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Datasheet for the decision of 21 October 2014

Case Number: T 1748/10 - 3.3.07

Application Number: 04748592.5

Publication Number: 1633377

IPC: A61K33/32, A61K33/00, A61P3/02, A61P17/02, A61K31/198, A23L1/29, A23L1/305, A23L1/302, A23L1/304

Language of the proceedings: EN

Title of invention:

A METHOD OF TREATING OR PREVENTING CHRONIC WOUNDS AND A COMPLETE NUTRITIONAL COMPOSITION COMPRISING GLYCINE AND/OR LEUCINE FOR USE THEREIN

Patent Proprietor:

N.V. Nutricia

Opponent:

Fresenius Kabi Deutschland GmbH

Headword:

Relevant legal provisions:

EPC Art. 54(2), 56

Keyword:
Availability to the public of commercial brochure (yes)
Novelty - Main request and first auxiliary request (no)
Inventive step - auxiliary requests 2 to 10 (no)

Decisions cited:
T 1140/09, T 0743/89

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

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Case Number: T 1748/10 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 21 October 2014

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Appellant: (Opponent)	Fresenius Kabi Deutschland GmbH Else-Krömer-Strasse 1 61352 Bad Homburg (DE)
Representative:	Weber, Martin Jones Day Prinzregentenstraße 11 80538 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 2 July 2010 concerning maintenance of the European Patent No. 1633377 in amended form.**

Composition of the Board:

Chairman	J. Riolo
Members:	A. Usuelli
	P. Schmitz
	D. Semino
	D. T. Keeling

Summary of Facts and Submissions

I. The appeals of the patent proprietor and the opponent lie from the decision of the opposition division, announced at the oral proceedings on 27 April 2010, concerning the maintenance of European patent No 1 633 377 in amended form.

The application from which the patent originated was filed on 19 May 2004 and claimed a priority date of 22 May 2003. The patent was granted with 17 claims. Independent claims 1 and 13 read as follows:

"1. Use of leucine in the preparation of a composition for use in a method for the treatment and/or prevention of pressure ulcers, pressure sores, decubiti ulcers and/or diabetic food ulcers, said method comprising enterally administering to a patient a serving of a composition wherein protein represents between 10 and 40% of the total caloric content of the composition; carbohydrate represents between 15 and 90% of the total caloric content of the composition; and wherein the protein provides between 1 and 5 grams leucine per serving, said serving providing between 150 and 400 kcal."

"13. A composition for enteral administration to patients wherein protein represents between 10 and 40% of the total caloric content of the composition; fat represents between 10 and 50% of the total caloric content of the composition; and carbohydrates represents (*sic*) between 15 and 80% of the total caloric content of the composition, said composition comprising

(i) between 4 and 20 mg leucine per kcal; and

(ii) between 2 and 32 mg glycine per kcal and/or between 3 and 32 mg proline per kcal."

II. The patent was opposed under Article 100(a), (b) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, the patent was not sufficiently disclosed, and its subject-matter extended beyond the content of the application as filed.

III. The documents filed during the opposition proceedings included the following:

D1: Brochure Fresenius Kabi "Protenplus®"
D2a: Sworn statement of Mr Michael Germroth
D2b: Sworn statement of Ms Jasmin Burgmer
D2c: Sworn statement of Ms Andrea Richter
D14: Invoice No. 1500591169 of 12 January 2001, Fresenius Kabi Deutschland

IV. The decision was based on three sets of claims filed during the oral proceedings as main request and as first and second auxiliary requests. The subject-matter of the relevant claims of these requests can be illustrated as follows:

a) Claims 1 and 13 of the main request were identical to the corresponding claims of the granted patent.

b) Claim 1 of the first auxiliary request differed from claim 1 of the granted patent in the addition of the feature: "...wherein the composition further comprises between 1 and 5 grams arginine per serving".

c) Claim 1 of the second auxiliary request differed from claim 1 of the granted patent in the addition

of the feature: "...,and wherein said composition further comprises between 1.5 and 8 grams proline and between 0.5 and 5 grams glycine per serving".

