not occasioned by a ground for opposition (Rule 80 EPC).

VI. The board sent a communication on 14 April 2014 pursuant to Article 15(1) RPBA as an annex to the summons to attend oral proceedings. In said communication the board drew attention to a possible typing error in claim 2 of auxiliary request 6 filed with the statment of grounds of appeal, and mentioned that there were some problems in relation to Article 84 EPC for some of the dependent claims. The board also expressed its preliminary view that remittal of the case to the department of first instance would be appropriate if one of the claim requests, which was admissible, was to be found allowable within the meaning of Article 123(2) and (3) and Article 84 EPC.

VII. As a response to the board’s communication the patentee submitted an amended auxiliary request 6 with its letter of 27 October 2014.

VIII. Oral proceedings scheduled for 11 November 2014 had to be cancelled.

IX. A summons to attend oral proceedings on 29 June 2015 was sent on 7 April 2015.

X. With a letter dated 15 May 2015 the appellant maintained its main request and submitted four further auxiliary requests numbered I, II, III and X. Furthermore, it requested that the pending auxiliary requests 1 to 6 be renumbered IV to IX, respectively. The appellant stated that if auxiliary requests I to III and X were admitted into the proceedings, it intended to withdraw some of the already pending requests.

The appellant also mentioned that if deemed necessary it would present arguments in support of novelty and inventive step at the oral proceedings.

XI. With a letter dated 21 May 2015 the respondent requested that auxiliary request 6 filed with letter of 27 October 2014 not be admitted.

XII. With a letter dated 12 June 2015 the respondent requested that auxiliary requests I to III and X filed with the letter of 15 May 2015 not be admitted into the proceedings.

XIII. The respondent agreed with the board's previously expressed intention to remit the case to the first instance on the basis of any formally allowable request. It further requested that the board confirm its earlier intention to remit the case for novelty and inventive-step assessment.

XIV. The board sent a communication dated 18 June 2015 in order to inform the parties that it did not intend to discuss novelty and inventive step at the oral proceedings on 29 June 2015.

XV. Oral proceedings were held on 29 June 2015. At the oral proceedings the appellant withdrew its auxiliary requests II and IV to VI. As regards auxiliary request I, it expressed its wish to withdraw it after the board had already announced that it was not admitted into the proceedings. Therefore, it was no longer possible to withdraw it.

XVI. Claim 1 of the main request is identical to claim 1 of the main request before the opposition division, since the main request filed with the statement of grounds of appeal is identical to the set of claims of the main request filed with the letter of 19 November 2009.

Claim 1 of the main request reads as follows:

"1. LNAA supplement for treating by enteral administering a subject suffering from phenylketonuria and/or phenylalanemia consisting of Tyr, Trp, Met, iLeu, Thr, Val, Leu and Lys, optionally basic amino acids selected from Arg and His, wherein the LNAA supplement is substantially free from phenylalanine and wherein the weight ratio of Leu to iLeu is greater than 0,5:1, and the weight ratio of Leu to Val is greater than 2:1, and optionally suitable additives in the form of vitamins, minerals, excipients, diluents, carriers, granulating and disintegrating agents, binding agents, lubricating agents, wetting agents and /or preservatives".

Claim 1 of auxiliary request I reads as follows:

"1. LNAA supplement for treating by enteral administering a subject suffering from phenylketonuria and/or phenylalanemia consisting of the LNAAs Tyr, Trp, Met, iLeu, Thr, Val and Leu, optionally basic amino acids selected from Arg and His, and which supplement further comprises Lys, wherein the LNAA supplement is substantially free from phenylalanine and wherein the weight ratio of Leu to iLeu is greater than 0,5:1, and the weight ratio of Leu to Val is greater than 2:1 and optionally suitable additives in the form of vitamins, minerals, excipients, diluents, carriers granulating and disintegrating agents, binding agents, wetting agents and/or preservatives".

Claim 1 (sole claim) of auxiliary request III reads as follows:

"1. LNAA supplement for treating by enteral administering a subject suffering from phenylketonuria and/or phenylalanemia consisting of LNAAs Tyr, Trp, Met, iLeu, Thr, Val and Leu, optionally basic amino acids selected from Arg and His, and which supplement further comprises Lys, wherein the LNAA supplement is substantially free from phenylalanine and wherein the weight ratio of Leu to iLeu is greater than 0,5:1, and the weight ratio of Leu to Val is greater than 2:1".

