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Datasheet for the decision of 7 June 2022

Case Number: T 0292/17 - 3.3.01

Application Number: 10807402.2

Publication Number: 2515920

IPC: A61K35/20

Language of the proceedings: EN

Title of invention:
LOW-CALORIC HIGH-PROTEIN NUTRITIONAL COMPOSITION FOR THE STIMULATION OF MUSCLE PROTEIN SYNTHESIS

Patent Proprietor:
N.V. Nutricia

Opponents:
Société des Produits Nestlé S.A.
Groupe Lactalis

Headword:
Whey-leucine composition/NUTRICIA

Relevant legal provisions:
EPC Art. 100(a), 56
RPBA Art. 12(4)
RPBA 2020 Art. 13(1)

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Keyword:
Main request - inventive step (no)
Auxiliary requests I to IV, VI and VII - inventive step (no)
Auxiliary requests VIII to XIV - admitted (no)

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Case Number: T 0292/17 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 7 June 2022

Appellant: (Opponent 1)	Société des Produits Nestlé S.A. Avenue Nestlé 55 1800 Vevey (CH)
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Party as of right: (Opponent 2)	Groupe Lactalis 10 rue Adolphe Beck 53000 Laval (FR)
Representative:	Cabinet Le Guen Maillet 3, impasse de la Vigie CS 71840 35418 Saint-Malo Cedex (FR)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 23 December 2016 rejecting the oppositions filed against European patent No. 2515920 pursuant to Article 101(2) EPC**

Composition of the Board:

Chairwoman	T. Sommerfeld
Members:	J. Molina de Alba
	P. de Heij

Summary of Facts and Submissions

I. The decision under appeal is the opposition division's decision to reject the two oppositions filed against European patent No. 2 515 920.

II. The following documents are referred to in the present decision:

D1: WO 2004/056208
D1a: US 2004/0122097
D2: K. Smith, Dried Dairy Ingredients, Wisconsin Center for Diary Research, 15 May 2008
D37: K.D. Tipton et al., App. Physiol. Nutr. Metab., 2009, 34, 151-161
D38: J.W. Coburn et al., J. Strength Cond. Res., 2006, 20(2), 284-291

D1a is the published priority application of D1.

III. The patent had been granted with 24 claims. Claim 1 as granted reads as follows:

"*1. Nutritional composition comprising per 100 kcal:*

(i) at least about 12 g of proteinaceous matter which comprises at least about 80 weight% of whey protein, relative to the total proteinaceous matter, and which comprises at least about 11 weight% of leucine, relative to the total proteinaceous matter, of which at least about 20 weight% is in a free form, relative to the total leucine,
(ii) a source of fat and a source of digestible carbohydrates,

for use in the prevention or treatment of a disease or condition which involves muscle decline in a mammal, wherein the nutritional composition is administered as 1 to 2 servings daily, each serving comprising between 80 and 200 kcal,
wherein the term 'about' means a deviation of 5 % or less from the given value."

IV. Two oppositions were filed against the patent on the grounds that the claimed subject-matter lacked novelty and inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed (Article 100(a), (b) and (c) EPC).

V. In the decision under appeal, the opposition division held with respect to the patent as granted that:

- claim 24 did not contain added subject-matter
- the medical use defined in claim 1 was sufficiently disclosed
- examples 2 and 3 of D1a did not anticipate the subject-matter of claims 1 to 3, 6 and 13, and
- the subject-matter of claim 1 was inventive starting from document D1 as the closest prior art

VI. Opponent 1 (appellant) filed an appeal against the opposition division's decision. It requested that the decision be set aside and that the patent be revoked. With the statement of grounds of appeal it filed documents D37 and D38.

VII. With its reply to the statement of grounds of appeal, the patent proprietor (respondent) filed the claims of

auxiliary requests I to VII: auxiliary requests I to V were identical to those filed on 30 September 2016 in the opposition proceedings; auxiliary requests VI and VII were new.