Claim 9 of the second auxiliary request differed from claim 13 of the granted patent in the requirements that the composition comprised both between 2 and 32 mg glycine per kcal and between 3 and 32 mg proline per kcal (i.e the expression "and/or" was replaced by "and").

V. The decision of the opposition division can be summarised as follows:

a) In the light of the evidence and specifically the testimony of the witnesses during the oral proceedings, it was considered that document D1 formed part of the state of the art under Article 54(2) EPC.

b) Document D1 disclosed an enteral formulation for wound healing containing *inter alia* 2.12 g lucine per serving (corresponding to 8.5 mg/Kcal), 0.4 g glycine per serving (corresponding to 1.6 mg/kcal) and 1.96 g proline per serving (corresponding to 7.85 mg/kcal). The disclosure of this document anticipated the subject-matter of claims 1 and 13 of the main request.

c) Document D1 was considered to represent the closest prior art for the assessment of inventive step of the first auxiliary request. The subject-matter of claim 1 differed from the disclosure of the closest prior art in view of a higher amount of arginine. There were no effects linked to this distinguishing feature. The technical problem was therefore

formulated as the provision of an alternative preparation for the treatment of chronic wounds. Providing an arbitrary change in the amount of one of the ingredients of the composition of D1 was regarded as a trivial activity for the skilled person. Hence, the subject-matter of claim 1 was obvious in view of the teaching of D1.

d) Document D1 was regarded as the closest prior art also in respect to the subject-matter of auxiliary request 2. The distinguishing feature of independent claims 1 and 9 was represented by the higher amount of glycine. Example 2 showed better protein kinetics for the compositions PGL as compared to the compositions PL. This improvement was to be attributed to the higher amount of glycine in the PGL compositions. Hence, the objective technical problem was formulated as the provision of an improved preparation for the treatment or prevention of chronic wounds. None of the prior-art documents suggested increasing the levels of glycine in order to solve this problem. The requirements of Article 56 EPC were therefore met.

VI. Both parties lodged an appeal against that decision. With the statement setting out the grounds of appeal the patent proprietor submitted the following document:

D26: Journal of Wound Care, (2004), 13, 8, 319-323

VII. In a letter dated 9 October 2014, the appellant-patent proprietor requested that the decision under appeal be set aside and that the opposition be rejected, or alternatively that the patent be maintained on the basis of auxiliary requests 1 to 10 filed therewith.

The subject-matter of the relevant claims of the auxiliary requests can be illustrated as follows:

a) Claim 13 of auxiliary requests 1 was identical to claim 13 of the granted patent.

b) Claim 13 of auxiliary requests 2, 3, 5 and claim 9 of auxiliary request 6 differed from claim 13 of the granted patent in the requirements that the composition comprised both between 2 and 32 mg glycine per kcal and between 3 and 32 mg proline per kcal (i.e the expression "and/or" was replaced by "and").

c) Claim 13 of auxiliary request 4 differed from claim 13 of the granted patent in the deletion of the feature "and/or between 3 and 32 mg proline per kcal".

d) Claim 1 of auxiliary request 7 was based on claim 1 of the granted patent with the addition of the following feature:

", wherein said composition further comprises between 1.5 and 8 grams proline and between 0.5 and 5 grams glycine per serving."

e) Claim 1 of auxiliary request 8 was based on claim 1 of auxiliary request 7 with the addition of the following feature:

", between 0.5 and 8 grams glutamine per serving and wherein the composition further comprises (i) between 2 and 100 mg iron per serving;

(ii) between 5 and 100 mg zinc per serving; and
(iii) between 200 — 2000 mg ascorbic acid per serving."

f) Claim 1 of auxiliary requests 9 and 10 differed from claim 1 of auxiliary request 7 in the indication that the protein provides per serving between 1.5 and 8 grams both of arginine and of glutamine and with the modification of the amount of glycine per serving from 0.5 to 5 grams to 0.5 to 8 grams.