Claim 1 of auxiliary request VII reads as follows:

"1. LNAA supplement for treating by enteral administering a subject suffering from phenylketonuria and/or phenylalanemia consisting of per 500 mg of LNAA supplement

from about 100 mg to about 290 mg of Tyr;

from about 25 mg to about 75 mg of Trp;
from about 15 mg to about 50 mg of Met;
from about 15 mg to about 55 mg of iLeu;
from about 15 mg to about 50 mg of Threo;
from about 15 mg to about 55 mg of Val;
from about 15 mg to about 200 mg Leu;
from about 10 mg to about 30 mg of His; and
from about 5 mg to about 200 mg of Lys,
and optionally the basic amino acid Arg,

wherein the weight ratio of Leu to iLeu is greater than 0,5:1, and the weight ratio of Leu to Val is greater than 2:1, and optionally suitable additives in the form of vitamins, minerals, excipients, diluents, carriers, granulating and disintegrant agents, binding agents, lubricating agents, wetting agents and/or preservatives".

Claim 1 of auxiliary request VIII reads as follows:

"1. LNAA supplement for treating by enteral administering a subject suffering from phenylketonuria and/or phenylalanemia consisting of per 500 mg of LNAA supplement

from about 100 mg to about 290 mg of Tyr;
from about 25 mg to about 75 mg of Trp;
from about 15 mg to about 50 mg of Met;
from about 15 mg to about 55 mg of iLeu;
from about 15 mg to about 50 mg of Threo;
from about 15 mg to about 55 mg of Val;
from about 15 mg to about 200 mg Leu;
from about 10 mg to about 30 mg of His; and
from about 5 mg to about 200 mg of Lys,

wherein the weight ratio of Leu to iLeu is greater than 0,5:1, and the weight ratio of Leu to Val is greater than 2:1, and optionally suitable additives in the form of vitamins, minerals, excipients, diluents, carriers, granulating and disintegrant agents, binding agents, lubricating agents, wetting agents and/or preservatives".

Claim 1 of auxiliary request IX reads as follows:

"1. LNAA supplement for treating by enteral administering a subject suffering from phenylketonuria and/or phenylalanemia consisting of 195 mg Tyr, 51 mg Trp, 32 mg Met, 35 mg iLeu, 32 mg Thr, 35 mg Val, 80 mg Leu, 20 mg His and 20 mg Lys, and optionally suitable additives in the form of vitamins, minerals, excipients, diluents, carriers, granulating and disintegrating agents, binding agents, lubricating agents, wetting agents and/or preservatives".

Independent claim 2 of auxiliary request IX reads as follows:

"2. LNAA supplement for treating by enteral administering a subject suffering from phenylketonuria and/or phenylalanemia consisting of 195 mg Tyr, 51 mg Trp, 32 mg Met, 35 mg iLeu, 32 mg Thr, 35 mg Val, 130 mg Leu, 30 mg Arg and 30 mg Lys, and optionally suitable additives in the form of vitamins, minerals, excipients, diluents, carriers, granulating and disintegrating agents, binding agents, lubricating agents, wetting agents and/or preservatives"

Auxiliary request X contains only two independent claims. Claim 1 of auxiliary request X reads as follows:

"1. LNAA supplement for treating by enteral administering a subject suffering from phenylketonuria and/or phenylalanemia consisting of
195 mg L-Tyr,
51 mg L-Trp,
32 mg L-Met,
35 mg L-iLeu,
32 mg L-Thr,
35 mg L-Val,
80 mg L-Leu,
20 mg L-His, and
20 mg Lys".

Claim 2 of auxiliary request X reads as follows:

"2. LNAA supplement for treating by enteral administering a subject suffering from phenylketonuria and/or phenylalanemia consisting of
195.0 mg L-Tyr,
51.0 mg L-Trp,
32.0 mg L-Met,
35.0 mg L-iLeu,
32.0 mg L-Thr,
35.0 mg L-Val,
130.0 mg L-Leu,
30.0 mg L-His,
30.0 mg L-Arg and
20 mg Lys".

XVII. The respondent's arguments, as far as relevant for the present decision, may be summarised as follows:

a) Main request; added matter

The language of claim 1 of the main request was not present in the application as filed. There were three main issues why claim 1 of the main request contained added subject-matter (Articles 100(c) and 123(2) EPC):
(i) the replacement of the expression "comprising" by the expression "consisting of" ("consisting of" meaning that nothing else could be present)
(ii) multiple selections
(iii) features broadened as compared to the application as filed.

As regards the first point, the respondent mentioned that the appellant had cited in the letter of 15 May 2015 decisions T0457/98 of 6 February 2001 and T0425/98 of 12 March 2002. However, these decisions were old case law and did not reflect the developments over recent years shown in the seventh edition of the book Case Law of the Boards of Appeal of the European Patent Office, 2013, page 410. The respondent cited decision T0759/10 of 22 March 2012.

The respondent further submitted that the appellant's arguments about common general knowledge in relation to Prekunil were not reflected by the application as filed. The skilled person would not read the description on page 7, lines 24 to 33 as excluding the presence of other components. This passage did not disclose a "closed" list for the LNAAs to be present. In fact, not only the naturally forthcoming LNAAs were possible, also synthetically LNNAs (page 17, lines 29 to 31).