VIII. In subsequent letters, the parties made, among others, the following submissions:

- the appellant raised a new novelty objection based on the product MegaWhey™ disclosed in paragraph [0007] of D1a (letter dated 25 October 2018, point 1.1.1)

- the respondent filed additional sets of claims as auxiliary requests VIII to X (letter dated 6 November 2018), auxiliary request XI (letter dated 4 March 2019) and auxiliary requests XII to XIV (letter dated 5 December 2019)

IX. Opponent 2 (party as of right) did not file any substantial submissions or requests during these appeal proceedings.

X. The board scheduled oral proceedings and issued a communication with its preliminary opinion.

XI. The respondent and the appellant both filed additional letters in response to the board's preliminary opinion.

XII. Oral proceedings were held before the board on 7 June 2022. During the oral proceedings, the respondent withdrew auxiliary request I and made auxiliary request V its new auxiliary request I.

At the end of the oral proceedings, the board announced its decision.

XIII. The claim requests on file are the following:

The main request is the claims as granted.

Claim 1 of auxiliary request I (filed as auxiliary request V with the reply to the grounds of appeal) differs from claim 1 as granted in that it contains the following sentence in feature (ii): "*the sum of the amounts of fat and carbohydrate ranging between 10 and 60 en%*".

Claim 1 of auxiliary request II is identical to claim 1 as granted.

Claim 1 of auxiliary requests III and IV are identical and differ from claim 1 as granted in that they specify that the nutritional composition is liquid.

Claim 1 of auxiliary requests VI and VII are identical to claim 1 of auxiliary request I.

Claim 1 of auxiliary requests VIII and IX are identical and differ from claim 1 as granted in that they specify that the nutritional composition is in liquid form and that each serving comprises 50 to 250 ml of the composition.

Claim 1 of auxiliary request X combines the limitations of claim 1 of auxiliary requests I and VIII.

Claim 1 of auxiliary request XI differs from claim 1 as granted in that the words "*or condition*" have been deleted.

Claim 1 of auxiliary requests XII and XIII are identical and differ from claim 1 as granted in that the use is limited to the prevention or treatment of sarcopenia.

Claim 1 of auxiliary request XIV differs from claim 1 of auxiliary request XII in that it contains the additional conditions in feature (ii) that "*the carbohydrate content is in the range of 10-35 en%*" and "*the fat content is in the range of 10-35 en%*".

XIV. The appellant's arguments relevant to the present decision can be summarised as follows.

The subject-matter of claim 1 as granted was not inventive starting from Example 2 of D1a. Contrary to the respondent's view, there was nothing in D1a to interpret that the powder in Example 2 was an intermediate product; all the examples in D1a disclosed complete recipes of final products.

The only distinguishing feature was the higher amount of whey in the proteinaceous material of claim 1. According to common general knowledge, represented by D2, the whey protein concentrate in Example 2 of D1a inevitably contained some fat and lactose. Furthermore, although D1a dealt with the stimulation of muscle protein synthesis for non-therapeutic purposes, it also disclosed a therapeutic indication in paragraph [0032]. Lastly, D1a disclosed (paragraphs [0018] and [0021]) a preferred serving dose of 25 g, which for the composition in Example 2 amounted to 103 kcal.

The clinical study in the patent did not demonstrate that the distinguishing technical feature brought about any technical effect; the composition Control 3 was not

a proper comparison with the closest prior art. Considering its fat and carbohydrate content, Control 3 was high caloric while the powder in Example 2 of D1a was low caloric.

Therefore, the objective technical problem was the provision of an alternative composition for preventing or treating diseases or conditions involving muscle decline. A pointer to a particular combination of features was not needed.

The solution proposed in claim 1 was obvious since D1a taught (paragraph [0028]) that in its formulations the proteinaceous matter contained preferably more than 90 wt.% of intact protein and that the preferred protein was whey.