VIII. Oral proceedings were held on 21 October 2014.

IX. As far as relevant for the present decision, the arguments of the appellant-opponent can be summarised as follows:

Claim 13 of the patent as granted and of auxiliary request 1 - Novelty - Public availability of document D1

The public availability of document D1 before the priority date was supported by the date printed on the brochure, by the invoice of document D14 and by the testimony of the witnesses. In the light of this collection of evidence, document D1 was to be considered as being part of the state of the art.

Claim 13 of auxiliary requests 2 to 5 and claim 9 of auxiliary request 6 - Inventive Step

The closest prior art was document D1. The composition disclosed in this document contained 1.6 mg glycine per Kcal, i.e. 0.4 mg per Kcal below the lower limit defined in claim 1. The amounts of the other components of the composition of D1 were included in the ranges defined in

the opposed patent. The patent did not contain any comparative data with the composition of D1, and there was no evidence of improvements associated with the higher amount of glycine. Furthermore, there was no clear relationship between the parameter "FSR - FBR" measured in example 2 of the patent and the wound-healing properties of the compositions. The technical problem was to be defined as the provision of an alternative nutritional composition. The solution was obvious in the light of the teaching of document D1, because the mere fact of adjusting the amount of glycine did not involve any inventive activity.

Claim 1 of auxiliary requests 7 and 8 - Inventive Step

Since the product of D1 was sold in a package of 200 ml, this amount represented the serving of the composition of D1. It could be calculated that the amounts of leucine and proline per serving in the composition of D1 were included in the ranges of the claims. The amount of glycine per serving was 0.4 g whilst the amount defined in the claim was between 0.5 g and 5 g. However, since there were no effects attributable to the increased amount of glycine, these claims too did not comply with the requirements of Article 56 EPC.

Claim 1 of auxiliary requests 9 and 10 - Inventive Step

The subject-matter defined in these claims differed from the disclosure of document D1 also on account of the amount of arginine per serving. Since the beneficial effects of arginine were disclosed only in post-published document D26, and the patent did not disclose any information with regard to the effects and the importance of this amino acid, these beneficial effects

should not be considered in the formulation of the technical problem.

X. As far as relevant for the present decision, the arguments of the appellant-patent proprietor can be summarised as follows:

Claim 13 of the patent as granted and of auxiliary request 1 - Novelty - Public availability of document D1

Since document D1 was a brochure of a product of the opponent itself, the level of proof upon the appellant-opponent had to be "up to the hilt". The date printed on the brochure was not to be considered as the date on which the brochure was distributed to the public. As to the witness statements made during the oral proceedings before the opposition division by employees of the opponent, these could not be regarded as evidence on the basis of which it could be verified whether document D1 was available to the public before the priority date. It was striking that the appellant-opponent did not call as witness any person who had actually received the brochure. Therefore it was not sufficiently proven that the brochure was available to the public before the priority date.

Claim 13 of auxiliary requests 2 to 5 and claim 9 of auxiliary request 6 - Inventive Step

The composition defined in these claims contained at least 2 mg glycine per Kcal which was 0.4 mg per Kcal more than the amount contained in the composition disclosed in document D1. There were data in the patent showing that the wound-healing capacity of the claimed composition was better than that of the composition of D1. The results disclosed in Table 2 indicated that the

composition PGL, containing high levels of glycine, leucine and proline, was more effective than the composition PG, which was low in leucine, and the composition PL, which was low in glycine. These results suggested a synergistic interaction between the three amino acids. Altogether the results of Table 2 made it credible that the higher amount of glycine had a beneficial effect on the wound-healing properties of the composition of the invention. Since this effect was not suggested in the prior-art documents, the compositions defined in the auxiliary requests 2 to 6 met the requirements of inventive activity.

