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Datasheet for the decision of 13 February 2024

Case Number: T 1717/21 - 3.3.07

Application Number: 14196763.8

Publication Number: 2865382

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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:
Fresenius Kabi Deutschland GmbH
Société des Produits Nestlé S.A.

Headword:
Whey-leucine composition/NUTRICIA

Relevant legal provisions:
EPC Art. 100(a), 56

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It can be changed at any time and without notice

Keyword:
Inventive step - (no)

Decisions cited:
T 0292/17, T 0786/00

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Case Number: T 1717/21 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 13 February 2024

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Appellant: (Opponent 1)	Fresenius Kabi Deutschland GmbH Else-Kröner-Str. 1 61352 Bad Homburg (DE)
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Appellant: (Opponent 2)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 2 August 2021 concerning maintenance of the European Patent No. 2865382 in amended form**

Composition of the Board:

Chairman	A. Usuelli
Members:	J. Molina de Alba
	Y. Podbielski

Summary of Facts and Submissions

I. The decision under appeal is the opposition division's interlocutory decision rejecting the main request and auxiliary requests 1 to 11 and concluding that European patent No. 2865382 as amended according to auxiliary request 12, and the invention to which it relates, met the requirements of the EPC.

II. The patent had been granted with 23 claims. Claim 1 as granted read as follows:

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

(i) at least 12 g of proteinaceous matter which comprises at least 80 weight% of whey protein, relative to the total proteinaceous matter, and which comprises at least 11 weight% of leucine, relative to the total proteinaceous matter, of which at least 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."

III. The following documents cited by the parties during the opposition and appeal proceedings are referred to in the present decision:

D2 WO 2004/056208 A1

D5 K. Smith, Dried Dairy Ingredients, Wisconsin Center for Diary Research, 15 May 2008

D11 WO 2009/113858 A1

D18 US 6,462,181 B1

D19 D. Paddon-Jones et al., Curr Opin Clin Nutr Metab Care, 2009, 12(1), 86-90

D20 E. Volpi et al., J Clin Endocrinol Metab, 2000, 85(12), 4481-90

D27 I.F. Kramer et al., J Clin Endocrinol Metab, 2015, 100(11), 4124-32

D34 Y. Rolland et al., The Journal of Nutrition, Health & Aging, 2008, 12(7), 433-50

IV. In the decision under appeal, the opposition division concluded, among other things, that:

- the subject-matter of claim 1 of the main request (patent as granted) and auxiliary requests 2 to 9 was not sufficiently disclosed,
- the subject-matter of claim 1 of auxiliary requests 1, 10 and 11 was not novel over Example 2 of D2, and
- auxiliary request 12 met the requirements of Articles 123(2) and (3), 84, 83, 54 and 56 EPC.

V. The patent proprietor, opponent 1 and opponent 2 each filed an appeal against the decision. As each party is both appellant and respondent, in the following they are referred to as "patent proprietor", "opponent 1" and "opponent 2".

VI. In its statement of grounds of appeal, the patent proprietor requested that the decision under appeal be set aside, the invention be declared sufficiently

disclosed and the case be remitted to the opposition division for further prosecution. Alternatively, it requested that the patent be maintained as granted. The patent proprietor also filed four new documents and 26 sets of claims as auxiliary requests 1 to 26.

VII. In their statements of grounds of appeal, the opponents requested that the decision under appeal be set aside and that the patent be revoked in its entirety. Opponent 2 filed two new documents.

VIII. With its reply to the opponents' statements of grounds of appeal, the patent proprietor filed two additional documents and two sets of claims as auxiliary requests 27 and 28. It also referred to decision T 292/17, which had just been issued and dealt with the patent stemming from the parent application of the patent in suit.

IX. In their replies to the patent proprietor's statement of grounds of appeal, the opponents also discussed T 292/17.

X. The Board scheduled oral proceedings and gave its preliminary opinion on the case.

XI. Oral proceedings were held by videoconference, as agreed by the parties. During the oral proceedings, the patent proprietor withdrew auxiliary requests 1, 8 to 21 and 23 to 28. Auxiliary request 22 was renumbered auxiliary request 7b. Thus, the claim requests at the end of the oral proceedings were:

- the claims as granted (main request)
- auxiliary requests 2 to 7 as filed with the patent proprietor's statement of grounds of appeal

- auxiliary request 7b, filed as auxiliary request 22 with the patent proprietor's statement of grounds of appeal

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

XII. The wording of claim 1 of each of the auxiliary requests on file is as follows.

Claim 1 of auxiliary request 2 differs from claim 1 as granted in that the mammal has been limited to a human of the age of 50 or more and the disease or condition which involves muscle decline has been limited to the group consisting of sarcopenia, muscle dystrophy, muscle atrophy, muscle wasting and frailty.

Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 2 in that the disease or condition which involves muscle decline has been limited to the group consisting of sarcopenia and frailty.

Claim 1 of auxiliary request 4 differs from claim 1 as granted in that the mammal has been limited to a human of the age of 50 or more and the disease or condition which involves muscle decline has been limited to the group consisting of sarcopenia, loss of muscle mass related to ageing, insufficient muscle protein synthesis, muscle degradation, impaired muscle recovery, muscle damage, muscle proteolysis, muscle atrophy, muscle dystrophy, muscle catabolism, muscle wasting and frailty.

Claim 1 of auxiliary request 5 differs from claim 1 as granted in that the wording of the use part of the claim has been reformulated as: "*for use in ~~the~~*

~~prevention or~~ a method for treatment of a mammal by therapy, wherein a disease or condition is prevented or treated which disease or condition involves muscle decline in the~~a~~ mammal [...]"

Claim 1 of auxiliary request 6 differs from claim 1 of auxiliary request 5 in that the disease or condition which involves muscle decline has been limited to the group consisting of sarcopenia, loss of muscle mass during or following physical trauma treatment (such as fractures), muscle proteolysis, muscle atrophy, muscle dystrophy, muscle catabolism, muscle wasting, loss of muscle strength, loss of muscle function, impaired mobility, frailty and disability.

Claim 1 of auxiliary request 7 differs from claim 1 of auxiliary request 5 in that the disease or condition which involves muscle decline has been limited to the group consisting of sarcopenia and frailty.

Claim 1 of auxiliary request 7b differs from claim 1 of auxiliary request 5 in that the mammal is a human of the age of 50 or more and the disease or condition which involves muscle decline is sarcopenia.

XIII. The opponents' arguments relevant to the present decision can be summarised as follows.

Remittal

The case should not be remitted to the opposition division for assessing novelty and inventive step for the main request. The opposition division had already considered these grounds for narrower claim requests. Furthermore, novelty and inventive step had also been

considered for the same subject-matter in related appeal T 292/17.

Novelty over D2 - claim 1 as granted

D2 disclosed compositions for stimulating the generation of muscle tissue in mammals. The composition in Example 2 met the requirements of claim 1 on the content of whey protein and L-leucine. It contained 22 g whey protein concentrate (WPC) and 4.4 g L-leucine. Example 2 specified that the content of whey protein in the WPC was 17.6 g, which upon hydrolysis gave 20.8 g amino acids. Thus, the total amount of proteinaceous matter in Example 2 was 22.0 g (17.6 g whey protein plus 4.4 g L-leucine), and whey protein constituted 80% of it. Furthermore, according to the patent (paragraph [0024]), the natural content of L-leucine in whey was 11 wt.%. Therefore, the content of L-leucine in whey was 1.93 g. The total content of L-leucine was 6.33 g (1.93 g in whey plus 4.4 g in free form), 69.5 wt.% of which was in free form.

With regard to the presence of a fat source and a digestible carbohydrate source, the WPC in Example 2 contained 80 wt.% whey protein. Therefore, it had to be a standard WPC80 product as disclosed in D5 (pages 42 and 43) and contained 9 wt.% lactose and 6 wt.% fat. D18 also disclosed in Example 4 that a standard WPC80 contained fat and lactose.

Lastly, the composition had a total weight of about 25 g which, according to D2 (page 6, lines 22 and 23, and page 7, line 9 to 11), constituted a serving. This was also the daily amount recommended by D2. The caloric content of the composition, as calculated using the Atwater factors, was of 107.8 kcal.

Inventive step - claim 1 as granted

Example 2 of D2 was a suitable closest prior art. D2 was directed to the stimulation of muscle protein synthesis not only for aesthetic reasons but also for therapeutic purposes. The compositions of D2 could be used for preventing the loss of large amounts of muscle mass in patients recovering from surgery. Example 2 disclosed a composition that could be directly served for oral administration. Contrary to the patent proprietor's contention, there was no basis in D2 to consider the composition in Example 2 an intermediate product that had to be admixed with further ingredients for consumption. D2 did not suggest that the composition of Example 2 was too bitter for oral administration.