The feature in claim 1 of auxiliary request I that the sum of the fat and carbohydrate ranged between 10 and 60 en% did not produce any technical effect either. The objective technical problem remained the provision of an alternative. The claimed range was an arbitrary selection and could not confer inventive step.

The limitation of the composition in claim 1 of auxiliary request III to a liquid composition did not render the claimed subject-matter inventive either. There was no evidence on file that the administration of the composition as a liquid had a benefit over a powder. It was obvious that the powders in the examples of D1a could be suspended in a liquid for their consumption and that they would provide the same technical effect as in solid form. Furthermore, paragraph [0030] of D1a suggested the administration of the compositions in liquid form.

Auxiliary requests VIII to X should not be admitted. They were late filed and not suitable for overcoming the objections raised against the previous requests.

Auxiliary requests XI to XIV were also inadmissible. They could and should have been filed earlier because they dealt with objections that were on file from the outset of the opposition proceedings. Furthermore, they were not suitable for overcoming the objections raised against the previous requests.

XV. The respondent's arguments relevant to the present decision can be summarised as follows.

The novelty objection based on the product MegaWhey™, which included a new interpretation of granted claim 1 as encompassing non-therapeutic embodiments, changed the focus of the appellant's case at a late stage of the proceedings. For reasons of fairness and procedural economy, it should not be admitted into the appeal proceedings.

The subject-matter of claim 1 as granted was inventive.

Example 6 of D1a was closer to the invention than Example 2 of the same document. Example 2 merely disclosed the formulation of a powder which was not a final product but an intermediate that needed to be combined with additional ingredients before consumption.

The powder contained less whey than required by claim 1 and no fat or digestible carbohydrates. Furthermore, it was not disclosed in connection with any use, let alone a therapeutic use with a specific dosage and caloric content per serving.

These distinguishing features brought about an advantageous effect: the clinical study in the patent demonstrated that the choice of a composition having high-whey and low-caloric content produced unexpectedly high serum levels of total amino acids, including essential amino acids and leucine. This effect made the composition of claim 1 particularly suitable for stimulating muscle protein synthesis and, hence, for preventing or treating diseases involving muscle decline. Therefore, the objective technical problem solved by the claimed subject-matter was to provide a composition for use in the prevention or treatment of a disease or condition involving muscle decline wherein the bioavailability of amino acids was increased, in particular in terms of higher peak concentrations. There were no pointers to the claimed solution.

Even if the advantageous effect was not acknowledged and the objective technical problem was formulated in terms of an alternative, there was no suggestion in the prior art to make all the necessary changes in the powder of Example 2 of D1a to arrive at the composition of claim 1 and to use it for the purpose and at the dosage defined in claim 1.

The subject-matter of claim 1 of auxiliary request I was also inventive. Example 2 in D1a was not a reasonable starting point. The amounts of fat and carbohydrate defined in claim 1 provided an additional energy source in the composition so that more protein was available for the synthesis of muscle protein. The effect of increased bioavailability of amino acids was even more pronounced. This resulted in an enhanced formation of muscle. The objective technical problem was the same as argued for the main request. Even if

this improvement was not acknowledged and the objective technical problem was formulated as an alternative, there was no motivation in the prior art for the skilled person to add fat or carbohydrates to the powder in Example 2 of D1a up to the claimed level, let alone to at the same time maintain the ranges of the other features of the claim, because it would increase the serving size.

The limitation of claim 1 of auxiliary request III to a liquid nutritional composition rendered the claimed subject-matter inventive. D1a did not suggest the administration of the powder in Example 2 as a liquid. It was not obvious that a liquid composition would be effective in increasing the blood levels of amino acids as shown in the patent. The skilled person had no motivation to try this.

Auxiliary requests VIII to X should be admitted because they were filed "*in view of the objections to AR III and AR IV, which are directed to liquid compositions*".