Claim 1 of auxiliary requests 7 and 8 - Inventive Step

The feature "serving" had a clear meaning for the skilled person, as pointed out in the decision of the opposition division. In document D1, the volume of the product Protenplus® per serving was 200 ml. The amount of glycine per serving was 0.4 g, i.e. below the lower limit of 0.5 g defined in claim 1 of auxiliary requests 7 and 8. Hence, taking into account the effects due to the higher amounts of glycine, these claims too complied with the requirements of Article 56 EPC.

Claim 1 of auxiliary requests 9 and 10 - Inventive Step

In claim 1 of auxiliary requests 9 and 10 the amount of arginine per serving was at least 1.5 grams. Hence, in addition to the higher amount of glycine the uses defined in claim 1 of these requests were characterised also by a higher amount of arginine. The skilled person would have appreciated that arginine was an important component of the nutritional preparations of the invention, since the compositions disclosed in Table 1 of the patent were all characterised by a high amount of

this amino acid. Furthermore, the post-published document D26 described the effectiveness of nutritional supplements enriched with arginine in the healing of pressure ulcers. The prior-art documents did not suggest the beneficial effects of arginine. The subject-matter of auxiliary requests 9 and 10 therefore complied with Article 56 EPC.

XI. The appellant-patent proprietor requested that the decision under appeal be set aside and that the opposition be rejected, alternatively that the patent be maintained in accordance with auxiliary requests 1 to 10 filed on 9 October 2014.

XII. The appellant-opponent requested that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

Public availability of document D1

1. Document D1 is a commercial brochure of the product Protenplus®, which is a nutritional composition produced by the appellant-opponent. The appellant-patent proprietor disputed that it was sufficiently proven that the document was available to the public before the priority date.

Based on the evidence on file the Board is convinced that D1 was distributed to members of the public before the priority date and thus is to be regarded as being part of the state of the art in accordance with Article 54(2) EPC.

1.1 The appellant-opponent submitted during the opposition proceedings written sworn statements of employees in

charge of informing professionals such as nutritionists and pharmacists about the products of the company (documents D2a, D2b and D2c). They all declared that starting from the second half of 2000 they distributed brochure D1 to the clients visited. These declarations were confirmed by the testimony made by the employees at the oral proceedings before the first instance. Some witnesses clearly stated in their testimony that the writing "GB 05.2000" on page 3 of D1 indicated the printing date of the brochure. This date is about three years before the priority date of the patent in suit.

1.2 Since the main purpose of document D1 was to inform potential customers about the product, the appellant-opponent had a strong interest in making it publicly available. To assume that D1 was not yet distributed at the priority date of the patent would be implausible and it would speak against the very reason why the document was produced.

1.3 The appellant-patent proprietor pointed to the absence of any form of evidence originating from persons who received document D1. However, these considerations do not cast doubt on the validity of the evidence submitted by the appellant-opponent. The fact that other possible evidence could have been submitted, such as declarations from clients receiving the brochure, does not diminish the probative value of the evidence available.

Moreover, a further evidence supporting the public availability of D1 is represented by D14, which is the copy of an invoice sent on 12.01.2001 by the appellant-opponent to a pharmacy, i.e. a third person. The invoice relates to the sale of two boxes of the product Protenplus Vanille. The product is identified by an article number and by an additional number (Designated

"PZN"). The same numbers are used in D1 to identify Protenplus Vanille. One of the witnesses heard during the first-instance proceedings declared that the article number was normally used by the clients to order the product. D14 corroborates therefore the conclusion that brochure D1 was received before the priority date of the patent by third parties, such as clients interested in ordering the product.