Even if the Board agreed with the patent proprietor that claim 1 contained four distinguishing features, those features did not provide any technical effect. There was no suitable comparison on file between the composition in claim 1 and the one in Example 2 of D2. Therefore, the objective technical problem was providing an alternative composition that promotes muscle protein synthesis.

The solution proposed in claim 1 was obvious from D2 alone, as concluded in T 292/17 (Reasons 4.9). Even if the presence of low amounts of fat and digestible carbohydrates was regarded as a distinguishing feature, it was obvious from D2 in light of the common general knowledge represented by D5.

Inventive step - auxiliary requests

The limitation in the auxiliary requests to the prevention or treatment of sarcopenia in elderly humans was obvious. D2 remained a suitable closest prior art since it was directed to stimulating anabolism, which was a strategy applicable to prevent or treat sarcopenia in elderly humans. This was confirmed by D34, D11 and D19, which taught that sarcopenia was due to an age-related decrease in muscle protein synthesis, and that it could be countered by stimulating muscle protein synthesis by leucine supplementation, in particular using whey protein.

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

Remittal

The case should be remitted because the opposition division had not decided on novelty and inventive step for the main request. Decision T 292/17 should not be taken into consideration because it dealt with a different case and the arguments put forward in that appeal were not the same as in the case in hand.

Novelty over D2 - claim 1 as granted

Example 2 of D2 did not disclose the subject-matter of claim 1.

First, the amount of whey in the composition of Example 2 was lower than 80 wt.% of the proteinaceous matter. Besides 17.6 g whey protein, the WPC of Example 2 contained an additional source of proteinaceous matter

since the total amount of amino acids it provided was 20.8 g. The opponents' calculations to demonstrate that the hydrolysis of 17.6 g whey protein gave 20.8 g amino acids were flawed. Thus, the total amount of proteinaceous matter in Example 2 was 25.2 g (20.8 g from the WPC and 4.4 g free L-leucine), and whey constituted 70 wt.% of that total amount (17.6 out of 25.2 g).

Second, Example 2 did not disclose that the WPC contained fat and digestible carbohydrates. In accordance with T 786/00 (Reasons 3.7.1), D5 could not be used to interpret the content of D2 because D5 had been published four years after D2.

Third, D2 did not disclose the use of the composition in Example 2 in a medical use. The only medical use illustrated in D2 was in Example 7. This example involved the intravenous injection of a mixture of amino acids, while claim 1 was directed to a composition comprising whey protein for oral administration.

Fourth, D2 did not disclose the administration of the composition of Example 2 at a dosage of one to two servings daily, each serving comprising between 80 and 200 kcal.

Inventive step - claim 1 as granted

D2 was not a suitable starting point for assessing inventive step because it was not directed to the therapeutic indication of claim 1. Furthermore, Example 2 did not disclose a serving for oral administration but an intermediate product to be admixed with additional ingredients before consumption. For

instance, a taste-masking agent had to be added to mask the bitterness of L-leucine.

If Example 2 of D2 was nevertheless considered to be the closest prior art, claim 1 contained four distinguishing features, as discussed for novelty. The composition of claim 1 induced muscle protein synthesis to a greater extent than the composition in Example 2 of D2. This was demonstrated by the faster and higher serum concentration peaks of leucine, essential amino acids and amino acids observed in the clinical studies in the patent and in D27. Therefore, the objective technical problem solved by the subject-matter of claim 1 was providing a nutritional composition resulting in an improved muscle synthesis rate after ingestion.

The solution proposed in claim 1 was not obvious. D2 did not provide any guidance on how to solve the problem posed. At best, it suggested administering a composition by intravenous infusion as in Example 11 or increasing the amount of leucine as in Example 7.

Inventive step - auxiliary requests

D2 was even less suitable as a starting point for the auxiliary requests since D2 was not directed to the prevention or treatment of sarcopenia in elderly humans.

The skilled person seeking to stimulate protein synthesis in the elderly would exclude digestible carbohydrates from the nutritional composition. It was known from D34 (page 440, right-hand column, second paragraph), D19 (page 2, second paragraph) and D20 (page 8, second paragraph) that carbohydrates impaired the anabolic effect of amino acid supplementation in

elderly humans. Therefore, the subject-matter claimed in the auxiliary requests was not obvious.