Auxiliary requests XI to XIV should be admitted as a response to the new novelty objection based on the product MegaWhey™.

XVI. The parties' final requests were the following:

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

- The respondent requested that the appeal be dismissed, implying that the patent be maintained as granted or, alternatively, that the decision under appeal be set aside and that the patent be

maintained on the basis of any of the following auxiliary requests:

- auxiliary request I, filed as auxiliary request V with the reply to the statement of grounds of appeal
- auxiliary requests II to IV, VI and VII, all filed with the reply to the statement of grounds of appeal
- auxiliary requests VIII to X, all filed with the letter dated 6 November 2018
- auxiliary request XI, filed with the letter dated 4 March 2019
- auxiliary requests XII to XIV, all filed with the letter dated 5 December 2019

- The party as of right did not make any request in the appeal proceedings.

Reasons for the Decision

1. The appeal is admissible. It meets the requirements of Articles 106 to 108 and Rule 99(2) EPC.

2. The party as of right did not attend the oral proceedings before the board, as announced with its letter dated 20 May 2022. In view of this and in accordance with Rule 115(2) EPC and Article 15(3) RPBA, the board decided to continue the proceedings in the absence of this party.

The party as of right had not filed any submissions or requests in writing during the appeal proceedings although it had had ample opportunity to do so. Therefore, the board was in a position to announce a decision at the conclusion of the oral proceedings, in accordance with Article 113(1) EPC and Article 15(6) RPBA 2020.

3. Admittance of new novelty objection and documents D37 and D38

3.1 In the statement of grounds of appeal, the appellant contested the novelty of the subject-matter of claim 1 as granted in light of example 3 of D1a. Subsequently, by letter dated 25 October 2018 (point 1.1.1), it introduced a new novelty objection based on the product MegaWhey™ disclosed in paragraph [0007] of D1a. The admittance of this new objection is to be assessed under Article 13(1) RPBA 2020 (see also Articles 24 and 25 RPBA 2020), which establishes that any amendment to a party's appeal case after it has filed its grounds of appeal or reply is subject to the party's justification for the amendment and may be admitted only at the discretion of the board.

In its preliminary opinion (point 13.1), the board noted that the new objection was substantiated by a long discussion which included calculations and the consideration of additional prior-art documents. It also noted that the appellant had not provided the justification required by Article 13(1) RPBA 2020. Therefore, the board was minded to not admit the objection.

At the oral proceedings before the board, the appellant did not wish to make any further comment on the

admittance of the objection. Therefore, there was no justification for admitting the objection, which added complexity to the case at an advanced stage of the proceedings to the detriment of procedural economy. Thus, the board decided not to admit the objection into the proceedings pursuant to Article 13(1) RPBA 2020.

3.2 In addition, the board decided not to admit documents D37 and D38 either. These documents were filed with the statement of grounds of appeal to support the appellant's inventive step arguments. In view of the board's conclusions on inventive step and the outcome of the appeal proceedings, the decision not to admit documents D37 and D38 into the proceedings pursuant to Article 12(4) RPBA 2007 needs no further reasoning.

4. Inventive step - claim 1 of the main request (patent as granted)

4.1 The patent (paragraph [0001]) concerns low-caloric high-protein nutritional compositions suitable for stimulating muscle protein synthesis in a mammal. The proteinaceous material of the nutritional compositions consists essentially of whey and some free leucine. The patent explains (paragraphs [0003] to [0005]) that the principle underlying the invention is the prior knowledge that muscle protein synthesis is stimulated by high blood levels of essential amino acids, especially leucine, and that whey protein contains higher level of leucine than casein protein. Via the clinical study disclosed in the patent, the inventors found that a nutritional composition as defined in claim 1 produces high serum concentration peaks of leucine and essential amino acids. Therefore, the nutritional composition of the invention is believed to be suitable for promoting muscle protein synthesis and

preventing or treating diseases and conditions which involve muscle decline.