1.4 As to the proper standard to be applied for deciding on the public availability of D1, the appellant-patent proprietor argued that this should be "up to the hilt" in view of the fact that the brochure originated from the appellant-opponent. In this respect the Board considers that the circumstances underlying the present case differ from e.g. an allegation of prior use in which all the evidence is in the possession of the opponent. Although D1 originates from the opponent, it was distributed to the public for the reasons explained above. Therefore both parties were able to access and adduce evidence relating to the availability of document D1. In such a situation the Board considers it more appropriate to assess public availability on the "balance of probabilities". In this respect the Board notes that this standard has been applied also in other decisions of the boards of appeal concerning the public availability of commercial brochures (see T 1140/09 and T 743/89).

Main request (patent as granted) and first auxiliary request

Claim 13 - Novelty

2. The claim (identical in both requests) relates to a composition characterised by a defined caloric content of protein, fat and carbohydrate. The composition must

furthermore comprise leucine in a defined amount, and at least one of glycine and proline in defined amounts (see point I above).

2.1 The composition of Protenplus® is disclosed on pages 4 and 5 of document D1. The amounts of protein, fat and carbohydrate represent respectively 32%, 36% and 32% of the total caloric content of the composition. These values are included in the ranges defined in claim 13. The amounts of leucine, glycine and proline in 100 ml of composition are respectively 1.06 g, 0.20 g and 0.98 g (page 5, Table at the bottom). Since the caloric content of 100 ml of Protenplus® is 125 Kcal (page 4), it can be calculated that the amounts of leucine, glycine and proline, expressed in mg per Kcal, are respectively 8.48, 1.6 and 7.84. The amounts of leucine and proline are therefore included in the ranges defined in claim 13.

The correctness of these data has never been disputed by the appellant-patent proprietor.

2.2 The composition of Protenplus® therefore fulfils the requirements defined in claim 13. Accordingly, the main request (granted patent) and the first auxiliary requests do not comply with Article 54 EPC.

Auxiliary requests 2, 3, 5 and 6

Claim 13 of auxiliary requests 2, 3 and 5 and claim 9 of auxiliary request 6

3. These claims are identical. Their subject-matter differs from the subject-matter of claim 13 of the granted patent in that it requires the mandatory presence of both glycine and proline in defined amounts.

Novelty

3.1 The compositions defined in these claims differ from the composition of document D1 in the amount of glycine (see point 2.1 above). This finding was not disputed by the appellant-opponent. The requirements of Article 54 EPC are therefore met.

Inventive Step

Closest prior art

3.2 The patent addresses the problem of providing nutritional compositions for the treatment and prophylaxis of chronic wounds (see [0001]). It was common ground between the parties that document D1 represented the closest prior art for the assessment of inventive step. Indeed according to the information disclosed in this document, Protenplus® is a nutritional composition which promotes wound-healing and can be used in the prophylaxis of various conditions such as decubiti ulcers (page 1). The Board therefore sees no reason to disagree with the selection of D1 as closest prior art.

3.3 It was also not disputed by the parties that the composition of the product disclosed in this document contained 1.6 mg glycine per Kcal (see point 2.1 above), whilst claim 13 requires the presence of this amino acid in an amount comprised between 2 and 32 mg per Kcal.

Technical problem

3.4 In order to define the objective technical problem it is essential to determine the effects achieved by the

claimed compositions over the product disclosed in D1, i.e. Protenplus®.

Experimental data directly comparing the compositions of the invention with Protenplus® are not available. The appellant-patent proprietor argued that it was nevertheless possible to deduce from the results of the experiment disclosed in example 2 of the patent that an increase in the amount of glycine determined an improvement in the wound-healing properties. On the basis of this observation it was possible to conclude according to the appellant-patent proprietor that the composition of the invention was more effective than Protenplus® in the treatment of wounds in view of its higher amount of glycine.