XV. The parties' final requests relevant to the present decision were as follows.

- The patent proprietor requested that the decision under appeal be set aside, the invention be declared sufficiently disclosed and the case be remitted to the opposition division for further prosecution.

  As an auxiliary measure, the patent proprietor requested that the patent be maintained as granted or that the patent be maintained in amended form on the basis of one of auxiliary requests 2 to 7 as filed with the patent proprietor's statement of grounds of appeal or auxiliary request 7b, filed as auxiliary request 22 with the patent proprietor's statement of grounds of appeal.

- Opponent 1 and opponent 2 requested that the decision under appeal be set aside and that the patent be revoked.

  Opponent 2 also requested that the case not be remitted to the opposition division for further prosecution.

Reasons for the Decision

2. Remittal (Article 111(1) EPC and Article 11 RPBA)

2.1 The patent proprietor requested that the decision under appeal be set aside, the invention be declared sufficiently disclosed and the case be remitted to the opposition division for further prosecution. Therefore, at the oral proceedings before the Board, the patent proprietor did not agree with discussing novelty and inventive step for the patent as granted in the first place.

2.2 It is established case law that the parties have no absolute right to have their case examined at two instances (Case Law of the Boards of Appeal, 10th edition, 2022, V.A.9.2.1). Under Article 111(1), second sentence, EPC the Board has discretion to decide on an appeal by exercising any power conferred on the opposition division or by remitting the case to the opposition division. In addition, Article 11 RPBA establishes that the Board should remit the case to the opposition division only if special reasons present themselves for doing so. In the following, the Board explains why in the current case there were no such special reasons.

2.3 Novelty and inventive step over D2 were discussed in the decision under appeal for claims narrower than claim 1 as granted. On the one hand, the opposition division concluded that the subject-matter of then auxiliary request 1 was not novel over D2 (decision,

point 30.2). On the other hand, inventive step starting from D2 as the closest prior art was also discussed for the claim request held allowable by the opposition division (decision, point 38.2).

2.4 Therefore, at the oral proceedings, the Board and the parties were in a position to discuss novelty and inventive step over D2 for the patent as granted. There were no special reasons to first assess sufficiency for the main request and, if applicable, remit the case to the opposition division for further prosecution. Even if the claimed subject-matter had been considered to be sufficiently disclosed, remitting the case to the opposition division for further prosecution was not justified.

3. Interpretation of claim 1 as granted

Claim 1 is directed to the prevention or treatment of a disease or condition which involves muscle decline in a mammal. Opponent 1 submitted in its statement of grounds of appeal that frailty, a condition involving muscle decline according to dependent claim 13, is not a pathological condition. As a consequence, claim 1 encompassed non-therapeutic methods of treatment and could not be regarded as a purpose-limited claim in accordance with Article 54(5) EPC. Therefore, the use recited in claim 1 was not limiting. In its reply to the opponents' appeals (point 6), the patent proprietor argued that frailty was a pathological condition.

For procedural efficiency, the Board asked the parties to first present their cases on the assumption that the prevention or treatment of a disease or condition which involves muscle decline in a mammal is necessarily therapeutic. On that basis, the use recited in claim 1

was considered to be limiting, in accordance with Article 54(5) EPC. In view of the outcome of the assessment of inventive step in points 5.9 and 6.5 below, there was no need to further discuss the issue of claim interpretation thereafter.

4. Novelty over D2 - claim 1 as granted

4.1 The parties disputed the novelty of the subject-matter of claim 1 in view of Example 2 of D2.

D2 is directed to compositions that induce the generation of muscle tissue (page 1, lines 1 to 4). It focuses on inducing muscle protein synthesis in healthy subjects (page 2, lines 3 to 9). However, it also proposes using the compositions for preventing the loss of large amounts of muscle mass in patients recovering from surgery, who are often restricted in their food intake (page 10, lines 15 to 18). Example 2 of D2 discloses the preparation of a composition as follows:

"*A powder was prepared of 22.0 grams whey protein concentrate (which provides 17.6 grams whey protein and 20.8 grams amino acids) and 4.4 grams of L-leucine*."

4.2 The patent proprietor identified four features that distinguished the composition of claim 1 from the one in Example 2 of D2:

(i) at least 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, and

(iv) it is administered as one to two servings daily, each serving comprising between 80 and 200 kcal.

The Board agrees that the subject-matter of claim 1 presents those differences over Example 2 of D2.