4.2 Document D1a (paragraph [0001]) is directed to the preparation of compositions for inducing the generation of muscle tissue. Like the patent, D1a (paragraph [0020]) relies on the principle that the availability to muscle cells of high amounts of essential amino acids and leucine stimulates the synthesis of muscle proteins. Preferably, the proteinaceous material in the compositions is mainly composed of whey and leucine (paragraph [0028] and examples). Although D1a focuses on inducing muscle protein synthesis in healthy subjects (paragraph [0005]), it also contemplates the use of its compositions for preventing loss of large amounts of muscular mass in patients recovering from surgery, who are often restricted in their food intake (paragraph [0032]).

4.3 The similarity of the compositions of D1a with those in the patent and their use for inducing muscle protein synthesis make D1a a suitable starting point for the assessment of inventive step. The appellant started from the powder in Example 2 of D1a, which contains 22.0 g whey protein concentrate and 4.4 g leucine. The board agrees that this is a suitable starting point.

The respondent contended that the starting point should be Example 6 of D1a because its composition was closer to the invention than that of Example 2. However, in accordance with the established case law of the boards, when two or more pieces of prior art may reasonably be used as the starting point for the assessment of inventive step, a conclusion that the subject-matter claimed is inventive can only be reached after assessing this requirement starting from all the

possible closest prior art. Therefore, the respondent cannot argue against assessing inventive step starting from Example 2 of D1a.

The respondent also argued that Example 2 of D1a was not a suitable starting point because its composition was not disclosed for direct consumption. Rather than a final product, the composition in Example 2 was an intermediate to be admixed with further components to produce a product such as the food bar in Example 6. This argument is not convincing. As noted by the appellant, all the examples in D1a illustrate its invention. There is no basis in D1a to derive that some examples disclose intermediate products rather than final products. Therefore, the powder in Example 2 is a composition for promoting muscle protein synthesis according to D1a.

4.4 The respondent identified four distinguishing features between the composition of claim 1 and the one in Example 2 of D1a:

(i) at least about 80 wt.% of the proteinaceous matter in the composition is whey protein
(ii) the composition contains fat and digestible carbohydrates
(iii) it is used for the prevention or treatment of a disease or condition involving muscle decline
(iv) it is administered as one to two servings daily, each serving comprising between 80 and 200 kcal

4.4.1 It was common ground that feature (i) was indeed a distinguishing feature. Claim 1 requires that at least about 80 wt.% of the proteinaceous material be whey

protein, with "about" meaning a deviation of up to 5% of that value. The parties agreed that this meant that the content of whey in the proteinaceous material of claim 1 was at least 76 wt.%.

The powder in Example 2 of D1a contains 22.0 g whey protein concentrate (WPC), which provides 17.6 g whey protein and 4.4 g leucine. According to the parties' calculations, this gave an amount of whey of approximately 70 wt.% of the proteinaceous material (statement of grounds of appeal, point 8.2.1.1; reply to the statement of grounds of appeal, page 21, last paragraph). So the proteinaceous material of the nutritional composition of claim 1 has a higher proportion of whey.

4.4.2 Regarding feature (ii), the board agrees with the appellant (statement of grounds of appeal, point 8.2.1.1.) that it is not a distinguishing feature.

The powder in Example 2 of D1a was prepared from 22.0 g of a WPC, which provided 17.6 g whey protein. This means that 80 wt.% of the WPC was whey and the remaining 20 wt.% was made of other components.

D2 is a handbook on dairy ingredients which represents common general knowledge on the priority date of the patent. This was not disputed. According to D2 (page 43), a WPC is a final dry product containing at least 25% protein. It is obtained by removing lactose, minerals and other materials from milk by ultrafiltration. Thus, the more concentrated the WPC, the lower the content of materials other than whey. The typical composition of WPC is the following (D2, page 43, upper table and page 44, right-hand column):

Component	WPC 34	WPC 55	WPC 80
	%		
Protein	33	53	77
Lactose	52	31	9
Ash	7	6	4
Fat	4	6	6
Moisture	4	4	4

It is apparent from this table that increasing the protein content of the WPC from 33 to 77% reduces the lactose from 52 to 9% while fat remains at 4 to 6%. D2 also refers (pages 45 and 46) to whey protein isolates, which are highly purified WPCs. They contain typically 89 to 93% protein, 2 to 3% lactose and 1% fat. Thus, a WPC having a protein concentration as high as 90% still contains some fat and lactose. Therefore, the board concludes that the only technically sensible interpretation of Example 2 of D1a is that its WPC, which contains 80 wt.% whey, also contains some amounts of fat and lactose. Therefore, the respondent's interpretation that the powder in Example 2 does not contain any fat and digestible carbohydrate (e.g. lactose) has to be rejected.

4.4.3 As to feature (iii), even though D1a mentions the possibility of using its compositions for preventing muscle decline in patients undergoing surgery, the main focus of D1a is on non-therapeutic indications (see point 4.2 above). Example 2 is not disclosed in connection with any purpose, let alone with the aim of treating a disease or condition involving muscle decline. Accordingly, the board agrees with the respondent that feature (iii) is a distinguishing feature.

4.4.4 Similarly, there is no disclosure in D1a that the composition of Example 2 is administered to a subject

in one to two servings of 80 to 200 kcal each. So feature (iv) is also a distinguishing feature.

4.5 In view of the above, the board concludes that the features distinguishing the subject-matter of claim 1 from Example 2 of D1a are (i), (iii) and (iv).

4.6 The next step in the problem and solution approach is to establish the effect that these distinguishing features bring about. For this, the respondent referred to the clinical study in the patent (paragraph [0080]). This study shows the serum levels of amino acids, essential amino acids and leucine produced by four nutritional compositions, namely a high whey-protein, low-caloric composition according to claim 1 ("Active"); a high casein-protein, low-caloric composition (Control 1); a high casein-protein, high-caloric composition (Control 2) and a high whey-protein, high-caloric composition (Control 3). According to the respondent, a comparison of the serum amino acid concentrations produced by Active and Control 3 demonstrated that reducing the caloric content of a high whey-protein composition has an advantageous effect. This proved that the composition of claim 1 was more suitable for inducing muscle protein synthesis than that in Example 2 of D1a.

The board disagrees. The powder in Example 2 of D1a is not a high-caloric composition. On the contrary, it contains only small amounts of fat and digestible carbohydrates, and, like the composition in claim 1, it is a high whey-protein, low-caloric composition. Therefore, a comparison of the effects brought about by the compositions Active and Control 3 does not allow drawing any conclusion on the powder in Example 2 of D1a. A comparison with Control 1 or Control 2 would not

be suitable to show any effect either since they are based on a different protein. Consequently, the clinical tests in the patent do not show any advantageous effect of the composition of claim 1 over the powder in Example 2 of D1a. The technical effect of the distinguishing features is merely that a composition is provided for the treatment or prevention of the specified diseases.

4.7 Therefore, the objective technical problem has to be formulated as the provision of a composition for preventing or treating a disease or condition involving muscle decline in a mammal.

4.8 The board is satisfied that the solution proposed in claim 1 solves this problem. The clinical study in the patent demonstrates that a composition according to claim 1 (Active) produces high serum concentrations of leucine and essential amino acids. The common general knowledge referred to in the patent (paragraphs [0003] to [0005]) that high serum levels of essential amino acids, especially leucine, induce muscle protein synthesis, has not been contested. Therefore, the evidence in the patent makes it credible that the nutritional composition of claim 1 is suitable for promoting muscle protein synthesis and that it can be used for preventing or treating diseases and conditions which involve muscle decline.

4.9 However, for the following reasons, the solution proposed in claim 1 was obvious.

4.9.1 D1a teaches (paragraph [0028]) that the proteinaceous matter in a formulation according to its invention comprises preferably more than 90 wt.% of intact proteins or peptides, whey being the most preferred

protein source. Hence, there is a clear motivation in D1a for the skilled person to increase the whey content of the composition of Example 2 beyond 80 wt.% of the proteinaceous material to provide an alternative composition that promotes muscle protein synthesis. So feature (i) does not contribute to inventive step.

4.9.2 As to feature (iii), the compositions of D1a produce high serum levels of essential amino acids and leucine (see point 4.2). Like the patent, D1a relies on the common general knowledge that high serum levels of essential amino acids and leucine stimulate muscle protein synthesis. Although D1a focuses on the promotion of muscle protein synthesis for aesthetic purposes, in paragraph [0032] it suggests the use of its compositions for preventing an important loss of muscular mass in patients recovering from surgery, who are often restricted in their food intake. Therefore, it was obvious to the skilled person that the compositions of D1a are also suitable for preventing or treating diseases or conditions involving muscle decline.

4.9.3 Regarding feature (iv), D1a suggests (paragraphs [0018] and [0021]) serving doses of 25 g, which is essentially the weight of the composition disclosed in Example 2. The appellant calculated the caloric content of such a serving dose, which resulted to be slightly above 100 kcal (statement of grounds of appeal, point 8.2.1.1 and letter of 27 April 2022). This calculation was not contested by the respondent. Thus, D1a suggests serving doses as defined in claim 1. In addition, a serving frequency of once or twice daily appears to be customary in the field of nutritional compositions and there is no evidence on file that it is associated with

any technical effect. Accordingly, feature (iv) cannot contribute to inventive step either.

4.9.4 The respondent argued that the skilled person had no motivation to combine all the distinguishing features. Therefore, they would not have arrived at the subject-matter of claim 1.

This argument cannot succeed. In a case such as this in which the distinguishing features do not interact with each other to produce a combined or synergistic effect but merely constitute a juxtaposition of independent modifications of the starting point, there is no need to find a motivation for combining all the distinguishing features; a motivation to arrive at each of these features independently when intending to solve the problem posed suffices. The board has explained that the skilled person would have considered the composition in Example 2 of D1a suitable for preventing or treating diseases involving muscle decline. It has also explained that a composition containing higher amounts of whey was not only a feasible but even a preferable alternative; that the composition had a preferred serving size of 25 g, which amounts to approximately 100 kcal; and that administration once or twice daily was a customary measure for nutritional compositions. Therefore, the board holds that the skilled person would have arrived at the subject-matter of claim 1 in an obvious manner.

4.10 Consequently, the subject-matter of claim 1 does not involve an inventive step (Article 56 EPC), and the ground for opposition of Article 100(a) EPC prejudices the maintenance of the patent as granted.

5. Inventive step - claim 1 of auxiliary request I

Compared to claim 1 as granted, claim 1 of auxiliary request I additionally requires that the composition contains fats and carbohydrates in such an amount that their sum provides 10 to 60% of the total energy of the composition. At the oral proceedings before the board, the parties agreed that this limitation constituted an additional difference: the contribution of fats and carbohydrates to the total energy of the powder in Example 2 of D1a was below 10%. The respondent submitted that this difference produces an increase in the production of muscle protein. However, there is no evidence on file supporting such an allegation. Therefore, the objective technical problem to be solved remains the same as for the main request.

On obviousness, the respondent argued that the subject-matter of claim 1 was now inventive because the skilled person had no reason to add fats or carbohydrates to the composition of Example 2 up to the claimed level and at the same time maintain the ranges of the other features of the claim, since this would increase the serving size. However, the board agrees with the appellant that this feature is just an arbitrary modification that cannot render the claimed subject-matter inventive. The addition of fats and carbohydrates to a certain extent without modifying the amount of other ingredients falls within the obvious modifications the skilled person would carry out to the teaching of D1a. Therefore, the subject-matter of claim 1 of auxiliary request I does not involve an inventive step, contrary to Article 56 EPC.

6. Inventive step - claim 1 of auxiliary request II

This claim is identical to claim 1 as granted. Therefore, for the reasons put forward for the main request, the subject-matter of claim 1 of auxiliary request II does not involve an inventive step either (Article 56 EPC).

7. Inventive step - claim 1 of auxiliary request III

Claim 1 of auxiliary request III differs from claim 1 as granted in that it specifies that the nutritional composition is liquid. Apart from the obvious differences in properties between a powder and a liquid composition, the limitation to liquid compositions does not provide any effect over the powder in Example 2 of D1a. Therefore, the objective technical problem to be solved remains the same as for the main request.

D1a suggests in paragraph [0030] that its compositions may have the form of a beverage, a powder, a pudding-like product, a snack or a bar. Formulating the composition as a liquid (beverage) was merely one of the obvious alternatives proposed by D1a. The appellant's argument that the powder of Example 2 would not be expected to exert its technical effect if it were administered in liquid form is once again an unsupported allegation. Therefore, the subject-matter of claim 1 of auxiliary request III does not involve an inventive step (Article 56 EPC).

8. Inventive step - claim 1 of auxiliary request IV

This claim is identical to claim 1 of auxiliary request III. Therefore, for the reasons put forward for the

latter, the subject-matter of claim 1 of auxiliary request IV does not involve an inventive step (Article 56 EPC).

9. Inventive step - claim 1 of auxiliary requests VI and VII

This claim is identical to claim 1 of auxiliary request I. Therefore, for the reasons put forward for auxiliary request I, the subject-matter of claim 1 of auxiliary requests VI and VII does not involve and inventive step (Article 56 EPC).

10. Admittance of auxiliary requests VIII to XIV

10.1 Auxiliary requests VIII to XIV were filed by the respondent after its reply to the statement of grounds of appeal. Therefore, their admittance is to be assessed under Article 13(1) RPBA 2020 (see also Articles 24 and 25 RPBA 2020).

10.2 For auxiliary requests VIII to X, the respondent submitted (letter dated 6 November 2018, page 14, lines 20 to 22) that they had been filed "*in view of the objections to AR III and AR IV, which are directed to liquid compositions*". This vague statement cannot qualify as the justification required by Article 13(1) RPBA 2020 on why the requests should be admitted.

At oral proceedings, the board gave the respondent the opportunity to comment on the admittance of these requests. However, the respondent declined making any further submissions on this matter.

10.3 With regard to auxiliary requests XI to XIV, the board noted in its preliminary opinion (point 16) that the

respondent had filed them to overcome the novelty objection based on the product MegaWhey™, filed by the appellant in its letter of 25 October 2018 (respondent's letters of 4 March 2019, page 16, lines 8 to 10 and 5 December 2019, page 19, lines 16 to 25, page 21, lines 3 to 6 and page 22, lines 9 to 18). Therefore, the admittance of auxiliary requests XI to XIV was bound to the admittance of this new objection.

At oral proceedings, the board decided not to admit the objection into the proceedings. Furthermore, inventive step was discussed only for the subject-matter involving therapeutic uses, i.e. the new interpretation of claim 1 was not taken into account either. Therefore, the board saw no reason for admitting auxiliary requests XI to XIV. Moreover, at the oral proceedings, the respondent declined the board's invitation to comment on the admittance of auxiliary requests XI to XIV.

10.4 Consequently, the board did not admit any of auxiliary requests VIII to XIV into the appeal proceedings (Article 13(1) RPBA 2020).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairwoman:

M. Schalow T. Sommerfeld

Decision electronically authenticated