3.4.1 Example 2 of the patent (paragraph [0037] to [0042]) relates to an experiment based on a rabbit ear model to evaluate the effects of four different nutritional compositions on the regeneration kinetics of the skin. The parameter measured is the difference between the fractional synthesis rate and the fractional breakdown rate ("FSR - FBR"), which is indicative of the regeneration kinetics of the skin (paragraph [0037]). A higher value of the parameter indicates an increased skin regeneration speed. The tested compositions are denominated PG, PL and PGL (Table 1) and are characterised by high amounts respectively of proline and glycine (composition PG), proline and leucine (composition PL), and proline, glycine and leucine (composition PGL). Additionally, also a control composition having lower amounts of proline, glycine and leucine has been tested. The compositions also contain variable amounts of alanine and glutamic acid/glutamine and the same amount of arginine.

The results in terms of FSR - FBR disclosed in table 2, indicate that the most effective composition is PGL (FSR - FBR = 8.81) followed by compositions PL (FSR - FBR = 4.93), PG (FSR - FBR = 1.84) and the control (FSR - FBR = 1.07).

3.4.2 In this respect the Board notes that the arguments of the appellant-opponent that no clear correlation existed between the parameter FSR - FBR and the treatment of chronic wounds, cannot be followed. In paragraphs [0037] and [0039] of the description it is explained that the fractional synthesis rate (FSR) and the fractional breakdown rate (FBR) are respectively a measure of the synthesis and of the breakdown of the protein. Hence, the parameter determined in the experiment of example 2 can be regarded as an indicator of the capacity of the compositions tested to promote protein synthesis. According to the description, protein synthesis and protein deposition in the wound area appear important factors in the process of wound healing (see [0037] and [0003]). The Board considers therefore that the parameter determined in example 2 can be used to predict the possibility of using a composition in the treatment of wounds.

3.4.3 Although the best performing composition (composition PGL; see point 3.4.1 above) has the highest amount of glycine, in the Board's opinion the data of example 2 do not allow to establish any clear correlation between the amount of glycine and the parameter FSR - FBR as suggested by the appellant-patent proprietor (see point 3.4 above). The compositions tested differ from each other not only in the amount of glycine, but also in the amounts of glutamic acid/glutamine, leucine and proline. Furthermore, the total amount of amino acids is not the same for all the compositions, and composition PGL is

the one containing the highest quantity of amino acids. Under these circumstances, attributing the better results of the composition PGL to the higher amount of glycine seems an arbitrary conclusion. Moreover, compositions "PG" and "Con" appear less effective than the composition "PL" despite containing a higher amount of glycine. This fact appears to be at odds with the conclusion that an increased amount of glycine improves the effectiveness of the compositions.

3.4.4 The Board is additionally of the opinion that the results of example 2 cannot suggest the presence of a synergistic effect between the amino acids glycine, leucine and proline. In this respect it observes that these amino acids are present in all the compositions tested and also in the product Protenplus®. In addition composition PG, in which the amounts of the three amino acids are within the ranges of claim 13, provides an FSR - FBR value which is below the level of composition PL which is not encompassed by the claim on account of a too low amount of glycine. Thus, even admitting the presence of a synergistic interaction between glycine, leucine and proline this would not be enhanced by the fact of combining these amino acids in the amounts defined in the claim.

3.4.5 The data disclosed in table 2 of the patent demonstrate in the Board's opinion the effectiveness of the composition of the invention in the treatment of chronic wounds. On the other hand, in the light of the observations made in points 3.4.1, 3.4.3 and 3.4.4 above, the Board considers that there is no convincing evidence supporting an improvement with respect to the composition of D1. The technical problem over D1 is therefore to be formulated as the provision of an

alternative composition for the treatment or prevention of chronic wounds.

Obviousness

3.5 Modifying the amount of a single component of Protenplus® is within the routine activity of the skilled person faced with the mere problem of providing an alternative composition for the treatment of chronic wounds. In the present case, the small difference in the amount of glycine between Protenplus® and the composition of the claim (see point 3.3 above) suggests also that the modification would not imply any particular technical difficulty. Nor has the appellant-patent proprietor submitted arguments in this respect.