4.2.1 With regard to feature (i), Example 2 discloses the combination of 22.0 g whey protein concentrate (WPC) with 4.4 g L-leucine. The example specifies that 22.0 g WPC provide 17.6 g whey protein and 20.8 g amino acids. However, it is unclear whether those 20.8 g amino acids result from the hydrolysis of 17.6 g whey protein or whether the WPC contains a source of amino acids in addition to whey protein.

According to the opponents, the correct interpretation of Example 2 is that the specified amount of amino acids results from the hydrolysis of whey protein. This would mean that the total proteinaceous matter in Example 2 would be 22.0 g (17.6 g whey plus 4.4 g L-leucine), and the 17.6 g whey protein would constitute 80 wt.% of it. In contrast, the patent proprietor contended that the WPC of Example 2 contains proteinaceous matter other than whey protein because the hydrolysis of 17.6 g whey protein would not result in 20.8 g amino acids. The total amount of proteinaceous matter would be 25.2 g (20.8 g amino acids plus 4.4g L-leucine), and 17.6 g whey protein represents about 70 wt.% of that total amount.

In the Board's view, it is unclear whether the composition of the WPC in Example 2 contains whey protein as the only source of amino acids or whether whey is present in combination with a secondary source of amino acids. The ambiguous information in Example 2

would not allow the skilled person to conclude which of the interpretations provided by the parties is right, both being technically sensible. Under such circumstances, the Board holds that Example 2 of D2 does not directly and unambiguously disclose a composition in which at least 80 wt.% of the proteinaceous matter is whey protein.

4.2.2 With regard to feature (ii), the opponents argued that the WPC of Example 2 was a standard WPC80 product because it contained 80 wt.% whey protein (17.6 g out of 22.0 g). The composition of standard WPC80 products was common general knowledge at the filing date, as disclosed in D5, pages 42 and 43. D5 showed that, in addition to whey protein, WPC80 products generally contained 9 wt.% lactose and 6 wt.% fat. Therefore, the composition of Example 2 contained a source of fat and a source of digestible carbohydrates.

On this point, the Board agrees with the patent proprietor that, when considering novelty, common general knowledge which did not exist at the publication date of a prior-art document cannot be used to interpret such a document (T 786/00, Reasons 3.7.1). As D5 was published four years after D2, its content cannot be used to interpret D2. Therefore, at the publication date of D2, the skilled person would not derive that the composition of Example 2 contained fat and digestible carbohydrates.

4.2.3 With respect to features (iii) and (iv), Example 2 is not disclosed in connection with any purpose or administration frequency. As noted in point 4.1 above, D2 is mainly focused on inducing muscle protein synthesis in healthy subjects rather than on preventing or treating muscle decline as part of a therapeutic

treatment. Therefore, D2 does not disclose a link between the composition of Example 2 and a therapeutic prevention or treatment of muscle decline. Similarly, D2 does not disclose that the composition of Example 2 is daily administered in one to two servings of 80 to 200 kcal each.

4.3 Therefore, D2 does not disclose features (i) to (iv) as defined in point 4.2 above.

5. Inventive step - claim 1 as granted

5.1 The patent concerns low-caloric high-protein nutritional compositions suitable for stimulating muscle protein synthesis in a mammal (paragraph [0001]). The proteinaceous material of the nutritional compositions consists essentially of whey protein and free leucine. The patent explains in paragraphs [0003] to [0005] that the principle underlying the invention is the prior knowledge that muscle protein synthesis is stimulated by high serum levels of essential amino acids, especially leucine, and that whey protein contains higher levels of leucine than casein protein. With 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 can be expected to promote muscle protein synthesis and be suitable for preventing or treating diseases and conditions which involve muscle decline.

5.2 The parties disputed whether D2, in particular Example 2, was a suitable starting point for assessing inventive step.

5.2.1 D2 is directed to the preparation of compositions for inducing the generation of muscle tissue (page 1, lines 1 to 4). Like the patent, D2 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 (page 5, last line to page 6, lines 2). The proteinaceous material in the compositions of D2 is preferably mainly composed of whey protein and leucine (page 8, lines 18 to 27 and examples). Even if D2 focuses on inducing muscle protein synthesis by provoking an anabolic response in healthy subjects (page 2, lines 3 to 11), it also contemplates using the compositions for preventing the loss of large amounts of muscle mass in patients recovering from surgery, who are often restricted in their food intake (page 10, lines 10 to 18).