In order to arrive at the subject-matter of claim 1 of the main request the skilled person had to perform at least three selections from three different sources, disclosed as separate aspects in the description of the

application as filed, namely the selection of seven LNAAs from page 7 leaving out phenylalanine, selection of the aspect on page 11, lines 11 to 16, picking one of the possible options encompassed by this aspect (from page 11 to page 13, lines 10 to 11) and the list of the optional additives to be present, which was not identical to the list of additives on page 7, last paragraph. Some of the additives on page 18 concerned specific dosage forms such as tablets, others concerned syrups and elixirs. The respondent further mentioned that the appellant had also cited, in order to support a more generous approach to the requirements of Article 123(2) EPC (see written submissions of 15 May 2015), the board of appeal decision T0667/08 of 20 April 2012, but that decision had no bearing to the present case. Moreover, there was a body of jurisprudence about the lack of allowability of selections from several lists.

A "closed" list of eight LNAAs was not disclosed on page 7 and the two provisos stated in claim 1 to define the weight ratios were not disclosed as preferred embodiments but as possibilities among many other options.

The result of using the expression "consisting of" in claim 1 of the main request was that the claim defined a complete LNAA supplement, including not only seven LNAAs but also Lys, Arg, His and excipients and additives. The language "consisting of" was nowhere in the application as filed. Even if the skilled person considered the information concerning Prekunil, Prekunil was a very specific product containing the specific components in specific amounts and ratios. Therefore, there was an unallowable generalisation since the definitions of the claimed composition were broader than that in example 2.

b) Admission of auxiliary requests I, III, VIII, IX and X

Auxiliary request I should not be admitted into the proceedings since it had been filed very late, more than one year after the communication pursuant to Article 15(1) RPBA. Claim 1 had been reformulated and was not clearly allowable; there was a shift of scope. The amendments were not occasioned by a ground for opposition (Rule 80 EPC). The appellant had not given in its written submissions any justification for the late filing. The respondent raised analogous objections against the admission of auxiliary request III. Rule 80 EPC did not allow amendments to tid up the claim's drafting.

As regards the admission of auxiliary request VIII the respondent referred to its written submissions. It objected to its admission was objected because the mere cancellation of an optional component (namely Arg) could not overcome the objections of added subject-matter against auxiliary request VII and did not address any ground for opposition.

As regards auxiliary request IX, the request could have been filed earlier. The request should not be admitted since it was not clearly allowable under Article 123(2) EPC.

As regards auxiliary request X, it could have been filed earlier. Moreover, it was *prima facie* not allowable since the examples could not be taken as a basis. If SuppM2 in Table 5 was a "closed" composition ("consisting of"), then Prekunil, appearing in the same

table, had to be a "closed" composition. However, this was not the case since it contained additives and excipients.

c) Auxiliary requests VII to X

As regards auxiliary request VII, the respondent raised objections under Articles 84 and Article 123(3) EPC on the grounds of lack of clarity of claim 1. It also objected to the claim under Article 123(2) EPC (in view of the combination of features and the multiple selections). The expression "consists of" concerned the whole supplement and not only the amino acids content.

Analogous objections applied to claim 1 of auxiliary request VIII.

As regards auxiliary request IX, the list of amounts of amino acids in claim 1 was taken from SuppM2 in Table 5. The list of constituents of the supplements in Table 5 was not complete, for the reasons already expressed in relation to Prekunil. The amino acids in human milk related to the list of amino acids but did not concern a list of all components including additives and excipients. However, the disclosure in the application as filed defined different additives and excipients depending on the dosage form to be administered (page 18 of the application as filed). Moreover, the stereochemistry of the amino acids was defined in the examples as being the L-form. Hence, auxiliary request IX contained added matter.

As regards auxiliary request X, it derived from SuppM2 and SuppM3 in the examples, but there was no mention of the "closed" language in claims 1 and 2 ("consisting of").

XVIII. The appellant's arguments, as far as relevant for the present decision, may be summarised as follows:

a) Main request; added matter

The patent was granted in July 2008. Claim 1 of the main request was a purpose-limited product claim falling within the transitional provisions under Article 7 of the Act revising the EPC. Board of appeal decisions T0457/98 and T0425/98 did not represent old case law for the amendment concerning the expression "consisting of". Moreover, claim 1 derived from claim 6 as originally filed, which was drafted as a claim directed to a method of treatment, since the application had been filed as a PCT application with claims drafted in US style. The Enlarged Board of Appeal decision G 2/08, OJ EPO, 456, did not mention any requirement for a *verbatim* support when redrafting medical use claims.

Claim 6 which requiring the presence of lysine had to be understood together with the disclosure on page 7, last paragraph, of the application as filed, which had to be read as explicitly giving a list of eight specifically mentioned LNAAs and their combinations of two, three, etc., eight being the upper limit, since one could combine all eight LNAAs ("more than six"). The skilled person would look through the description and in particular would consider example 2, where Prekunil, SuppM1 and SuppM2 were given in Table 5 and SuppM3 in Table 7. None of them contained phenylalanine (Phe).