In view of the above, the Board concludes that the subject-matter of claim 13 of auxiliary requests 2, 3 and 5 and the subject-matter of claim 9 of auxiliary request 6 do not comply with the requirements of Article 56 EPC. These requests are therefore rejected.

Auxiliary request 4

Claim 13 - Inventive step

4. The composition defined in this claim differs from the composition of the claims considered in point 3 above in that it does not require the presence of between 3 and 32 mg proline per Kcal.

4.1 The parties agreed that the distinguishing feature of the composition of claim 13 of auxiliary request 4 over the composition of Protenplus® was again the amount of glycine. There were no additional arguments submitted by the parties in relation to this claim as compared to the

arguments considered in relation to the claim of point 3 above.

4.2 In the light of the above, the Board concludes that claim 13 of auxiliary request 4 likewise does not comply with the requirements of inventive step.

Auxiliary request 7

Claim 1 - Inventive step

5. The claim is drafted in the "Swiss-type" format and it relates to the use of leucine in the preparation of a composition for use in a method for the treatment and/or prevention of various conditions such as pressure ulcers, pressure sores and decubiti ulcers. The method comprises the administration of a composition which is characterised *inter alia* by the fact that it contains defined amounts of leucine, proline and glycine, wherein these amounts are expressed in grams per serving.

5.1 It was not disputed by the parties that the closest prior art was again document D1. It was also common ground between the parties that the package of 200 ml of Protenplus® disclosed in D1 could be regarded as a serving in the sense given in the patent to this term, i.e. an amount which is delivered or meant to be delivered to a subject in a single administration event ([0021]). It was furthermore agreed that the distinguishing feature of the subject-matter of claim 1 of auxiliary request 7 over the disclosure of document D1 was the amount of glycine per serving (0.4 g in D1 and at least 0.5 g in claim 1).

Both parties relied substantially on the same arguments submitted with regard to the inventive step of the product claims of auxiliary requests 2 to 6.

5.2 The considerations made in points 3.4.1 to 3.4.4 above as to the absence of any convincing evidence supporting the presence of beneficial effects due to an increased amount of glycine apply also for the assessment of inventive step of this request. Also the conclusion that in these circumstances modifying the amount of a component is within the routine activity of the skilled person holds good.

Therefore the Board finds that this claim does not involve an inventive step.

Auxiliary request 8

Claim 1 - Inventive step

6. Claim 1 of this request differs from claim 1 of auxiliary request 7 in that it specifies the amounts per serving of glutamine, iron, zinc and ascorbic acid.

6.1 The substances additionally specified in claim 1 of auxiliary request 7 are included also in the composition of document D1. It can be easily calculated from the data disclosed in this document that a package of 200 ml of Protenplus® contains 4.42 g of glutamine, 5 mg of iron, 3.76 mg of zinc and 37.5 mg of ascorbic acid (data for 100 ml are on pages 4 and 5 of D1). Since the package of 200 ml can be regarded as a serving of Protenplus® (see point 5.1 above) the amounts of glutamine, iron, zinc and ascorbic acid calculated above correspond also to the amounts contained in a serving.

6.2 The amounts of glutamine and iron per serving of Protenplus® are included in the corresponding ranges defined in claim 1 of auxiliary request 8, i.e. between 0.5 and 8 g (glutamine) and between 2 and 100 mg (iron). In contrast to that, the quantities of zinc and ascorbic acid per serving of Protenplus® are below the lower limits of the corresponding ranges of claim 1, i.e. between 5 and 100 mg (zinc) and between 200 and 2000 mg (ascorbic acid). It follows from the above that the subject-matter of the claim differs from the disclosure of D1 also on account of the amounts of zinc and ascorbic acid per serving, in addition to the amount of glycine per serving.

6.3 The patent does not contain any experimental data useful for assessing the effects linked to the amounts of zinc and ascorbic acid. Nor has the appellant-patent proprietor submitted any arguments in this respect. In line with the conclusions reached in respect of the previous requests, the Board considers that a mere modification in the amounts of some components of a composition which does not result in any improvement or different effects is to be regarded as an arbitrary measure that cannot support the presence of an inventive step.