The similarity of the compositions of D2 with those in the patent and their use for inducing muscle protein synthesis by increasing postprandial serum levels of leucine and essential amino acid make D2 as a whole a suitable starting point for assessing inventive step.

5.2.2 With respect to Example 2 of D2, the patent proprietor argued that the composition in this example could not be the closest prior art because, contrary to the requirements of claim 1, it was not suitable for oral administration. According to the patent proprietor, the composition of Example 2 was an intermediate product to be admixed with further ingredients for producing the final product that was to be ingested. This was clear because the composition of Example 2 contained high amounts of L-leucine, which made it too bitter for direct ingestion (D2, page 3, lines 12 to 15). Therefore, additional ingredients, e.g. taste-masking agents, had to be added before consumption. This was

illustrated in Example 1 of D2, which disclosed a final composition including aspartame and vanilla flavour.

This argument is not convincing. The examples in D2 illustrate the invention and there are no reasons for assuming that this is not the case for Example 2. The patent proprietor's contention that the composition of Example 2 is an intermediate product that cannot be directly administered orally is based on speculation. Nothing in D2 suggests that the composition of Example 2 needs to be admixed with further ingredients or that it is too bitter to be administered as it is. As argued by the opponents, the high amount of WPC could also mask the bitter taste to a sufficient extent. Furthermore, the fact that the composition is bitter does not necessarily make it unsuitable for oral administration. Consequently, the composition of Example 2 has to be regarded as a composition for oral administration which promotes muscle protein synthesis in accordance with the teaching of D2.

5.2.3 Therefore, Example 2 of D2 is a suitable starting point for assessing inventive step.

5.3 In the discussion of novelty (point 4.2 above), the Board concluded that the following features were not directly and unambiguously disclosed in Example 2 of D2:

(i) at least 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, and

(iv) it is administered as one to two servings daily, each serving comprising between 80 and 200 kcal.

5.4 With regard to the technical effect produced by these distinguishing features, the patent proprietor referred to the clinical studies in the patent and in D27.

5.4.1 The clinical study in the patent showed the postprandial serum levels of amino acids, essential amino acids and leucine produced in 12 healthy elderly humans using four nutritional compositions (Table 1 and Figures 1 to 3): 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).

The patent proprietor argued that by comparing the serum amino acid levels produced by Active and Control 3, it was apparent that reducing the caloric content of a high whey-protein composition has an advantageous effect.

The Board does not dispute this conclusion. However, a comparison of the effects of Active and Control 3 does not demonstrate any effect over the composition in Example 2 of D2 which, like the composition of claim 1 and Active, is a high whey-protein, low-caloric composition.

5.4.2 The clinical study in D27 was performed in 45 non-sarcopenic older men who were distributed in three groups. The "Pro-En" group received a leucine-enriched whey composition containing some amounts of

carbohydrate and fat, i.e. according to claim 1. The "Pro" group received the same leucine-enriched whey composition with no carbohydrate and fat, i.e. according to Example 2 of D2. The "En" group received an isocaloric mixture containing only carbohydrate and fat. The patent proprietor argued that Figure 4 of D27 showed that the nutritional composition according to claim 1 (Pro-En) was advantageous over the product in Example 2 of D2 (Pro). This was because the former produced higher levels of serum amino acids than the latter.

The Board disagrees. The results presented in Figure 4 of D27 show slight differences between the postprandial serum levels of leucine, essential amino acids and amino acids produced by Pro-En and Pro. These differences are not always in favour of Pro-En. But, more importantly, the authors of D27 conclude from the clinical study that no significant differences were observed in postprandial muscle protein synthesis rates between the Pro-En and Pro groups (abstract, "Results" section). Therefore, D27 does not demonstrate any technical effect over the closest prior art, either.

5.4.3 In the absence of evidence demonstrating an advantage over the closest prior art, the composition of claim 1 is considered to induce muscle protein synthesis to an extent equivalent to that of Example 2 of D2. The technical effect of the distinguishing features is merely that the composition of claim 1 is used for promoting muscle protein synthesis in a therapeutic context.

5.5 Therefore, the objective technical problem may be defined, in line with the proposal of opponent 2, as

providing an alternative nutritional composition for use in promoting muscle protein synthesis.

5.6 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 paragraphs [0003] to [0005] of the patent that high serum levels of essential amino acids, especially leucine, induce muscle protein synthesis, was undisputed. 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.

5.7 However, the proposed solution is obvious. In a case such as this one 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. In the following, the Board explains how the skilled person would arrive at each of the distinguishing features in claim 1 in an obvious manner.

5.7.1 With regard to feature (i), D2 teaches that the proteinaceous matter in a formulation according to the invention comprises preferably more than 90 wt.% of intact proteins or peptides, whey being the most

preferred protein source (page 8, lines 21, 22 and 27). Therefore, the skilled person has a clear pointer in D2 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. Consequently, feature (i) does not contribute to inventive step.

5.7.2 With regard to feature (ii), the Board's conclusion on novelty was not that the composition in Example 2 of D2 does not contain a source of fat and digestible carbohydrate but that D2 does not directly and unambiguously disclose that the composition in Example 2 contains a source of fat and digestible carbohydrate. This conclusion was reached because D2 did not contain any information on the non-proteinaceous components of the WPC in Example 2, and document D5, which represented common general knowledge published between the publication date of D2 and the priority date of the application, could not be used to interpret D2 when assessing novelty. In accordance with T 786/00 (Reasons 3.7.1), common general knowledge that did not exist at the publication date of a prior-art document cannot be used to interpret that document in the context of novelty.

According to D5 (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 protein. The typical composition of a WPC is the following (D5, 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% concomitantly reduces the lactose content from 52 to 9%, while fat remains at 4 to 6%. D5 also contains common general knowledge on whey protein isolates (WPIs), which are highly purified WPCs (pages 45 and 46). WPIs contain typically 89 to 93% protein, 2 to 3% lactose and 1% fat. Thus, the skilled person knew at the priority date that a WPC prepared according to common general knowledge and having a protein concentration as high as 90% still contained some fat and lactose. Therefore, it was obvious that a nutritional composition containing a WPC as in Example 2 of D2, prepared according to the process generally known at the priority date, contained a source of fat and a source of digestible carbohydrates. Consequently, feature (ii) cannot contribute to inventive step, either.

5.7.3 As to feature (iii), the compositions of D2 produce high serum levels of essential amino acids and leucine (see point 5.2.1). Like the patent, D2 relies on the common general knowledge that high serum levels of essential amino acids and leucine stimulate muscle protein synthesis. Although D2 focuses on the promotion of muscle protein synthesis for aesthetic purposes, on page 10, lines 13 to 18, it suggests the use of the compositions for preventing the loss of large amounts of muscle mass in patients recovering from surgery, who are often restricted in their food intake. Furthermore, D2 clearly teaches that the nutritional compositions

provoke an anabolic response and prevent or reduce a catabolic state (claims 19 and 24). Therefore, it was obvious to the skilled person that the compositions of D2 were suitable for preventing or treating diseases or conditions involving muscle decline.

5.7.4 Regarding feature (iv), D2 suggests serving doses of 25 g, which is essentially the weight of the composition disclosed in Example 2 (page 5, line 9 and page 6, lines 21 to 23). Opponent 1 calculated the caloric content of such a serving dose, which resulted to be slightly above 100 kcal (statement of grounds of appeal of opponent 1, table on page 15). The patent proprietor did not agree with the opponents on the exact content of proteinaceous material, lactose and fat in the Example 2, but it never disputed that the total caloric content of the composition in Example 2 is in the order of 100 kcal. Therefore, D2 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) does not contribute to inventive step.

5.8 The patent proprietor argued that D2 could not render the subject-matter of claim 1 obvious because D2 did not contain any guidance on how to improve the rate of muscle protein synthesis. The patent proprietor considered that, at best, the skilled person would modify Example 2 in accordance with Examples 7 and 11, which would teach away from the invention.

This argument fails because it overlooks that the objective technical problem is not based on the

provision of an improved but an alternative composition.

5.9 Therefore, 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.

6. Auxiliary requests 2 to 7 and auxiliary request 7b

6.1 Claim 1 of each of auxiliary requests 2 to 7 and auxiliary request 7b contains limitations compared to claim 1 as granted. Nevertheless, in all cases claim 1 covers the situation in which the mammal is an elderly human and the disease or condition which involves muscle decline is sarcopenia. These limitations do not render the claimed subject-matter inventive.

6.2 The patent proprietor contended that D2 was not a suitable starting point for assessing the inventive step of a claim directed to the prevention or treatment of sarcopenia in elderly humans.

The Board disagrees. It was undisputed that sarcopenia is a condition caused by a decline in muscle protein synthesis associated with ageing (see also patent, paragraph [0007]), i.e. it results from a gradual reduction of the anabolism rate. Therefore, the skilled person would consider the nutritional compositions in D2, which are intended for stimulating protein anabolism in general, suitable for preventing or treating sarcopenia. In fact, the patent proprietor relies on the clinical studies in the patent and in D27 to demonstrate that the invention works, even if those studies only show the amino acid serum levels produced by nutritional compositions in healthy elderly humans.

Therefore, D2 remains a suitable starting point for assessing inventive step for the auxiliary requests.

6.3 The opponents cited D2, D34, D11 and D19 to argue that the additional distinguishing features in the auxiliary requests (elderly humans and prevention or treatment of sarcopenia) were obvious. The Board agrees with this view.

The general teaching of D2 is directed to provoking an anabolic response and preventing or reducing a catabolic state, as explicitly stated in claims 19 and 24. This effect is relevant for the treatment or prevention of sarcopenia in the elderly.

D34 (abstract) is a review of the knowledge on sarcopenia up to 2008. According to D34, sarcopenia was thought to reflect an age-related decrease in the synthesis of muscle protein rather than an excess of catabolic process associated with disease or from a reduced caloric intake (page 434, left-hand column, third paragraph). An important issue in sarcopenia was a possible resistance to the natural stimulatory effect of leucine in ageing muscle, implying that higher leucine concentrations could be necessary to stimulate protein synthesis in elderly subjects (page 440, right-hand column, second paragraph). In the paragraph bridging pages 442 and 443, D34 refers to a report stating that essential amino acids stimulate protein anabolism in elderly subjects. It then explains the role of leucine in stimulating muscle protein synthesis and proposes protein supplementation with a rich source of leucine, such as whey, as a safe strategy to prevent sarcopenia.

D11 (page 6, lines 12 to 19) acknowledges that whey is one of the richest sources of branched amino acids, in particular leucine, which play an important role in muscle protein synthesis. It states that, therefore, whey is the protein of choice for treating sarcopenia.

D19 (abstract and page 4, second paragraph) proposes the intake of sufficient high quality protein per meal and leucine supplementation to enhance muscle protein synthesis in the elderly and prevent or treat sarcopenia.

Therefore, it was obvious to the skilled person that the nutritional composition in Example 2 of D2, based on whey and supplemented with leucine, was suitable for enhancing protein synthesis in elderly humans at risk of or affected by sarcopenia.

6.4 The patent proprietor argued that the skilled person seeking to stimulate protein synthesis in the elderly would not have included a source of digestible carbohydrates in the composition of Example 2 of D2. According to the patent proprietor, there was a strong prejudice in the art to do so because carbohydrates were known to impair the anabolic effect of amino acid supplementation in the elderly. This prejudice was allegedly supported by D34 (page 440, right-hand column, second paragraph), D19 (page 2, second paragraph) and D20 (page 8, second paragraph).

The Board does not find this argument convincing. As explained in point 5.7.2 above, the skilled person was aware that WPCs prepared according to common general knowledge contained some amounts of lactose. Thus, a source of digestible carbohydrate did not need to be added. It was present in the WPC as a consequence of

its preparation by milk ultrafiltration, which did not achieve a complete removal of lactose. Furthermore, D34, D19 and D20 did not establish a prejudice against the presence of residual amounts of lactose in WPCs intended for administration to elderly humans.

D34 (page 440, right-hand column, second paragraph) states that adding carbohydrates to protein supplementation may impair the anabolic effect in elderly subjects. D19 (page 2, second paragraph) teaches that the co-ingestion of carbohydrates with protein may reduce anabolic efficiency in the elderly. D20 (page 8, second paragraph) teaches that the addition of glucose to an amino acid mixture does not add a real benefit in stimulating muscle protein anabolism in the elderly and that it may even be detrimental.

Suggesting that the anabolic effect in the elderly may be impaired by the addition of carbohydrates does not mean that the anabolic effect is necessarily impaired, nor that when such impairment occurs it results in a significant reduction in the anabolic effect. In addition, the presence of a residual lactose content in WPCs cannot be equated with the addition of carbohydrates meant in D34, D19 and D20. Therefore, D34, D19 and D20 cannot counter the opponents' argument that the limitation of the subject-matter of claim 1 to the prevention or treatment of sarcopenia in the elderly is obvious.

6.5 Consequently, none of the auxiliary requests meets 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:

L. Malécot-Grob A. Usuelli

Decision electronically authenticated