Thus, the skilled person would derive the technical information that the invention relied upon the presence

of seven LNAAs, together with lysine as in claim 6 as originally filed, and that phenylalanine was absent. Furthermore, the appellant cited *inter alia* claims 8 and 11 to 16 as originally filed.

At the effective date of filing Prekunil (which this year was about thirty years old) was the only commercial product for phenylketonuria (PKU). Thus, the amino acid content of Prekunil belonged to the general knowledge of the skilled person and it was acknowledged in the application as filed.

The respondent's objection in relation to the presence of additives had not been put forward during the written proceedings. The definitions were in accordance with pages 17 and 18 of the application as filed.

The subject-matter in claim 1 of the main request derived from claim 6 as originally filed and the general disclosure. The evolution of the general knowledge was acknowledged in the description of the application as filed, the product Prekunil (with seven LNAAs) was the starting point (page 30, last two lines), the presence of Lys and the boosting of Leu were the characteristics of the claimed invention (example 2). The two provisos could not be deleted in view of Article 123(3) EPC. The weight ratio Leu to Val 2:1 was the more important proviso.

b) Admission of auxiliary requests I, III, VIII, IX and X

The reason for the late filing of auxiliary requests I and III was the revision of the case in preparation of the oral proceedings to be held on 29 June 2015. The amendments introduced in auxiliary request I

represented an attempt to overcome the objections under Article 100(c) EPC against claim 1 of the main request.

As regards auxiliary request III, the patentee had tried to pre-empt any possible objections to the presence of additives or excipients. Moreover, auxiliary request III had only one claim in order to overcome any possible objection to the dependent claims. The basis for claim 1 of auxiliary request III was claims 6 to 16 as originally filed and the general description.

Auxiliary request VIII was not late-filed and the amendments concerned an attempt to overcome the reasons set out against the main request in the opposition division's decision.

Auxiliary request IX had been filed as a direct reply to the board's communication pursuant to Article 15(1) RPBA. Auxiliary request IX corresponded to a corrected version of auxiliary request 6 filed with the grounds of appeal. A typing error in claim 2 had been corrected and some claims had been deleted. Admission of auxiliary request IX did not put any burden on the respondent.

Auxiliary request X had been filed as an attempt to address all issues and overcome all thinkable objections. Table 5 was absolutely clear. There was a complete list of total amino acids content, Table 5 conveyed absolute and relative amounts (ratios) for the amino acids present. No excipients were mentioned since they did not concern active ingredients. The same applied to Table 7.

c) Auxiliary requests VII to X

Claim 1 of auxiliary request VII derived directly from the incorporation of dependent claim 7 as granted into claim 1 as granted. A discussion about the requirements of Article 84 EPC was outside the scope of the appeal (see Enlarged Board of Appeal decision G 3/14 of 24 March 2015). Moreover, the subject-matter claimed found its basis in the description of the application as filed (page 13, line 15 to page 14, line 7). The expression "includes" (in the description) allowed the interpretation "consisting of" for the claim. The reason for the word "includes" in the description was that the composition could be substantially free from Phe and include Arg.

The arguments for auxiliary request VII applied *mutatis mutandis* to auxiliary request VIII (particular embodiment on page 13, and Arg was no longer present).

As regards auxiliary request IX, claims 1 and 2 derived from the examples in Tables 5 and 7. They were designed, as stated on page 31, from Prekunil by increasing the levels of Leu and Lys. The additives were mentioned on pages 17 and 18 of the application as filed. The core of the invention was the active ingredients.

Auxiliary request X, claims 1 and 2, corresponded to SuppM2 and SuppM3 of the examples.

XIX. The following requests are on file:

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the main request filed with the grounds of appeal, or,

alternatively, on the basis of one of auxiliary requests I and III, filed with letter of 15 May 2015, or, alternatively, on the basis of one of auxiliary requests VII to IX, filed as auxiliary requests 4 and 5 with the grounds of appeal and as amended auxiliary request 6 with letter of 27 October 2014, or, alternatively, on the basis of auxiliary request X filed with letter of 15 May 2015.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Main request; added subject-matter

Claim 1 of the main request concerns a purpose-limited product claim within the meaning of Article 54(5) EPC 2000 which relates to a multiple component composition for the specific use "treatment by enteral administering a subject suffering from phenylketonuria and/or phenylalanemia" (i.e. for a use in a method referred to in Article 53(c) EPC). The claim specifies the active ingredients which exert their function in the treatment of phenylketonuria and/or phenylalanemia) as a "closed" list of seven large neutral amino acids (LNAAs), together with lysine, and optionally containing the basic amino acids Arg and/or His.

The "closed" list of the seven LNAAs includes: Tyr, Trp, Met, iLeu, Thr, Val and Leu (the claim explicitly establishes that the LNAA supplement is free of phenylalanine). Claim 1 of the main request further requires that the relative proportions in which the active ingredients are present have to fulfil two

conditions, namely that the weight ratio of Leu to iLeu is greater than 0,5:1 and that the weight ratio of Leu to Val is greater than 2:1.

When assessing whether or not the subject-matter of a claim infringes Article 123(2) EPC (i.e. contains added subject-matter within the meaning of Article 100(c) EPC) one has to examine whether the subject-matter is, be it explicitly or implicitly, directly and unambiguously disclosed, to the skilled person using common general knowledge, in the application as filed.

Determining whether or not that is the case requires a technical assessment of the overall technical circumstances of the individual case under consideration. In particular, it is to be assessed whether the claim incorporates technical information which the skilled person would not have objectively derived from the application as filed. Thus, the findings in the technical board of appeal decisions cited by the opposition division and the parties during appeal proceedings in relation to added subject-matter and the dispute concerning the expressions "comprising" and "consisting of" cannot be directly applied to the present case since its circumstances (*inter alia* a purpose-limited product claim under Article 54(5) EPC 2000; characteristics of the generic and specific disclosure) are different from those of the cases underlying said decisions.

Claim 1 of the main request has no *verbatim* counterpart in the application as filed. The application as filed (WO 2005/016330), which is written in the US style, defines the invention on the one hand as relating to three separate options for methods of treatment of a subject suffering from phenylketonuria and/or

phenylalanemia (page 6, lines 6 to 10; lines 11 to 16; and lines 17 to 22) and on the other hand as relating to products *per se*, concerning three basic options for minimum requirements of the alternative components in LNAA supplements (page 6, lines 23 to 25; lines 26 to 28; and lines 29 to 31).

The products, LNAA supplements, are defined under the heading "Detailed description of the invention" (paragraph bridging pages 7 and 8 of application as filed) as referring to "any composition which includes, at a minimum, **one or more** large neutral amino acids, **such as** Phe, Leu, Tyr, Trp, Met, iLeu, Val and Threo. The LNAA supplement **can optionally include other components**, such as basic amino acids (e.g., Arg, His, Lys, etc.) and/or **other amino acids**, vitamins, minerals, binders, diluents, dispersing agents, and other excipients. Illustratively, the LNAA supplement can include one, two, three, four, five, six or more than six large neutral amino acids. The LNAA supplement can be substantially free from one or more specified amino acids, as in the case, for example, where the LNAA supplement is substantially free from amino acid Z" (emphasis added).

This passage does not specifically disclose products in which the **seven specific LNAAs** recited in claim 1 are simultaneously present, and which are free of phenylalanine. Moreover, this passage does not point to the option which concerns the mandatory presence of the amino acid lysine, which is merely listed as one among three possible basic amino acids which may or may not be present. Additionally, the generally disclosed products in the passage cited above are not linked to a specific medical use, which, as can be seen from the paragraph bridging pages 8 and 9, may relate to the

treatment of humans suffering from several metabolic disorders, among which are mentioned tyrosinemia or alkaptonuria (see page 9, first paragraph). Thus, the products on page 7 are not exclusively disclosed as addressing subjects suffering from phenylketonuria or phenylalanemia. Therefore, there is no explicit disclosure in the general description of the application as filed of a product for use in the treatment of phenylketonuria and/or phenylalanemia which necessarily contains the seven LNAAs recited in claim 1 of the main request together with Lys.

For the sake of argument, it can be assumed that when tailoring a product according to the general disclosure under the heading "Detailed description of the invention" for the treatment of a subject suffering from phenylketonuria and/or phenylalanemia, the skilled person would implicitly understand that phenylalanine should not be present. However, a product for the treatment of these specific disorders (as stated in claim 1 of the main request) which contains the seven LNAAs explicitly listed together with Lys is not directly and unambiguously disclosed on pages 7 and 8. The general description does not disclose either that the product for the treatment of phenylketonuria and/or phenylalanemia has to contain the seven LNAAs specifically listed in claim 1, and Lys, and has to simultaneously fulfil the two conditions concerning the weight ratios Leu to iLeu, and Leu to Val.

Independent claim 6 as originally filed relates to a method for treating a subject suffering from phenylketonuria and/or phenylalanemia, said method comprising: enterally administering to the subject an LNAA supplement which comprises one or more LNAAs and which further comprises Lys. It can be accepted that

the supplement in claim 6 is one falling within the general definitions on pages 7 and 8 of the application as filed, but the option concerning the mandatory presence of the seven LNAAs specified in claim 1 of the main request is not singled out. In fact, claim 6 of the originally filed set of claims is followed by several claims (e.g. claims 7 to 12, 15) which individually and directly refer to claim 6 and reflect separate options for the content of LNAA supplement (*inter alia*, presence of Leu, presence of Leu and iLeu in a certain weight ratio, presence of Leu and Val in a certain weight ratio, or presence of Leu, iLeu and Val in certain weight ratios, etc.). None of these claims (or combination of claims) mentions the simultaneous presence of the seven LNAAs as defined in claim 1 of the main request, together with the two provisos which derive from the combination of claims 12 and 14 of the set of claims as originally filed.

A detailed inspection of the description further supports the view that products for use in a method of treatment of phenylketonuria and/or phenylalanemia wherein the conditions concerning the weight ratio of Leu to Val being greater than 2:1 and of Leu to iLeu being greater than 0,5:1 simultaneously apply, and wherein the seven LNAAs specifically mentioned in claim 1 are mandatorily present, are not specifically disclosed nor are they singled out. The product "which includes one or more LNAAs and which further includes Lys" is disclosed on page 11, lines 11 to 16; this product may further include Leu ("this aspect of the present invention can be one which includes Leu"). Furthermore, it is implicitly derivable that it may include iLeu and Val in order that the weight ratios stated on page 12, lines 28 to 33 apply. However, there is no explicit or implicit disclosure in the

application as filed from which can be unambiguously derived the product in which the active ingredients are the seven LNAAs (together with Lys) fulfilling the two specifically defined minimum weight ratios ("greater than") appearing in claim 1 of the main request for the particular uses.

The embodiments on pages 13 and 14 of the application as filed, which refer to particular compositions wherein the amounts of amino acids are defined as ranges of amounts expressed in mg "per 500 mg of LNAA supplement" or "per 600 mg of LNAA supplement", respectively, are not linked to the condition that the specific weight ratios of Leu to iLeu and Leu to Val as expressed in claim 1 of the main request have to be fulfilled.

A further inspection of the experimental part starting under the heading "Examples" on page 23 shows the following. The content on pages 27, 28 and the first paragraph of page 29 relates to an analysis of the background knowledge in relation to different hypotheses underlying the options generally known from the prior art to address *inter alia* the treatment of phenylketonuria (PKU), one of them concerning the commercial product Prekunil (page 29, first paragraph). Prekunil is acknowledged at the end of page 30 as the "LNAA supplement currently used for PKU treatment", and it is mentioned that it is "based on the amino acid makeup of human milk", as "shown in Table 5" (page 31, line 1).

Table 5 reproduces the total amino acid content of Prekunil, SuppM1 and SuppM2 which results from the addition of the absolute amounts of the specific amino acids present, expressed as mg (and as mmol

equivalent). The stereochemistry of all the amino acids present is the L-form. Furthermore, it can be seen from the table that SuppM1 does not fall within claim 1 of the main request in view of the absence of lysine. Additionally, Prekunil contains the seven LNAAs: L-Tyr, L-Trp, L-Met, L-iLeu, L-Thr (or L-Threo), L-Val and L-Leu; however, Prekunil does not fulfil the condition that the weight ratio of Leu to Val is greater than 2:1. Prekunil further contains L-His and L-Arg. Therefore, the skilled person would not directly and unambiguously derive the weight ratio requirements as expressed in claim 1 of the main request from his knowledge about the actual amino acid content of the Prekunil product.

As regards SuppM2, it contains the seven LNAAs mentioned for Prekunil. SuppM2 further contains L-Lys and does not contain L-Arg. The specific weight ratio Leu to Val is 2.28:1 and the specific weight ratio Leu to iLeu is also 2.28:1. SuppM2 corresponds to an amino acid composition which is the result of increasing the levels of Leu and Lys in comparison to the Prekunil product (see page 31, lines 6 and 7 of the application as filed). However, the specific weight ratio Leu to iLeu is much greater than that expressed as the minimum weight ratio to be fulfilled for Leu to iLeu (it is much greater than 0,5:1). Similarly, the specific SuppM3 in Table 7 contains the seven LNAAs of SuppM2, L-Lys and L-His, together with L-Arg. The weight ratio Leu to Val is 3.71:1, and the weight ratio Leu to iLeu is also 3.71:1, so the weight ratio Leu to iLeu is much greater than the ratio expressed in claim 1 as minimum requirement (greater than 0,5:1). Correspondingly, the skilled person knows from the application as filed about specific values of absolute and relative amounts of LNAAs present as active ingredients in the

composition, but he would not be able to directly and unambiguously derive from the specific examples (SuppM2 and SuppM3) the two minimum weight ratio conditions (i.e. weight ratio Leu to iLeu and Leu to Val) to be simultaneously fulfilled by the LNAA supplement for the medical use appearing in claim 1.

Therefore, claim 1 of the main request contains added subject-matter which concerns the technical information relating to the choice of the seven LNAAs **and** the fulfillment of the two specific weight ratio conditions (for Leu to iLeu and for Leu to Val), together with the presence of Lys, for the medical use specified in the claim.

The description as a whole does not teach that the optional suitable additives mentioned in claim 1 of the main request have a bearing on the medical use disclosed. Hence, the possible presence of the optional additives in claim 1 does not change the conclusion reached above in relation to added subject-matter for the purpose-limited claim 1.

Consequently, the main request fails since claim 1 contains added subject-matter (Articles 100(c) and 123(2) EPC).

3. Admission of auxiliary request I and III

3.1 Auxiliary requests I and III were both filed with the letter of 15 May 2015, i.e. long after the opponent's reply to the statement of grounds of appeal and some time after the board's communication dated 7 April 2015.

The amendment made in claim 1 of auxiliary request I diverges from those introduced in the auxiliary requests previously on file (i.e. auxiliary requests 1 to 6 filed with the grounds of appeal) in that it introduces the alternative words "consisting of the LNAAs" and "and which supplement further comprises". These amendments attempt to address objections which were already raised in opposition proceedings and which were maintained by the respondent in its reply to the statement of grounds of appeal. Therefore, the lateness of their filing cannot be justified merely in terms of the need to prepare the oral proceedings to be held on 29 June 2015.

Additionally, claim 1 of auxiliary request I is *prima facie* unallowable since it does not overcome the objections of added subject-matter in respect of claim 1 of the main request.

Consequently, auxiliary request 1 was not admitted into the proceedings (Articles 12 and 13 RPBA).

3.2 Claim 1 of auxiliary request III differs from claim 1 of auxiliary request I in that the optionally suitable additives have been deleted. Therefore, the reasons given in relation to auxiliary request I apply by analogy to auxiliary request III, since the amendments diverge from those in the auxiliary requests previously on file and they do not overcome all the objections of added subject-matter against claim 1 of the main request.

Consequently, auxiliary request III was not admitted into the proceedings.

4. Admission of auxiliary requests VII, VIII and IX

4.1 Auxiliary request VII was filed as auxiliary request 4 with the statement of grounds of appeal. Its admission has not been objected to by the respondent and the board sees no reasons not to admit it into the proceedings.

4.2 Auxiliary request VIII was filed as auxiliary request 5 with the statement of grounds of appeal. This request was filed, as was the case of auxiliary request 4 (now auxiliary request VII), in order to overcome the opposition division's findings that claim 1 of the main request contained added subject-matter. In order to examine whether the requirements of Rule 80 EPC are fulfilled, the amendments introduced in the claim have to be compared with the claims of the set of claims as granted. Such comparison shows that auxiliary request VIII relates is an attempt to address the ground for opposition under Article 100(c) EPC. The fact that there is only a small difference between claim 1 of auxiliary request VIII and claim 1 of auxiliary request VII is due to the definition of the embodiment on page 13 of the application as filed, which does not specifically mention Arg. Therefore, the amendment is aimed at bringing the claim closer to that embodiment.

Correspondingly, auxiliary request VIII is admitted into the proceedings.

4.3 Auxiliary request IX was filed as amended auxiliary request 6 with the letter of 27 October 2014.

In the communication pursuant to Article 15(1) RPBA (which was sent on 14 April 2014) the board had drawn attention to a typing error in claim 2 of auxiliary request 6 filed with the statement of grounds of

appeal. This error was corrected in the amended auxiliary request 6 (now auxiliary request IX). In said communication the board also pointed out a major inconsistency between claim 1 and dependent claims 8 and 9 (Article 84 EPC). The appellant deleted these two dependent claims as a direct response to the board's objections. Moreover, the amendments introduced in auxiliary request VII, when compared to auxiliary request 6 filed with the statement of grounds of appeal, are clear and easy to deal with.

Therefore, auxiliary request IX is admitted into the proceedings.

5. Auxiliary requests VII and VIII; added subject-matter

5.1 Claim 1 of auxiliary request VII derives from the incorporation of dependent claim 7 as granted into claim 1 as granted. Since Article 100(c) EPC is a ground for opposition in the present case, a full assessment of added subject-matter has to be made.

The analysis made above of the disclosure in the application as filed in relation to the main request applies *mutatis mutandis* to auxiliary request VII, since there is no basis (either explicit or implicit) in the application as filed for the combination of the embodiment disclosed on page 13, lines 18 to 26 with the condition expressed by the two provisos in claim 1 in relation to the weight ratios Leu to iLeu and Leu to Val.

Therefore, claim 1 of auxiliary request VII contains added subject-matter (Articles 100(c) and 123(2) EPC).

5.2 Claim 1 of auxiliary request VIII differs from claim 1 of auxiliary request VII only in the deletion of the optional presence of the basic amino acid Arg. Therefore, the reasons given for auxiliary request VII directly apply to auxiliary request VIII, which cannot be allowed since it contains added subject-matter (Articles 100(c) and 123(2) EPC).

6. Auxiliary request IX; added subject-matter

6.1 In claim 1 of auxiliary request IX the specific amounts of the seven LNAAs and the specific amounts of His and Lys are defined. Moreover, claim 1 includes the definitions of suitable additives which may be present. The specific amounts for the amino acids have been taken from SuppM2 in Table 5, page 31 of the application as filed. The stereochemistry of the amino acids disclosed in SuppM2 is the L-form, which is not mentioned in claim 1 of auxiliary request IX, and SuppM2 is not disclosed in the application as filed together with the additives mentioned in claim 1 of auxiliary request IX. In fact, the dosage form in which the specific SuppM2 is administered is not disclosed in the examples. Some of the additives listed in claim 1 of auxiliary request IX are disclosed on page 18 of the application as filed only in connection with particular dosage forms. Therefore, claim 1 of auxiliary request IX relates to an unallowable generalisation of the specific embodiment on page 31.

Analogous reasons apply to independent claim 2 and SuppM3 on page 35 of the application as filed.

6.2 Consequently, auxiliary request IX fails since it contains added subject-matter (Article 123(2) EPC).

7. Auxiliary request X

7.1 Auxiliary request X is *prima facie* allowable since it overcomes all the objections pursuant to the ground for opposition under Article 100(c) EPC; not only those put forward in writing during appeal proceedings but also those raised for the first time at the oral proceedings before the board, in particular also those raised *ex officio* by the board. Thus, the date of filing of said request (15 May 2015) does not preclude as such its admission, but has to be weighed up against the other relevant factors in the particular circumstances of the present case. In fact the request, which corresponds to the most limited option possible in the light of the content of the application as filed, was filed as a last resort when preparing the oral proceedings to be held on 29 June 2015, in order to pre-empt any further possible objections of added subject-matter, and was not presented only at the end of a full discussion about added subject-matter at the oral proceedings before the board.

Auxiliary request X was filed more than one month in advance of the oral proceedings and the board had announced that it intended to remit the case to the department of first instance for the discussion of novelty and inventive-step issues if it came to a positive conclusion in relation to Article 123(2) and (3) EPC (see board's communication of 18 June 2015). Thus, the respondent had enough time to prepare for the limited discussion of added matter in relation to auxiliary request X and thus it could be reasonably expected to deal with this request without adjournment of the oral proceedings. Moreover, since the respondent had agreed with the board's intention to remit the case to the department of first instance and had even

insisted on confirmation from the board, procedural economy and the prospect that the opposition proceedings would have to continue was of no relevance in the exercise of discretion in relation to the admission of this auxiliary request.

Auxiliary request X converges and does not diverge from the amendments in auxiliary request IX (filed as corrected auxiliary request 6) to delimited claims restricted to the examples.

Therefore, auxiliary request X was admitted into the proceedings.

7.2 Auxiliary request X contains two independent claims drafted as purpose-limited product claims concerning the specific amino acid compositions disclosed as SuppM2 on page 31 and SuppM3 on page 35. Therefore, the product for which protection is sought is limited to the medical use "for treating by enteral administering a subject suffering from phenylketonuria and/or phenylalanemia". The multiple component composition is defined by its total amino acid content according to SuppM2 and SuppM3, respectively. As can be directly and unambiguously derived from the content of the application as filed, the LNAA supplements (also SuppM2 and SuppM3) are to be administered by enteral administration. Additionally, the experimental part of the application as filed shows that said specific amino acid supplements in the examples were developed for the treatment of the metabolic disorders mentioned in claims 1 and 2. Claims 1 and 2 specify as purpose-limited claims the complete amino acids content ("consist of") to which the medical indication is to be attributed. In this context, the discussion about the possible presence of excipients which may be used to

form a dosage unit form is purely academic. The claim's language has to be technically and meaningfully assessed within the framework of Article 54(5) EPC 2000. The description of the application as filed allows the claim's wording, since the total amino acids content in Tables 5 and 7 corresponds to a total list of active ingredients developed for the purpose stated in the claims.

Consequently, the subject-matter claimed in claims 1 and 2 of auxiliary request X meets the requirements of Article 123(2) EPC.

Moreover, the subject-matter in claims 1 and 2 of auxiliary request X is encompassed by granted claim 1, since the weight ratios Leu to iLeu and Leu to Val in both SuppM2 and SuppM3 fall within the definitions given in claim 1 as granted. Therefore, the requirements of Article 123(3) EPC are also met.

8. Remittal under Article 111(1) EPC

The opposition division's decision only concerns the ground for opposition under Article 100(c) EPC.

Since auxiliary request X, filed during appeal proceedings, is found allowable in this respect, the board considers that it is essential in the present case, where the written appeal case dealt mainly with the issue of added subject-matter, to allow two instances especially for the substantive assessment of the grounds for opposition under Article 100(a) EPC, novelty and inventive step.

Thus, the board makes use of its discretionary power and remits the case to the department of first instance

for further prosecution on the basis of auxiliary request X (Article 111(1) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of auxiliary request X.

The Registrar: The Chairman:

N. Maslin U. Oswald

Decision electronically authenticated