Thus, auxiliary request 8 does not fulfil the requirements of inventive step.

Auxiliary requests 9 and 10

Claim 1 - Inventive step

7. Claim 1 of this requests differs from claim 1 of auxiliary request 7 in that it specifies the amounts per serving of glutamine and arginine. Furthermore, the

upper end-point of the range defining the amount of glycine per serving has been modified from 5 g to 8 g.

7.1 As discussed in point 6.1 above, a serving of Protenplus® provides 4.42 g of glutamine. This amount is within the range defined in claim 1 (1.5 to 8 g). As to the arginine, it can be calculated from D1 that Protenplus® contains 0.72 g of this amino acid per serving, whilst claim 1 requires an amount between 1.5 and 8 g. It follows that the subject-matter of claim 1 of auxiliary requests 9 and 10 differs from the disclosure of document D1 in terms of the amounts of glycine and arginine per serving (see also point 5.1 above).

7.2 Having regard to the definition of the technical problem, the appellant-patent proprietor relied on the teaching of document D26, which was published after the filing date of the patent, to argue that the increased amount of arginine resulted in an improvement of the effectiveness of the composition in the healing of pressure ulcers.

7.3 Document D26 is a report relating to a clinical experiment carried out on patients with pressure ulcers. In the abstract of the article, it is stated that the objective of the study was to investigate the effectiveness of a nutritional supplement that is rich in protein and enriched with arginine, vitamin C and zinc. Also in the sections "Discussion" and "Conclusions" (see pages 321 and 322), the authors underline the importance of a nutritional supplement rich in the three components for obtaining a significant reduction in ulcer area. There appears to be no indication in document D26 that in the absence of an enrichment of the amounts of vitamin C and zinc, the

arginine's enrichment would alone provide the same improvement of the wound-healing properties of the composition.

In the light of the above, the Board considers that the teaching of D26 does not support the conclusion of the appellant-patent proprietor that increasing the amount of arginine results in an improvement of the effectiveness of the composition in the healing of pressure ulcers.

7.4 Independently and in addition to the considerations set out in point 7.3 above, the Board remarks that the application as filed does not indicate that a correlation may exist between the amount of arginine and the effectiveness of the compositions in the treatment of wounds. In fact, it is emphasised in the "Summary of the Invention" of the original application that the "invention relates to the replenishment of the glycine/ proline pools" (page 3, lines 4 and 5) and that "in a further aspect, the present invention relates to the use of compositions high in leucine" (page 3, lines 13 and 14). In line with the summary of the invention, example 2 relates to the "Effects of leucine, proline and glycine on wound healing" (see title of example 2). Thus, whilst the original application underlines the importance of leucine, proline and glycine for the wound-healing properties of the composition, it fails to attribute any specific function to the amount of arginine. In this respect it is also observed that the compositions tested in example 2 (PG, PL, PGL and Con) all contain the same amount of arginine. This appears to underline the fact that observing the effects of the amount of arginine on the effectiveness of the composition was not an objective of the invention. Consequently, it cannot be inferred from the application

as filed and on the basis of the general knowledge of the skilled person that increasing the amount of arginine results in an improvement of the healing properties of the composition. Hence, independently of the question whether said improvement is convincingly demonstrated in D26, it cannot be taken into account for the definition of the technical problem, as it cannot be deduced from the application as filed.

7.5 As discussed in respect to the previous requests, there is no evidence supporting the presence of beneficial effects associated with the other distinguishing feature of the claim, namely the amount of glycine per serving.

7.6 Accordingly, the conclusions reached in respect of the previous requests (see in particular points 3.5, 5.2, 6.3 above) hold good also in respect of the subject-matter of claim 1 of auxiliary requests 9 and 10. It follows that also these requests do not fulfil the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated